From Novice to Expert:

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An examination into how a novice engineer within the pharmaceutical engineering industry gains the skills and acknowledgement of their abilities by other industry experts?

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ABSTRACT – evt. vedlægges

Dette forsknings grundlag er, at klarlægge hvorledes en nyuddannet ingeniør indenfor den farmaceutiske industri kan udvikle sig fra at være nyuddannet til at blive anerkendt som en ekspert indenfor deres respektive område. De vil i så fald også blive anerkendt som en 'Specialised Marketing Ekspert' (efterfølgende 'SMEs'). Dermed ønskes der at undersøge hvilken rolle 'SMEs' har, samt hvorledes deres karrierer har udviklet sig, dels professionelt, dels i videreuddannelse i deres respektive kompetenceområder. Nysgerrigheden i dette emne blev spændende efter samtaler, samt deltagelse i diverse samarbejdsprojekter med nogle af verdens ledende farmaceutiske firmaer. Det blev ligeledes klart at nogle af disse firmaer blev meget interesserede i denne undersøgelse – dog blev det ligeledes tydeligt at en evt. undersøgelse blev lagt på is fra firmaerne grundet måden jobs blev skabt, samt ansættelses procedurer. Det ville derfor være spændende, hvis 'Pandoras Æske' kan åbnes og derfor denne undersøgelse. De indledende undersøgelser endte med en aftale med " Nordich Affiliate of the International Society of Pharmaceutical Engineers (efterfølgende ISPE) for dermed at sikre at kun medlemmer af ISPE vil have adgang til de akademiske informationer som er tilgængelige via ISPE. Der er foretaget en kvalitativ undersøgelse baseret på empirisk information via indsamling af interviews fra bund til ledelse i den akademiske verden. Det blev besluttet at bruge elementer fra 'Actor Artwork Theory and the Social Constructial Therory the Orgy' som et værktøj til at udvide forståelsen af de underliggende strukturer i forhold til de farmaceutiske ingeniører og administratorer.

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Abstract

This research study sets out to examine how novice engineers in the pharmaceutical engineering industry may transit to be recognised as experts in their field (commonly termed as either 'subject matter experts'/'specialised market experts' – SMEs). This researcher examines the role of SMEs, their career path that enabled their professional development, and their professional education. This author interest in the subject was initiated after framing and conducting several collaboration projects with some of the World's leading consulting pharmaceutical engineering companies, during which this author's desire to make a contribution to the work of these companies was ignited – which was very soon stalled by the obscurity of the job creation, recruitment, and development process. It was a desire by this author to unpack this 'black box' that led to this study. This author very early enquiries, combined with previous professional encounters, led to a close alignment with the Nordic Affiliate of the International Society of Pharmaceutical Engineers (ISPE) as a method to secure access to career pharmaceutical engineers and information resources that was only available to ISPE members. This author conducted qualitative research, based on Grounded Theory, in order to analyze the empirical data gathered in the interviews that were conducted with the engineers and ISPE administrators. It was decided to use elements of Actor Network Theory and the Social Construction of Technology theory as tools to gain a more detailed understanding of the underlying structural issues encountered by the pharmaceutical engineers and administrators.

Contents

1. Introduction to the collaboration

One of the criteria for this Masters programme was to explain the principles and methods used in the development of a specific technology in a specific technological organisation. This researcher chose to interpret the application of codified knowledge within the pharmaceutical engineering industry as the technology under investigation, and as the ISPE was the main umbrella institution for most of the individuals under scrutiny this author formed a working collaboration with the ISPE Nordic Affiliation.

This author was interested in establishing what the 'normal' or expected career path was or might be for pharmaceutical engineers in Scandinavia – and, through a practical allocation of resources and access, this basically meant an examination of the Danish engineers' experience and expectations.

Initial enquiries very quickly pointed this author in the direction towards contacting the Membership Secretary of the ISPE Nordic Affiliate, whom saw the potential of this line of research, and gave this researcher access, direction, and encouragement during the research process. His agenda was to provide existing ISPE members with the means to create and encourage professional networks and provide access to educational and information resources, and also find ways to encourage enrolment of new members.

Mention of this study also reached the global Headquarters of the ISPE, and this author was contacted by one of the administrators with the purpose of promoting this study through a published interview in their in-house, members' magazine.

This author attended ISPE Networking events and several technical conferences during the duration of this study as a method to establish contacts that were agreeable to be interviewed and to form potential career building opportunities. This author was asked to attend the ISPE Nordic Annual Conference in Stockholm, during which this author was requested to be a member of the ISPE Nordic Affiliate Board – with the purpose of creating methods and opportunities to recruit and service the needs of students and Young (new) Professionals within the ISPE.

2. Problem formulation

From novice to expert – how does an engineer within the pharmaceutical industry acquire, quantify, and gain acknowledgement of their skills and expertise by their peers?

3. Research design

What is the purpose of this (and any other) research project? Bruno Latour (1999), in Pandora's Hope: Essays on the Reality of Science Studies, terms research as the

> '…zone into which humans and non-humans are thrown in…the most extraordinary collective experiment to distinguish, in real time, between the "cosmos" and "unruly shambles" with no one…knowing in advance what the provisional answer will be.' (Latour, 1999:20)

For this researcher, this means creating a selection of methods and analytical techniques from which to address an initial puzzle and from the discovered "disorderly messes" (ibid:21). When opening this black box, this researcher also knew that, borrowing from Latour (ibid:23), that all the ills and pains would also be released from this Pandora's Box – but little did this researcher know just how much the initial question would be challenged by the germs emanating from this particular Pandora's Box.

When designing a methodological approach for this study this researcher had to consider several factors required to satisfy both a need to find a selection of approaches appropriate to the subject and academic requirements. These conditions meant making a subjective choice of possible theoretical positions and analytical approaches to collect and analyse the empirical data.

When researching approaches on a coordinated Research Design approach this researcher found surprisingly little appropriate literature on the subject for the purpose of this study. However, one author, John Creswell, stood out with a clear and comprehensive methodology in his book Research Design: Qualitative, Quantitative, and Mixed Methods Approaches (Creswell, 2003), and it was this guiding template that this researcher choose to take inspiration from.

Creswell's work, although comprehensive in helping to plan an overall research structure, lacks depth in specific areas – including that of conducting interviews. To aid the understanding of the interview theory this researcher took the advice of others when

selecting Steinar Kvale's (1996) Interviews and his 2007 rewrite of same, Doing Interviews, as an appropriate methodological roadmap.

Both Creswell and Kvale offer assistance in an area central to one of the learning goals of Techno-Anthropology at the Masters level, that is, the question on what and how ethical considerations may enter into play and how this researcher treats these concerns during the study and subsequent reporting of such considerations. While these authors offered valuable information this author found them too superficial when confronted with interactional expertise and the problem of disciplinarity encountered by this researcher: this researcher quickly realised that the initial researcher question of how to move from being a novice to an acknowledge 'expert' was no-where near as simple as merely gathering data on administrative structures and drawing some overarching and a few specific conclusions on such; the almost limitless range of engineering disciplines and disparate methods of how corporations (employers and customers) define and select their experts caused a complete re-evaluation of the entire research project – thus creating potential for a further, more in-depth study that can build on the results and conclusions found here.

Creswell identifies three (3) core elements that any researcher should seek to address:

1) What knowledge claims are being made by the researcher (including a theoretical perspective)?

2) What strategies of inquiry [knowledge claims positions] will inform the procedures?

3) What methods of data collection and analysis will be used?

(Creswell, 2003:5)

It is important to note that out of the four (4) alternative knowledge claims positions put forward by Creswell (2003:6) this researcher could only consider two (2) areas: Constructivism and Advocacy/Participatory. This researcher takes the position that the other two (2) positions (Postpositivism and Pragmatism) could not be examined due to the

structural constraints of commercial sensitivity and the reluctance of non-technical staff to release information – although a further study may be able to address these claim positions when commercial enterprises have had more time to digest and accept the validity of this, initial study and its supporting partners.

From the basic investigative options open to this researcher (quantitative, qualitative, and mixed methods), it was evident that a quantitative approach would not be suitable nor practical given both the timeframe and nature of this study – the ISPE were very slow in adopting the study, meaning that this researcher could not reach a large enough number of potential respondees to generate a meaningful data set. It was, therefore, only feasible to explore a qualitative approach. i.e. making a direct approach to a cross-section of individuals based in the Danish pharmaceutical engineering industries. In order to gain ready access to these individuals this researcher made a conscious choice to align with several Community of Practice within the socially-constructed Nordic Affiliate of the ISPE. The third option (mixed method approach) may also be suitable in a further study, but the absence of any meaningful quantitative data prevents its application in this study.

In attempting to turn these approaches into the practice of inquiry this researcher had to make several decisions and partially-informed assumptions in a number of areas due to pressures brought on by factors outside the control of this researcher – the most frustrating of which was the initial acceptance of a large group of ISPE members whom agreed to be interviewed but then retracted their cooperation (85% of those initially accepted to be interviewed in the first round of planned interviews withdrew their cooperation. This same figure was also repeated by the second of potential interviewees!) These withdrawals led to a second pressure factor: a lack of time to arrange additional interviews to replace the withdrawals. An earlier factor that caused a great deal of confusion and delay was the sudden silence of trusted, long-term personal and professional contacts in the pharmaceutical engineering business whom had given sufficient initial encouragement to the initial research study that this researcher decided to embark on the study.

Once the fog had cleared and the data sources had been confirmed this researcher then had to decide on the method(s) of approach. In the cases where ISPE members had confirmed their wiliness to be interviewed, there then came the question of how and what data was to be collected; would a fully-structured or semi-structured interview process be most appropriate, should interviewees be given advance notice of the subject area or even the actual questions in order to be best prepared and (potentially) supply more rounded input? Could the respondents merely supply written replies to written questions?

The above brings this researcher to the halfway point in Creswell's section on Design Processes of Research (Creswell, 2003:5). The only thing left now is to analyse and write up the data and find some way to validate the findings.

In taking Creswell for the basis of this research design, I also took a point of departure within his qualitative approach in that this researcher choose to use a Grounded Theory approach in order to maintain and confirm the direction of data collection. Although, to state that using Grounded Theory is a departure from Creswell is stretching the definition of departure as Creswell neither explicitly includes nor omits Grounded Theory as an approach – nor does he do so with any other approach he mentions in his 2003 work entitled Research Design (Creswell, 2003:13) from which many of this researchers approaches take inspiration from. However, although crediting Strauss and Corbin with their contribution to Grounded Theory, Creswell overlooks the earlier and formative contribution of Barney Glaser.

From previous studies encountered while taking the Techno-Anthropology course, it is clear to see that the direction of study and any outcomes from the research are largely dictated by the researcher's personal choice of theoretical approach(s) – theoretical positioning; this researcher's initial intuition was to follow a Social Construction path of investigation, however it became evident that this path may not have revealed the true extent of the actual performativity/enactment of the actors in the redefined study. This researcher does, however, expect that a further, enlarged study – along the lines of the initial question – may well find a Social Construction position appropriate.

4. Literature review

What is the – 'state of play' regarding research devoted to examining the professional development of engineers in the pharmaceutical engineering industry

When starting this research it is necessary to examine what existing research has been undertaken in this subject area. Whom, if anyone, has previously addressed issues raised in this area, and what conclusions, if any, have been drawn?

As with many professions, many individuals in the pharmaceutical engineering industry have attended academia and then entered the professional workplace. However, is it safe to assume that these two elements are naturally synchronous or even linked in a complimentary way. In order to understand these issues it would be first necessary to understand how engineers are formally educated in academia.

This researcher was both fortunate and unfortunate with regard to timing as a PhD thesis was published in June 2015 that examined the nature of engineers' education at Aalborg University, as was a research paper published by the Dublin Institute of Technology on the subject of education and knowledge transfer encountered by engineers. The author of this latter paper has encouraged this researcher to develop a proposal for a PhD study to follow-on from the initial study.

Both of these recent publications were released too late in the process of this study for this author to properly consider any content, proposals, and/or conclusions found within – if, indeed, any were found to be appropriate. Given this position, this author is reliant on work published prior to the above papers.

Review of previously published works

This author wishes to acknowledge the work of Galvan (2006) and Mongan-Rallis (2014) in providing a framework for this review of existing literature with regard to this line of research. When embarking on this study this author was previously aware of literature written by various academics, including some by staff members whom work in Aalborg

University's Techno-Anthropology programme, and this was the starting point for gathering potential leads for this line of research. Additional sources were highlighted by this author's present academic supervisor and by communicating with a recent doctoral candidate whose work laid in a similar field of research. Other sources were discovered via conducting searches within Aalborg University's Library databases.

Overview of research study

The initial line of research set out to examine how a novice (newly (academically) qualified) engineer may move, evolve, be educated, and/or be recognised as an expert in any particular branch of pharmaceutical engineering. However, as the study proceeded, complications arose that challenged various initial assumptions with regard the nature and definition of what is understood and accepted in order to fulfil the role of an expert in pharmaceutical engineering – this discovery, therefore, also needed to be addressed in this study, and literature be sourced, examined, and, if found relevant, placed appropriately within this study.

Line of argument

Given the above initial line of research and it subsequent complications, this study seeks to establish three lines of investigation; firstly, to understand how engineers in the pharmaceutical industry accrues knowledge, both formal academic and professional education. Secondly, establish how this knowledge is transmitted between peers and the nature and importance of networking within this particular industrial sector. Thirdly, how this learning is acknowledged by peers, employers, and customers.

Justification for the study

Previous to this study, this author had collaborated with numerous commercial enterprises that had a range of connections with the pharmaceutical engineering industry. These experiences ranged from being an employee in several of their customers, to initiating academic joint projects during undertaking the Master's Programme in Techno-Anthropology at the Copenhagen campus of Aalborg University, and even long-term social

interaction with career engineers whom work in the pharmaceutical engineering and manufacturing sectors. Throughout these interactions this researcher attempted to establish and realise a career with the pharmaceutical engineering industry. However, questions constantly arose as to how best develop such an endeavour – there appeared to be a series of black holes and boxes with fences placed in every direction. This research had to discover how the network of interactions worked if this researcher was to reveal a path through this blackness and series of obstacles.

Definition of key terms

When attempting to make an initial definition of terms some key terms and ideas were relatively logical and easy to reveal to the non-initiated. However, the more this researcher tried to reveal the finer mechanisms of the networks the more some apparently simple concepts proved to be more elusive and less demarcated.

With regard to this study, the use of the term 'novice' is, comparatively, uncomplicated; that is, a novice is universally accepted to mean and applied to someone who is a person without experience of the industry and, however, may have various and often very high academic qualifications, including Masters and PhD, but none-the-less are still classified as novices as they (at least initially) contribute little to the fortunes of their employer.

An area that this study reveals as less clear is that of what and whom is defined, recognised, and accepted as an 'expert'. As a series of informal talks, formal interviews, and numerous rebuttals reveal, individuals in this industrial sector are often very careful and self-deprecating when asked to represent themselves as an 'expert' – this is especially so when in the company of their peers. This makes the formation of any meaningful definition of what is accepted to mean being or universally accepted as the, expert in this area almost impossible across enterprises and technical disciplines.

Identifying the problem area

In addition to the lack of a universally accepted definition of whom is/can be an expert, there is very little existing research in this particular industrial sector, other areas of

medicine having being examined by many more studies over many years. When establishing the first academic collaboration as part of the Masters Programme with an enterprise in a market-leader position, this researcher was to learn that this was the first occasion that such a collaboration was permitted – a new type of 'None Disclosure Agreement' had to be constructed as it was the first collaboration of its type for the Company.

Importance of the study

This present line of research is seen by this author, senior members of the International Society of Pharmaceutical Engineers, and by several commercial enterprises as bringing new insights, objectivity, and raise potential monetarisation opportunities to an otherwise ad hoc and unregulated set of critical criteria that many commercial enterprises, regulative bodies, and governmental institutions use on a regular basis to qualify the people whom are selected or authorised to commission, design, implement, qualify, and approve projects and processes that can have a significant impact on the everyday lives of millions of people whom rely on the medicines and life-enhancing products produced by the machines and processes that are designed, fabricated, and approved by so-called 'experts' in the pharmaceutical engineering companies.

Findings through research and other sources of information

Existing academic sources can only tell the reader about what previous research has been able to discover, usually from a very specific position and set of objectives and, over time, this information may change, be made redundant, or become irrelevant. However, even if still current, it is unlikely that any previous study can address the precise issues of any other present line of research. This set of conditions results in the need to confirm the validity of previous studies and to seek new data sources.

As inferred above, no existing studies can be expected to provide all the answers to questions posed in the present – at best, some researchers may be able to find similar lines of research, on which they can build and refine their methodology and data for the purpose presently under consideration. Sometimes, the researcher is only able to the structure of previous studies as a method of moving forward.

However, regardless of the number and applicability of available studies to the researcher, things change, the data changes, the settings change, and the requirements set down for the studies are more than likely to change. These changed conditions results in the need for the present researcher to gather fresh data. Whether by empirical observations or objective data gathering, the researcher must attempt to gather, analyse, and present the current 'state of play' in the particular field under scrutiny.

In this study, this researcher was attempting to tackle a previously untouched and very conservative (some would say 'secretive') business sector. This meant that there was very little previous academic work available to this author on which to develop and build a strong academic thesis. The result of these conditions meant that this author had to place a strong reliance on existing and emerging personal and professional networks for the collection of empirical data.

Academic studies

An examination of existing academic work brought to light not only the general lack of research in the pharmaceutical engineering sector but also the need for this researcher to critically filter a wide range of potentially useful supporting works and areas of research – it would have been unproductive and confusing to the reader to investigate, digest, and present findings across the entire spectrum of studies that could have been brought in to aid this study; possible areas of interest included working lives studies, sociology, psychology, discourse analysis, and even governmental studies just to mention a few. This author chose to follow two main lines of published academic work; firstly, an examination of a theoretical positioning – in this particular study this author selected to follow a social constructive theoretical path, a line of research that would help this author to navigate the social interactions (networks and nodes of activity) and frame the multiple findings. Secondly, a further line of research was selected to attempt to reveal the particular specialties of the engineers' culture and practice.

Flaws in existing knowledge

Regardless of resources, any academic would be hard pressed to find any direct, published research done on or in partnership with pharmaceutical companies. There are many studies published in the area of the medical industry but very few that focus on the people and companies behind the scenes that generate the infrastructure for the production of medicine and associated processes.

Gaps in existing knowledge

There appears to be one very obvious omission with presently available published studies that this line of research has revealed; this author found very little material that explores the professional development of technically trained individuals within the pharmaceutical industry. This is such a concern to one market leader that they have expressed an interest to this author with regard develop this study into a potential job market game changer.

The role and importance of personal networks within the pharmaceutical industry (and engineering in general) does not appear to have been a subject of any study that this author is aware of. There are an extremely limited number of studies published in the Far East that could be developed to include these areas of concern, but given that most research and development within the industry occurs in either Europe or the USA this is an area that would appear to be ripe for further exploration.

Major trends and patterns in academic research

As mentioned above, there is very little existing direct research along the lines of this study. However, it is possible to explore the trends and patterns that helped create this study's theoretical framework, namely those that examine networks and the sociology of (industrial) product development.

Actor Network Theory

As this author started to reveal the importance of networking within the industry it was necessary to explore what material that might exist that would assist with creating a

framework that could help develop and explain the complex relationships that emerged through empirical observations and interviews. Fortunately, this is an area rich in academic research, with many devoted authors/researchers that have been widely read and critically discussed over many years. Perhaps, the most 'famous' of these researchers is Bruno Latour, who, along with co-developers, has developed an extensive list of reference works in the area of network analysis, associated actors' boundary objects, and the concept of conscription of others with the aim to promote a singular focus of attention.

The main focus of the early works appear to lay in establishing the concept of 'Actor Network Theory' (ANT), in which Latour et al. try to expose how various actors and actants interact with the ultimate purpose of promoting a particular idea, course of action, or goal.

The main strength of this concept is the transportability across every sphere and set of conditions. However, some (including founding theoretical developers) have raised concerns that the use of this theoretical modelling tool ignores the sociology (and, this researcher, suggests, also the political dynamics), where, for example, people's strength (or lack thereof) of personality can have a significant impact on the strength of ties and promotion of ideas and goals within a particular strand of a network – thus (more often than not) resulting in an unplanned/unexpected biased direction of action.

Relationships among studies

Since the publication of first paper on ANT there has been a steady stream of notable contributions to the study both by colleagues and contempories of Latour and by academics whom have become notable by their very publications relating to ANT. Both Michael Callon (1986) and the 1989 paper by Star and Griesemer addressed the important need to find common identities of objects/ideas (to make things translatable) between actants. Later on, people such as John Law and Vicky Singleton (mainly in the years 2004 and 2005) addressed the issue of the need to identify what is important – what objects really matter. More recent publications by Venturini (2010) and Vikkelsø (2007) examine how controversies, including engagement and resistance, may be explored in systems through the application of ANT.

Identify categories of studies

This author suggests that most of the studies can be classified within two (2) main categories; firstly, the exploration and development of the 'pure' theory and, secondly, the application of the theory to particular case studies. It could also be justified to include a third category, as a sub-set of the first, of works that address what the authors deemed as omissions or areas not given sufficient strength in the theoretical development category: this, third, set of studies addressed some of the social concerns that the developers of the theory placed as a lower priority (or missed completely) in their earlier works.

Social construction of technology

The second area of published research that this author draws inspiration are those that examine and develop the concept of 'the social construction of technology' (SCOT). Many students and researchers are introduced to this line of study through the work of Wiebe Bijker, Thomas Hughes, and Trevor Pinch (1987 – reprinted 2012) entitled 'The Social Construction of Technological Systems'.

Pinch and Bijker (2012:11-44) set out to reveal the relationships and discourse that result in the artifacts we use in our everyday lives in the chapter entitled 'The Social Construction of Facts and Artefacts'. Their view is that no-one will ever have full access to reality as a holistic system, as individuals we may only have access to a partial reality. Their example of the development of the bike is a common enough technology that nearly human alive today will understand the principles they are trying to convey. One of the key points is that technology also has a history and the design process is subject to unequal but largely recorded pressures – meaning that the bike as seen today may or may not be the best bike, but it is possible to understand (to a large degree) how the present design was agreed on. This interplay of actors in the formation of the artifact draws on what they term as 'interpretive flexibility': the various different social groups all have different ways of framing their understanding of the issue under consideration, and thus must also produce different ways of recognizing the solution and result(s).

This particular line of theoretical understanding could also be argued to fit nicely into Actor Network Theory in that different parties create alliances and preferred solutions, which are then knowingly or unknowingly linked through the artifact to other groups and individuals whom also have a hand in the development and interpretive use of the artifact.

The main strength of their work lies in the ability of the theory to be applied to every technical artifact. However, the weakness of the theory lies in their assumption that there has to be a closure and stabilization stage of an artefact. It assumes that there has to be a closure to a particular controversy. The closure argument means that all the participating social groups see the problem as being solved. However, throughout history, how many times can we point to a particular artifact and confidently state that 'it is finished'? Although, this author would support their assertion that a problem can be redefined in such a way to permit the majority of the social groups to accept a common solution – this they term 'translation'. This 'fudging' in order to produce a conclusion to effort is a prime factor when considering how society changes in order to cope with new technical developments.

Practice

Current Practice Theory (now referred to as 'practice') can be traced back to founding works by people such as Clifford Geertz (1972) and his work: 'Deep Play – Notes on the Balinese Cockfight'. Others, such as Pierre Bourdieu (1977): Outline of a Theory of Practice, and Gideon Kunda, (1992): Engineering Culture, have sought to tease out some understanding of the sociology underpinning how things are actually done. Many other notable practitioners have also produced works since, some of the leading authors include Lave (Chaiklin, S. and J. Lave (1993): Understanding Practice), Etienne Wenger (1997): Practice, Learning, Meaning, Identity and, more recently, people like Silva Gherardi (1999): Learning as Problem-Driven or Learning in the Face of Mystery, have directed their research in an attempt to understand how so-called 'communities of practice' evolve, organise, and are taking the lead in community learning.

A little more recently, authors such as Schatzi (with K. K. Certina and E. von Savigny (Eds.) (2001): The Practice Turn in Contemporary Theory) have become very popular with a large

number of academics, while, on the other hand, other notable authors such as Dreyfus and Dreyfus have fallen out of favour.

This author has relatively recently 'discovered' the work of Harry Collins (with R. Evans (2002): The Third Wave of Science Studies of Expertise and Experience, and R. Evans, R. Ribeiro, and M. Hall (2006): Experiments with interactional expertise), in which he addresses the complex nature trading knowledge at a high level of technical understanding.

A further area worth examining related to practice looks at the role of identities – specifically 'self-identities' in engineering. One particular author known to this researcher, Anders Buch, has produced numerous peer-reviewed article on the subject, especially as much of his research is based on the Scandinavian engineering business model.

While many of the above works may present an insight in the general field of engineering practice none examine the pharmaceutical field. Even though the pharmaceutical industrial sector is one of the largest contributors to the Danish economy, this lack of academic material in this very specialised field is unlikely to be fulfilled in the near future as the conservative nature of both the technically-minded employees and the businesses result in a black box to the outside world.

5. Data collection

This investigation largely relies on the input of data from people involved in the pharmaceutical engineering industry and, to a much lesser extent, to electronic and 'hard copy' media. It is possible to further divide the former category into two (2) distinct groups; firstly, the administrators and, secondly, the technical staff. There is a third category of staff, the support workers (marketing, sales, etc.), but this final category has little or no input to add to this investigation and will, therefore, not be taken into consideration at this time.

It could also be argued that the staff employed by the ISPE could form a further group that has valid input to this investigation. However, given that all the ISPE Nordic staff also fall into the technical staff category it would only to complicate the investigation and confuse those being questioned. If this investigation is taken further then the potential input from ISPE staff could be examined in more depth, especially those employed as full-time staff based in the United States of America (USA).

From preliminary studies into how this researcher might gain data, it became apparent that in addition to gaining data from interviews (formal and informal) there was also the opportunity to gain observational data at what the ISPE Nordic organisation terms 'Community of Practice Networking Events'. Through practical necessity, this researcher was required to take student membership of the ISPE in order to gain access to on-line data that was only available to ISPE members. A late, additional avenue was also opened up when this researcher was invited to attend the 'ISPE Nordic Sustainability Conference'. Each data stream will be explored below.

It should also be noted that this researcher had previous access to data and personal contacts through previous employment activity in the pharmaceutical engineering equipment manufacturing industry and through social interaction. Further access was also permitted through two (2) Masters projects conducted in collaboration with several pharmaceutical engineering and manufacturing enterprises. However, this pre-knowledge (previously accrued data) gained through employment and social activities that may add to current data sources will not be brought into this investigation at this time, but this

additional source could be utilised if the study is taken further or if needed for supplemental data. NOTE. As this research study progressed, this researcher deemed it necessary to bring in previous accrued data gained from interviewing technical staff employed within the pharmaceutical industry due to a large number of new potential interviewees retracting their offer to be interviewed.

When referring to 'interviews' in this investigation it is intended that this only refers to the prearranged, formal question and answer sessions in a one-on-one situation. So-called 'informal interviews' or 'chats' that took place outside the above definition will be discussed in sections relating to observations at networking events.

6. Approaching the interviews

Many avenues were explored with the purpose of finding an appropriate theoretical framework in which the study could be both developed and analysed. However, given the large number of unknowns and the desire to discover data, this author decided to use both 'traditional' Grounded Theory (as developed by Strauss and Corbin), and later into Post-Grounded Theory by Adele Clarke.

Additional tools were also selected for the analysis of the discovered data. The theoretical tools included both Actor Network Theory (ANT) and the Social Construction of Technology (SCOT).

Each of these methodological approaches will be introduced below.

Grounded theory

Given this researcher's lack of detailed knowledge in the realities of engineers' professional development and that data from a range of sources would be sought and analysed in order to understand the systems and applications of such it this researcher turned to Grounded Theory as a method to navigate and reach substantive conclusions as to the processes and interactions that may be encountered in this study.

In order to help the reader understand how Grounded Theory can help the researcher it might be helpful to briefly describe what Grounded Theory was intended to do.

In short, *'Grounded Theory is a general methodology for developing theory that is grounded in data systematically gathered and analyzed'* Strauss and Corbin (1994:273). Although this builds on the earlier work entitled 'The discovery of grounded theory' by Barney Glaser in 1967. The main (essential) element of the methodology is the requirement for the researcher to constantly compare newly discovered data to existing data. But this is not the whole story. From the above, it is suggested by this researcher that the term *grounded theory* is a misnomer – it should logically be termed *grounded methodology*, and that it can led to *theory(ies) grounded in data*.

Grounded Theory has the potential to see the data in new ways and analyses the data in all its forms from the outset of the study. Although Grounded Theory is a systematic method it has flexible guidelines for the collection and analysis of data. It can be seen as a heuristic device rather than a set of strict rules (Charmaz, 2006:1-5).

The intention of using this method is to generate an initial theory, which can then *'be elaborated and[/or] modified as incoming data are meticulously played against them'* (ibid). It is worth noting that this approach can also be used in any future study that seeks to expand on this thesis as it permits the researcher to examine data from a wide range sources, both qualitative and quantitative.

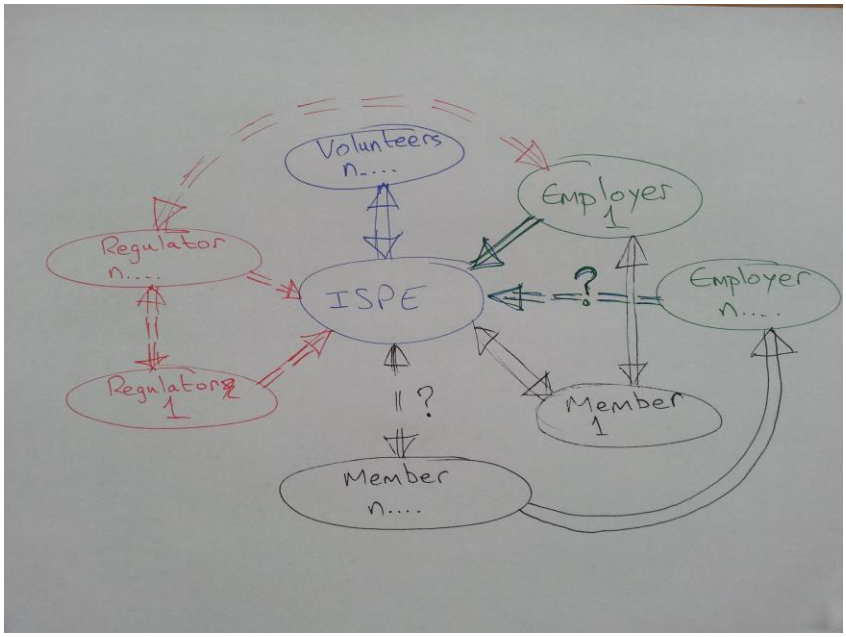
As Grounded Theory relies on a comparative analysis it also, therefore, largely dependent on the interpretive skills of the researcher. By implication, the more knowledge that the researcher has on the subject the better any interpretive comparison concluding theory should be. However, this closeness of the researcher also has dangers: for example, there will be inbuilt preconceptions within the researcher that may skew any interpretations and conclusions. This potential bias must be accounted for before the study starts, and methods must be established to eliminate these distortions as far as possible.

The development of theory need not lead to an overarching, general theory – it is also possible to develop *'a theory of great conceptual density and with considerable meaningful variation'* (ibid:274). It is with this conceptual density that the near infinite details and differences seen in the relationships can be explored – an examination of these relationships can be developed by the application of both an Actor Network Theory (ANT) approach and by the use of tools developed by Adele Clarke in her postmodernist take of Grounded Theory.

Adele Clarke's updated, postmodernist, framing of Grounded Theory offers additional inspiration during the initial analytical process. According to Clarke, the postmodernist turn shifts to permit an analysis gained from exploring the *'problematics of differences and complexities'* (Clarke, 2003:553).

In this post-modernized version of Grounded Theory Clarke offers researchers additional methodological tools such as situational maps and observations made before, between and post-interviews. These resources, which Clarke presented as a cartographic approach based on earlier work of Strauss's situatedness, proved to be very useful when used in conjunction with Latour's work on Actor Network Theory (ANT): the use of initial/messy situational maps, which this researcher chooses to term *network nodes*, can be used as the precursor to any Actor Network Theory development.

Initial/messy Situational Map



Although many elements of traditional and post-modern Grounded Theory have been applied to this thesis other elements could not be fully adopted. Even though a constant comparison of the data and coding were fulfilled, other processes such as the asking of *generative and concept-relating questions, theoretical sampling* (Strauss and Corbin, 1994:275), and development of a conditional matrix could not be fully explored. Most of these points of departure from the ideal were mainly imposed on this researcher as conditions arising from the retraction of interview volunteers. However, it is expected that these issues could be fully developed in a later, larger study.

Actor network theory

An exploration of how Actor Network Theory (ANT) can be used to identify the relationships encountered by the International Society of Pharmaceutical members' when in establishing how individuals can transition from being a novice to an expert within the pharmaceutical engineering industry.

In order to aid this exploration it may be helpful to briefly introduce Actor Network Theory (ANT) by stating that it is has been called an enrolment theory, which is also termed the sociology of translation. However, in Latour's 1996 paper *On actor network theory: a few clarification*, Latour addresses some misconceptions on ANT and offers us a broader term *relationist* (Latour, 1996:376) as a way to placate some of the more excitable researchers and theorists.

ANT was developed by Michel Callon, John Law, and Arie Rip (Latour, 1996:369) in the early 1980s. It was developed in an attempt to analyze and understand processes involved in technological innovations and scientific knowledge-creation. However, even John Law does not place an exact date on when *'actor network theory achieved recognizable form as a distinctive approach to social theory'* (Law:2009:146).

ANT states that everything is connected to everything else and no-one acts alone, thus all surrounding factors have equal importance and have to be considered. This offers the researcher the ability to *'...destroy spheres and domains, to regain the sense of heterogeneity, and to bring interobjectivity back into the centre of attention'* (Latour 1994), thereby presenting a method to avoid (or greatly reduce the likelihood of) partisan or undue influence of the more powerful (more represented) actors in the net.

The ANT method was selected as a tool in which some of the relationships and mechanisms of negotiation could be discovered, which will help to inform the investigation's analysis of how novice pharmaceutical engineers may move into a position of expertise within their selected field. John Law's introduction in his chapter entitled *Actor Network Theory and Material Semiotics* gives a concise description of the purpose and scope of ANT:

'Like other material-semiotic approaches, the actor network approach thus describes the enactment of materially and discursively heterogeneous relations that produce and reshuffle all kinds of actors including objects, subjects, human beings, machines, animals, "nature," ideas, organizations, inequalities, scale and sizes, and geographical arrangements.' (Law, 2009:141)

However, as Latour noted, ANT is *'...bad for differentiating associations...'* and *'...has very little to do with the study of social networks'* (Latour, 1996:369). According to Law, post-late 1990s ANT now also examines the *how* in the discovered networks:

> *'…how it held together; how it shaped its components; how it made a center and peripheries; in short, of how differences were generated in a semiotic relational logic'* (Law: 2009:146).

Above all else, ANT cannot exist outside practice. There has to be a case on to which it is applied.

For the very necessary examination of the social other approaches need to be considered – in this study it has been decided to use a Social Construction of Technology (SCOT) approach to help with understanding the entanglements that may be encountered – this approach will be discussed later.

It is important to mention that ANT does not differentiate between nature and society, human and non-human, agency and structure, context and content. ANT further states that all entities are related with each other through various networks and in this way they achieve significance in relation to each other (Crawford, 2005:1). But it should be noted that these networks are only a snapshot – a discovery of these *'provisionally commensurable connections'* (Latour, 1996:370) cast a light on this network at one instant of time and in one set of circumstances. It could be argued that closure is not and can never be attained as the network can be constantly expanded and refocused.

ANT considers both human and non-human (machines, animals, texts, etc.) as having agency, which are connected in different networks (multiplicity) and is conceived as a

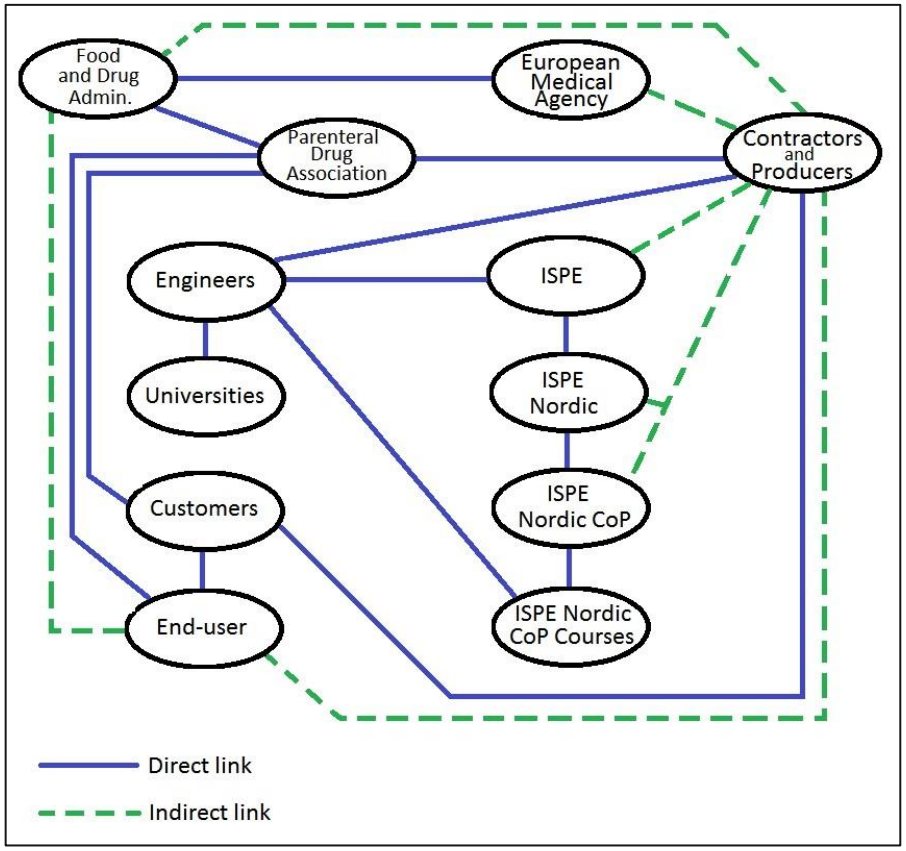
heterogeneous amalgamation of textual, conceptual, social, and technical actors. An actant is the term used in ANT for an actor which can exercise deliberate intent. An actant can be any agent, both, collective or individual, that can freely associate or disassociate with other agents. Actants are defined through their participation in networks. Networks provide actants with name, substance, action, intent, and subjectivity. The nature of actants is derived through association to those networks, and they don't have to have prior substance or essence (Crawford, 2005:1).

In order to summarize the main aspects of ANT this author refers the reader to a short abstract from a chapter written by Crawford, which was written as the section on Actor Network Theory for an encyclopedia of social theories:

> *'ANT is interested in the ways in which networks overcome resistance and strengthen internally, gaining coherence and consistence (stabilize); how they organize (juxtapose elements) and convert (translate) network elements; how they prevent actors from following their own proclivity (become durable); how they enlist others to invest in or follow the program (enroll); how they bestow qualities and motivations to actors (establish roles as scripts); how they become increasingly transportable and 'useful' (simplify); and how they become functionally indispensable (as obligatory points of passage).'* (Crawford, 2005:1)

It is important to appreciate, as Latour points out that; *'A network is all boundary without inside and outside'* (Latour, 1996:372) – meaning that it is realistically impossible to depict a network. This also means that to speak of a multiplicity of networks is logically wrong – there can be only one, universal network. However, it is possible to discuss these sub-networks using Latour's term *nodes*.

Initial network node map:



One of the initial corner-stones of this research is the identification of the actors by using aspects of classic ANT. Among these actors are likely to be a number of boundary objects that have one or more particular meanings/uses to one (1) or more actant – the concept of what a *boundary object* is and how they come into being was raised by Star and Griesemer in an article published in the Social Studies of Science titled *'Institutional Ecology, `Translations' and Boundary Objects'* that was intended to be an ecological amendment to the *interessement* model of Latour, Callon, and Law and develop the concept of boundary objects (Star & Griesemer, 1989:388) – the objects (physical items, ideas, and thoughts) that have influence on more than one (1) actor are termed *boundary objects* (ibid: 390).

The prime consideration in the Star and Griesemer paper is *'…the problem of common representation in diverse intersecting social worlds'* (ibid) – various actants working with the same material in different ways. This stems from the fact that *'…scientific work is heterogeneous'* (ibid:387) and in order to make any progress in a network system ideas and

thoughts must be translatable between these very different actors and actants. Likewise, this author's group investigation task also has to establish a common representation of objects in a heterogeneous system if the task of intervening is to be successful.

At this stage of the investigation is not possible to establish an exhaustive list of actors and boundary objects as some known actors choose to keep their distance from this investigation (every Human Resources Department that was approached choose to observe but not participate with this study) – but through preliminary research has been able to realise that a number of these objects do exist and that they are used by various actants in various ways to achieve very different objectives and results. The quest for now is to work out what these objects mean to the actants and how they may be used in the future.

The application of ANT enables the research to conclude what factors (actors) are really important and *'…how they become increasingly transportable and 'useful' (simplify); and how they become functionally indispensable (as obligatory points of passage)'* (Crawford, 2005:1).

One of the core elements of ANT is translation, where materials, actors, and texts are being translated into inscriptions also called *immutable mobiles*, which in their turn influence other actor networks, thus it is necessary that the translation is being defined and controlled through development of strategies and application of considerations. Latour (1999) provides a very good example of this process in his chapter Circulating Reference, where the use of a simple colour chart permitted the transfer of one kind of data into a different form that researchers from two different academic fields could understand and use.

These translations are necessary in order to permit communication between actors – to provide a common frame of reference. Immutable mobiles could be described as combinable textual, cartographic, or visual representations that remain stable through space and time (Crawford, 2005:2).

> *'To translate is to make two words equivalent. But since no two words are equivalent, translation also implies betrayal: traduction, trahison. So translation is both about*

making equivalent, and about shifting. It is about moving terms around, about linking and changing them.' (Law: 2009a:144)

It is, therefore, safe to state that translation is always somewhat insecure and susceptible to failure, and thus deserves additional attention as an aspect which has great influence in different networks (Law, 2009:144).

To leads on to the *obligatory point of passage*; when the actors are identified, they have a certain problem in common and usually the problem is defined by one of the actors (a spokesman). The actors have to deal with, relate to and adopt the problem before they are able to pass the obligatory passage point (Callon, 1986:7-8, 20).

There is then a need to sort the attachments that the actors selective choose to be identified with or by them. The very term *attachments*, as Jensen notes (Jensen, 2007:239) is not free from meaning – to attach is to give strength to a connection and, hence, it should also be possible to qualify and even quantify the strength of the attachment(s) if we so wish. How, then, if so desired, can the Group reach an accommodation as to the organisation of these matters? One approach the Group will be using to aid untanglement is detailed by Law in his 2004 paper *Matter-ing: Or How Might STS Contribute?*, in which he builds on the 2003 paper by Barad – *differential mattering/intra-activity* (Barad, 2003:817). Law attempts to critique some of the modes of mattering encountered within a specific public scare issue. In short, and even Law states that his list could have been longer or shorter, he presents six (6) modes of matter in two (2) phases that permit this author's research group to order a complex and wide-ranging data of empirical data; the first phase consisting of a critique, a puzzle solving, and a balancing.

These considerations can then be moderated within the second phase modes of *interference*, *avant garde*, and *inspiration*. (Law, 2004:3-9) For the Group, it is too early in the project to see how, if any, arising attachments may be moderated through the application of Law's modes of mattering approach.

The results of sorting and re-sorting of attachments are, according to Jensen (2007:249), not predictable and could be seen as more as a tool for the managerial strategists – as is the case for this author's group in reporting its findings to the client's company.

An alternative view could be drawn from Law's 2009 paper *The Greer-Bush Test: on politics in STS*; where he counters Latour's attempt at singular ontology to that of a plurality of ontologies, where a multiplicity of realities are *'…uncertain and provisional…'* (Law, 2009b:4). However, both Latour and Law agree that there is a need to create a singular, common understanding of the world.

Inspiration can also be drawn from Casper Bruun Jensen's paper (2007) *Sorting Attachments* and the paper *Object Lessons* by John and Vicky Singleton (2005) to provide tools with this *'action-orientated research'* (Jensen, 2007:237) but, as Jensen goes on to note (ibid), this is contrary to the constructivist approach that this investigation initially wished to adopt. However, this constructivist approach may now look premature given that the investigation examines how a series of processes with many actors may function. These, apparently disparate processes, as Jensen notes, can also be thought *'as a kind of machine for making element cohere as an event'* (ibid – referring to Brown, 1997,65).

The greatest danger for the researcher investigating a process was very clearly portrayed in the paper *Object Lessons*, written by Law and Singleton (2005), when Vicky Singleton was asked by the Director of Research and Development for a local area Hospital Trust in The United Kingdom to examine the management and treatment of alcoholic liver disease; So-called *messy data* prevented the Trust's management from gaining a clear image of the issues but, somehow, they knew something was wrong and *'he wanted know more about how patients with alcoholic liver disease travelled through the hospital system'* (Law & Singleton, 2005:332), and, as Law and Singleton point out, *'it is not possible to know messy objects'* (ibid:333) and, therefore, it would be unreasonable, in hindsight, to expect the Director to find a single, one-size-fits-all solution.

In the Singleton case study, from the outset of conducting interviews with a wide range of staff it was immediately obvious to the researchers that each interviewee saw a different

picture, which they found *'more or less impossible to fit them together'* (ibid) – the collection of differing accounts is also a very real prospect for this investigation as every potential interviewee will have a very different set of experiences and terms of reference from which to express their responses to the questions and, like Law and Singleton (ibid), the initial methodology is also starting to look lacking when addressing these strikingly similar contextual processes.

So, what can this author take from the experiences and findings portrayed in the Law and Singleton paper? Perhaps, as proposed by Law and Singleton, it would be possible to take various approaches to examine each individual system (nodes of activity) – each providing unique insights but also generating fresh issues relating to the reporting of the interpretation of the findings.

So far, no ethical positioning has been addressed with regard to the topic under investigation. Although the work of Jensen highlights some *'costs of intervention'* (Jensen, 2007:249) – the use of the term *costs* in this context must be taken to mean consequences in this application – Jensen does not wish the researcher to abandon these aspects, he merely highlights that there must be a mechanism that:

> *'…facilitate[s] a reconsideration of the possibilities of social science engagement, based on an ethics of specificity, which acknowledges that 'usefulness' and 'intervention' are never singular terms, but always cover a multiplicity of meanings and practices, which may well be in tension'*. (ibid)

He continues with a reassuring openness in the application of sorting attachments that this researcher finds useful when addressing the ethics of this particular intervention:

> *'…a performative approach stresses that research always deals with multiple attachments to other actors. But it also allows us to ask whether the enactment of the 'joint' must by necessity remain so unidirectional. Rather than accepting as given the established forms of cooperation between research and policy, with their in-built understandings of practical interventions, this suggests that it would be a highly useful*

task for STS researchers to experiment—in both theory and practice—with alternative modes of sorting attachments.' (ibid)

From the above, it is clear to see that Jensen is instructing the researcher to find new and novel ways of sorting those attachments that are under tension and a study of the ethical considerations may offer at least one new approach to the examination of the system and, at the very least, that *'…[the] social research can do other, more and better than speaking a simplified truth to power'* as Jensen hopes (ibid).

The important phase for this investigation will be reporting phase of the work, that is, how the various actors and actants organise, focus, and reports their findings on a collection of key attachments – the very real question of *'how to speak truth to power'*. It may be perceived that this author's attempts and objectivity be seen *'…as a cover up for the exercise of power over weak practices…'* (Jensen & Lauritsen, 2005:59).

As Carlile noted in his 2002 paper on *A Pragmatic View of Knowledge and Boundaries: Boundary Objects in New Product Development,* knowledge is always locally situated and is very difficult to transfer (Carlile, 2002:442). This investigation must, therefore, also be aware that there is an additional *boundary object*; the *'knowledge boundaries'* (ibid), not only between the organisations and researcher as highlighted by Carlile but also between the employees being interviewed and the researcher – each with their own metalanguage, pre-existing thoughts, and patterns of understanding. The remoteness of the Human Resources Department also means that this researcher cannot be sure what boundaries exist between their offices and the employees being interviewed. Careful attention will have to be paid to these issues, but previous cooperation between the researcher and actants within some the commercial entities has been proved to be successful when communicating results and conclusions of previous investigations.

This researcher must try to take encouragement from the work of Isabelle Strengers in arena of communicating proposals and awareness of ideas where these knowledge boundaries occur.

Although meant for a very particular application, Strengers (2005) *The Cosmopolitical Proposal* gives encouragement and encourages the researcher not to lose spirit given the severe time restrictions in place for this *intervention*. There must be time set aside for reflection, both for the researcher when writing reporting findings and for the client (ISPE) to take in these thoughts.

This does not mean that it is realistic to expect a global understanding of a single truth, it merely means that the fullness of the possibilities should be appreciated. (Strengers, 2005:995)

Boundary objects

One of the initial corner-stones of this research is the identification of the actors by using aspects of classic Actor Network Theory. Among these actors are likely to be a number of boundary objects that have one or more particular meanings/uses to one (1) or more actant – the concept of what a *boundary object* is and how they come into being was raised by Star and Griesemer in an article published in the Social Studies of Science titled *'Institutional Ecology, `Translations' and Boundary Objects'* and was intended to be an ecological amendment to the *interessement* model of Latour, Callon, and Law and develop the concept of boundary objects (Star & Griesemer, 1989:388) – these objects may be physical items, ideas, and/or thoughts that have influence on more than one (1) actor (ibid: 390).

A concern when discussing these boundary objects is the choice/use of terminology. Often the infralanguage is poor (Latour, 1996:378), meaning that it can be difficult to make translations between actors and (especially) network nodes. One (1) example of this difficulty this researcher came across can be seen in the use of the term *SME*. For economists and many others, for example, the term *SME* means small- and medium-sized enterprises, but for the pharmaceutical engineers this term refers to specialised market experts. These tokens of transfer (ibid:279) are central to the collective understanding and acceptance that is needed in order for the stabilisation of the network.

The issue for finding accepted conventions is a prime consideration in the Star and Griesemer paper, where there is *'…the problem of common representation in diverse intersecting social worlds'* (Star & Griesemer, 1989:390) – that is, various actants working with the same material in different ways. This stems from the fact that *'…scientific work is heterogeneous'* (ibid:387) and in order to make any progress in a network system ideas and thoughts must be translatable between these very different actors and actants. Likewise, this researcher's task also has to establish a common representation of objects in a heterogeneous system if the task of observing (intervening) is to be successful.

Even mid-way through this thesis it was not possible to establish an exhaustive list of actors and boundary objects as some known actors choose to keep their distance from this investigation (every Human Resources Department that was approached choose to observe but not participate with this study) – but through preliminary research has been able to realise that a number of these actors and objects do exist and that they are used by various actants in various ways to achieve very different objectives and results. The quest for now is to work out what these objects mean to the actants and how they may be used in the future.

The application of Actor Network Theory enables the researcher to conclude what actors are really important and *'…how they become increasingly transportable and 'useful' (simplify); and how they become functionally indispensable (as obligatory points of passage)'* (Crawford, 2005:1).

The process of translation within Actor Network Theory, where materials, actors, and texts are being translated into inscriptions also called *immutable mobiles*, which in their turn influence other actor networks, requires that the translation is being defined and controlled through development of strategies and application of considerations. Latour (1999) provides a very good example of this process in his chapter Circulating Reference, where the use of a simple colour chart permitted the transfer of one kind of data into a different form that researchers from two different academic fields could understand and use.

It was initially expected that an important phase for this investigation would have been reporting phase of the work, that is, how the various actors and actants organise, focus, and

reports their findings on a collection of key attachments – the very real question of *'how to speak truth to power'*. It may have also been the perception by some that this author's attempts and objectivity be seen *'…as a cover up for the exercise of power over weak practices…'* (Jensen & Lauritsen, 2005:59). However, the evolution of the thesis has meant that these phases are best left to a hoped for, longer, more in-depth study.

This does not mean that it is realistic to expect a global understanding of a single truth, it merely means that the fullness of the possibilities should be appreciated (Strengers, 2005:995). But, as Strengers reminds us; at all costs, *'Express yourself, express your objections, your proposals, your contribution to the common world that we're building'* (Strengers, 2005:996).

The social construction of technology

According Wiebe Bijker, the credit for the term *social construction* is attributed to Berger and Luckman in 1966 – with their argument being that *'reality is socially constructed'* (Bijker, 2009:88).

The development of Social Construction Of Technology (SCOT) took root in northern and western Europe and The United States of America in the 1970s, emerging from the studies of science-technology-society, sociology of science, and history of technology (ibid).

Early methodology borrowed much from the Edinburgh School's *Strong Programme*, but it also clear to see many elements from the Bath School's Empirical Program of Relativism (EPOR) programme have been incorporated into current methodology, especially interpretative flexibility, the concept of a closure of controversies, and the identification of a closure mechanism. But it was not until the conclusion and publication of the findings of the 1984 meeting in The Netherlands that a coordinated approach emerged (ibid:90).

The combination of the academic rigours encouraged by the Strong Programme and interpretative skills promoted by the EPOR programme gave researchers a stronger academic standing, which gave more credence to their work than had previously been the

case, especially to the scientific community in whose area the researchers would be exploring.

For this thesis it is important that it is possible to identify and use a single artifact as the point of examination if the SCOT approach is to be useful, and this effort is ably assisted by this researcher's decision to use Actor Network Theory in order to identify key actors and actants – one of which may be selected as the single artifact. Or, more precisely, the multiple single artifacts closely matches the tokens that move between the network hubs – these networking hubs already having agreed on a single token to be promoted (and possibly translated) to others in the larger, systemic network.

Pinch and Bijker (2012) describe the social construction on facts and artefacts. Their view is that it is never possible to have access to reality in full, there is only access to partial reality. They use the design of the bicycle as an example to explain the process of a technological development. In the past, bicycles where used by men for fun, not for commuting. The point is that technology has a history as well and it is not possible to know if the bicycle as seen today is the best bicycle, but the design process is known. They explain SCOT in terms of interpretive flexibility, meaning that there are different social groups, people have different ways of framing, and there are different ways of recognizing the solution.

> *"...there is widespread agreement that scientific knowledge can be, and indeed has been, shown to be thoroughly socially constituted. These approaches, which we refer to as "social constructivist," mark an important new development in the sociology of science. The treatment of scientific knowledge as a social construction implies that there is nothing epistemologically special about the nature of scientific knowledge: It is merely one in a whole series of knowledge cultures…"* (Pinch and Bijker, 2012:12-13)

As SCOT seeks to explore the aggregation of developments that have led to closure and also to explore the impact on society of an artifact(s) (Bijker, 2009:91) the application of SCOT could prove to more useful in the redefined question being examined in this thesis. The advent of new information so late in the time frame permitted for this thesis meant that many potential interesting avenues of investigation that might reveal one or more closure

mechanisms that could not be fully explored here. However, the application of SCOT could even more useful in the development of a later, larger study.

Present SCOT research, according Bijker (ibid), now turns its attention to the rationales and to the administration of technical innovations. For this researcher, these issues have proved to be the most critical to the study but also the most difficult to discover. Again, it is hoped that a follow-on study would be able to gain the necessary access to the mechanisms presently hiding in the shadows. The three steps described by Bijker as a heuristics for research of finding the relevant social group/interpretative flexibility, an examination of the process of dominance/stabilization, and analysis/interpretation in a broad theoretical framework (ibid:92) cannot be addressed in this thesis due to the late discovery of key data, but the emergence of this important data has opened-up the potential to engage in a study that has been strongly encouraged by industry.

7. The interviews

The theoretical approach – Grounded Theory

Grounded Theory was selected as the methodological approach for the interviews. In this 'theory', which should really be termed as a methodological approach rather than 'theory', reality is always changing and constantly evolves through the involvement of the negotiation between people (Richards & Morse, 2013:61). The Grounded Theory approach can be used to investigate which experiences, for example, the employees have in a situation where change is expected or new, additional data raises potential new avenues of investigation.

It was not always possible to address every open question or line of enquiry as many of the subjects under review travel extensively. The formal interviews gathered information through the use of semi-structured interviews with ISPE members whom agreed to be interviewed. However, as mentioned above, after most of the first-round interviewees retracted their offer to be interviewed alternative solutions had to be sought in order to continue the study. This interview form was selected because there was certain, basic information needed from every participant, but this author did not want to limit the knowledge gathering opportunity by imposing an overly strict line of questions. When this author approached potential interviewees it was with the realisation that the cross-section of these individuals would be largely left to chance – with a high risk that several interviewees may have similar roles and professional backgrounds. However, this was done in the hope that getting access to one individual might lead to a chain reaction of offers from people whom would agree to be interviewed.

As the research questions in Grounded Theory are based on processes and changes it is intended that, through them, a researcher can construct a theoretical structure. Often, these questions will explore a process or a certain situation within a process. In this study, this researcher intended to investigate the process of how pharmaceutical engineers may move from being seen as a novice to being recognised as an expert – a soon-to-be-realised issue of a lack of accepted definitions raised further avenues of investigation. There was also a need (desire) to reveal how the ISPE may fit into this professional development structure.

Although not part of the main line study, data was revealed that gave a brief insight into the ethical considerations that the individuals encounter or address.

Reliability

An interview guide, with an overview of the topics we needed input on, was made before conducting the semi-structured interviews. There was also a realisation that the Masters Programme learning goals that had to be addressed when seeking data. This also included a template for the format of the interviews. Each interviewee was to be asked a series of set questions that would be applied to every interviewee, and then the new data discovered during the interview would lead the discussion. After each interview questions were reappraised for suitability, and were rephrased or changed according to need (including making them more relevant to the background and working area of the next interviewee). A vital element of the data collection process was the need to understand the technologies and processes encountered by the interviewees, hence the attendance at ISPE networking events and revisiting previous employment and study experiences. This also made it easier to formulate supplementary, relevant questions during the interviews.

To make sure that the study had a high as possible reliability it was necessary to make the process and results from each interview have the same format so data could be easily compared and analysed – this also included the transcriptions (see Appendix for all interview transcriptions). This, across-the-board, symmetry of format aided the coding of the interview data, where key words, themes (categories), and broad subject matter were realised. This, coding and theming could have been made more reliable with the inclusion of more researchers – whom would able to see passed personal (unacknowledged/unappreciated) bias held by this researcher.

Key themes (known as 'abstractions' in Grounded Theory) were selected on the basis of results realised from the interview data and with aim to reveal answers to the main problem formulation and the learning goals. As mentioned above, if more researchers had been a part of the process the reliability of the entire process would have been more secure.

Bias

There are some biases that have to be addressed. It should be noted that a bias may exist that affects the impartiality of this report due to previous employment within the pharmaceutical equipment supplier industry sector, and that it was necessary to become a member of the ISPE in order to gain access to 'member only' material and data sources.

Additionally, contact with the ISPE main administration led to a formal request from the ISPE to receive this investigation's findings and a request for this researcher to be interviewed for the ISPE Pharmaceutical Engineering in-house magazine.

Further, the collection of data, according to Grounded Theory, is an established method of critical empirical data enquiry, where 'data [is] systematically generated and analysed. Theory evolves during actual research, and it does this through continuous interplay between analysis and data collection' (Strauss & Corbin, 1994:273).

This approach has a need for in-depth and detailed information and, therefore, there is an acceptance that more semi-structured interviews and empirical observations would improve the reliability as, in Grounded Theory, the data collected has to be as in-depth and as detailed as possible – This researcher is aware that the limited number of semi-structured interviews and informal 'chats' might not fulfil this criteria to the degree that the study truly requires. The interviews were also set in times and locations that were not always idea – relying on the good will of the individuals agreeing to be interviewed. The limited number of semi-structured interviews meant that extensive coding and theming expected in the Grounded Theory process could be improved with more formal interviews. The lack of more coded data prevented a building on the issues raised in the absent subsequent interviews. But, nevertheless, attendance at various ISPE Networking events enabled this researcher to conduct further, informal 'chats' (informal, largely limited-structure interviews) with the other attendees. Follow-up questioning would have been useful but this was not possible within the time frame. Therefore, Grounded Theory was mainly used to gain insights and knowledge arising from the analysis to replies given to questions in the interviews.

Interview methodology

It was decided to use Adele Clarke's updated, postmodernist framing of Grounded Theory as, according to Clarke, the postmodernist turn shifts from traditional modernist emphasis on:

> '...universality, generalization, simplification, permanence, stability, wholeness, rationality, regularity, homogeneity, and sufficiency, then postmodernism has shifted emphases to localities, partialities, positionalities, complications, tenuousness, instabilities, irregularities, contradictions, heterogeneities, situatedness, and fragmentation - complexities.' (Clarke, 2003:555)

In Clarke's version of postmodernist Grounded Theory differences and complexities are used

> 'to develop means and modes of regenerating and updating a very popular and epistemologically sound approach to qualitative analysis called grounded theory to focus on these problematics of differences and complexities.' (Clarke, 2003:553)

However, this does not prevent the application of methodological aspects of the post-modernized version of GT in this research, namely situational (network nodes) maps and observations made prior and post-interview, which Clarke (2003) presented as a cartographic approach based on earlier work of Strauss's situatedness. A limited number of situational maps will be presented in a greater detail in other sections of this paper.

While it has not been possible to make observations from interviews of staff whom administer the staff development functions (Human Resources or Personnel Departments) in pharmaceutical engineering companies – for reasons that will be explored later – it was possible to draw on personal experience of working within such companies and from the attendance at various ISPE Nordic Community of Practice networking meetings in order to know whom to approach to get the greatest likelihood of receiving a positive outcome in respect to obtaining interviews. In most cases, these approaches for interviews were only possible on the condition of becoming a 'Student Member' of the ISPE (by gaining direct access to engineering staff at networking events) – and this approach presented this

researcher the view of looking with the eyes of an outsider within – in many ways, similar to the oft quoted work of Clifford Geertz (1973) and his observations of the rituals of remote village life in Bali.

These networking meetings, as the name implies, are intended to facilitate the exchange of information and experiences by ISPE members and other, invited, non-ISPE members. In addition to seeking out potential interviewees it also afforded the opportunity for this researcher to informally interview various attendees on a wide range of issues ('chats'), including seeking opinions on the validity of this investigation – the result being that subject of this investigation was universally warmly welcomed as an interesting and worthwhile endeavour by those questioned.

Reliability

An interview guide was made before conducting the semi-structured interviews and a provisional list of questions was submitted for review and was amended where necessary. Before the start of the first interview this guide presented an overview of the topics that input was needed on and the format of the interviews. It was decided that each interviewee would be asked about 20 questions that aimed to be as specific as possible in a limit number of subject areas, and more detailed follow-up questions would be asked if and when necessary. These, very detailed questions were proceeded with questions that gathered basic data relating to the interviewees educational and professional development background. This also made it easier for to make supplementary, relevant questions. Questions were to be refined for each subsequent interview following analysis, coding, and abstracting the interviewee responses. However, due to factors that will be discussed later, many (nearly all) of the initial and second-round interview volunteers recanted their involvement, and thus further work is needed in order to produce a more accurate analysis.

To ensure high quality transcriptions were made a professional was used to produce the written record used to aid the historical integrity and analysis of the interviews. It was not deemed necessary to include pauses, sighs, or hesitations that occurred during the interviews – this consolidation of effort also permitted a reduction in costs and time needed

to produce the written record. Given the limited number of formal, recorded interviews it was also decided not to make a formal coding and category map as may be expected in Grounded Theory-based investigations. Although comparatively little formal coding was done this does not mean that areas of interest and commonality (themes and categories) were not noted for later examination – indeed, one particular theme proved to be critical to the direction of this investigation; namely, the lack of a formal definition of what is meant by an 'expert' in pharmaceutical engineering. If working within a group researchers on this same investigation it is likely (expected) that a full coding and categorisation exercise would have been performed in order to reach a degree of common understanding and to develop further lines of enquiry.

All potential interviewees were made aware that their input could be made anonymous, but no interviewee deemed it necessary.

8. Analysis of formal interviews

The interview process occurred in very distinct and different stages; first, the initial planning of the interview process for presentation to prospective interviewees; second, early large uptake of offers by ISPE members to be interviewed; third, the rejections; fourth, grasping for straws in order to obtain any data; fifth, a change of direction, selecting to obtain data through informal interview at ISPE Networking event s and conferences; the sixth, and final step, the analysis of recorded data.

The series of retractions had a very negative effect on this researcher for many reasons. Some of the practical effects was the lack of data that could be processed, and this delay in obtaining data produced a structural issue related to the time frame for the study, and (perhaps the most damaging) there was a large psychological impact on this researcher – resulting in stress-related illness. However, later data revealed that these rejections were to be expected and quite normal in this particular cultural arena.

The first two (2) interviews focussed on their education, training, and activities with the ISPE. It was an over-sight on the part of this research not to include more in-depth questions on how they process ethical concerns and professional responsibilities. However, this omission is somewhat mitigated as this area was addressed in some depth in several interviews conducted by this researcher and a small group of student colleagues during a previous collaboration project with pharmaceutical professionals – the conclusions of which can be easily translated into this study.

Interview 1: A long-serving pharmaceutical project engineer.

In many ways this first encounter with an American-trained engineer served to provide an alternative to the later, Nordic, data set of experiences. There was an overall atmosphere of openness with the responses to the questions posed. However, in hindsight, the experiences revealed by this interview could be seen as merely clouding the issues gained in later interviews and chats – all of whom had been educated, trained, and gained nearly all of their professional experiences in the Nordic states.

For this first interviewee, his value to his employer was solely based on his broad professional experiences – where he was expected to successfully overcome any unexpected issues while working with clients and suppliers from many different disciplines. He could be defined as the expert bridge builder and problem solver, bringing people and ideas successfully together.

His reply to questions relating to qualifications in the industry led to the first interpretation of what the term 'expert' in the pharmaceutical industry might be: when relating his professional education he laid out the terms of a now defunct series of courses that formed the Certified Pharmaceutical Industry Professional qualification: "You know that you are not necessarily an expert because you know A, B, and C, but you had to have a complete understanding of how they interact within the full scope of the pharmaceutical industry". From this response it is clear to see that to be accepted as a qualified expert an individual had to be able to understand the wider concerns of many concurrent issues and be able to place them in context.

When asked about his connection to and of his view towards the activities of the ISPE his input and views of the organisation were both limited and yet focussed. Like most later interviewee respondees, he maintained links with only two or three ISPE 'Community of Practice' areas – stating that this was a conscious choice in order to concentrate on a few lines of development and the nature of project work (time/finances) preventing deeper involvement even if desired.

However, later statements from this individual highlighted the fact the options for ISPE involvement were often linked to the sponsorship/acceptance of the opportunities of ISPE involvement by individual managers – some leaders were encouraging of membership, and even taking an active role in the ISPE events, and others much less so.

Interview 2: Experienced pharmaceutical industry manager/leader

In contrast to the first interview, the second interviewee had been wholly educated and trained within the Danish/Nordic working environment. However, his overall personality

showed to this author that he was also a self-motivated person, who also taken every opportunity presented to him. And both interviewees had taken the opportunity to learn from informal mentors from an early stage in the engineering careers. As with the first interview, there was an overall atmosphere of openness with the responses to the questions posed. However, the roles in which they employed their skills were very different; the former being a 'hands on' project engineer and the later taking the management direction.

Like the first interviewee, his value to his employer was also based on his broad professional experiences. The one difference being that this, second, interview had carefully developed a wide professional networking web of contacts – and this network was responsible for obtaining his present role as no job actually existed before he expressed an openness for a change of job to a contact:

> "I was kind of indicating that I was interested in making a move and then again actually XX from XX, so I had a discussion with him and I was saying that maybe if you think that XX could have a person like me then consider it, and then he shared that knowledge with his colleagues, and other colleagues said yeah, we actually want to be a little stronger in this area, and then they contacted me and we had a meeting."

When asked what his what, if any, special ability helped his professional development he immediately pointed to the ability to network and interact with people. It would appear that the ability to network successfully is a requirement for a successfully career path within the pharmaceutical industry. This might also explain why companies like NNE Pharmaplan have two lines of promotion; one for pure researchers whom have a very high degree of technical proficiency and another for the management of technical projects – where the ability to network is a highlighted skill in itself.

When asked about his connection to and of his view towards the activities of the ISPE his input and views of the organisation were very broad and involving – having taken various on many Communities of Practice with the ISPE over many years. Although he taking a step backwards from these events he still maintains his links with wide range of technical practice areas and ISPE Board members.

The 'chats': Informal interviews and meetings at ISPE events

As previously mentioned, in order to overcome the obviously limited results brought on by the initial acceptance then retraction of interviewee offers, it was necessary to seek alternate sources of data within the concept and time frame permitted by this research study constraints. One solution to this was to seek empirical data from attendees at various ISPE Networking events and conferences.

It immediate became obvious during these 'chats' that this mode of information exchange was preferable for most of the attendees – being away from their place of work they felt more relaxed and were there to network (talk), so when this researcher approached individuals they were mostly very open to brief Q and A sessions.

The one down-side of these Q and A sessions was that it was impossible to predict whom would attend the event and that it would be most unlikely that I would be known to them in advance. However, with the active support of the event Chair I was able to approach and 'interview' several people at each event. One problem with approach was the lack of immediate recording/note taking opportunities – this researcher was hugely dependant on making very brief and fast notes after event (see 'Empirical Observations' section for the event process). This researcher took the decision not to stifle potential open and flowing conversational opportunities by the use of recording devices and note taking during the short interval periods.

Conclusion

It would be reasonably safe to conclude that every ISPE member approached with the purpose of obtaining data during the networking events was amenable to discussing their education, backgrounds, and roles with the pharmaceutical industry – which is in direct contrast to taking formal interviews. The most common reason for later retraction of interview offers was based on along the assertion that they did not feel they were qualified to talk on a subject – this response applied to about 75% of interview call-offs. It is possible that the requested prepared list of questions might have been one reason for their position

– perhaps the number and content of the questions was a factor in their decision-making process.

Summary

Overall, the informal nature of the ISPE Networking event should have alerted this researcher to the general nature of those whom attended the events – the 'soft' approach gaining most opportunities and data.

Most of the above was only possible to the access permitted by being an ISPE Student Member, the encouragement of the ISPE Nordic Affiliate Membership Secretary, and support from the ISPE International Secretary. This researcher was even asked and consented to be interviewed for the in-house published ISPE global magazine (see appendix) on the strength of support for this line of study.

9. Empirical observations

Empirical Observations taken during the ISPE Nordic CoP networking events. This study includes an in-depth report from the first attended ISPE event. As subsequent events followed the exact same pattern this author has only placed limited notes from the second and third events.

Event 1. Date: 19 February, 2015. Location: Ramboll, Copenhagen.

Event: International Society of Pharmaceutical Engineers (ISPE) Nordic Process Analytical Technology (PAT) Community of Practice (CoP) Networking Event.

Observations: Made during event on an iPad.

The event was officially coordinated with Ramboll. Ramboll provided the room, ID tags, WiFi, free parking, and refreshments.

Introduction and presentation 1) Received name tag, welcome pack: feedback form, list of attendees, list of upcoming events, membership application forms, advert for European Conference. 29 people at event (plus 3 late arrivals), for 2 hours. Attendee profiles: Only half attendees were ISPE members. Gender mix: 9 females, 23 males. About 10% from academia. No senior (management) staff present. Two students (including me). Attire: business casual. Ages: post-graduate to mid-level professional. 80% appeared to be middle-aged. General observation: Very diverse audience, from masters students and PhD lecturers to experienced industry professionals. 15 minute welcome and introduction: general introduction to ISPE and overview of event: 3 speakers on different Process Analytical Technology (PAT) applications.

Presentation 2) Given by Postdoc at CU. Used a screen and Prezi slides. Presenter not previously aware of participants' backgrounds. 35 minute presentation plus 10 minute Q&A. Subject of presentation: rheology, study of the flow matter and deformation. Polymers. Rheometry: measurement of flow and viscoelastic properties.

Interval 1) 5 minute break, coffee, water, soda, fruit, and small cakes. Many small group discussions. Contacted Mark Palanker and asked for interview, got his business card, and asked why he was there. Contact presenter for interview and got business card from her and her boss. I asked her how she choose the subject for presentation and how they were selected to present: she was asked earlier in the same week by her boss as the event had an open slot to fill. Contact student member and his boss for interview and got his boss' business card.

Presentation 3) Presenter from CU. Subject: manufacturing processes, batch *primary and secondary, continuous. Used basic slides. quality by design (QbD). 25 minute presentation, 5 minute Q&A.

Presentation 4) from Post/doc at DTU. Used basic slides. Subject: High quality products and production resulting in high customer satisfaction – but then talks about costs! Continuous improvement in the pharmaceutical industry, QbD, lean production system (LPS), and PAT. Use of novel tools in pharmaceutical industry. Manufacturing routes – simplification of process. Faster reactions. Modelling for small-scale to permit up-scale. Acknowledges supervisors and commercial partner etc. 30 minute presentation, 5 minute Q&A.

Presentation 5) Wrap-up. Moderator sought overall feedback. Qs about industry intending to use imaging by moderator relating to own commercial interest – some limited input. Most feedback tended to be by one person (Mark Palanker). Questions raised regarding trends in production. Question regarding format of meeting. Advert for next event ends formal event.

After presentations: nearly all attendees went elsewhere. This researcher took opportunity to conduct an informal interview with Henrik Goldschmidt on the role of Community of Practice (CoP) networking meetings.

Notes taken on his thoughts: Nordic CoP PAT meeting is a new idea. First meeting failed to get enough members to start. Designed to be informal exchange of ideas among friends. ISPE Nordic trying to move away from American methods to European/Nordic informality. Networking events aimed at knowledge, community, and profession. CoP: a forum, to

increase knowledge and increasing understanding. To develop the community and the social. Acknowledges and request to get more students as members.

Reflections on the event: The event structure consisted of an introduction of the ISPE by Henrik Goldschmidt, who is a Senior Project Consultant at Ramboll and also the ISPE Membership Secretary – it was evident at this time that many attendees were not ISPE members (some presenters were not members). The main presentation consisted of four short presentations, with time for questions after each. Overall, the presentations were very technical and very specific to a particular situation – which could not (nor intended to) be transplanted. Questions tended to be used as a method of confirmation of understanding and, perhaps, used as a bonding exercise with other attendees. Previous relationships (personal and professional) were not evident – however, most (nearly all) attendees came with a colleague.

Most of the presenters were approached at short notice to give their presentations by either their immediate superior or a colleague whom was unable to attend, and this might indicate why the presented subject was very specialised to the particular area of professional concern to the presenters.

The event was designed to be informal and facilitate a networking environment. However not much time was given to the networking activities (5-10 minutes between presentations), and most people left very soon after the final presentation.

Although all printed material and presentations were in English it was clear that there was a language barrier – not everyone was Danish nor had confidence in speaking English. Questions arising from the presentations were usually from fluent English speakers.

During the short breaks and after the final presentation, I approached several attendees to ask informal questions regarding their reasons for attendance and to their background and current roles. I also took the opportunity to solicit their participation in interviews. Some of the potential interviewees asked for more information and a list of questions – this was done in a mail from me asking them to confirm their participation.

Attendees agreeing to be interviewed:

a) Mark Palanker, Consultant Engineer, PEC A/S. Interviewed on 23 March, 2015.

b) Johanna Aho, Postdoc, University of Copenhagen. Retraction mail received 27 February, 2015. First presenter.

c) Jukka Rantanen, Head of Department – Pharm. Tech. Eng. No reply to mail.

d) Karen Stern Nielsen, Senior Process Engineer, NNE Pharmaplan. No reply to mail.

e) Apostolos Kaperonis, Intern, NNE Pharmaplan. No reply to mail.

f) Henrik Goldschmidt, Senior Project Consultant/ISPE Membership Secretary, Ramboll. No reply to mail – until much later (only after communication with ISPE HQ in USA).

Event 2. Date: 28 April, 2015, Location: IDA House, Copenhagen. Chem. Networking Event. Location: IDA, Copenhagen.

Event: International Society of Pharmaceutical Engineers (ISPE) Nordic Chemicals Community of Practice (CoP) Networking Event.

Observations: Notes made on iPad during event and additional notes made after event.

The event was officially coordinated with IDA. IDA provided the room, ID tags, WiFi, and refreshments. Had to pay for parking.

Introduction and presentation 1) Received name tag, welcome pack: feedback form, list of attendees, list of upcoming events, membership application forms, advert for European Conference. 34 people at event, for 3 hours. Attendee profiles: Approximately half attendees were ISPE members. Gender mix: 10 females, 24 males. About 15% senior (management) staff present. One student (me). Attire: business casual and very casual. Ages: post-graduate to senior-level professional – mostly middle-aged. General observation: most appeared to be

very technical and business drivers. 15 minute welcome with overview of event and introduction to ISPE. 3 speakers on different chemical process applications.

Overall, the process and mix of attendees match the first event – both events intended to be as informal as possible.

Event 3. Date: , 2015. Location: NNE Pharmaplan, Gentofte.

Event: ISPE Nordic Affiliate Biotech Community of Practice Event.

Observations: Hand-written notes made during and after event.

The event was officially coordinated with NNE Pharmaplan. NNE Pharmaplan provided the room, ID tags, WiFi, free parking, and refreshments.

Same general comments as regard to the process and occurrences.

The process

Each event was designed and encouraged to be relaxing and informal. The hosts' responsibilities were minimal from a resources level point of view – basic identification processing (for building safety reason) and light refreshments.

Issues

It was evident that no current (active) senior management figures attended any of these events, perhaps to encourage a relaxed atmosphere. Many of the attendees did not know more than two (2) days in advance that they could attend due to work commitments. – most of the attendees travelled extensively (this also hindered access for this researcher when requesting access for interviews).

Conclusions

The entire event process and interaction between individuals required an acceptance of a softly-softly approach, with informality taking priority. The technical presentations were at odds with intentions of attendees – with many presentations being a form of concept

checking with a loose form of peer group reviewing. The ability to network at these events would appear to be a very good place for any outsider wishing to take a look through the window of the pharmaceutical engineering industry in northern Europe, but other than revealing a loose set of interwoven threads, a researcher wishing to gain a deeper appreciation of the engineering culture at play would have to seek an alternative path to that of attending the various ISPE networking events.

10. Other data sources

As mentioned above, this researcher is able to draw on previous collaboration efforts within the pharmaceutical engineering industry when attempting to understand the culture of engineers in this highly specialised field.

These previous encounters were very enlightening when attempting to understand how they see their responsibilities and ethical considerations while performing their daily duties. These encounters consisted of a series of semi-structured, formal interviews conducted within a condensed time frame at a world-leading pharmaceutical consulting engineering company.

Much of the content of these meetings and interviews are still covered by a non-disclosure agreement – the first of its type for both the Company and the University – so much of what was discussed is not available for reprint in this study. However, a redacted version of the transcript has been included in the Appendices.

In order to secure that no accidental release of confidential information is revealed within this report this author will only explore issues related to how the employees experienced and processed ethical concerns.

In the interview with 'Andreas', when asked how he addressed ethical concerns the study group were a little surprised and concerned by his apparent lack of awareness surrounding this issue:

> "It was not in my mind at all when it was introduced but afterwards when Anders told me about your involvement I said well [claps one time] off course so that is also… the mind-set but I think also that we can learn a lot about you know [mmm] think of all the aspect or involve people that can help us to think about all the aspects." (Anders)
>
> "So, you saw the ethical aspect as being irrelevant at this time or?" (interviewer)

> "No because I didn't know I didn't thought of it and suddenly when Carsten introduced me to this mind-set I said off course there is a lot of things we have to consider." (Andreas)

This view, as it later turns out, is largely contrary to that of most other interviewees. And it was hoped at that time that this line of questioning might spark some form self-questioning within the individual being interviewed.

The second failed to address the question of ethical considerations – which was, in hindsight, an obvious oversight by the researchers.

The third responder related his considerations as being strictly limited to the technical solution under consideration and, therefore, this author cannot include his input at this time. However, this strict interpretation of where he places ethical considerations in may offer a glimpse into how he makes a deliberate choice as to where and when ethical considerations may or may not be accounted for in any particular project that he works on.

The fourth responder accounted for any ethical concerns as being mute, in that most concerns have already been either accepted or merely just and extension of present practice:

> "I think the ethical issues are I imaging are mainly about staff tracking and invasion of where you are. I think those issues are essential covered by the present ID badge, because, at the moment, we are tracked…effectively by an ID badge and lots of the time particularly in erhm some areas there will be cameras. Particularly, for example, I mentioned when I packaged-up dia-morphine, there were cameras on you the whole time. Erhm, so we tend to get those ethical issues…it would not raise further ethical issues than are already there." (Daniel)

Other comments on this subject by the same person are still cover by the confidentiality agreement.

Comments related to data given by the fifth responder directly relate to the application covered by the non-disclosure agreement.

The sixth responder professed to be totally ignorant on any issues related to ethical concerns. This author finds this troubling as not only was this person in charge of the company's 'Corporate Social Responsibility' programme' they are also on the ISPE Nordic Affiliation Board.

Conclusion

From the responses given by these individuals it is clear to see that although many are aware of the wider principles of ethics in the public sphere, they are less likely to place ethical concerns as a high priority in their working lives – believing that the issues are either already accounted for or are not of sufficient concern for them to alter their course of action.

11. Expert cultures

To get a better understanding of what is meant by the term 'expert' we first must learn what the so-called expert culture is we are looking at. The dictionary the definition of an expert is: 'A person who has special skill or knowledge in some particular field; specialist; authority' (http://dictionary.reference.com/browse/expert+?s=t). There are many studies and theories on how an individual achieves knowledge and what knowledge is or may be. Flyvbjerg has made a review of the Dreyfus model – the phenomenology of the human learning.

Flyvbjerg's model describes five levels in the human learning process. However, it is worth noticing that people are different and that it is unrealistic (impossible) for all individuals to achieve the highest level in a given field: that is, for example, not everybody that can become a famous musician, a premier league-level football player, or a surgeon. But in many areas of daily life it is possible to learn to ride a bike and drive a car and, over time, may become experts in these activities.

A 'novice' must first learn the rules and elements for a particular activity but it is always context-independent. When an individual takes up driving for the first time, and before actually driving on public streets, the student must learn about the 'rules of the road' and how cars work – but these rules are independent of any particular situation on which the skill(s) are to be applied. The first rules form the ground work for gaining experience but no real experience is needed while being a novice.

The second level is the 'advanced beginner'. This stage results in the novice gaining actual experience, for example, driving a car on the road. These new experiences gives the individual the ability to learn to identify relevant elements, and this recognition is only possible due to multiple similar previous examples of the same situation.

The third level is the 'competent performer', in which an individual is able to use their interpretation and judgment as a basis for action. Goals, plans, and choice are used to structure information, which are both context- dependent and -independent.

The 'proficient performer' (the fourth level) is able to make intuitive choices from their own experiences but also is able to involve analytical decision making prior to action.

The fifth level is the 'expert'. The expert does not need to refer to rules – the expert reacts on instincts in a holistic way in a wide range of situations. This is the level of expertise permit an individual to perform in what appears to be an easy (effortless) manner, where high-level performance flows from task to task, without recourse to overt analysis. The expert looks at a given task or situation and is able to act instantly, and with a plan of action.

Flyvbjerg writes that as societies focus on rationalism and is rarely able to consider experience, intuition, and context judgment as more important (or at least equal) to rationality. If Flyvbjerg's way of thinking is used it is possible for everyone to be skilled as human beings and we can become experts in our own life by education, law (rules), social norms, experience and judgment – but this allows depends on the wiliness of individual to behave as individuals and apply thought to their actions. As discussed in the first interview with a long-serving pharmaceutical engineer, he (unknowingly) supports the position that an expert is not someone who knows all the rules and thinks rational, but is someone who thinks in a holistic way on a range of issues. Culture does not stand still, it is always changing, as do social norms. Every day in on news programmes 'experts' appear on an ever increasing range of specialised subjects – but allocates the title of 'expert' to these topics, and whom is really qualified to decide on whom is THE expert. Is it ethical for an individual to call themselves an expert, or does it require outside acknowledgement and public recognition?

Experts are now a part of modern everyday life. However, not everyone can live their dreams and become an electrician, an engineer, or even a university professor, but everyone can have an opinion about on a particular subject – but this does not mean that members of the untrained public can expect the more knowledgeable and trained to listen and take these views into account when making decisions that affect everyone – this is why most states have elections to delegate the decision-making process (but the advert of mass, electronic, data input and analysis tools is starting to challenge this long-established mode of Government.

The question of whom are all these experts are and whom decides which expert is the best to solve a particular question, and what does it take to become an expert in a field creates another field in which experts are created. To some, it seems like you have to be an expert with a degree to have a valid opinion. However, is academic achievement enough to be a leader in this field and, if not, how does an individual get additional experience, and how is this set of skills to be recognised? Modern, Western society has seen the rise of so-called consulting companies, whose only claim for existence is to supply 'experts' in a particular field of activity. It is clear to see (but harder to prove) that the use of expertise and experts by governmental administrator is largely a political choice (not always the rational choice).

The experts whom the politicians may consult are not experts in everything and their personal agenda and scoop of practice (and experience) may well be very tightly focussed, even to the point where it is difficult to equate the available skills with the task at hand. A technical expert may offer a solution that they claim is the best and the cheapest, and the decision-makers may well have to go with this solution due to a lack of alternatives or lack of other opinions, or because it is the rational solution for the problem – but this does not mean the most appropriate solution for everyone concerned.

Every decision concerns a range of stakeholders; the Government, civil servants, the experts, and even the public. For some politicians it might be easier to pass any responsibility for errors or mistakes on to these other professional stakeholders if things go wrong.

To overlook these real-life conditions is likely to result in failure or at least a corruption of the original intent. It is too often it is easy to ignore or overlook ethical concerns on the grounds of practicality – this is where various industrial codes of conducts play a critical role in the development of technologies. Many trades, including those covered by the ISPE membership, have comprehensive codes of conduct by-laws. These by-laws are the rules by which many pharmaceutical engineers conduct their practices, and they ignore them at their peril. An example is the concept of 'redundancy', and it is an almost universal practice for industrial design engineers on the grounds of safety, yet it is also practice that increases costs and duration of projects, but it is an area that every professional engineer would not

compromise in. Can you imagine having a nuclear power station being built and operated without the principle of redundancy!

12. Conclusion

This study was initiated by this author partly through desire to enter an industry which is seen by many (including this author) as being secretive and operating within a 'black box'. This author wished to gain a greater understanding of what was required in order to develop a successful career within one of Denmark's largest and most financially successful areas of business.

The below findings are framed in the context of free researchers within the field of Techno-Anthropology. The study set out to establish whether it was possible to discover how a novice pharmaceutical engineer may move to a position of being a recognised expert in this field.

Currently, this author asserts that it is not possible to answer the initial problem as there is no agreed end point on which all can agree – for this to even be considered there must first be a structure put in place that recognises objective steps and, somehow, also account for subjective knowledge.

The next step in the process, if there is any chance of moving forward, is to establish whom is qualified to establish such a framework, is it industry management, the peer-recognised, so-called expert, or even an initially perceived outside such as this researcher. Perhaps, a more extensive study could answer some if not all of the issues related to this problem.

13. Discussion

This section will discuss findings related to the problem formulation and apply Techno-Anthropological ethics to them. Techno-Anthropological ethics is a combination of four ethical considerations; an ethical technology assessment, the social responsibility of researcher, professional ethics and codes of conduct, and CSR.

Social responsibility and ethics

One of the main themes of the Masters Programme was the social responsibility imposed on us as researchers. As Techno-Anthropology students at Aalborg University it was impressed on us that we need to address ethical considerations throughout our research and application of technology. This, if done at all, has to be done without favour and without exceptions.

How can ethics and responsibility be pushed to the fore, or should they be pushed at all?

By taking a more holistic approach, individuals and the ISPE have the opportunity to incorporate ethical considerations from the beginning of the engineers education and professional development process. The holistic approach would reveal more to the project staff about how the many actors/actants interact and interlink, thus leading to a more overall efficient process and thereby result in a 'better' outcome. In the short term, the ISPE would have to provide more educational support to overcome the lack of knowledge in ethical considerations, perhaps by outsourcing ethical expertise to relevant collaborating partners. This knowledge gap could be filled by the establishment of a new class of 'expert' – the knowledge (information application) expert.

There are CSR programmes within most large companies today but, as established in the interviews, some programmes are clearly not effective, and it has to be activity supported by the corporate level. Ethics and responsibility normally fall under the responsibility of the Sustainability, HSE and Energy Managing Partner at most pharmaceutical engineering companies. The person is responsible for developing and establishing a more comprehensive

CSR program must be in position to get new programmes actioned across the entire organisation, and not just at the chalk face – the doctor has to be willing to take their own medicine.

This leads on to the question of whether change is possible. Although the management of the employees interview in the previous project recognize their need for a culture change in relation to ethical considerations, they admit that the company might not be ready to incorporate so many changes – the profit margins are so fine in the industry that incurring an expense that their competition do not might be economically untenable.

Barriers to developing a responsible design

As with most business practice, a company wishing to develop a project would approach one or more potential suppliers – but at what levels are the initial discussions? Do they include ethical concerns? At present, it is highly unlikely that experts in ethical considerations will be involve at any time of the projects' development process, never mind at the concept stage. If ethical considerations are to be given a higher priority it is necessary for the company to develop specific expertise in this area, and for this expertise to be recognised by the customer as an essential part of the entire process. This is not unrealistic, as with any industrial project, if a company does not have a person with the required skills they will hire someone who has.

In additional economic constraints, if an organisation does not have the required skills in processing ethical concerns then these concerns will become more diluted as the project progresses.

A further factor to be considered is that if ethical considerations are fully integrated early in the project individuals and structural barriers are less likely to compromise the overall goals. There is a final word of warning: if engineers are to operate in a wholly ethical way they may have to put the interests of the public or their customers above these of corporate and/or professional considerations.

This last consideration would be very hard for even an acknowledged expert never mind a novice, and present legislation in most national states legally insist that the profit motive overrides that of many other, ethical considerations. This raise the spectre of maintaining motivation for an employee – it would be very hard for the employees to maintain their drive if they were constantly being pressured to deliver other, competing targets.

Corporate social responsibility

The Corporate Social Responsibility programmes (CSR) are still too ill defined within many companies operating within the pharmaceutical engineering sector, and many employees are not aware of any such programmes. It would seem logical to address this omission at the point of entry for a novice entering a company or, even better, during their formal education before entering the workplace.

Expert cultures

Many companies, as revealed via the interview process have informal or formal structure for 'mentoring' employees. But, as reported in interviews, the people whom have volunteered to be interviewed are also the same whom have gone seeking mentors – perhaps there is a strong correlation between the people whom reach for knowledge and those whom are more successful are spreading knowledge – either through structured networking efforts or being widely recognised as experts in a particular field. Perhaps this is the real lesson for any novice: they should be active in seeking knowledge and guidance. It is only with guidance that novice engineer will be in a fit position to fully understand the responsibilities allocated to them within a project. The question now also arises about whom should be responsible conveying this message.

It is clear to see that senior engineers are mostly well aware of their personal strengths and weaknesses, and have a very clear view on their profession, but it also clear to see that many are not in a position to direct certain ethical considerations. This can lead to ill-designed or poorly framed projects and outcomes, and have the potential to generate a conflict between the engineers' (and ISPE) code of conduct and the corporate entity.

14. Learning goals and process

This section of the report examines the context and experiences of the Group within a specific educational framework, the Aalborg Project Based Learning (PBL) model.

Aalborg university's problem based learning programme

This report was researched and written in line with the published objectives stated within Aalborg University's 'Principles of Problem and Project Based Learning' (Barge, 2010).

For students, the Problem-Based Learning model focuses on three core themes: problem formulation, project work, and group activity. The latter is obviously omitted when students produce an individual piece of work.

The identification and constant refining of the 'problem' is also part of the educational process. The evolving, identified problem under examination has to be based in a specific context and "...should stand as one specific example or manifestation of more general learning outcomes related to knowledge and/or modes of enquiry." (Barge, 2010:7)

The Masters Programme requires that work is produced in a time-limited, structured approach to problem analysis, which takes into account the changing nature issues encountered in the wider environment.

The below details the processes, outcomes, and experiences encountered by this author within the above framework.

Techno-Anthropology – learning goals

Within the Aalborg Problem-Based Learning model, the Masters course programme identified three core competence and subject areas that all students must address in their respective reports:

Aalborg University Master Degree programme in Techno-Anthropology have to show knowledge, skill, and competences to explain the development of a specific technology

within a specific organisation, using and then explaining qualitative research methods. The students are required to develop specific proposal(s) for responsible technology design, which identify the codes and rituals of expert cultures in a specific technological context. These must then be placed within the conceptual landscape of innovation and responsibility in that particular context, investigate and analyse the drivers and barriers for responsible technological innovation, including guidelines for responsible design, corporate social responsibility, stakeholder involvement, and undertake an ethical analysis of a specific technology (The Faculty of Engineering and Science, The Study Board for Techno-Anthropology, 2012:12).

Project process

As with most projects, especially within an educational programme, the actual programme deviated from plan. As more knowledge and data was gained, the project scope was refined and even redefined.

The formation of the final direction of the study fundamental changed about half way through caused by the lack of a universally accept set of notions of basic definitions. Once the basic direction of the study was agreed, an exploration of possible collaboration opportunities began – hence the involvement by members and staff belonging to the ISPE. A review of technical and academic literature enabled this researcher to actively investigative suitable approaches, with the aim to gather data from as wider cross-section of the pharmaceutical industry as possible.

Through a combination of the elimination of unviable contacts and negative responses from some of those approached, the utilisation and subsequent expansion of this author's existing personal network generated the most fruitful leads. However, the (then unrealised) extent reluctance by potential data sources to place themselves on record presented severe conditions to the study.

Collaboration with the ISPE

The collaboration between this author and various individuals representing the ISPE was obtained without hindrance once the basic scope of the research endeavour was discussed. However, it was not until the North American Headquarters became aware and offered support to the study did the local, Nordic, administration take an active role in assisting with data collection.

This author has since been invited to join the ISPE Nordic Affiliation Board, with the remit to promote the activities of the ISPE to prospective young academic and professional members.

There have also been on-going discussions with various parties to expand this research study, perhaps adding a further dimension to a recently completed PhD research programme or a privately backed study by a well-known industrial consultancy concern into how to commercialise the identification and codification of professional skills and knowledge held by technical employees.

The non-disclosure agreement and resultant issues

The collaboration between NNE Pharmaplan and this researcher when compiling a series of interviews for a previous project which was brought into this study is covered by a non-disclosure contract. Therefore some data present in the full interview transcript has been redacted in order to maintain the contractual agreement. The previous study could have only proceed on the condition that all members of that study group (which this author created and led) connected with the project paper and its readers sign a Non-Disclosure Agreement (NDA). At that time, it was established with the University administration that the semester project be written under 'closed dissertation' conditions – meaning only members of the Group and the examiners could read the submission – and this was confirmed and authorised by the Head of the department and project supervisor after the Legal Department examined the contract submitted by NNE Pharmaplan. Members of the Group are only permitted to discuss the primary technology but not the potential application(s).

Issues encountered while preparing this masters thesis

There were some issues resulting from self-imposed deadlines mid-way through the project. These issues were further compounded by yet-to-be-discovered data that would have led, if known in advance, to a re-framing of the study's structure and timetabling. At the beginning of the interview process the study was delayed by several weeks due to retractions of offers by interviewees. This series of retractions led to on-going, reoccurring personal health issues which have now been put down to the additional stress caused by the withdrawal of expected interviewees.

Due to these structural present within the target group – the extensive amount of business travel – it proved to be very difficult to replace the prospective interview candidates, which, in turn, cause this researcher to seek alternative solutions to the collection of data. This is most evident in the planned section relating to 'Expert Cultures', where the expected contribution by numerous volunteer interviewees was expected to create most of the data for analysis in this thesis.

The discussion related to expert cultures has, therefore, been truncated and some data in this section was based on accrued, previous knowledge. The above issues were reported to the thesis academic supervisor, and measures were taken to account for the conditions.

Achieved learning goals

This author believes that all the required learning goals have been addressed in completing this Masters Thesis report. Learning goals not fully explored in the report will be presented during the examination.

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16. Appendices

Pharmaceutical Engineer 1 (PE1)

Q: How would you describe your formal academic background.

PE1: My formal academic background. I have got a BSc in Biology and a minor in Sociology.

Q: Was this in America?

PE1: This was in America and I think this is also in relation to a lot of our some of our discussion on the actual SPE, the ISPE in which I come from a culture in which real experience is valued not certificates not pieces of paper that say that you are book smart and you know can apply this in a vacuum. Ah, it comes from actual real work experience, and when you both have been within these same firm, you are surrounded by people that had a clear understanding and therefore hopefully a closer perception to reality of what you are actually looking for. I think the difficulty is dual fold for me personally. I left the organization that I worked for 15 years, so I have lost all of my yeah built up collateral perception sort of the expertise that have been awarded me within that environment, and force to come to the Danish culture which puts much more of an emphasis on papers and certificates and the fact that you can actually get that that you have got the paper to support it rather than the actual experience to support it. Eh, eh it has definitely been an interesting sort of switch. For me and I may have picked up a few more pieces of paper along the way, had I actually foreseen this coming.

Q: If you could just develop that point. Have you taken any other formal courses in support of your academic background? It sounds like you have done many small courses, but have you done any specific courses related to pharmaceutical engineering?

PE1: Nothing. And the only certification to that matter that I have actually bothered to get in the last few years has been recently discontinued, which was ISPE´s CPIP. The certified pharmaceutical industry´s professional which is there is only a handful of us in Scandinavia and it was supposedly when it was rolled out this was their big picture. You know not that you are necessarily and expert you know in A, B, and C, but that you had a complete understanding of a, b and c and how they all interact within the full scope of the

pharmaceutical industry business, you know when you are talking about manufacturing, it scopes from development to scale up to yeah subculture?, purification, shipping, distribution etc. But that you also understand the quality, you understand the IT systems involved in all of these aspects. So it was sort of geared as a this person has enough experience and originally it was needed at least 10 years' experience working in to even qualify for the program to try to be certified in it.

Q: Do you know why this program was stopped?

PE1: It was stopped because at least the information we received was that it was actual very labour intensive for ISPE to maintain the annual recertifications in it and that because there was so few people that actually qualified for it there was a lack of energy from the organization going into maintaining these certifications for very few people.

Q: Has this course in any way been replaced?

PE1: It is actually not a course. It is basically a self-study and they expect you to you require. Once again they require you to have 10 years´ experience before you can actually apply to it. And then they open up, a database of electronic review tools for you but the expectation is that you actually experience these and apply them throughout your career and you have actually worked with all aspects of this…

Q: Sorry this is the replacement or the original?

PE1: This is the original, so there were some course books etc. For better or worse I did not need to study much for this Yeah, to be able to pass the exam. Based on the fact that I´d had actual real life application in these arrears, and for example on that there was actually to people in my company that had this certification. Ah, and both of them actually said we got the certification but we have really actually had to study to fill in the gaps in our experience. You actually have the experience and we expect you to be able to dive right in and get your certification without any additional efforts or experience needed or any studying which is basically what I did.

Q: That seems a little odd from a development point of view. All that is doing is really just proving what you have already done and it is actually not developing the person.

PE1: No a 100%. So, this was definitely there was dual development involved. This was once again to my point getting the piece of paper that the Europeans prefer to see. Once again as an external consultant that does not have 15 years´ worth of collateral built up in an organization it was also important to me to have these sort of industry certifications/buzz words available for the customers.

Q: In your development and in your education were you working with a mentor or was it self-studying and formal education only?

PE1: This was self-study and formal education only, but I would also say that I had the luxury flash luxury in quote of working for the first 15 years of my career for an organization that believed in having one person for every 3 jobs and to the point at which this American organization came to Europe and started looking at European candidates and looking at the job descriptions for the same parallel role with the new organization they realized that they had about 30 per cent of the responsibilities of their American counterpart and so I actually have, yeah, I cannot put this on paper or quantify it but at least in the internal discussions within the American organisations it was felt that for every year of American experience within our firm not everywhere but the way our organization was ran very mean and aggressively that for every year in that organization in America you had two to three years´ of experience equivalence in the European organization. So under that period for that 15 years I spent and the scope of activities there I was fortunate to have seen once again all aspects of the pharmaceutical industry to prepare me for the sort of role I am in now.

Q: Very briefly, could you just do a chronological career path for me just to lay out in general terms from High School up with.. just one or two line on each.

PE1: High School. Yeah. I think not so much to say there. American High School does nothing to prepare you for your actual career and there is no special eye on the Science or Engineer path before you actually graduate the equivalent of gymnasia.

Q: How did you qualify from High School to your University course?

PE1: That was based for the most part on the fact that I was had very good standardized test scores and I was chor? So I qualified on sort of two reasons that I was smart enough on paper to them as well as I qualified for need financially.

Q: Can I ask which university you qualified at?

PE1: Quite a few actually, virtually most of the schools I applied to but in the end I went to North Eastern University in Boston, and the reason I selected that was because once again from very early it was actually a five year program rather than a four year programme and it was geared on providing applicable experience in the form of internships so. Twenty years ago this was on the cover of US news and world of report as the most innovative approach to a college education in which you got to school for the first year full time like any other program, but then for your second through your fifth year you are working as an intern in your actual field for six months then you come back to school for six months and then you go back to the field for six months then you come back to school for six months.

Q: For four years?

PE1: Yes and you alternate that way for the next four years. Yes, however, I got my first internship and at the end of that six-month said to the firm that actually brought me to Denmark 15 years later said I am not going to get this side? of experience waiting tables so now that my internship is over you run a 24 hour shift and I was wondering if there was any opportunity for me to work either nights or weekends while I am back in school full time in which they said absolutely. They were happy to have me and I worked from 7 pm until 11 and I am sorry from 11 pm til 7 am two days a week and then went straight to school for the full day and I worked 7 am 7 pm on Saturday and Sunday So I Actually worked a full 40 hour a week as an internship while I was still going to school full time and I did that for the remainder of my school so the last three and a half years of my school I both worked.

Q: Can I ask what the internship position was described as before you started and what you actually did during that internship? I am trying to get an idea of your career.

PE1: The internship itself was actually an operator. They had positions in so culture?, purifications, and media. They interviewed a few people. I was told I had my choice to select which group I wanted to go into and the most challenging they felt was so culture? So naturally that was the one I selected. I was there for six months. At the end of that though I actually moved into purification operator role when they extended my internship and actually about the end of that six months or about a year later they decided to merge those two groups together and I was actually all though I was still an intern I was the only employee in the entire company that was trained in both facilities. So at that point it gave me a lot of leverage to get involved and start leading activities at a very young age so.

Q: Could you explain what that means?

PE1: Back then we had a very lean organization that was based on volunteering working overtime to sort of get experience or get it.

Q: You say we who is the we?

PE1: The Company. You would like the company name?

Q: Well it is not essential. Is it a pharmaceutical company?

PE1: A biotech company. Also my experience started off in a biotech. In 1994, so sort of, it was absolutely not brand new but it was still at least doing it right with confidence and earning a lot of money was brand new to the industry at that point of time and I was fortunate enough to get into an organization that had a clear focus on where one will do and wanted to do it, and I was fortunate to get in at the right time and be along for the ride and sort of see quite a few projects to success as a part of that.

Q: What was your first formal job after you left your education?

PE1: When I left my education I was hired as a process operator I sub culture? I then as a process operator we had no validation department, so I was sort of the validation lead as the operator then I started doing matrix management in which I would identify three to five

people to form different groups and take them on to my team for about three to four months at a time and we would actually then work with the engineers because it was actually clinical manufacturing site so we were changing over a registered facility about every four to six months for a new product and entire new process.

Q: If I can try to get some background information on that process itself. You mention you are a team leader. It sounds like it was a position that needed a great deal of official oversight perhaps honoured by the products. What qualified you to take that role? How were you trained to do that role or was it just your experience that allowed you to do this?

PE1: This was based on really experience, and once again it is, I think, at least back then with the lack of focus in the USA within this organization on any external training it was based on experience internal and understanding our processes and our equipment. It was really just something that came naturally to the type of person I am and I think when I sort of work with an operator like this now it sort of reminds me of myself and people ask me what is so good about that guy why do you request his support you know. Some people just read the SOP and it just says open valves 15, 41, 15, 43, 15, 55. Some people just walk up to the HMI and press the three numbers that it tells you in the SOP, and open them and follow the SOP.

Q: Can I just ask you, SOP means Standard operations procedure?

PE1: Standard operations procedure.

Q: HMI means human machine interface?

PE1: Exactly.

Q: In some industries the same initials mean different things. I need to clarify tis for a future reference.

Q: I say what training did you do to as part of this job or is it just a case of feel how things went and then just adapt to what was required by outside parties? Was there any formal training offered by these qualification departments or…

Q: No, and once said we did not have a qualification dept. So the reality was is they took the people that had either experience aptitude or passion for the equipment that were willing to work night and weekends and put in extra efforts for no extra pay because once again these positions were off salary positions in the USA so if yeah if you once again the development and the experience came with the extra 20 hours that you worked for free. Perpetually, that is the way the American systems works.

Q: Just relating to the your American experience. Did you have any idea that the ISPE existed or did you have any concept with that organization?

PE1: Yes. Yeah. Actually for many years. For better or worse though. When in 1994 at least ISPE was again is geared towards pharmaceutical engineering and the term pharmaceuticals now is automatically assumed to include biopharmaceuticals. IN 1994 pharmaceuticals and biotech was two different industries. Pharmaceuticals was still viewed as traditional small molecule chemical synthesis standard sort of old school processes. They had been making them for a hundred years in some cases and some of those processes and products had not evolved in ancient? a hundred years. Biotech, however, was a very novel sort of, yeah, thing in 1994 and I think the once again I was fortunate enough to join a biotech firm in 1994 and not a pharmaceutical firm in 1994. I would not have gained the, yeah, I would have not spent 10 years gain experience that will suit me for the next 50. Had I been in a pharmaceutical firm. It would really have limited my focus to small molecules.

Q: If I can just go back to the ISPE. What was your exposure to the ISPE?

PE1: And back then at least within our industry we felt that ISPE was geared towards the pharma. The traditional pharma. Small molecule chemical synthesis. What we were doing was biotech. It was, we actually had a thing. We actually had our own Lean organization. Quote on quote a key performance indicator matrix organization that was very much ahead of its time. Twenty years later I´d say it was still ahead of its time and ahead of all the lean fit modern? Initiatives I have seen to-date and the, yeah, I am not sure I would bother with that?

Q: So the ISPE hub though is relevant by name it was not relevant to your professional involvement?

PE1: Yeah exactly and just to tie that up. The organization and our firm sort of our area of business was always at least in the USA was geared towards the PDA, the parental drug association. We were making large molecules.

Q: Sorry, what drug association?

PE1: Parental it means injectable. Basically drug that are being injected. So, within the USA back then the PDA was by far and large the focus of any biotech or biopharm industry. We had large molecule injectable drugs. These were not synthesized chemical tablets that people were taking. So back then there was at least within our organization the ISPE was viewed as yeah sort of nice to have you may learn something but also my background was not engineering my background was biology and I just had a mechanical aptitude so yeah.

Q: Okay if we could move onto Europe. You moved across to Europe. How long have you been in Europe now?

PE1: Seven years now?

Q: And the same role ?

PE1: No very different roles actually.

Q: Okay. Could you explain me your current role? What are you doing now?

PE1: My current role is am an external consultant supporting project management and all the system quality engineering activities at biopharma pharmaceutical companies.

Q: Okay. When you have been doing your work in your plus seven years. What was your exposure to the ISPE? Was it the same you experienced in America or was it a different relationship?

PE1: It is interesting because I think it is very much at least in my experience very much based on you r immediate organization. So if your boss is in ISPE and your boss will then put it on your goal that you should probably join this affiliation. You should gain some affiliations etc. or maybe the organization you know all your co-workers are a part of it and therefore you sort by diffusion sort of sign up for it. It I honestly to your point at least I have never looked at it as sort of enabling development or organization for myself. I have always looked at it as a networking place of peers. And obviously within those peers there are. You can sort of forge your own development but yeah I think I can confess that it has been a long time since I have been able to find an applicable senior level training course that is actually worth travelling to.

Q: If I can ask so just to clarify your relationship with the ISPE was a case of networking and perhaps social a little bit pushing in the work place to say this might be a good idea.

PE1:Yeah.

Q: Okay we met up a communities of practice event for process under the school of technology what was your reason for attending that meeting? Were you a member of that community of practice and if so why did you choose that one?

PE1: I think that is rather a good one to differentiate but also in the States we never focused on communities of practice and I think it was a less organized organization from that regards it was more so. Yeah you may attend a conference or you may go to an annual meeting or something but there was not the local group focuses like we have now with the cop and so my at least based on my experience yes you can go to annual conference with 10000 people and hopefully, If you are lucky you can talk to the right person by chance that may have something in common with you or you may have a similar role or similar issues they are trying to resolve, but I felt that the cops really helped an area that focus geographically as well within the scope so to me I think they are very valuable for both the networking and the baseline.

Q: Okay so the next question is really in 3 parts. How long have you been a member of the ISPE in Europe?

PE1: In Europe?

Q: Or wider. Were you actually a member in the States?

PE1: I was actually a member in the States. It lapsed. My membership lapsed during my transfer and I have been a continues member for about the last five years again.

Q: Obviously, you joined the PAT community practice. Are you a member of any other community practice?

PE1: I am a member of the cleaning? Community practice. And there has also been a quality community practice quality systems but it has actually not met it is actually not a local

Q: What was your reason behind joining these particular groups?

PE1: These are sort of my either areas of expertise or my areas of passion. Areas at which I feel I have enough experience to breath and make a difference in.

Q: Have you play any role within the administration of these organisations either the community practice or the ISPE?

PE1: Absolutely not. Almost by desire with laugh and once again I think this is also depending on the organization as well. I have seen global directors of ISPE at one firm I worked for that was actually very happy that the current president the global president of the ISPE was working for them and they felt that they could get some press out of that and on their dime they flew him to every single ISPE conference on the planet He was proudly on site for seven months a year and they paid as if he was at a seminar a course. He was basically paid to support the ISPE initiatives with a company name underneath his.

Q: Is that not rather against the regulations of the ISPE to do this?

PE1: Honestly, I am not quite clear what the regulations of the ISPE is, but it is also my understanding that they encourage companies to use development funds towards these types of activities.

PE1: Sorry I actually cannot say anything?

Q: it is a grey area that is perhaps understandable.

PE1: But perhaps in other organisations in which the president literally president in the exact same role was told you can take one trip a year anything else you have to pay via your own pie so to me it is very much dependant on the organization as to how much time and once again unless you that someone who has that organizational support or have a strong desire to be part of the administration there is a lot of energy involved there that yeah that you would need to find time for.

Q: Okay. What do you take from these meetings most of all is it just the networking or do you take any kind of actual education from these communities of practice or from the organization as a whole?

PE1: I´d say it is probably 80 per cent networking 20 per cent you know content or learning.

Q: Do you feel there is something missing from the organization that you would like to see in form of maybe courses education or better networking or more focus on particular areas?

PE1: Yeah I still feel that is almost by design but I still feel there is far too much stuff for senior level people. To actually conduct the sort of the current and future discussions to make sure we are driving sort of the industry? best current standards versus continuing apply status quo that we do not really have a lot of forward thinking forums to maintain you know you know current or forward thinking we do not have. And I would say outside of the actual authorship groups that actually write the books or the stringing materials etc.

Q: So perhaps are you suggesting there is a barrier that has been set up or do you think it is perhaps a lack of information being passed forward to the membership?

PE1: No I would say it is hard for me to describe.

Q: shouldn´t web design?

PE1: It is hard for me to describe an attribute? to it but it almost seems for you to look at the training course and say 90 to 98 per cent are either geared towards entry or beginner level maybe and quite honestly probably that last 10 per cent even just 10 per cent is geared towards at intermediate there is really nothing for senior level and I do not know if sort of the intend sort is that well at that point you are ready to get a certification. And then you can point to your certification as your you know yeah but there is not a lot and maybe the explication once again is that well here is the beginning and entry level and you will built the rest up through experience but there does not seem to be a lot actually that is really geared towards helping people get a frein? or helping people getting to the middle ground there does not seem a lot within the organisation to sort of to take the middle people and push them over the top or help anybody sort of to get there.

Q: Do you think there is a role for an expanding role for the individual communities of practice do you think there should be a greater number or a greater specialty within these communities of practice? Or do you think it should be a more coordinate centrally coordinated or regionally coordinated activity or education?

PE1: I think they should probably start with just with the size and the geography they should start with the regional but they should also have a way of allocating and promoting sort of topics for clarification or alignment through a global organisation. The global cop had to issue this as sort of our current standard and it just not at Scandinavian standard or and Indian standard that these because these cops should be the sort of the local expertise that sort of that any new or novel ideas would probably put through them.

Q: You are in a rather unique position that you are able to see the American model and the European model up for operation. Do you see the cops operating in different ways in American and in Europe?

PE1: unfortunately I did not have the either the opportunity or even the option to participate in COPs 10 years ago in the USA if they did I was not aware of them and they were and they definitely were not marketing themselves or were putting in the effort to be as activate 10 years ago.

Q: There is an increasing number of COPs in the so-called Baltic region, do you see that increasing even further? Becoming more specialized? Is that something you would want to see?

PE1: I think it is good to a point and it also depends on sort of what is the role of these cops if the goal of these cops is to actually generate deliverables and standards and sort of drive these areas of practice into the future. I think speciation is probably fine because yeah you will end up with some more detailed people that are more focused on the specific problems but at the same time there is a fine line because you also risk compartmentalizing things obviously so I am not sure what the right number is? It appears to be close to that now but I already find myself saying okay I am a member of 3 cops and I can't always attend all of them and some of them actually have similar topics at times so there definitely seems to be a fine line that needs to be.

Q: Given the current activities of the communities of practice and ISPE. Are these acknowledged by your employer in any way? The meetings you attend and the knowledge you pick up from them or the networking. Does your company encourage it or does it want you to get anything else from it?

PE1: This is one where I think it is very much based on the individual and the company once again. So if again I had this even right side by side where we have a new higher that is a junior level person that was hired straight out of university. For one of their first assignments they were working on something that was the subject of a COP. So she was going to the same COP meeting as I was. My boss expected her to get a lot of technical knowledge and really understand something about it and getting some sort of technical content from that. My boss expected me to get nothing but networking from the same meeting.

Q: How was your boss aware of the meeting? Do you have any knowledge about how your boss became aware?

PE1: My boss is actually fairly active in this and I would say that my current organization definitely looks at the ISPE as the primary source of either training or sort of industry standard information.

Q: If you can develop that point. How does it recognize the skills I mean the knowledge that you pick up from these events? Is there a formal process` within your company or with another company to actually recognize these so called educational qualifications?

PE1: Yeah I think it depends. I mean if it is less formal than a certificate there is not much. There is often at least we internally have a policy where if we are paying you to send you to a training course, you need to at least present for 20 minutes at the next break feast and tell us what you learned. Maybe all of us already knew that or maybe there is something to add on or it may spur a discussion or maybe we all get to learn something from what you gained from that conference. So I mean we at least have these forms in which sort of yeah it forces acknowledgement that these people have attended it and gained something from it and they actually have an opportunity to share this and sort of drive alignment of their understanding but I would say there is not there is not a real formal recognition or way of doing this.

Q: How is a person acknowledged to be an expert then in these particular fields that the cops actually consists of is that possible to have an expert in these areas?

PE1: It´s I think it is once again down to perception.

Q: The individual perception or the management perception? Or both?

PE1: It depends within which context.

Q: The both I think.

Q: So if you think you are an expert you are an expert and no one can disapprove you is that what you are saying?

PE1: Almost the opposite if you think you are an expert it does not matter if that is not the popular culture if that is not the ongoing you know thinking of the organization it does not matter and I think also the term expert is it also depends a lot because you can be a technical expert but then have a terrible time with arriving ? in the organization. And therefore they say that guy is not an expert that we can utilize you know so I mean it is.

Q: So it is all about knowledge utilization within the company from your point of view?

PE1: It is about knowledge utilization about the company but it is also very much based on perceptions from individuals and if you are lucky the perceptions of individuals may trigle up and become the perceptions of an organization but as an external person it is very hard for me to expect to influence that without a long term assignment or an assignment that has meet interaction with a lot of areas? of scope.

Q: Given your particular role as a contractor what is your normal way of communicating your expertise. Is it a case of you do the work yourself and write reports or do you have another way of communicating of what you know to your clients? Is it the case of reporting to them and letting them do the work or.

PE1: It depends if you are talking about before being hired during an assignment or

Q: Both. I am trying to understand the process of knowledge transfer cause a person knows a lot of things about a lot of different areas in that particular specialty and the more experience you have and the more knowledge you have. You know things. And I am just wondering how you express your knowing to other people to get the job done or to express to them I think it should be done this way because of x, y, and z. How do you communicate your 'knowing' normally?

PE1: It is obviously it is a difficult question because I also really had a large audience a lot of this would be on one on one and face to face interaction or sort of slowly but surely you

know building up collateral with individuals and therefore once again sort of getting a comment you know perception on yourself but is.

Q: If we plight to the cop meetings some people in these general meetings where you have people from different companies are a little reserved some people are more outgoing How would you express your technical superiority for the lack of a better word in the meeting to oppose another viewpoint? Would this be expected in the communities that practice that you would be able to express your expert opinion or would it be a case of you would withhold your expert opinion and then perhaps approach it at a different time in a different format.

PE1: Honestly I think? To sort of qualifty it but it is very much individual based you know there is a guy that actually works for my firm that works directly across from me that is in a very similar role he goes into meeting and he is very quiet he does not say much of anything he takes it in he lets everybody else talk. He is viewed as a quiet leader and I think also as a very European dynamic. In America we do not have quiet leaders. We have loud and louder leaders. So to me and my upbringing if I was to go in a room or give a speech for a lead a discussion and be the most quiet person in the room I am not in control I am not leading that discussion. I am sort waffling in the wind sort of letting the chips lay down and sort of recording what everyone else decides or whereas I am actually the type of person I have been told that drive discussions lead discussion present these things. I do not think within the Danish context that I look any smarter that the guy that does not say a word. Whereas in the American context everyone would say I have a ? question I am going to this guy, they would come to me. I think in the Danish context it is hard to actually tell because I think they are much more comfortable with quiet leaders and they assume there is a lot more going on inside the head. I am not saying there is not it is just sort of the style in America if we invite you to a meeting and you actually do not say anything. We won't invite you to the next meeting that actually you are considered a waste of space. I am sure you could be doing something more valuable to the company on your own time actually cranking stuff up you could read emails afterwards and still get up to speed, but to have you in a meeting that you are not going to actively participate in. Makes no sense to anybody. So once again if you look

at the way I was taught and the way I was brought up and I have literally had to throw it all out the window in order to, you know meeting culture in America you better not call a meeting to have a discussion and make a decision that needs to be done offline you need to present everyone with all the information they should come with their own opinion to this meeting fully formed and then we can discuss it and finalise it. Whereas in Denmark I find I can never actually even get to that point once I call for a meeting to get people in the room to actually sit down for the first time and formulate some opinions.

Q: So your experience would be more of the sprint kind of events where people would have pre-knowledge given to them and then they would come to the meeting after analyzing that information then just action at that meeting.

PE1: You do not call a meeting to present something that would get you in trouble in America whereas here it is very much people do not have time to look at it and will not open that attachment in the email for 3-4 days unless ?noise cannot hear guy to sit down and do this on an overhead.

Q: Just to reassure I am keeping quite as much as possible because I want you to talk the tape is not for me to talk it is for you to talk.

PE1: I figure with all the talking you can find something on there later.

Q: If we relate this directly to the COP meetings and the ISPE meetings that you might have been too. Would you find that there is a valuable discourse or would you say it is mainly a case of presenting and then listening and then taking that away?

PE1: No, and I think that is really to me the difference of the COP, I think there is really some valuable discourse and I think whereas in the context you know if you listen to somebody giving a 20 minutes speech at the annual ISPE meeting having people in a giant auditorium there is really no opportunity for discourse. There is no and if there were it would not be sort of court room discourse and if there were it would be shouting and. Whereas in the COPs it is the right size. The right form and also sort of a trust and assumption that everybody has the right level of experience to engage each other and therefore, there is very honest, open

and honest feedback. So I think actually the discussions generally at the COP meetings are, yeah, happened by default. Good discussions happen by default based on the way people approach it.

Q: There is another PAT meeting in Malmø. I believe it is Malmø in the near future. Do you have intentions to attend that meeting and if so why? What do you expect to get from this meeting?

PE1: I am actually considering it, but I am waiting to see in more detail the agenda. So its yeah it's difficult for me to if I keep one thing on my agenda that sort of have my scope of interest. It is hard for me to dedicate a day for that. So yeah for the most part I would need to see detailed agendas before I could. Could commit to a knot, but I am debating it right now.

Q: Okay. Do you see there are benefits by having many different subjects being discussed at these communities of practices. The last meeting for the PAT, I believe there were three presentations. Do you seeing this as being valuable or do you see it more of a diluting element?

PE1: No I see it as more valuable than diluting, but they should also be careful to group these or find some sort of commonality. Obviously to keep it together. I mean at least for that one, I would say they were all focused on pat. So if your focus was pat yes, but I can promise you there was virtually nobody in the room that had applicability to all three of those applications. They were so far apart. So I can promise you for at least one if not two of the presentations I sat there saying: how does this possibly apply to what I know and understand. And I promise you that I was not the only one in that room they were very disparent in sort of subject matter, so you can say, yes these were all related to pat and you can see how people are doing PAT, but once again ? be careful because there is obviously a point which you dilute it.

Q: If I can just drop? a small tangent to this. You are a member of three communities of practice. Do you see that as being. Do you see the joining of multiple communities of

practices being essential for membership or do you see the value for one individual just focusing on one community of practice or do you think it is really essential for them to ? as much as possible?

PE1: I think it depends and once again for the most part I have got I mean I have 20 years of experience and I wanna stay a part of the communities of practices at which I have a passion for and feel I have a spur to maintain that. So I have a desire to be a part of those. For a new person entering I would say limit it. You should not sign up for every COP and try to move forward and find directions. I would definitely try to limit it.

Q: Okey. One of the key levels that I will be looking at is the role of international experts. These are the bridge builders between the different knowledge basis. It seems to me that your experience is really quite broad especially compared to some of Europeans. Would you see yourself as a bridge builder in the industry?

PE1: Absolutely. Absolutely to a fault.

Q: Would you see many other bridge builders in your experience in the communities of practice or within the ISPE?

PE1: I think within the communities of practices, yes. Within the larger eyes obviously yes by default within the ISPE? But I think it I think it a ? parent? at least at least in my discussions with people in the networking that people are bridge building a lot of thinking of the bigger picture and sort of seeing how this fits in and seeing how this works best for a as well as b and sort of.. People have sort of a fuller understanding rather than just an expertise on a certain thing.

Q: what do you think the driver for that is? Do you think it is the ISPE promoting that aspect or do you think it is the individual recognizing that they have to be more abroad in their approach to different subjects?

PE1: I think it is probably the individuals and the organisations that they are in. I and you know you also asked earlier how you present your expertise once again I´d been an expert in

many different areas of pharmaceutical manufacturing shipping and transport to yeah distribution to private complaints to engineering to quality systems to validation to maintenance and qualification and I have also been on enough projects where I have interacted with enough experts in those individual areas where I actually learned things from them. To get myself to the point where the hardest part of being on a project is when you have more experience than the person that is actually assigned the task that is the most difficult part of working in I think the Danish organizations. Is and I have talked about this and I got a few pages towards a white paper on what I call default ownership and saying yes if I was just the queen ? validation guy. My quality guy cannot make a decision of confidence and do not really understand the impacts. You know what it is easy for me to say well I am working for the quality guy all I understand is cleaning but when I have got 15 years of in quality and quality systems and engineering and these type of systems. It is hard for me to sit by and watch somebody squirm when I am very comfortable with that. I end up then hopefully carefully overstepping sort of my scope and trying to guide these decisions trying to help us to make the right decisions. Obviously the right decisions as I see them or I have experienced them or learned them but that to me is the hardest part.

Q: Do you see the ISPE as being able to take a role in this to mediate disputes or misunderstandings or perhaps any quality information? Do you see a role for the ISPE to take any part in this? Knowledge transfer or knowledge negotiation?

PE1: I see maybe a potential area for ISPE to sort of come up in at least at something that calls to me? Ground work for how operating firms work with consultants and how operating firms work with their mission builders and often as consultants we are the ones between that. Because I see a lot of room for improvement between communication business practice standardization. It is almost as if yeah every time we deal with a machine builder it is like dealing with a banking system in a complete new country who uses all different codes. There is no standardization and all of a sudden you are left to literally find somebody that actually got it to work once and copy their solution which is not where you want to be.

Q: So you do see a role then perhaps?

PE1: I see a role in ISPE sort of helping industry to help itself that is actually the best way to put it. Helping industry does a lot of thing right but not all of the industry does it and a lot of industries continue to do those same things very wrong. How do we ? those should be well hanging fruits to people that are doing it completely wrong. Not everybody is doing it perfect. Nobody is doing it perfect. There is always room for improvement but how do we align better I so and I think a lot of the engineers standards have come on but as far as what is the real killer it is documentation GMP administration and actually…

Q: GMP you mean…

PE1: Good manufacturing practice and sort of the documentation requirements that go along with that and sort of say ISPE and ? these organisations have focused a ton on aligning the engineering standards and I guess yeah. Ultimately i.e. where we need to be but saying okay we have all got the same engineering standard but we all have a different way of going about it for business administrative documentation etc. and if we can actually align a little bit. It is better. I could realistically cut my procurement time down in half if I did not need to honestly I am buying the same machine I bought 3 times. I already know the machine. I know it is there but actually to order put the documents in the noble/local system takes us three months. Okay this is urgent it needs to happen yesterday. We are already. you know .it needs to be here by January 1. It takes 36 weeks to build it that is only 22 weeks away how is that gonna happen and we are already behind. We just need to come in and apply the system since there is no alignment in there as a consultant that works with the machine builder a lot with a lot of the other machine builders. I can tell you all four of those machine builders are doing the same thing. They are trying to get a standard way of actually handling this stuff the problem is us as operating firms all love our own special way for some reason and I see that that would be a great place for ISPE to sort of come in and try to align once again it gains you efficiency.

Q: Would you see them working with the people like yourself in a consultancy role or would you see them working with the management?

PE1: Probably a little bit of both but I would see them on either level coming up with best practices and try an d mould the best practices and trying to stamp out the worst of practices.

Q: Do you think the ISPE membership should be expanded to make it more maybe not compulsory but let us say encourage within the industry to be a member? Do you think there are enough members of the ISPE in the industry or do you think the membership push let us say should the ISPE be more like a governing body or practice or should it be more networking more casual organisation?

PE1: To me with the leverage and expertise that it has built up. I´d love to see it move more towards not to become a governing body but more towards and to help and push some of these initiatives from the industry´s side but yeah I also it is a non-profiting organization so from a membership perspective you sort of the only way to sort of look at that is to assume that more members equals more knowledge more networking potential greater ability to align and also wider scope but from the business of the ISPE it is running they obviously have an interest in that.

Q: Okay. I do not have any further questions down. I think you have covered everything very well. Do you think it is possible that the ISPE could take a regulative position on any event given the current structure of members involvement.

PE1: To that point probably not. They could make a should be willing to make recommendations but I do not think they would be wiling based on the politics and structure etc. to offer sort of non-binding rules to industry. I do not see that really serving their purpose inclusive.

Q: If it was to happen do you think the industry would be willing to accept such a role from a third party?

PE1: It depends I would say…

Q: e.g. Novo Nordisk would or a consultancy company they would obviously have two different business models but the ISPE would in fact be acting like a policeman.

Q: Do you think both companies would be willing to accept that role?

Xxx

Pharmaceutical Project Manager 1 (PM1)

Interviewer (I)

I: I do not know if you had had a chance to look through some of the questions?

PM1: So very shortly, actually, but I think we, you know it is not very difficult questions.

I: No. A lot of it is to establish your background and your experiences with the ISPE and your knowledge gained from the ISPE. What I would like to do is to ask you about your expectations with that knowledge in regard to what the company can take from it or the company rewards from that and that is not really expanded on this yet.

PM1: And it is especially for ISPE or is it also other organisations like

I: Mainly, the ISPE, because it is a Master Thesis with a maximum page count. The PhD will allow me to broaden this out if I take the PhD if I can find the funding and that way I can look more broadly with the pharmaceutical industry with all technical organisations linked to it. So that would be the aim. I just need to find a commercial sponsor.

PM1: It is just because that there is another organization called PDA and that is really

I: that is what I would look to look at as well

PM1: that is what I have putting even more if but I think a lot of that

I: parental drug administration or agency? Agency isn´t it

PM1: Association

I: Association yes

PM1: parental drug association.

I: Injectable drugs is that correct?

PM1: Yeah, yeah. So the difference between the ISPE is that ISPE is international society of pharmaceutical engineers so it is really a lot of engineers . Where the other one is more QA people and. So it is more pharmaceutical people.

I: Okay and process loads validation would you say?

PM1: it is more the validation. It is more the whole ? issues around marking pharmaceuticals. So It is more the pharmaceutical

I: So it is a balance to the engineering side.

PM1: Exactly that is why it is a little so traditional I believe. The ISPE has been more so you know how do we built the facilities the engineering and the others how do we run the facilities and then how we run the processes has been shared both places.

I: That is interesting.

PM1: that is kind of. To some extent I feel ISPE has been through a crisis because we kind of know how to build a facility you know. We cannot talk anymore about it how to build water equipment and things like that while the whole ? ? has been a big thing and that is why ISPE has tried to come in and PDA has you know a little struggle to say you know we wanna go together you know and that has been the situation where they want to merge which I think they should do because we all have the same interests. We wanna help you know the industry to make safe drugs. Have good interaction with the authorities and do training and so on, so they do a lot of the same things.

I: As long as you have the individual affiliates I cannot see any reason for the two organisations to come together because each one has their own specialties and that won't change.

PM1: Yeah.

I: The lobbying side might change for the ISPE.

PM1: But I think the problem was there was some ? then there was the person you know who should be the boss and things like that and then you know then it went bad. So sometimes there is a actually a lot of competition, you cannot go to ISPE meetings if you are PDA. So it is kind of you selecting side a little bit.

I: That is interesting.

PM1: and I am working against that so I really want to go to both to really keep it together, but I am a little more a PDA person than I am.

I: There is a little seed in my brain here and it is a ? to actually strengthen the case for a PhD.

PM1: Yeah, but that is of course a long story between you know and early room you know.

I: I can imagine.

PM1: And those interactions. It is a bit like Sweden and Denmark. It is like brothers and sisters.

I: It turns out ? to be the worst fighting of all.

PM1: Yeah exactly.

I: It gets really nasty. Civil wars tend to be more messy than.

PM1: Yeah.

I: What I would like to do also is to set up this. Just to do a second recording. In case the first one fails.

PM1: Sure.

I: I do not expect it to be a problem but you never know.

PM1: No. But I am guessing like an hour should be.

I: Maximum, maximum because when I have to transcribe it that is the. An hours transcription is 12 hours on the type writer.

PM1: Really

I: Yeah to make sure.

PM1: And you do not have any automated that just is?

I: Yeah if I work for NASA. Even the most recently priced commercial software does not really do a good job.

PM1: Okay.

I: You would need to go to government institutions.

PM1: Yeah.

I: People with badges.

PM1: It might be that NASA is releasing it at some time.

I: Or the CIA, but I cannot see them really helping in this case, but… This is a little bit embarrassing I can't find the speaker on this one, but what I might do is just trust my memory, my notes and the original one that is like maybe the way to go. Just do not mess about with technology. It is there to serve me.

I: You got a print of the questions.

PM1: Yeah.

PM1: The first ones I read through them today and I think they are very, very close to How I would like to start. If we could just start with a little about your background and built a case of how you gained your expertise, basically. Yeah.

I: So could you describe your academic background first.

PM1: Yes.

I: The formal academic background.

PM1: Yeah, so it is very fast actually. So I have a bachelor in chemical engineering. So I actually got my job at Nordisk Gentofte in 85. So only 23 years old or something like that. So only 3-4 years formal education and when you have this bachelor, then you normally go into the manufacturing. So I went into manufacturing were there for a, a little more than a… I actually got the responsibility for a department very quickly, very small department 3 people and then I already at that time after half a year we had to expand that and I was actually allowed to be the head of making that expansion of the department of the facility. Already at that time I get very close with the engineering people that is that later one actually became NNE pharma or NNE.

I: Given my limited knowledge of the Danish education system that does seem like a very quick set of promotions.

PM1: Yeah, I do not know. I think I was a little lucky, actually, that I was.

I: It always helps.

PM1: But it helps, but it was clear we had a facility that like two side this area and it was really not working. They wanted to make insulin and there was a big part of that and I think my job was actually to those guys. They had been working for a year on this and they made like a kilo and I was told that when the next year they should make like 200 kilos. So It really was you know a huge ramp up and then going to the next year, we should make like 1 ton or something. Really a big ramp up, we need to make another facility a much more automated facility. So to some extent lucky, but also that was the situation and then that facility was made and I was always interested more in development. So I managed to ? to get a shift into the development area which is normally, they normally require that you have a master degree or a PhD. and at that time 30 years ago, it was very few actually takin g a PhD. The

normal would be a master degree, but my you get pretty much the same salary. There was really not a lot of if you were able to get a job that quickly the whole year the whole life span would have to be more advances from taking that bachelor. Then coming back to in 2000 no in 1995-98, I took additional education actually in Ballerup called ETM something technology management. It is a little like a mini MBA, so you have two courses every week in the evening on quality project management and things like that.

I: You very nearly jumped on to question to there. Have you taken any other formal courses to support your academic education.

PM1: Yeah, exactly.

I: Okay, now you briefly covered your career path at the early stage.

PM1: Yeah.

I: if I can just miss out the question 3 on your list. Have you taken any courses, educational courses provided by the ISPE?

PM1: No.

I: Okay.

PM1: I only have gone to a lot of conferences. I did actually start up, they had this, there is a, yeah what is the name of that c…

I: The SOP? Yeah SOP?

PM1: and I started to get that certification.

I: Yeah.

PM1: But it stopped relatively quickly, I was not able to.

I: I understand that course really folded sometime back as well, I am not quite sure the reasons for that, but I think they were structural more than anything else.

PM1: Yeah there were some structural issues around that

I: It would be nice I think to see that kind of course re-established.

PM1: Yeah.

I: But that is not for this event.

PM1: No.

I: Okay, you have also covered question four about your first job, after you left your education. You also covered how you were qualified to do that role. Did you receive any training while you were doing this. The beginning of your career? Did you do any on the job training?

PM1: It was ? but I did have a management course at that time. Like a week course where you know.

I: Okay.

PM1: Also on personal development and how to yeah become a manager.

I: Okay. Did you have a mentor appointed to you or did someone step into that role?

PM1: No it is not a formal mentor, but I had actually quite a few around that I saw as mentors.

I: Okay.

PM1: And I think actually coming back to maybe I am going to quickly, one of the advantages why I have been relative successful in my career is that I have never been afraid actually to get ask for help and when I have had help from somebody that has a lot more experience

than me. I have been very clear to tell that to the others. You know when I was successful so and so the reason why I was successful was because this an d this person was helping me. So next time I asked for help it would be very easy to they would like to help me again.

I: Okay.

PM1: And that has been a big advantage for me, so and that has some relation to the ISPE. So that is why I feel, a big advantage to be part of organisations like that because you meet, you have that network. You have that advantage of talking to people to peers and if you have issues, you can get that input for your daily work.

I: Just to clarify. Do you have any formal professional qualifications specifically for this industry?

PM1: Not.

I: Or is just the case of a BA and then work experience and some courses?

PM1: Yeah.

I: No formal specific academic courses to your current position?

PM1: No.

I: What was your first contact with the ISPE?

PM1: So that was in 2001 and I was, they contacted me and asked me to give a presentation at a, they just started to get Mølgaard and Flemming Steen Jensen that was a group there and then very shortly after they asked me to join the Board of Directors.

I: Okay.

PM1: Yeah.

I: Who were you working with then and what was your role? So coming a little back to my career, I was 14 years with Novo Nordisk and then in 2001 I was a cofounder of a CMO called CMC biologics and I had just started CMC Biologics when I joined the board.

I: Okay. What was the basic business of CMO what ?

PM1: So the CMO what we were doing ? So a CMO is a contract manufacturing organization.

I: I see, just to make sure.

PM1: So it is simply, if you have a monopanto antibody?, you wanna produce from the university or whatever. You ask us to develop and make the product.

I: I have experienced that, you can ask what in this assessment this was meaning. In one case, you can get two or three different answers from different people, so each industry has the same initials, but it can mean completely different things. I just need to clarify.

PM1: Sure, sure, yeah.

I: What is your current involvement with the ISPE?

PM1: So I stayed in the board for like 10 years. I am actually still a member of the board, an honourable member of the board, because CMC is a little small organization they had a little difficulty to fully support the normal career path, so you are normal member, then you are a secretary, the treasure, the vice and then the chair and I was not able to got to be the chair. I knew that was going to be to much work, but I was the treasure for 6 or 8 years, because when you it takes a lot of time to get started on that when you have established your system so that then it actually not that much work and your still part of the offices? So today I still participate in probably participate in every second board meeting. So it is a little less, but I am kind of one of the old guys where you know where you can drag in when you need a little help so. You know I have been on certain conferences giving presentations. I was at an ISPE meeting yesterday actually an international meeting giving a round people discussion.

I: So in many ways you have gone full circle and now you are the mentor?

PM1: Yeah.

I: Okay.

PM1: Exactly.

I: Can I ask what was you reasons for attending the community of practices event and how many communities of practices do you belong to?

PM1: So I believe I belong to two, but I am not active in any of those, but the reason why I did join them was this about getting knowledge, sharing knowledge, but I do not find it to. It does not really work for me. I do not put questions in and wait for answers there. Normally, my network would be I would know who to contact directly and then contact them or you know meet them at conferences and so on. I travel a lot and I go to a lot of conferences both in ISPE and the PDA, so I am probably at one every month.

I: Which raises the question then what is your primary reason for attending these cop meetings ? Is it just to network?

PM1: That is just networking yeah.

I: Yeah.

PM1: Yeah, it but also of course to be sure that I am on top of what is the new development in the industry. So it is keeping my mind my knowledge at

I: We are down to question 14 which you have already answered about the board positions. Are your current employers aware of you work for the ISPE and your history in the ISPE?

PM1: yeah very much and they do appreciate it and it is part of my title actual, it is part of what I have to do here is to have those internal or external relations.

I: Okay. Was that always the case with your job at Novo Nordisk. Were you involved in the ISPE at that time?

PM1: No, not at Novo Nordisk. It was just when I started at CMC I got involved, so that was in 2001. I was not involved prior to that.

I: Okay. Did they stipulate any requirements with regard to your membership and your current positions? Did they set any limits with regard to which involvement you can take in this?

PM1: No, I have been able to put the limits myself.

I: Yeah.

PM1: But in my job both at CMC and here. It is appreciated and it is expected that I do work with ISPE. So I am encouraged to do it, but of course it is always a balance you know do it but without saying it directly please mostly your spare time for it.

I: It appends to question 16. Does the company encourage your participation in ISPE events. IN particular in the last few days you have had the events in Europe. Did the company support your participation in this event?

PM1: Yeah

I: Okay.

PM1: and it is because my role is business development, so it is a lot of, so the company sees ISPE as a marketing tool to give higher visibility for NNE Pharmaplan and NNE Pharmaplan has historically always been a very strong sponsor and support of ISPE, and but also looking more also to those other organisations like PDA. So to some extent not. I think there is a little concern if we get any enough value of our working to ISPE or contribution to ISPE.

I: Okay, if I can just take an additional question at this point. You are obviously not the only member of the ISPE within NNE Pharmaplan. Do you communicate on a formal or informal basis with other employees. On a particular issue or generic issues with that related to the ISPE as a separate group or is it just an ad hoc network ? Do you discuss between the members in NNE Pharmaplan your any issues relating to the ISPE or is it just and individual.

PM1: I think the problem, the reason I am so, a lot of the people I know at NNE Pharmaplan I knew through the ISPE because I was at CMC and so that is why so I have a special relationship to a lot of those people and actually discussing career. So maybe one of the reasons why I have this job at NNE Pharmaplan is because I knew those people through ISPE. So maybe I would not have this job I have today if I had not been active member of the ISPE so that is very clear you know how it can work for you. And I actually believe in general that it is you know a lot of people have that reason to join those because it really gives a good chance to you in the future to get another job and that is of course a balance for the organisation. You have to support your worker in the organization knowing that that might be the step to go to another company.

I: If we can built on that point. What do you think of the value of the ISPE for students to create a career path?

PM1: I think it is a huge value. I do not understand why they do not do it anymore, you know why they are not more active because when you get your job and of course it is more and more when you are later in your career, you are so dependent on having network. Very few of the jobs in this industry are actually put on the internet and again you have such a big advantage if you know somebody already.

I: I have certainly come across that.

PM1: So you might stud? He is offered a free ISPE membership and he said no, I do not wanna do that and I tried to say that why do you not do it because you you will have that chance to go to those conferences and you will talk to those people and the people and it has been one of my things I would like to do in ISPE to say how can we get it so it is more younger people so it is not only old men like me that is joining those conferences and I think a huge that you get that network and you will have a chance to interact and get your job and also after you get your first job to advance.

I: I must admit my initial reason for joining the ISPE along with the general interest in the industry was the resources available on the website e.g. were only available to members.

PM1: Yeah.

I: Including the community of practices information, so that was actually very useful.

PM1: Exactly.

I: However, career-wise I do not really see an advantage at the moment

PM1: No, okay.

I: But that is maybe to develop.

PM1: But again I really do not and I think ISPE and I do not understand both ISPE and PDA, they always you know during our time we had student chapters. We have been inviting representatives for the students to come to our meetings. We really give them VIP treatment and you know they do not feel the get the advantage. They disappear. We do not see this. So I do not know what the ISPE.

I: I tend to agree with that issue at the moment. I would like to I can see the tremendous possibilities, but I must admit I do agree with that position as a student.

PM1: Yeah. You do not see the advantage?

I: I do not see any short term advantage as a student to be a member. Long term obviously, yes, there are some advantages but it would be nice to see some more career support.

PM1: Yeah.

I: Some more student activities with invitations of companies e.g. talks mentoring maybe not direct mentoring, but presentations at universities about the industry, because there is a lot of misconceptions about the pharmaceutical industry, if you mention the word Monsanto to a student, they will just go white and just faint.

PM1: Yeah, the naughty ones.

I: Well, let us say there is a distinct lack of information coming through from these organisations that could be addressed by the ISPE. Do you think there is a scope for someone to develop that in the Danish market?

PM1: Yeah, I definitely again we have tried it and we have not been successful and it is not because we have not tried and it might be simply that there is this gap between the young and the older ones because normally when you are allowed to go into the organization you are normally a little more senior, that means that you are maybe in your 40ies and so on and it might be the mentor gab between when you are in your twenties and your forties is too big. So what we can imagine would be beneficial for a one student is really not. So what is important for them at the end of the day we can say we have had this discussion so many times and we have not succeeded

I: You say we have had this discussion what do you mean by we?

PM1: The board of directors in the ISPE.

I: Have students been brought into this discussion?

PM1: Not sufficiently, sure so there has been those. Also one of the reasons we tried to bring in some form the university and say could you actually be the one that had those discussions and had those discussions with a smaller group. Some that was more energetic about that to say what should we do. So there has been some discussions. I have not had it directly, but it is also kind of the I think it is seen as an old man club also so.

I: In many ways these questions have gone around the subject a little. The subjects of my investigation relates to two parts. First of all how do people move from being a novice to an expert and that links into this series of questions. Do you see it is possible to be moving from a novice to an expert within the ISPE framework of knowledge development or as you say is it an organization for people with expertise already?

PM1: No I do think, it is part, it is not the only thing. You have to do other things. You have on job training and but it is definitely supporting this, if you use it right and there is a lot of resources there, if you spent the time exploring it.

I: Okay. Do you see any formal recognition by companies to support the training offered by the ISPE or is it something the companies are not addressing at the moment?

PM1: I am not completely sure that I know the full answer as I say there are some companies that are doing and see the value and again actually use the PDA and the ISPe those organization to give that training, but I see a lot of a and that is maybe part of the problem that a lot of this is more an advertising or business development visualization of your company. So a lot of those conferences is really people who want to sell to others and there is a little too much of that selling and that is maybe what I do not wanna get you know into that kind of environment. Yeah I do not know, but I feel that is the reason I am supported to go there, is that it is part of our selling NNE services. I am not supported to go there to get more experience. I am supported to go there and get more selling of NNE Pharmaplan.

I: Okay, If we can just move to one side, but in the same subject area. How is a person actually recognized as being an expert in a particular field within a particular field pharmaceutical industries? How it feels? How is an expert defined when is an expert recognised as an expert? Or is it up to the individual to say I have enough experience. I am now an expert in my field. Or is it possible from someone from the outside the ISPE or a company to say, okay you have reached a certain level, you are now an expert. How is an expert defined?

PM1: I do not know the definition. It is

I: So how do you move from being a novice to be an expert if no one can define what an expert is ?

PM1: I think it is a very difficult question because it is also you know you qualify. It is not like one day you go from one to the other, but it is when your knowledge is recognized y others. You are asked to give presentations. If you are asked for advice. So it is gradually the more

and sometimes you are thinking because you are being asked so much then you are an expert and you try to put it into your CV that you have expertise in those areas here. So to some extent I feel that is somebody else who is defining when you are an expert. You cannot do it yourself.

I: I have found people today tend to look more towards paper qualifications than previous generations e.g. having a masters qualification is an entry point for making an application for many jobs and a PhD is quite normal for a company like NNE Pharmaplan, but if you go back one or two generations as you mentioned before, PhD were not normal.

PM1: No. those are different types of experts. Those are experts that had some formal education and is following maybe coming from the university had that background and then you have this more self-learned experts and I feel I am the latter one and it is more difficult to define this self-learned you know when because and at least at that you need to have other the communities recognition of your to be an expert. You cannot.

I: What is your official job title at the moment?

PM1: I am senior technology partner.

I: Now partner how do you define partner within NNE what does that mean?

PM1: It just mean that you are at a relatively high level. It is not like you have ownership of company or anything but it is the highest. So I have the highest level where I do not have to have anybody reporting to me.

I: So you are self-managed person?

PM1: Yeah, definitely.

I: So you are an expert in your field?

PM1: Yeah.

1: Without a PhD, but you are an expert.

PM1: Yeah.

I: Okay, so when you applied for this job, did you apply for this job or where you asked to apply? What I am trying to get is.

PM1: I was kind of indicating that I was interested in making a move and then again actually Gert Mølgaard from, so I had a discussion with him and I was saying that maybe you if you think that NNE could have a person like me then consider it and then he was sharing that knowledge with some of his colleagues and the other colleagues said yeah we actually wanna be a little stronger in this area and then they contacted me and then we had a meeting.

I: As you said at the beginning jobs are sometimes created for the right person.

PM1: It was actually created for me this job yeah.

I: So they recognized your expertise from your network.

PM1: I think they recognized my expertise more from my career that they recognized that I have so coming back to my I was fourteen years at Novo Nordisk and I was working close together with NNE Pharmaplan at that time, so I knew some people here, so of course it is part of the network and then at CMC biologics being a founder coming from a few people and built it up to 450 people and everything is very successful and that and I think that is really the background they are buying that I have gone through that form developing. Yeah starting up a company to make that successful that was primarily what they bought.

I: So your career and development has been a little when we take it as a whole it has been like a spider's web it is all come together to the centre of where you are now. It was not one particular direction it was not particular your education, it was not particular your membership of the ISPE, it was a case of your experiences. It was a case of amalgamating everything together. Is this correct?

PM1: Yeah, but I think there is one, you know my.

I: Could you identify one particular area that helped more than the rest.

PM1: I think it is my ability to network with people that is really my strongest competencies. It is really to interact with people and again, yeah.

I: Okay.

PM1: Of course but so but I also tried. Yah I do not know. It is difficult to say what things worked but I also had kind of a plan already at Novo Nordisk that I want to be os Novo Nordisk had those two career paths. You can go and be a manager and go that and have people reporting to you and I tried that and I did not really like that. So already at Novo Nordisk I got into that career I wanted to be an expert actually. So they have this where you are a principal scientist and normally with my education background that is a little difficult, but I worked hard to actually had and that was through the network as well to be sure that the people around was saying yeah. He is trying hard and he is working for this and he gets into get that knowledge and then I got that.

I: If I can just try to get a few more details about this career path at Novo Nordisk. Not particular you but in general. You mentioned they normally have two career paths, one for knowledge experts and one for administration managers.

PM1: Yeah.

I: At what point is that defined for the individual. When you join the company or as you go through the initial few months and next few years.

PM1: No. It is definitely after a few years.

I: Okay.

PM1: It takes a little ? if you come directly from university you will get a typical a manufacturing pos in manufacturing and then it is up to you and your yearly discussions with

your managers to try to make that career path and I do not and for a lot of people it is kind of they normally go the managers they get a team leader and then they figure out if they actually do that well and sometimes the other career is made for failures from that so you can comes as high and normally people are promoted one step higher than they really can do and then they of course fail, and then they go over to the scientist and that has been a problem that it was used as a garbage kind of for people who did not succeed in the managers and there was a small group saying we really think we should have that career path and it should be really difficult but also highly recognized to get into that and I am not sure if they are better at that now but there was a tendency that it was more accepted that I want to be an expert in those areas and I do not wanna and I see being a manager as being an expertise area like be an expert in building facilities. So if you wanna do that that is as highly recognized as the other.

I: Yeah, I came across a similar situation when I worked at Man Diesel as a technical writer. I wanted to become an expert in technologies and that career path was not available, so I moved on but I think Novo Nordisk saw this many years back in the nineties actually and they really wanted to make this highly recognized if you got that career to be a principal scientist and then have a senior principal scientist. Is there a role or was there a role for the ISPE network to be involved in this creating a development path for experts or was there another association or set of skills that people could attach to their career path as being an expert.

PM1: I did not know about that in the 90's at Novo Nordisk.

I: Okay.

PM1: but you know today I really would recognize that because you get that mentor and I think that one of my advantages was also that I had those mentors informal mentors but I found people that I said if I could see that they were doing good and maybe was a few years older than me. I kind of tagged onto them and followed their lives, but also I was quite clear myself what I wanted to do. I tried this and I really did not wanna go this. Yeah I wanted to have that science background

I: Okay. If I can move back to the communities of practice. Do you see a value of spreading network wide within different communities of practice or do you think people should be focusing on one or two key groups?

PM1: Yeah the focus otherwise it is diluted to much a few and then and make your community within this.

I: You have obviously given a great deal of strength to the idea of networking and mentoring and seeking to use the knowledge of others. If we can broaden that out to the concept of bridge builders in the industry interdisciplinary and knowledge workers. Sorry for using terminology like that. Do you see a role within NNE Pharmaplan for this multi-oriented set of knowledge skills and within the ISPE because you talked just now about people should focus on a few groups that would obviously limit the interdisciplinary effect. Do you see interdisciplinarity as being a good idea for the pharmaceutical industry or not in general. The bridge builders for knowledge.

PM1: yeah. I think there need to be both, but I just think you cannot be an expert in those interdisciplinary activities, you know you are an expert in a specific area and you have those different types. So we have the type that can get the people to work together, but they would not in my mind be seen as experts. An expert for me the definition of expert is relatively narrow area. You know everything about and of course you need to have the one who is more holistic and taken the broad perspective and of course you have the one who is really going into the deep and really knows everything about a specific area.

I: Okay then perhaps an awkward question for you. How do you see the holistic experts working within NNE. How is that functioning? Is that possible within NNE? To actually have holistic.

PM1: Yeah again this is maybe mixing again because to some extent I actually feel like myself to be one of those more holistic so I have a relatively good area of understanding of this huge area within this. But then I pick a few things that I feel I am an expert in e.g. so. I am

not an expert in making water systems or ? pieces. I have an understanding of that and then I am an expert in ?sick you system. So I try to be on both lines.

I: Is it possible to be acknowledge within the information flow between different departments in NNE ? Is there some kind of systemic place where this knowledge can be transferred between different departments? Is that possible?

PM1: Yeah so I actually believe that NNE has a very good knowledge sharing system here and it is built up basically using the Wikipedia software.

I: Sorry, could you say that again.

PM1: The software from Wikipedia.

I: Yeah.

PM1: Pretty much the same software. So when you have information that is two ways you can push information saying you should know this you should know this you have to read those sops and that really does not work in my mind. Then there is the other way where you make information available and then when you seek information. You get some information and then you can see there is actually more information around this and then you can seek it and you can seek the people and that is also a culture here that if you ask for question, ask for information. People will spend the time to give you the information in general.

I: Is that formalized in any way from the hr dept.

PM1: Yeah, it is and they spent quite a lot so right now they have a new program called peak. There was a survey saying who in your network is the one who actually is helping to give information and you know that kind of questions and based on this feedback. There are some that are really good at sharing that information in the organization and they call them rock stars. So there is really a support and this is run by HR. So there is really a way that people in the NNE that people who share the information and help the res t of the organisation are appreciated and valued.

I: If we can expand that to links outside the company. Do you see the system being used to use outside. Information sought of like the ISPE to support this system or or do they bring inside knowledge to support this construct?

PM1: for me it seems like it is more inside knowledge here but of course some of the knowledge is coming from the outside, but it has actually been one of my concerns around ISPE, is that how do you share that knowledge you have from the ISPE with the rest of the organisation and I do not feel it is done sufficiently and I also feel that there is actually not a lot among your peers recognition of the people who is putting a lot of effort into the ISPE, you know being global president and so on that has not been a career advance for them internally in the company, unfortunately.

I: Would it be fair to use the expression of the ISPE information system of being somewhat like a shotgun approach? Where you have massive set up bullets, but the spread is so wide before it hits the target it is unclear what you actually have hit.

PM1: Yeah, I think that is fair to say.

I: Do you think that if it was brought into a system within the HR dept. that you could perhaps target experts outside the company to help, do think it is possible to bring the ISPE within the system?

PM1: I believe it is and you know your idea about it actually going through the HR system instead of going directly to the members, is probably a good idea, I think that could be a way in.

I: A job for me maybe.

PM1: Exactly, I think not at the moment.

I: Do you think finally maybe contentious. Do you think the information and knowledge available from ISPE courses and members should be made compulsory to be people within the industry? Do you think it should be compulsory to learn, to have learning from

organisations like the ISPE or PDA as a career requirement. For novices in the company within NNE. For example; do you think it should be a requirement to attend the courses?

PM1: In general I do not know. I do not like this kind of requirements and pushing. I have more this. You give the option to take it and then it is people that is going for it, but it is more this your idea that instead of NNE Pharmaplan is developing their own tools for education. Why don't they use something that is out there already and why do the ISPE not use this as a source of to get more knowledge about the organization, but also to get income. That They are offering to help organisations to run their training to a larger extent than they are doing today.

I: Okay. Do you think that the industry and a company like the NNE would be open to accept a bigger input from the ISPE. For example,. educational qualifications with regard to specific expertise areas?

I: Obviously, the ISPE is a global network and companies like this NNE is also global, it raises the opportunity for certain education programmes to be developed and perhaps being made compulsory across the industry, not just NNE, but other companies like that. Do you think that is a possibility or…

PM1: I do not think it is a possibility, I think they have tried it and they have not succeeded completely. And I am trying to consider what is the reason why it is difficult to get it? I do not know if some organization s like NNE is a little afraid that sharing to much confidential information if that is why they are a little reluctant. I do not know if and also the whole set up of ISPE there is the professional then there is the volunteer and at least there has been a lot of it seems that it is the volunteers that is doing the best job. There has been a lot of criticism of the professional part of this that they have not been that professional actually and make things more difficult for the volunteers and I can see as a representative of NNE that I am a little. You know if do I rely on a training that is done by volunteers. Where so what is the certainty that those volunteers are doing the right thing. Sometimes they are busy, you know, you know. Is it just the one who wanted to be volunteer that is coming to

give the training or is it really the ones who are certified. So that uncertainty of the quality of the information coming there.

I: Is that due in part to people making decisions in HR having to justify their decisions with relation to the qualifications of these people?

PM1: Yeah I think that is a problem and again I had the, my own.

I: Which brings me to the question again how do you define an expert?

PM1: Yeah, exactly.

I: An expert in presentation or an expert in the knowledge. How do you define the expert.

PM1: Yeah, but is really also the quality of those people who is doing the training. How do I, how can I be sure that they are really qualified and do not have another agenda that they are coming here to you know if you wanna be trained in CIP systems and that it is actually not a vendor of a CIP system that want to sell you a new CIP system instead of getting the ? and that is why I feel that is both the strength and the weakness of ISPE and similar organisations, both the professional and the volunteers and the volunteers are by definition difficult to control because they are volunteers you cannot really push them too much. So that gives a lot of requirements to the professional part of the organization and that is maybe where I see the PDA has been a little stronger in the professional part than the ISPE and that is why I actually believe that the PDA has been used a lot more for internal training. They had their own training centre and they have been a more successful in this and very clear in their requirements to the people that was doing the training.

I: You just opened up a whole new avenue of investigations I should look at but I do not have the time for that. I think I got to the end of these questions thank you very much. For this It has been a very big help towards actually getting a submission for my master thesis. It has been very difficult to get people to commit to a time to be interviewed. I have approached your hr dept. but they are reluctant to go on record or an individual is reluctant to say I am qualified to go on record.

PM1: Yeah, okay.

I: Which tells me something in itself.

PM1: Yeah.

I: the absence of information is still information. Ideally if I could have approached the hr dept. of Novo Nordisk, NNE and Xellia, I would have been able to get some information of the official structure, but the information you have given me today will make up for any gaps on the official side.

PM1: So Mette did not respond back to you?

I: She asked me how I got her contact information and she said she did not feel like she was qualified to give me the answers I might be looking for.

PM1: Okay.

I: Which was fair enough.

PM1: Yeah.

I: But I my response to her was we met up 18 months ago when she just joined the company, she properly forgot. She is actually on my linked in connections as one, she obviously forgot about that. It is one of these connections where you have to keep reusing the connections, but we are not in the same line so to speak, but I attended the first facility of the future event at the end of 2013. I gave a presentation on the use of RFID in a cleaning room environment with some other students.

PM1: Okay.

I: that was very informative we had the director of the Nordic NNE area and some of the other managers as well. We ha d a full room. It was a valuable experience and they actually decided to take on the project into another, not sure how you describe it, but they are

looking to use it within marking medical equipment. Not in the cleaning room but more generally. So the idea of using an RFID has been taken on further it was actually presented at the last facility future event but they had no idea that we actually came up with the idea.

PM1: Okay

I: the information had been passed through, they were just given the projects in general terms say look Here is an idea run with it.

PM1: Sure.

I: but the information had been passed because the person we worked with now left and have gone to know what is the name it is a hearing aid company out in Ballerup. Should not mention his name without asking him.

PM1: but I am coming back I am actually a little disappointed why the hr do not wanna talk with you because I think it is a I do not know if you can send another type of mail to them to this and say if you would forward it internally because the one you should talk to should be responsible for internal training that is the one you should get in contact with and that is probably what you were asking Mette I do not know why she is so reluctant to take this.

I: I think I surprised her by getting her email or I addressed it to her email. I had sent to a link in ail which some people do not read that often. So I followed it up with a mail some days after and that came out as a bit of surprise from her.

PM1. Because I really feel that it is what you are doing here is important and I see that this is a because NNE as a company is actually investing a lot of money you know. Especially time there is a lot of people that is spending a lot of time on this.

I: When I saw the resources committed to the facilities of the future event I was thinking there is some serious money here.

PM1. There is.

I: Yeah.

PM1. And I think there is some concern if we are getting the full value of this and I think part of the reason why we are not getting the full value is because we are not taking advantage of all the things we could get for free actually, because we do not fully understand it and as I tried to indicate earlier I think it really should be because ISPE is going to the member, they should really try to focus more on the to getting into be responsible for the training in the company how can we work together.

I: it could also be a good revenue for the ISPE.

PM1: Exactly. And that is why and it shows that it must be very difficult if you are not even able to get a meeting with a hr person to discuss the advances of this. So I am actually a little disappointed and a little surprised.

I: I am not surprised.

PM1: Rally.

I: I have known NNE for some time probably 8-9 years and a bit longer. So for me this is just a continuation of what I have experienced before. In many ways it is an industry thing a lot of the companies in the consultancy business like NNE e.g. they tend to be very cautious about what information goes where, but what is stopping them from receiving information. There should not be any barriers from receiving information.

PM1. The only other reason could be that they are just bombarded with millions of people who want to sell them things, you know training systems and all kind of.

I: Of course. You know they don't really they assume you know I wanna have a meeting to discuss something no. If you are not applying for a job, they won't speak with you. I worked for the gear group for some time which is a German-based company they own Niro and I went down to a trade exhibition in Nurnberg and NNE had as obviously one as normal for the first or second biggest exhibition area.

PM1: Yeah

I: Down there. So they are very visible but I am also away from my direct contacts and they are very cautious about who get information because they are very worried about confidentiality and commercial possibilities and compromising that . I can understand it, but I do not really see a change, and I think this facility of the future attempt might stall unfortunately. I have seen efforts before along the same lines from NNE and the story is going around, but I do seem a slight change this time there I s much more investment this time wise and resource-wise.

PM1. I think as well, I have only been in the company for 4 months so I am still trying to understand this company, but part of the I got the job here is actually to have that my position is actually to be the bridge builder between the clients and the engineers because sometimes the jokes is that if you tell engineers a problems two seconds later here is the solution. And sometimes you have to go a little deeper to fully understand what is really the problem and what is really the need and then make a solution.

I: Knowing what questions to ask.

PM1: Exactly listen a little and less advices in the initial start.

I: Yes I would like to do the kind of education I am doing now teach me what questions might be able to ask to the right people and it what areas.

I: Thank you for your time.

PM1: I do not think you should give up you should try to take a short mail to her.

Transcription of Interview with Andreas

People in the room: Andreas, Istvan, Loreta ,Mark, and Linn

Mark: "We have two types of questions ones who gives an idea of the background and we want to understand the mind-set of the experts in the field and we think you might qualify as an expert."

Andreas: "Me?"

Mark: "Yes, [Andreas: "no"] yes the thing is we have to interview all kinds of experts within the field [Andreas: "yes"]"

Mark: "there are many kinds of different experts so we have to understand you."

Andreas: "Is it the company or me personally or bough?"

Mark: "Bough, and then the second series of questions, which are more specific to you and your role within what is coming in the next few weeks ahm."

Andreas: "yes"

Mark: "[aahh] – Linn, would you like to ask the questions and then we can make some notes?"

Linn: "[øhm] yes"

Mark: "[ooor] do around?"

Linn: "oh yes I can do that [Andreas: "yes yes"] we have done the questions in collaboration so it is not an issue."

Linn: "But our initial question is; what is your education/ your background for being here?"

Andreas: "mmm there are two kinds of stories normally I would say I am just an electrician so that is something when I make a little fun of it. Well I started as an electrician a long time ago but suddenly I thought I want to be an engineer. And now I am an engineer but first of all I am an electrical and automation engineer. But I only worked only worked a few years with that after I started because then suddenly I started to coordinate my colleagues and the I coordinated some extra people and then I worked with customers and the suddenly I was a project manager and then I worked as a project manager for many years and then I also worked [øhhh] around close to two years as an consultant in something we called project

consulting and it was all-round consulting for start-up companies and it was a great time because we are a big house with a lot of different skills and we could [øhhh] help [øhh] small start-up companies with a lot of different things. That helps them a lot and then after that [øhh] I act I was [øhh] the line manager for the project managers for [ehm] close to seven years and this year I am [øhhm] the program director for this facility of the future program."

Linn: "And so this just started?"

Andreas: "It started this year and [øhh] what it ends with we do not know yet. But it is a changed management project program that we want to change attitude towards competences that people are more… [øhh] inspired and more focused on competence development."

Mark: "That leads on to some other questions that [Linn: "yea"] we will return to later."

Linn: "So eh yes so we were going to ask oh what your role is within the company, but I think you already addressed some of that?"

Mark: "What is your perceived role within the company as a manager or a facilitator or a developer?"

Andreas: "Now I am a project director"

Linn: "Yes"

Finn: "For the program and this program director then you are then there is projects and portfolios within this change [øhh] towards developing our competences so this is. I don't know if I understand the question right. But it is a fulltime job with some [øhh] I also have a small organisation charge if you want."

Linn: "so [em ehm] what is [em]. I will just go on to: Why did you feel it was a good idea to introduce the '1001 Ideas' competition?"

Andreas: "It was not something I did I was a part of the management group In Nordic we had a workshop last November, not this November in 2012 then we had [ømm little pause] it is a long story there were some different things we wanted to change attitude or peoples mind-set [øhh] It was something and the we set up a program for facilitating of the future program and another program for the [øhh] project the name was as it was project correction and øh maybe I should kind of tell in a short slide show fast?"

Linn: "yes and why did you want to change the attitude?

Andreas: "It was we want to be a more customer orientated and… [øhh] wait just a second.. We want to set focus on changing focus on… I think I just have to show you the slide show just to to explain it proper."

[pause – Andreas is connecting his computer with the flat screen]

Andreas: "You can ask the next question then I can [Andreas is still trying to connect his computer]"

Linn: "Yea I will ask the next question soo oh øhm øhm what is your main responsibility in your everyday work?"

Andreas: "… Everything about the program make it succeed everything [Mark laughing] about the program, the employees, the goals theee team øhhmm and I am reporting to the steering committee ømm just a minute [still connecting the computer]."

Linn: "What are your expectations for the concept, i.e. process or product? [little pause] like the processes of the"

Andreas: "What the [ummm] this is my lucky day [referring to the computer and problems with the connection]"

Linn: "it is good that you are an electronic engineer [all laughing]"

Istvan: "[referring to the computer] it is moving right?"

Mark: "The question is which end do you want on this [referring to the computer]"

Andreas: "no no sorry I was stupid I was really stupid!"

Linn: "this one"

Andreas: "ahh okay [all laughs] thank you for the help [Linn: "well okay"] [Makr coughs two times]"

Andreas: "soo it has been a long vacation [Linn: "soo"]"

Andreas: "So I can also give you a printout [The group answers: "that would be really nice"] [Andreas starts doing the presentation]. Because there is a chart and I have a lot on my computer so that is more easy that…So what was started that we.. first of all we have a customer service what the customer means about us… that, and also they really want a long term relation with us and that is something we want to build up and trust based and then

they also thing because we are in this industry we really have to be specialised. That we have to have a consistent performance. Because when we are good we are really really good and sometimes we also have I don't know maybe in Danish it is something that the bottom level is to low sometimes. And then we also have and this is the part, the manly driver, the part that we really need deep technical competences in our company because that is what we live for [Mark coughs]. And then we set up and say we want a program where we want to that the customer would recognise our competences even better and we would do it by we would make a survey every year and then we put up two programs and one of the programs was this [øhh] facility of the future program."

Mark: "Does any of this link to your CSR program? [Andreas: "to to?"] Your CSR program within NNE Pharmaplan?"

Andreas: "What is that CSR?"

Mark and Linn: "Corporate Social Responsibility"

Andreas: "[thee thee] There is not a direct link but this is something we always [mumbels] but what about this program that it was launched together with all the employees in the Nordic. Because if we say if this change has to happen what shall we do then? And all the different departments say in our department if we should change this then we do like this and this and this and then we perform on a scoreboard where we thinks if we do this and then do it again and again and again then there will be a change and every week all the employees are meeting about the facility of future program for 15 minutes. And what the program is about is first of all connecting all the ideas, inspire people to discuss if we do this and this in our department and then it will have this and this effect. So there is a lot of discussions in the department about creating ideas. Why is this a good idea they discussion on a lot of different things in the departments your idea was like this, maybe this idea was a little better or what different kind of… so and if we collect a lot of ideas some of them, 100 of them would be rather good. That was the background for how sat things up. Then when we are in the department you choose whatever you think this are the best ideas from our department so there is a discussion and then you go in to a group, a booster group or a gate keeper group and say okay we will [øhh øhh øhh] allow these ideas to have a project manager that develop these ideas…and we will execute the ideas on the 14.th of November and it is rather soon and quite a big event in the company and I think and I expect that you are invited and maybe should make a small presentation, I understood?"

Mark: "yes"

Andreas: "Thank you for that"

Mark: "There is some about the size of the presentation at the moment"

Andreas: "Yes but there is different possibilities it is also that you should feel convenient about the level of the presentation."

Mark: "you mention this is for all the employees [ahhmmm] is that based only in Denmark? Or globally?"

Andreas: "This year it will only be in Copenhagen this is a Nordic [øhhh øhhm] program. But I can tell you next year on a company level is market driven competencies that is next year's theme and a lot of these things from the Nordic will be a global thing and I am discussing with our CEO what to adapt for the next global program [Mark: "mm, interesting"]… so here is [øhh] is where [øhh øhh] we introduce and celebrate all the ideas to each other, but the most important thing is afterwards what should happen with the ideas [Linn: "mmm"] because some of them should be developed further or maybe be a new product in our company and [øhh] some is maybe still a good idea and we will continue to work with it or this was one maybe that was a good idea but now it is in our 'wicky' and you can read about it in there and we will not continue working with it. So after the 14th of November there will be a big session among the project managers form the different projects where we want to find out what is the potential for this [øhh] ideas… And we have a lot of focus on the single employee so this is not a top down program it is a bottom up program sooo because we have a lot of skilled employees in our company and they are close to the customers and they øhh really know a lot and we øhh want to get their best ideas out…"

Linn: "So"

Andreas: "This is about the…"

Linn: "so do you see, is this more for the [eee] customers or is it also for the employees?"

Andreas: "The event"

Linn: "yes"

Andreas: "The event is [aaaa] first of all for the employees. But [øhmm drinks some water] the important thing for us is that for the coming years we will have an event and it will be more and more customer event. So this is the first step in a, in a travel for this work that we want to make a bigger and bigger event every year [Linn: "mmm"]."

Mark: "How did you [øhh] how did this idea become [øhh] established in your mind? What was the initiator for you?"

Andreas: "A long time ago when we [øhh] when the management group was [øhhm] starting up this program and got that idea about the facility of the future theme or?"

Mark: "The idea about the competition and the process to develop the ideas. How did this øhm coming to your mind-set and how was this brought to your attention initially, what was the spark?"

Andreas: "[øhhh] How I developed things or how the management group"

Mark: "the initial idea?"

Linn: "It was the management group"

Andreas: "The management group are saying if you want some people to be inspired what should inspire them then? Ok it was something telling about where does the competences go what are the competences what is the solutions of the future because then people could discuss or be inspired. If we are here now what is next then so inspire them if we should be better and better or if the technology should do this and this or the tools go this and this [mmm] and inspire them, do you know to say well okay everything is in your mind there is a lot to think and then come the idea, soo it was to have a lot of good discussions. Ok if this is the future if we can solve this and this problem for a customer and I can tell you that some of the ideas you are working with is about if you can put the thing in the clothe and you have an easier access or moreeee then it could be a real change for the customers."

Linn: "But I was also thinking when you have to decide which of these ideas you want to proceed [Andreas: "yes yes"] with you are in a board or you are in a with the project managers which are mainly [øhh] engineers or? So how do…"

Andreas: "this boars is a lot a lot of different persons and one of my… another thing that I also think was very good for this program we had a board we called the advisory board it is some employees it is not an official board it is on the what is not on the organization chart but some employees from different parts of the company that have a special mind-set that are very open minded and have a lot of ideas and then we put some ideas in and then [claps two times bam bam]. They work with not the technical but with the program ideas. How can we do to inspire? How can we do to influence and how can we do to communicate?"

Linn: "And also how, because right now you are actually you want to to do this idea for the customers sake – these 1001 ideas, so how do you… do you also think about how the customers will accept this? Do you also think about the users when you are thinking shall we implant this idea or shall we go further with this idea? Do you think about the users?"

Andreas: "yes we are thinking on different levels [Linn: "yes"] first of all what about the customers is that a good idea for the customer? Then we can impress them in a way that we got this idea and it can do like this and this and this and they will think that we are very good in technologyyy and project management and something else. But another thing is also some processes we can do better. So towards the customer we act more professional and more I don't know what and then we also have if it is something that is good for the employees? So you can come with the idea with different angles but one of the most important focuses is what benefits can this have for the customers."

Mark: "If I can aaahh just jump in here."

Andreas: "mmm"

Mark: "Connected with this answer. It is question six I am going to ask: do you when developing the skills of people do you have a bias or a focus on a particular set of skills within the company that you want to develop, for example engineers or technical or do you identify certain groups or certain sets of skills that you [mmmm] wish to promote within the company?"

Andreas: "To promote or develop further?"

Mark: "both"

Andreas: "okay [mmm] first of all we try to [eeeh] promote everybody that everybody should bring in ideas. And we also do it like some kind of competition or a scoreboard where you can see who is the most active department areas. This is a way to promote the whole concept about getting ideas that we think that everybody and we have more focus on some of those who is not delivering that many ideas to inspire them [emm] [øhhh] that was one thing the I forgot just recap that question?"

Mark: "Emmm [Coughs two times] do you have a particular focus on a particular set of skills?"

Andreas: "now I remember theee… another thing is also if there is something we have missed some areas we have missed if I can I don't know if I can explain it fast but first of all we have 100 ideas we want to work with further [soo] and then we try to group them, in a group of ideas and then we also say we put them/ these people into a stream [Andreas is drawing on a board to explain, he is drawing different areas] and then there are a lot of different reasons – first of all one stream owner who knows a lot of these streams try to get the big picture, also have a high level, this is about the [øhh øhh] sustainability for example. So there is a reviewer but we also have different ideas within sustainability and the we also

find out we have no ideas in this area. And why don't we have in this is it something we are not good at have we missed it or don't we have focus on that? So this is also another level of finding out where is the theee… is this the full subject and we have these kind of ideas sooo this is just you know [ømmm] alos to promote what is missing or should it be there or no it is okay it isn't there."

Linn: "and and what [mmm] just have to.. How would you describe the function/purpose of NNE Pharmaplan?"

Andreas: "the purpose?"

Linn: "Yes the function of NNE? How is the process because you were talking about you make the these ideas to the customers but we are wee – what is the process normally within the companies?"

Finn: "I don't think I understand the question right"

Linn: "no maybe"

Mark: "Which question are you asking?"

Linn: "we will take another question, question number five."

Mark: "Okay how would you describe the function/purpose of NNE Pharmaplan? [Ehmm] how would you describe the business plan for the company? [ehmm] I know that is a rather wage kind of question mmm but the what is the focus of the company is it project management with the customers or is it to promote certain skills of the excising employees? Or is it to just hit the market segment and then develop the skills to explore the segment?"

Andreas: "I think [eeeh] we should provide with something you know the customers no not the customers [laughing] our vision and mission why we are in this business."

Mark and Linn: "Yes that would be ideal."

Andreas: "Because we are here because of the customers and we are in this big but but small area but it is a big industry."

Mark: "yes"

Andreas: ".. and we want to help these kind of companies and it is something like if you want to make a change in this world you have come to the right industry because it is healthcare

and it is environmental things and Sooo but I think I will provide you with the mission and vision about the company. Because we have"

Mark: "that would be great"

Andreas: "Because we have you know greenfield projects we have a lot of consultancies and we have a lot of rebuilding and we have a lot of different so we are in this business and looks towards the clients what are they needing and we try to find out about what is the need of the customers and why should we be in this business and what should be our focus to be in this business?"

Linn: "And what was your initial thoughts when you were presented for – Carsten told us that he presented the idea of the intelligent XXXXXXXXX? [Øhh] did you have any initial thoughts when you were presented with this idea?"

Andreas: "[mmm] To the booster group or to the?"

Linn: "When Carsten was presenting the idea [Mark: "for the intelligent XXXXXXXXX"]"

Andreas: "so we changed to the room?"

Linn: "yes, what where your thoughts did you have any thoughts about it?"

Andreas: "First off all I am not an expert"

Linn: "No"

Andreas: "[øhhh] but I know a little about everything in this industry"

Linn: "okay"

Andreas: "And some of the ideas I can see this is really good ideas and some ideas I don't understand and the and that is not the important thing for a program manager to understand all the technical aspects but Carsten's idea was rather good. I have done a lot of project in this kind of areas with clean rooms and so we could really think that if this could succeed then we could make a change. And there are a lot of other aspects within these idea whit this access to clean room. Not only clothing a lot of different tools go in and out soo there is a lot"

Mark: "Have you been presented for our presentation?

Andreas: "I think I have seen a little but [ehhh] I cannot impression"

Linn: "What [emm] what, if any, did you have any concerns when he showed you [ehh] the idea?"

Andreas: "I don't have any concerns I think… only you know is this technically possible? But you know whit techniques it is always possible it is just a question of time [mmm]"

Linn: "yes soo you when you are presented with an idea you always think about the technical aspects – is it possible?"

Andreas: "Yes, and there is another thing because I am very happy that you are a part of this project and this is again because how does customer or the employees accept this new product? And I can [Linn coughs two times] long time ago when I made my first program of something that optimises the process in some small area and I was a young engineer I was very proud of what I had done and I should introduce it to the employees and say see how easy things are. Now you only have to go here one time a day you know 24 hours and then come back and they said: your idiot why should we do that? So again how people accept new technologies and [eehh] so that was something I learned more than 20 years ago [laughing] there is a lot of people involved and what I think is a great idea others maybe don't think it is a great idea."

Linn: "Yes and soo we were also thinking about if you [mmm] have any ethical concerns when you where presented with this idea did you have any?"

Andreas: "It was not in my mind at all when it was introduced but afterwards when Anders told me about your involvement I said well [claps one time] off course soo that is also… the mind-set but I think also that we can learn a lot about you know [mmm] think of all the aspect or involve people that can help us to think about all the aspects."

Mark: "Sooo you saw the ethical aspect as being irrelevant at this time or?"

Andreas: "No because I didn't know I didn't thought of it and suddenly when Carsten introduced me to this mind-set I said off course there is a lot of things we have to consider."

Mark: "[amm] but this would be at the latest stage you are bringing experts to look at this?"

Andreas: "you are you should inspire us soo we start with you."

Mark: "okay [laugh]"

Linn: "so [ehmm]"

Mark: "If you have 10 years we will give you a complete answer [laughing]"

Linn: "soo what is also this is also more about what is your knowledge about using clean rooms?"

Andreas: "me personally?"

Linn: "yes"

Andreas: "yes"

Linn: "have you ever used a clean room facility?"

Andreas: "used and used I have [øhhmm] I have been a project manager making the I have been there taking the clothing on I am very familiar with it but not it is not an area where I have worked a lot in – just you know there is a course a one day course I have tried just to put all the clothing on just feel what it is. As a project manager I have done a lot of XXXXXXXXXs."

Linn: "And [mmm] so we wanted to know do you see any issues whit the procedure of preparing to enter and to exit from the clean room?"

Andreas: "I am not an expert in that"

Linn: "no, it is just to have your opinion"

Andreas: "I have not considered it a lot [mmm] if I have first of all there is a lot of things that the employee should know what is good or bad and then there is precautions soo."

Mark: "Final question for the moment from the written side of things anyway [mmm] what do you know about the technology XXXX?"

Andreas: "[øhhh] it was…"

Linn: "Radio frequency identification the technology"

Mark: "We are looking for your instant response – what do you know about the technology? We are not expecting a full technical brief here"

Andreas: "no no can you please explain me in Danish what"

Linn: "vi vil bare høre om du ved noget om XXXX"

Andreas: "ok det er bare lige jeg skal lige være helt sikker. Hvad er det det er?"

Linn: "det er Radio frequency identification"

Loreta: "It is that chip that is going to be used"

Andreas: "yes [ppooo] I don't know that much"

Linn: "okay, but yes, because we, in this project we are going to have a look at the users as well soo we are just throwing out some questions [laughing] and then sometimes it"

Andreas: "I see sometimes needs further explanation [laughing]"

Mark: "do you have any exposure in your current working live with XXXX chips?"

Andreas: "No I don't think I have a GPS and not this kind of stuff"

Mark: "you have that one [points at id card]"

Andreas: "what is that?"

Mark: "that is XXXX"

Andreas: "this [takes his id card]? I didn't know that."

Mark: "Does that allow you access to rooms by putting it in front of a censor?"

Andreas: "yes yes"

Mark: "It is XXXX"

Andreas: "soo I have a lot of knowledge [everybody is laughing] as a user"

Mark: "as a user.. this is actually quite critical because sometimes people don't realise that they use XXXX in a daily basis [mmm] nearly every single id card has got XXXX chip insight it"

Andreas: "yes"

Mark: "annnd I am going to throw out a quote for you and I just like your opinion, quote: The only limiting factor for XXXX technology is the limitation of the developer/engineers to exploit the technology and the applications, would you agree in this statement? That the only limitation for the technology is the limitation of the engineers?"

Andreas: "no I think in spite of you I think there will be some other aspects a lot of other aspects. And another thing I think you are from England and in England there is video

cameras everywhere soo this is also something I don't think we will do in Denmark but there is also a lot of videos in Denmark. And a lot of you know you can be recognized everywhere in the world and even the Americans are fore sure listening to what we are talking about [laughs]."

Mark and Linn: "yes"

Andreas: "soo there is a lot of aspects and I think there will come a lot of discussion when people really know"

Mark: "Okay"

Andreas: "Or it will maybe be something okay that is life"

Mark: "could I perhaps refocus the question then? Who do you believe are the best people to develop applications for XXXX technologies? Do you think it is the engineers who are the best people to develop applications ooor is it up to the customers to say we have a question and then for you to find solutions? Do you see it as employee lead or customer lead?"

Linn: "It is not only XXXX but all technologies"

Andreas: "this is todays mission [Andreas hands Linn a folder] It is in Danish because it is about a lot of project tools and [mmm] and here I have some statements because it is a balance because one thing is what the engineer thinks and what needs another thing is that this also tells what the engineers need and I have some statements here about the engineer should be good finding out the different tools [ehh] also [ehhh] there should be [øhh] the customers or those who want to sell to the customers should ask the customers is that what you want? And I can tell you our mother company Novo Nordisk also makes a lot of tools a lot of different devises for injection medicine and they have also been very technical driven ohh we can do like this and this and this and they invented something fantastic but nobody wants to use it they didn't think about this and this and this soo they also really try to put them self in the customers situation soo."

Linn: "mmm"

Istvan: "Do you think there is a need for [øhh] someone between who can speak the engineer languages and the customer language as well?"

Andreas: "[aaa] I think there could be some kind of [øhh]"

Mark: "A bridge or?"

Andreas: "a facilitation of understand each other"

Istvan: "yes, and do you have such a thing?"

Andreas: "I don't think we – first off all it is very seldom that we have something project development as you are involved in now. But it could be so yes we are very seldom in this situation but we very often have you know that the customer wants something and our engineers want to find out so we have facilitators to understand in projects how the customers [øhhh] so make people talk better together understand each other better [Mark: "okay"]."

Linn: "[mmm] So there is a process between the company and the customer all the time [Andreas: "yes"] in order to make the best solution [Andreas: "yes"] for that customer?"

Andreas: "Yes or maybe understand the industry [Mark and Linn: "yes mmm"] and I also think that a lot of people try to find out what does the world need… you know there is a lot of companies has small APPs or small something really try to but to develop something that the world need and [Mark coughs] but I think that you also should try to find out what the customers what and what is needed but it's is a difficult area."

Mark: "okay [øhhm]"

Istvan: "[øhhm] I have another question, how do you do this [øhh], how do you try to find out what the customer needs, you said the survey [Andreas: "yes"] do you have other tools?"

Andreas: "yes, our world is you know [øhhm] our consultant group and our facility [øhhm…] concepts and [øhh…] the first study then it is really to understand what the customer needs but that is more you know if you want to make a facility or something else in our world it is… it is rather simple you cannot see that in your tape recorder [Istvan laughs] but in a way it is simple, but it is not you know to invent something a new APP for something or a new device for something that is not where we normally are but it is more to understand okay what are your needs to produce this product…"

Mark: "Okay [coughs two times] so it is very much customer driven from your experiences at the moment?"

Finn: "For some, in our industry customer, again they want you know have a new facility [Mark and Linn: "mmm"] because they have this and this needs because they have different amount of different devices, different kind of [øhhh] they have to produce 200 pieces a year [Mark: "mmhh"] or 200 million pieces then we try to help them with the concept. It is not

something what does [øhh] the old people have as needs this is not something not our normal we help the pharmaceutical companies to [Mark: "yes"] to meet their customers."

Istvan: "[mmm]"

Mark and Istvan: "okay"

Andreas: "with pieces"

Mark: "Well I, I think we have taking up more than your time that we scheduled so the question is"

Andreas: "so the next one should have been here orrr?"

Mark: "aaah, yes and I think Carsten was [ehm] volunteered to bring the next person to us soo"

Andreas: "you or somebody else or? [Andreas refers to Linn]"

Linn: "Me? No, Carsten. [Mark: "Carsten"]"

Andreas: "[ohh] Carsten [Linn: "aahh" [Laughs]]"

Mark: "soo I don't have a contact number for Carsten so [ehhm]"

Andreas: "I can try to call him"

Mark: "thank you"

Linn: "what is the time now Mark?"

Mark: "It is [ehhm] ten minutes after the schedule"

Andreas: "yes"

Mark: "What I can do is give you a copy of the questions we have asked you, just for your reference"

Andreas: "okay, thank you"

Mark: "[aaah] In case we have any [hmmm] cause to do a follow up or if you want to elaborate on particular issues"

Andreas: "yes"

Mark: "for some reason"

Linn: "But it was, it was, it would be very nice if we could get the mission and vision"

Andreas: "yes, I will try to find these materials for you"

Linn: "thanks…"

Andreas: "and if I can make a recommendation to you – next time you should study on a university you should go to Istanbul [all laugh]"

Andreas: "it has to been [ehhh] the [Carsten calls Andreas and Andreas says in Danish: de næste er klar, ja det er fint hej] My son he Is studying in Istanbul and we were there for three days just to visit him but also to see a football game [Mark and Linn: "ahhh"] [all laugh] and then it was a marvellous place – so go there if you have the chance [Carsten and Brian steps in]."

Istvan: "hello"

Mark: "thank you very much for your time."

Transcription of interview with Brian

People in the room: Brian, Carsten, Istvan, Loreta ,Mark and Linn

Carsten: "On the same project as I am at the moments, so I thought he was the right person to go to and it seems like so hopefully we will get something good."

Mark: "Ok, before we start may I just ask, do you mind if we record the session here?"

Brian: "No, it's no problem."

Mark. "That's ok. Thank you."

Brian: "If you cleared it with my boss [people laughing]"

Brian: "No problem."

Mark. "Your boss really."

Brian: "If you cleared it with my boss, it's alright."

Mark: "Ohh ok. "

Brian: "I am sure it's not a problem."

Mark: "So [clearing the throat]"

Carsten: "Du loger bare vinduet hvis det bliver for cold."

Linn: "Yeah"

Mark: "Ah ok. Yeah."

Mark: "So aaah"

Linn: "Do you know who we are, Brian?"

Brian: "No, I would like to, actually Carsten just briefly told me about the project, I found this aaa material to to Carsten aaa few days ago about we had aaa an XXX XXXX competition, which sort of sums up a lot of the design issues you have when you design an XXX XXXX."

Carsten: "Mmhm"

Brian: "And then he came and and asked me, if you if I would go and do the interview with you guys and I said yes of course and then I didn't know what the interview was about actually but you just briefly told [voices in the background] me what the idea was, you know just five minutes ago."

Mark: "We also kept it away from him as well."

Linn: "This is good, it's actually ok that you don't know that much."

Brian: "Yeah yeah yeah"

Linn: "and then it gives us ehhh another perspective."

Mark: "We trying to understand mind and the full process of an expert and we we appreciate there are many different kinds of experts "

Brian: "Yeah"

Mark: "and we are trying to understand your kind of expertise and your thought processes and how you think aaand it gives us picture of how ideas are generated, and communicated, and discussed."

Brian: "Yeah"

Mark: "And we have aaa list of questions, some are general about your background, and some are more specific to your area of specialty aahm [clears the throat]. And the third set of questions which are quite different from the other interviews, is aa, we would like to make a small presentation, which we made to you last week. We go through it very very quickly, and would lead us to some questions about our presentation."

Brian: "Yeah"

Mark: "If that's ok with you."

Brian: "Fine."

Mark: "Aaah do you do you want to start the questions?"

Linn: "Yes, I can start with the questions. Eehm, and I also want to just briefly introduce our education. We are master students in Techno- Anthropology, which is a mixture between technical and ehm anthropology, so it's"

Brian: "Yeah"

Linn: "actually more or less trying to understand how technical development influence eeh humans and eh so we try to understand the technical aspects, but we also try to understand the the expert of people making the the and we also have an understanding of this of the technical eeeh solutions. And we also try to understand the users"

Brian: "Yeah"

Linn: "of the this this"

Brian: "Yeah yeah"

Linn: "technology, eeh or not, we're not trying to understand them, but we are trying to understand their mindset."

Brian: "Yeah"

Linn: "So eehm what is your background, what is your is your education?"

Brian: "I'm traditional building architect."

Linn: "Yes."

Brian: "Eehm and have been working as as such until I came here eeeh which is eight years ago, I think, and and now I'm almost only involved in in process architecture eehm, which means often refitting eeh existing production areas and ehm making eeh often upgrade for one kind of production to often a cleaner production. Otherwise we doing here we doing line separation, which means we have to split two productions, but eeh and then rebuild the new facility in the same way as as the old, but still eeh taking dirty rooms making into clean rooms."

Mark: "Ok."

Linn: "Ok, and what isi your role within the company?"

Mark: "How do you see your role within the company? Purely as a technical person, or someone as a facilitator, how would you describe yourself?"

Brian: "Well I'm eehh, fuu that eeeh I'm a technical person regarding you know the building eehm eeeh I am as an architect we are having very holistic thinking, so we are of course facilitators to some of the other eehh eehm process guys, because they are we see them

often a little bit more isolated and they are thinking very much about how their pipes are going from from here to there and they always affecting our our stuff, because they have to penetrate our walls and they have to so so we are a little bit coordinating eeeeh but mainly eeeh specific about only our own eehh technical solutions."

Mark: "Ok."

Brian: "So a little bit of coordination eeh, but a whole lot of eeh technical solutions on our own civil disciplines."

Linn: "So what what is your main responsibility in your everyday work?"

Brian: "Eeeh I don't know how to answer that question. Eeeh main responsibility, well [breathes out]."

Mark: "From a personal"

Linn: "Or do you have any"

Mark: "Yes"

Linn: " responsibilities?"

Brian: "Yeah well I have the responsibility for for for my own packages, which is eehh the building, because eehhe, sometimes I I work as a leader architect, which is I have this all responsibility for the for the aa for the building package eeehh and sometimes I am in larger projects, I'm just a project architect, a responsible for specific works I'm doing right there. So it varies."

Linn: "Do you, so, I don't know if you know what CSR is?"

Brian: "Corporate social responsibility."

Linn: "Yes! Do you, how do your main responsibility contributes to the NNE cor eeh CSR program?"

Brian: "I can't say I have any specific thoughts about that, I'm just eehhh, ... no, I'm I'm I'm not ssssss ... I don't I don't have that in my mind set when to my work, I don't think it affect I don't think it it influence my my every day work."

Linn: "Ok."

Mark: "Ok, ok."

Linn: "So ehhh would you, some of these eehh are questions which we asked, which is not so specific to you, but. Eeeh how would you describe the function or the purpose of NNE Pharmaplan?"

Brian: "[Laughing] Oh I think you should aa [all are laughing] that's a difficult one. Eehm well we we we we are praising ourselves being in a life pharms industry so of course what we are trying to do is to help those making eh products that we you for for in our health industries ehhhh, being able to help them we are partly in in eehh in that business as well so. I think it in last proud of what I am doing, proud of being able to contribute to for for for pharmaceutical companies, for them being able to do what they are doing."

Linn: "Yes. And mmm are you involved in the 1001 idea initiative?"

Brian: "Yes. I think [Linn and Brian laughing] we all are, that's the compulsory thing here in the company, so yes, I am as well."

Linn: "And you say compulsory, do you mean it in a good way or in a bad way?"

Brian: "Eehh it it I'm sure some good will come out of it, but there is a lot of eehhh bad feelings about it, because it is an interference. Yes, we have these we are we we we are compelled to sort of come up with an idea or a task for every every Monday in our group and that can be a little bit stressful because it's time that you take out of your ordinary eeh work, and, but you are only given 15 min. a week to to, you know, to for the task, and it can be difficult to it's it's can be stressful to some to eeh keep delivering every week, and you only given 15 min. to work something really smart."

Linn: "Ah ok, and what are your expectations for the process?"

Brian: "Well, eehmm"

Linn: "Of of the"

Brian: "Of the"

Linn: "of the program."

Brian: "Of the program? I'm I'm sure there good things will come out of it, like eehhm I think now 100 idea have been highlighter and some of them of course will just be presented on the poster and and then go down the drain, or be forgotten, and some are lifted a little bit higher, and are given a lot of attention, like like this, like Anders's project now. Is very good

that we start discussing eehm eehh new approaches to things that we've been doing thousand times, because we been making XXX XXXXX for...yeah, many, many, many years. And eeeh, now giving eehh reconsideration about how could we improve the way we are acting in these XXX XXXXX is a brilliant, is brilliant, I am sure that will be used."

Linn: "So when you want to improve this, are you thinking about responsibility as well?"

Brian: "Responsibility in what way?"

Linn: "Yeah in in you, so you say you've been doing this for many years, but now we get this idea, is it because if improvement of, so you can have something to sell to the customers, or do you also think it it enhance the responsibility for the company the the customer, is it easier for them to maybe"

Brian: "Well"

Linn: "Do you when"

Brian: "That's"

Linn: "you when you when you create a mmm, so do you think about responsibility?"

Brian: "Yes, yes, yes, a lot actually. As one of the reasons we have this XXX XXXX competition you see every day when you are you see people are using their the XXX XXXXX in the wrong way, and they do it partly because of eehh of convenience, or they are not eehmm eeeeeh what do you call it, bendy enough to reach down and get eeh the new clean clogs, so they jump from one side to the other with the their socks on and actually polluting the areas because they are not designed eeeh in a very good way. Eeeh so we some of some of the ideas how should how do we design a thing like this this ehmm clog, what do you call it, wooden shoes"

Mark: "Mmhm "

Brian: "bench is is has it has been you see them in all pharmaceutical industries or eehm productions, and then actually not very good, because they are very wide, and they are, it's very very difficult to to to come from one [Mark clearing his throat] side to another, especially if you are a short stubby eeeh person one one meter and sixty, can be really a challenge, and if you sixty years old, you know, you tend to tend to if you are alone in the airlock to to do it the easy way, because nobody yeah."

Linn: "So when you say that"

Brian: "So if "

Linn: "a a"

Brian: "make new designs."

Linn: "Yeah"

Brian: "I think it's eeeh personally I I when I go through an XXX XXXX, I do the best I can to keep things eeeh apart, eeeh keep the dirty stuff on the dirty side and cleaned, but when I see the people, they go there, the the eehh people, who works in the production, has been doing that for 15 years, they don't, it really annoys me."

Linn: "When you see the people, do you see them on video, or you see them"

Brian: "No no I see them"

Linn: "You stand in the room, like observing?"

Brian: "Yeah yeah, because"

Linn: "And"

Brian: "when I when we do these productions, we would do the rethinking productions, we are sometimes in the airlocks with the people working there, so we see the way they are acting."

Carsten: "Mmhm"

Lin: "Mmhm"

Mark: "Mmhm"

Brian:"And eeeh, so it's not like we standing eeeh we standing silent observers, we just being in the facility with the people working there, you can see that they are ehh"

Mark: "Ok."

Brian: "sometimes not using the right."

Mark: "How long have you been using clean rooms, or been through clean rooms, how many, we talking five six years, or?"

Brian: "Eight years."

Mark: "Eight years."

Brian: "Yeah"

Mark: " Ok."

Linn: "Eehm"

Mark: " [Linn: " Eehm"] On the regular basis, or?."

Brian: "Yeah, on regular basis, yeah."

Mark: "Ok. All levels?"

Linn: "Eehm"

Mark: " Sorry."

Linn: "Sorry."

(Everybody laughing)

Brian: "Eeeh I've been eeeh ... yeah, I've I've been eeeh on all levels, which means going to class class B rooms into that, you never go into class A actually, we have some class A, which is actually rooms, but normally that's in glass boxes or in a under eeeh NDFS"

Mark: " Yes."

Brian: "or something like that. So yeah, but I have not been going in eeeh from from C to B airlocks with other people, never never in the production, never in life production,

Mark: "No."

Brian: "only"

Mark: "But you are a regular user of"

Brian: "Of airlocks."

Mark: "Yes."

Brian: "Yeah"

Linn: "So when you're regular user, do you see any issues with the procedures in the preparing to go in and out of the dressing the gowning procedure, and the degowning procedure?"

Brian: "Yeah it can be quite confusing eehm especially eeeh, because even if it's different overall size they have different eeeh descriptions of how how how they in which in which order you do things. Some places you have to go wash hands before you do anything else, and like in the right you go, and we discussed that with Anders, you put your hair net, and you go and wash your hands, and and you don't if you don't stop and read actually the text pane that, which you often not do, because you been in so many airlocks, and, you know, you you you think you know what you're doing eeeh, then you might do things wrong. "

Mark: "Ok, that's gre that's interesting."

Linn: "Yeah"

Carsten: "Mmhm."

Linn: "And how so if we eehm, shall we present him with the idea or?"

Mark: "Well I have a question. You have some papers in front of you, aaa are you wishing to make small presentation to us at this stage?"

Brian: "No, not really, it was only if you had, aso you aa this is an interview, so if you had some questions, I thought oh well if just to"

Linn: "But we will ask you about"

Brian: "if we discussing now you come from this side and it is it's just came from the eeeh"

Linn: "We would like to invite you to have eehm, we would ask you about that later, but now we, Mark will you present the idea?"

Mark: "Well I think we need to go from questions ten to sixteen first."

Linn: "Ok, how did you become qualified in designing clean room?"

Brian: "Well this eeeh this this it's a it's a a a I think it's a process you just get eeeh into one project as a project architect and there's another lead so it's just like apprenticeship life like

life. How do you how do you become an architect when you finish the school because you are not. I's something learning by doing really."

Linn: "Yeah"

Mark: "Ok."

Brian: "And then we have of course later on we have some courses in in GMP, but it's not, you know, I've been doing airlock and clean room designs long before I had any actually eehm course training."

Linn: "Yeah and what is the process of designing changing room for clean rooms?"

Brian: "Well eeeh generally we know clean room is about is about controlling the amount of particles in in the room, so that's up to the ventilation guys to do that, so to us it's interviewing the users eeh, knowing about how how many people eeeh you want to have in the airlock, how many people has to go through the airlock per day, what is your eeeh procedures for for dressing, do you have, you know, some some people they come in factory clothes, some people they come in the airlocks with their normal clothes and put over a gown and it's you know interview the users of how is, how is your procedure?

Linn: "Mmhm"

Brian: "And then we try to design a layout the room, so it can fit all the stuff that they need to put in the in the airlock and then eeeh see if all eeh it can hold enough people."

Linn: "Yeah, because eeeh so you say that you need to check that all the things can actually be in the airlock?"

Brian: "Yeah."

Linn: "And eehm because it's small rooms?"

Brian: "No no eeh well what you often need eehm place eeeh for for extra a gown for gowns, we need places for eehm extra shoes, eeeh clean shoes, and and place to put the old shoes, so that's why we often use these bench"

Mark: "Mmhm"

Brian: "people [Mark: "Yeah"] on one side they put dirty and clean on the other side."

Mark: "Ok, once you designed the layout, sorry to cut you off at that point. Aaam once you designed the layout, what's the next process, the next step in the process? Would you eeh get this to the customer or would you try to do some kind of mapping to gage a process people going through it?"

Brian: "No no, we are eehm, that's the new thing and new idea, which I think is good, because we just design with eeh from from the what you call the sub, what is that called? Standard of operation procedures"

Mark: "Yeah, SOPs"

Brian: "SOPs, yeah, eeh how how they do it and then we fit it like that and then we agree with the customer, yeah this is how we wanted. So eehm because often they decide often the customer knows very well what they want. Eehm we it's, I've I've rarely seen, I actually never been in the project, where I go and tell them, this is how we do it."

Linn: "Yeah"

Brian: "Because they know what they want. And eeeh they don't know it in a way that they can layout the room, but we can layout the room for them, also because the room is has to be, you know, fit with all the other"

Mark: "What happens if, given your expert knowledge on this, aaa if you suggest a layout and the customer says - sorry, we don't want this,- but from your knowledge you know that your ideas are correct and theirs are wrong, how do you address this issue?"

Brian: "Well I've never been in that situation actually, eeeh but I would if if I would if I would go there, because I've been in in in other situations where where the production facility was laid out in a wrong way, I could say this would not work, but the project was sold and the and the project manager from both Novo Nordisk and and here, they said - well we have to go, this is this is what we sold,- eeeh, and then I have to go to the main users and say you have to put a protest here, because if you protest, we can change this. So I will always try to to change the stuff if I know eeeh what we suggesting here is wrong."

Linn: "Mmhm"

Brian: "But I have not, within airlocks I have not been, yeah I actually have had tried to change the whole airlock concept, because that was one of the the leads from Novo Nordisk, they said - we have we want to have the airlock like this,- and we designed the airlock and eeh, then I met one of the users, he said - well that's that's completely wrong, that's not the way we we doing it, that's what, that the way the engineers eeh from top floor they entering

production, but the rest of us, we doing it differently, so we have to, you know, completely change the layout, so, but if I if I have some knowledge, that they don't have, of course I will try to to to put it into the project, but I have actually seen that."

Linn: "So what if any are the standard of specific building regulations you follow?"

Brian: "Taken?"

Linn: "[Laughing] Are there any standards, specific standards eeh regulations you follow when you build eeeh airlock?"

Brian: "Eeeh no, not really, there's only thing about"¨

Loreta: "Should I should I maybe"

Linn: "Yeah"

Loreta: "There is standard building building regulation, but is there something specific, some specific regulation for particularly airlock? Some standards that you have to follow? Is it more like"

Brian: "No the air the the the only standards that we have to follow in an airlock is the air cleanliness."

Loreta: "Ok."

Linn: "Mmhm"

Brian: "And then of course depending where it is in the building it can be in a fire section, but that's not a design issue as such, it's just a way it could be placed in in a specific layout of a building. Otherwise is no eeeh regulations that we have to eeeh, we can easy normally you say if you in a in a space you need to have two fifty to the ceiling, but doesn't even apply for the for airlock, because is not a a working."

Mark: "How about ISO standards, eehm safety standards, they obviously have to be taken into consideration, yes or no?"

Brian: "I have I have never worked with ISO ISO safety standards, so, I wouldn't have a clue."

Mark: "Ok."

Linn: "So so you you followed the when you designed, you followed request from the from the actual customer?"

Brian: "Yeah yeah, mainly yeah."

Linn: "Without with without knowing if the request is actually also up to safety standards?"

Brian: "Yeah, but there's not so much, I I don't see many safety issues in this, ... really."

Linn: "Ok."

Mark: "Ok. So this"

Linn: "So"

Mark: "you would say perhaps a costumer issue rather than a design issue, when you following safety standards or procedure standards?"

Brian: "Well the procedure is always about how we yeah how we eehm how they want how they have their, because, you know, they have a lot of documents written how to do it, so we can't change the way they do stuff."

Mark: "Mmhm"

Brian: "Because that's eeh that's something they have in their procedures, so if we start doing it differently, they have to change all their procedures, which is why we all have to do, you know, what they want us to do."

Linn: "Mmhm"

Carsten: "Often Novo Nordisk standards is so high so"

Brian: "Yeah"

Carsten: "it's not easy to make any big improvement on it."

Brian: "No."

Mark: " If there are deviations between aaa these SOPs, would you say that based on national requirements, or company requirements normally?"

Brian: "I would say in Novo Nordisk it's eeeh would be company requirements."

Mark: "If as aaa for let's say if a customer was approved a layout, would they follow guidelines issued by the nations states they bui building, or would they tend to follow their own company regulations more?"

Brian: "Well there is no, the only regulations I see within these production is is what they have themselves and then the the food and drug association. I I would see the eehm, that's always what they are scared about is if FDA, if they have some issues about any design, eeeh so that's eeeh, that's the main driver for them is to be in compliance with what FDA would"

Linn: "Yeah"

Brian: "And and again that's eeh, that's very difficult, because there is no like like in airlocks we only know, we we only have these standards for the air cleanliness, the rest is is is, you know, is so you can make things in so many different ways."

Mark: "Mmhm"

Brian: "that FDA approve it, it's not like have to do like this this this this, you can eeeh, depending on how you actually are going about, if you have factory clothes, or you've come with your own clothes, and stuff eeh, it's different how you how you rea how you

Mark: "Mmhm"

Brian: "do your stuff in in the in the airlocks."

Linn: "Yeah"

Mark: "Ok."

Linn: "And how do you address maintenance eeh procedures and routines in airlock clean rooms?"

Brian: "Well we tend to design everything so it's eehm, so it's very easy to clean. Eeeh we don't have a lot of things that is any mechanical we have some about that is doors doors is the most difficult thing to maintain or keep keep working and it is the most dirty thing to take out, you know, if you an engine standing pumping for two years, and whenever you open that, you will expect a lot of eeh dust and and all"

Mark: "I have seen rust in this situations."

Brian: "Yeah yeah yeah, so eeeh of course if you maintain that you have do eeh

Mark: "Mmhm."

Brian: "very good cleaning afterwards, but you have to do almost anytime you maintain something."

Mark: "Yeah and using special greases as well, eehm

Brian: "Yeah"

Mark: "occasionally."

Brian: "Yeah"

Linn: "Do you have any responsibility resulting from this? I think we have addressed that. Resulting from designing the clean rooms. Do you eeh do you know about XXXX?"

Brian: "XXXX?"

Mark: "Tag."

Linn: "Tag, that is the tag, so now we will"

Brian: "I I I know a little bit about it. [laughing]"

Linn: "Ok, now we will present you with the idea. Who, Mark, will you present the idea?"

Mark: "Yes, eeh [clearing his throat]"

Linn: "Just in short."

Mark: "My laptop is switched on and I just need a screen eeh [background noises]"

Linn: "people asking the questions."

Brian: "No, it's ok, it's ok."

Loreta: "So Carsten haven't presented you with the idea?"

Brian: "No, just"

Carsten: "Just shortly."

Brian: "Just five minutes, because we were waiting for me to get in here."

Carsten: "we haven't talked that much about it."

Brian: "So yeah."

Carsten: "Isn't it better that he doesn't know anything?"

Linn: "Yeah yeah yeah exactly!"

Mark: "Absolutely!"

Carsten: " he is open minded and yeah yeah... It's actually a bit eeh strange that we haven't talked about it, but we haven't, so."

Linn: "So just just briefly."

Mark: "And let's get rid of that or turn off my wireless, and we go to slide show [clears his throat] ... This is just easy to operate... [clears his throat] ... [Linn is laughing] Ok, we can"

Linn: "Eh eh just just take not this one, just take the actual"

Mark: "Yeah yeah will do [clears his throat]"

Linn: "This is ..."

Mark: "Ok... [Linn is laughing] Weee ok, this is to much on this ... Ok ..."

Linn: "Yeah"

Mark: "Ok "

Linn: "Oh but should we just explain the"

Mark: "Ok the the general concept is to use XXXX technology, radio frequency identification technology to improve traceability throughout the system, aaah including meetance and access of people, tracking and ordering of supplies, including items of clothing, eehm passive and active XXXX. Eehm we checked, there are active XXXX chips available, which are ATEX rated."

Carsten: "Ok!"

Brian: "Mmhm"

Mark: "And the cost is very nice."

Carsten: "Ok, good!"

Mark: "And we can supply eeh information about suppliers."

Carsten: " Ok, good."

Mark: "Aahm the idea is to use short range scanners, so we can localize as much as possible. Eeh we can use long range scanners, but then you talking less security of data integrity. Aahm [clearing his throat] the variables here are placement of scanners, the more scanners you have, the bigger facility you can have, the scanners are cheap and chips are very very cheap today. Aahm the only problem would be interference with longer range scanners, but since we using short range scanners, it's not an issue. Aahm [clearing his throat]."

Linn: "Ehm Mark, will you just present the idea and then we can have"

Mark: " Yeah"

Linn: "a Brian's thoughts afterwards."

Mark: "Ok the idea is to reduce costs and increase efficiencies, and it is upgradable according to the changes of facility. Ahm [clearing his throat] well the main concept is instead of reading all this list on the wall it all will be on a screen, personalized to the individual, so if SOP changed, an individual will be notified automatically of changes. These changes could be notified in many different ways. The idea is to reduce the stress of aa the workload and simplify training immensely. Aa it will give aah information on what people are doing well, what people are doing badly. Ahhm [clearing his throat] and ahh, whoooooh it streteched!"

Brian: "Mmhm, yeah"

Mark: "Wide screen."

(All are laughing)

Mark: "It works well on my screen. Aahm, ok. To to to to."

Linn: "So we"

Mark: "Ok, the laser doesn't work on this screen again. Ok eehm"

Carsten: "But anyway"

Loreta: "Just keep on clicking."

Linn: "Yeah"

Mark: "Yeah yeah I will click. The door of the entrance is at the bottom"

Brian: "Yeah"

Mark: "corner."

Mark: "those red marks the scanners. The idea is you enter the room, we thought that was nice touch, wash your hands for the first thing."

Brian: "Mmhm"

Mark: "Your hands ok and then after washing we check it with the hygiene cleaner before eeh and that would give you OK, upon you getting your OK, you'd be issued an XXXX active bracelet, which will then be personalized with your information."

Linn: "Because you you use your your key card to check in."

Brian: "Yeah"

Mark: "Enter the room."

Linn: "So so"

Brian: "So you put that every time you you"

Linn: "No, no you use it once before washing your hands."

Mark: "Eehm a"

Linn: "So it checks that you"

Carsten: "I don't know."

Mark: "I think that"

Brian: "Use the card you use the card to get in."

Linn: "Yeah"

Carsten: "Yeah"

Brian: " and then you wash your hands."

Linn: " And that's when it gets personalized."

Brian: " Yeah, ok, yeah"

Linn: " Because otherwise you don't know"

Mark: "Yeah so you only put your bracelet on after"

Brian: "So it gets it gets personalized from you going in?"

Linn: "When you when you "

Istvan: "Yes"

Linn: "yeah when you check that you washed your hands it it gets personalized."

Carsten: "Yeah"

Loreta: "You will get issued the wrist band."

Linn: "You you you so before you wash your hands."

Brian: "Mmhm"

Linn: "You you use your card, you charge your card and after that is a non-touch procedure."

Brian: "Yeah"

Carsten: "It should it should activate"

Linn: "Yeah"

Carsten: "activate the water."

Linn: "Yeah activate the water and"

Carsten: "in the washer"

Carsten: "It could be, and then you wash your hands"

Brian: "Yeah yeah"

Carsten: "scan afterwards"

Brian: " Yeah because"

Mark: "Yes absolutely."

Carsten: "you will get the bracelet

Istvan: "It will give you infrared or whatever"

Brian: "Yeah yeah yeah because sometimes you you will know sometimes come five six people at one time into in through"

Carsten: "Yeah"

Brian: "So you have to have a specific order"

Carsten: "Yeah very short"

Brian: "Yeah"

Mark: "This would be it. So these can be adentify personally identified. Aahm when you get the wrist band, you be presented with the screen. The screen could actually identify many different people at the same time, so you just look for your own screen, otherwise you could have a big TV, you could have six ten people on one screen if necessary. Aahm this will give a list of SOPs aah [clears his throat] for example it would say you what you have done, what you need to do"

Brian: "Mmhm"

Mark: "with and the coding and the given names. So you go to the area concerned, it would flag up on the board which number to go to to get the item. For example gown could be number one, gloves number 2, and you just do things in the order it says on the screen. [clears his throat] "

Carsten: "And you scan every time you take something out of the box."

Mark: "The scanner will be placed locally in the box."

Brian: "So so you use your wrist band?"

Linn: "Yeah"

Mark: "Your wrist band would automatically ideanitif trigger out the scanner"

Brian: "Mmhm"

Mark: "as you go into the box"

Brian: "Yeah"

Linn: "So at the screen it will say go to eeeh counter like like eeh go to"

Brian: "Box"

Linn: "H1 get this, then it will scan and you get it and then you will take it on"

Brian: "Yeah"

Linn: "And then it says on the screen the next step."

Brian: "Yeah"

Linn: "So you don't you can not"

Brian: "You can't mix up."

Linn: "Nej exactly."

Brian: "You do it in the right order."

Mark: "The great advantage is your size could also be preprogrammed into your own personal data."

Brian: "Yeah"

Mark: "So if you have"

Brian: "So you have like a dispensed"

Mark: "it could be automatically dispensed as well."

Brian: "Yes."

Carsten: "Mmhm"

Brian: "Which is actually seen in in other productions"

Mark: "Yeah"

Brian: "I've seen these clothing dispensers."

Mark: "And"

Linn: "And also good"

Mark: "if people got odd sizes for example, it would direct them into correct size first time, it wouldn't be hunting for the correct size."

Brian: "No, no and looking"

Mark: "People with large heads for example with the forehead they would be presented with the right size first time. So it would be quicker and more hygienic at the same time. Aah so you go through the system until you get all green lights, because you go to the scanner and check. At that point you the scanner will confirm whether or not you fulfilled the requirements in the right order, before you are allowed to the actual clean room area. So you will be presented with the screen at the end. [Clears his throat] Eeeh quick overview of the flow: enter room, wash hands, check hygiene, put on the wrist strap, this would give you personalized information, and then you follow the instructions, which will be personalized. Now this this data can actually be personalized to you and it could be on a global database for a company"

Brian: "Yeah"

Mark: "So it doesn't matter to which facility you go in to, the data will be up to date."

Brian: "Yeah yeah yeah"

Linn: "Ok."

Mark: "Aahm"

Linn: "And then for"

Mark: "Let's see"

Linn: "for questions. So now we take you just after presenting the idea. What are you initial thoughts when we are presenting this idea for you?"

Brian: "I think it's aah I think it's really really good idea. I think it's a wonderful idea, because everything else in the productions I saw, we know everything about what we put in all the badges and all that stuff, but we don't know the largest contaminer contaminant in in in the facility is always us. Going in and out the building, so if we can improve the way people are using the airlocks and we secure that by doing in the right way, we get a cleaner result, a cleaner person coming in and outside be eeh I'm sure everybody will love it, it will be they would they would sell easily! it would it would be, you know, it's that's a good sales point for for all the, you know, it's eeh very good idea."

Mark: "Do you seen that as being the main"

Linn: "What about"

Mark: "Sorry"

Linn: "Sorry"

Mark: "Do you see that as being the only selling point or theeee fact this would allow grater eeh resource tracking and ordering?"

Brian: "I think it's very good idea that you can eehm link it with ordering eeh stuff, so can always have the supplies ready. So you don't run out of the supplies."

Mark: "Mmhm"

Brian: "This is another important issue, because often times when we come to an airlock we go in there, oh is no more gowns, so one person has to go out again, one of the, or we have to call somebody."

Mark: "Mmhm"

Brian: "You know [laughing], we need we need somebody gowns in here from C to B lock, eehm B to C lock"

Mark: "Yes."

Brian: "Eeh and then if if it's not there you have to, yeah, can you contact so it's yeah that's very good! That's that will reduce time. Because it is time consuming"

Mark: "Mmhm"

Brian: "going in and out of these places, and often also you have so so limited space, so so the stock you have in in the airlocks is very limited, so if you could track this, that would be a huge huge benefit to the everyday eeh use of eeh"

Mark: "Mmhm"

Linn: "What if eeh what eeh did you have any concerns when we introduced you to this idea?"

Brian: "No, not really, because eeh I only the only concern I had was eeh something that Carsten said, that was before he said something about you had to go in a certain track eeh"

Carsten: "That was one of the first ideas."

Brian: "One of the first ideas, now I was I was expecting that [laughing]"

Carsten: "Mmhm"

Brian: " but I didn't see that."

Carsten: "A maze."

Brian: "Yeah the maze."

(Mark is laughing)

Carsten: "We were talking about it earlier"

Brian: "The maze idea I think it it is very hard, so, but I didn't see that, so I am only very very positive, because I think it would work."

Mark: "Mmhm"

Linn: "And eeh"

Brian: "The way in in in a simple layout, it doesn't change the way we actually do things, so we can we can put this, we can put this, it changes the way we using the locks, but doesn't change the way we have to design airlocks. Because one of the main drivers for us is also to have it very compact, because this space is always a problem, it is always a problem."

Mark: "Yeah do you see any potential barriers to people actually using the the wrist strip?"

Brian: "No, I think it comes so very close to that we are using our ID cards everywhere, so everybody knows where we are anyway. Eeeh so I don't think it's a problem that you eehm, that that you are registered and"

Mark: "Mmhm"

Brian: "another layer of registration. I don't see as problem at all."

Mark: "Ok."

Brian: "Eehm I think it could be clever, that, I think people would love it actually if have a wrist band and you actually presented, things come to you, just going through an airlock like that would be excellent, I would love to try."

(everybody laughing)

Linn: "But, yeah, but we, we are saying that, but but you also increase, because you make it personalized, so you will also increase the data collection."

Brian: "Yeah

Linn: "So you"

Brian: "I personally I wouldn't see it as an issue. I don't know how other people react, but you know, we are, our telephone, you know, everything is eeh, you watched from from all levels , aren't we? "

Carsten: "The concern we had, if I, may I interrupt,

Linn: "Yeah"

Carsten: "please say if I am not allowed, but but we were talking, no no, but it's your interview, but we were talking about this if you are making eehm eeh statistics about how people how fast they are taking their clothes on and how fast they are in and out, you know, if if the bosses can see, you know, in average you are an hour slower than your colleagues, you're fired."

Brian: "Yeah that could be a problem. I think it's very hypothetical though, because an airlock is not a it's not an interesting place to be, so"

Carsten: "No."

Brian: "normally people are in and out there as quick as they can."

Mark: "Mmhm"

Brian: "And that could be a problem actually, because, you know, it's it's it's not a nice room to be in eeeh, so so that's why people could could tend to slack a little bit in the cleanliness, because they just want to get in and out into the production"

Mark: "The the hand scanner would obviously stop people, until you pass the hand scanner, you could not proceed any further."

Carsten: "Mmhm."

Brian: "Yeah"

Linn: "But"

Istvan: "So maybe it's the opposite actually, that you are to quick, you are fired."

Carsten: "Yeah"

Brian: "Yeah"

Carsten: "We were we were talking about to slow"

Linn: "Yeah"

Istvan: "Yeah yeah"

Carsten: "but maybe"

Istvan: "it's opposite."

Carsten: "let's get through it and that's it."

Brian: "I don't see I don't see the problem at all. It's not like"

Istvan: " Mmhm"

Brian: "like you could also register how many clicks you had when you doing when you drawing on AutoCad, you know [Carsten laughs], you know, very slow

Carsten: "Yeah"

Brian: "that's the same thing"

Carsten: "Mmhm"

Brian: "It's been there, but nobody does it, really."

Carsten: "Mmhm"

Brian: "But I don't see I don't see issue here at all, because it's not a it's not a hangout place, where you [laughing]"

Linn: "No, but maybe it's also because people, you you know that you use your card and then you get, because you you you obviously have thought about it, but there are many people who haven't thought about it. And suddenly it will maybe ..."

Brian: "Yeah but"

Linn: "be a thing"

Brian: "Yeah but still"

Linn: "will think about it and maybe they will think about the data, and and where are we going, and this data, can you sell this data as well? What are you going to use the data for?"

Carsten: "Mmhm"

Linn: "Going to sell to the companies saying, you use oh we have this and we use this amount of time on launch brakes, eeh on cigarette brakes, on eehm, there is a huge amount of data, and suddenly people will, eeh people in general maybe more eeh"

Brian: "That's true but this is such such specific data this, that, you know, it's very hard for this outside this industry to use, and what should they use it for, it's eeh this is just controlling that you"

Mark: "Mmhm"

Brian: "you getting stuff in the right order."

Mark: "It's a very secretive industry as well."

Brian: "Yeah"

Carsten: "Yeah that's"

Mark: "Very secretive."

Carsten: "That's a good part of it."

Mark: "Yeah"

Carsten: "Because they won't give it away anyways."

Mark: "One factory site will not let the other factory site from the same company know what's going on, if they're more productive"

Carsten: "Mmhm"

Linn: "So you think that people will try to, because you say that they are doing this very quickly, you think they will try to find a way to cheat"

Brian: "No."

Linn: "the system?"

Brian: "No, I don't think so. I don't see how they should be able to."

Linn: "Mmhm"

Mark: "Ok."

Brian: "In general people are trying to, you know, what what eeeh, you know, what what they should do, what's written in the subs, but you know, eeh I I've just often notice, that this eeh step over bench is is"

Mark: "Mmh"

Brian: "you know, it doesn't work."

Mark: "It's it's I don't see the point for it, to be honest."

Brian: "No."

Mark: "I've I've used clean rooms myself and"

Brian: "Yeah"

Mark: "it's just inconvenience and I just said, I'm not small, but I had problem stepping over this bench."

Brian: "Yeah yeah, exactly, so."

Mark: "I mean, it was the wooden bench as well, I'm thinking."

Brian: "Yeah a wooden, well, that doesn't that doesn't go at all, actually we are we are somewhat trying to introduce that we have a threshold by instead."

Mark: "Yes"

Brian: "So you have these racks for for shoes and you can just put it over there and you can step directly into it."

Carsten: "Mmhm"

Mark. "Mmhm"

Brian: "Also a a a a bar instead of ehm, instead of these benches would make the air cleaning a lot quicker, because

Mark: "Mmhm"

Brian: "the air flow is better in the room which don't have these"

Mark: "Yes."
Brian: "bench with all these pockets in the middle, so I think"

Carsten: "Little river [everyone laughing] Why not?"

Mark: "Well, eeh you may say little rive be could be one of these sticky strips down the middle."

Carsten: "Yeah yeah"

Mark: "So people actually step on a sticky strip before they"

Carsten: "Yeah"

Mark: "progress."

Linn: "So ehh how easy or difficult it would be for you as now you don't know a lot about eeeh about idea, but to would it be to implement the ide the XXXX system in the actual clean rooms?"

Brian: "Well if the technology is there, and if if we can eeh if eeh and I don't think it's a problem, because we we have we have cabinets, we have dispensers today, but they are just, you know,

Mark: "Mmhm"

Brian: "manual dispensers, where you take from from top to bottom and it unisize eeh, or we have tree different sizes."

Mark: "Mmhm"

Brian: "So we have dispensers today, but they are just not personalized, so eeeh ...My the main, the main thing is how do we automate automate"

Mark: "Yes."

Brian: "automatisize"

Mark: "Automate"

Brian: "Automate, how do we automate these eeh these things in"

Mark: "Mmhm"

Brian: "in a good way, that eeh, but that's, you know, that's a design that's a design issue."

Carsten: "But you don't see the room has to change?"

Brian: "I don't see the room has to change."

Carsten: "No no"

Brian: "Because eeh these these automate dispensers they do not take more eeh place then then the manual dispensers, I don't see that should be a problem. Eeeh and I think we will have we we we we need space for all these different items anyway. And they are placed in the yeah, they are placed in the airlock, so I don't see it has any layout eeeh impact, the way it was presented there."

Mark: "It could be"

Carsten: "Mmhm"

Mark: "From a purely logistical point and cleanliness issue of course, these a dispensers, could actually be loaded from outside the clean room, couldn't they?"

Brian: "They they could, if you have if you building a new facility."

Mark: "Mmhm"

Carsten: "Space."

Brian: "But it can be very very difficult, often very difficult."

Mark: "Next question about the retrogre retrofitting."

Brian: "Yeah the retrofitting will be very difficult to make eeh eehm sometimes it can be difficult, because eeh we have other rooms that you you yeah if you really make straight it all out, it it of course it would be easier to to fill this eeh like the suspensors if they are sitting on the outer wall"

Mark: "Mmhm do you see that the system we presented to you could be retrofitted to the existing facilities?"

Brian: "Yeah yeah, but you would just normally you just go and fill your eehm dispensers eehm"

Mark: "Manually."

Brian: "Manually, but but no one having having the system telling you that we are out of size this and this"

Carsten: "Mmhm"

Brian: "eehm would be eeh enormous eeh"

Carsten: "It could send an email by itself."

Brian: "It could send an email yeah, that would be"

Mark: "Straight to the supplier."

Brian: "Yeah yeah would be really good."

Mark: "Mmhm"

Linn: "And eeh"

Brian: "That's the huge advantage."

Linn: "Ok ok sometimes is also a little bit difficult for us, because we haven't been into a clean room, so we didn't know that it was making mechanical actually with this with this system."

Brian: "With dispenser?"

Linn: "Yeah with the dispenser. So so yeah, but it makes sense that you can atomize it in a dispenser, it would

Carsten: "Mmhm"

Linn: "be very nice."

(Mark clears his throat)

Linn: "How would you ins how would you installation of the proposed ehm XXXX enabled system complications eeh complicate the design of the new changing rooms? No I don't"

Brian: "I don't think I don't see I don't see"

Linn: "Yeah yeah sorry sorry!"

Mark: "No it's a valid question, if it's not a valid then it's still a valid question."

Brian: "Yeah but"

Loreta: "But we just discussed that."

Brian: "Yeah I don't think it will it will affect the way eehm the way we design it normally."

Mark: "Mmhm"

Brian: "It depends, if it can depend of course, depending on SOP,[few people talking in the background] do we yeah do we put these eehm machines, or this dispenser in the right place, but it's it's a minor problem."

Carsten: "It's a small detail."

Mark: "It's a small detail."

Brian: "It's a small detail yeah yeah, it's not a general layout problem, it's just a small detail."

Mark: "Mmhm Ok. Eeh twenty tree ...?"

Linn: "Aa just aa"

Istvan: "Mmhm twenty tree is ok."

Mark: "Ok. Aahm would XXXX be in conflict with a building regulations that you've come across aahm at at all?"

Brian: "No. I can't find anything."

Mark: "Cuz we found yesterday is they are actually ATEX rated as well."

Carsten: "Yeah that's that's an issue I've"

Mark: "And also the scanners can be ATEX rated."

Carsten: "Yeah"

Mark: "So that's not an issue. Ok. I don't think I have any further questions at this stage."

Transcription of interview with Carsten

In the room: Carsten , Loreta, Mark and Linn

Linn: "Okay [Mark clears throat] yes… Carsten"

Carsten: "yes, now I am ready [laughs]"

Linn: "okay, what is your education/background?"

Carsten: "I am [øhhhh] an electronic mechanic from, from start from Lego I was there [ehhh] ten years ago and I [eeh] I am [eeeh] educated as a [ehhh] electronic engineer at DTU [ehh] from 2011 so it is nearly two years now so that is my background and I have worked different places soo and I have been here for one and a half year now."

Mark: "How long were you a mechanic at Lego?"

Carsten: "[øhhhh] four years [øhhh] but that was when I took the education and at that time the company was quite [øhhh] bad going with the economy so couldn't hire me afterwards they gave me half a year and then they… I had to take off so [ehhm] unfortunately because it was quite a nice place, a lot of developing so it was really nice, but afterwards I have worked for ten years within the mechanic industry [ehhm] not mechanic, electronic mechanic, to fix to fix weather stations for theee…"

Mark: "Automation engineer is that correct title?"

Carsten: "Not automation [ehhhm] if… repairing [ehh] electronic equipment that fails."

Mark: "okay [mmm]"

Carsten: "yes, and developing slot machines to [Mark: "mmm"] soo a lot of different things."

Linn: "mmm"

Mark: "okay [clears throat]"

Linn: "okay so within NNE, what is your role within this company?"

Carsten: "I am a instrumentation engineer so that means I have tooo [ehhh] design or specify how much and less, you know, which kind of instruments we have to use for example pressure or mass flow or [eeeh] equipment and so on I have, the companies we are working together with they ask for; we need so much [ehhm] you know, mass going through this pipe which kind of measuring equipment do we need, and I have to figure that out. So but I am in a learning process so I have this [eeeh] junior/senior agreement with some of my colleagues and they have to, you know, hold me in my hand and say now you have to this and that soo"

Linn: "yes"

Carsten: "I am in a, still in a learning process here"

Linn: "okay [Mark clears throat]"

Linn: "so [aaa] What is your main responsibility in your everyday work?"

Carsten: "[eeh] at the moment I am on a project for Novo Nordisk where I am, I am leads on this instrumentation part but I still have a senior next to me who will direct me in the right [eehhm] direction so, so it is my responsibility that all instrumentation parts are filling up to meet the requirements and [eeh] I have to sign all the documents and in the end QA will go to me if there is something wrong and say this [eehh]"

Linn: "QA?"

Carsten: "QA is Quality [mark; assurance] yeas, yes they have a big, a lot of people are sitting looking al the papers through and say ahhh this is not right or why did you write this [Mark: "hmm"] that way so it is always trouble but it is how it is so."

Mark: "yes, I have been audited by these people."

Linn: "So"

Carsten: "yes they are hard [little laugh]"

Linn: "So how do your main responsibility, do you know CSR?"

Carsten: "Not that much, I know the, the phrase but not the…"

Linn: "so nobody, have you ever been, when you were first assigned to work here did anybody [ehhm] tell you about the CSR of this company?"

Carsten: "But it is the main ideas of [eeehhh]"

Linn: "of responserbility"

Carsten: "yes [hmm] for our customers and the environment and so on, yes yes, we have some main [ehhm] you know criteria's and of course there is a lot of focus on that but it is, you know, it is ground material in a way so it is not something you think about every day and think oh I have to do this and that, but we have so many rules, we have so many systems we have to go through when we design things [ehh] different levels of where we are now and what should we deliver to our customers at this time so I think that is the main focus to to"

Mark: "These rules do they come from the customers or, or form NNE or is it?"

Carsten: "Both"

Mark: "Both?"

Carsten: "Both in a way because I think we have some ground rules but if we work for Novo for example [Mark: "mmhh"] they have some, some [eehh] request to how we do it and by that we have to for fill always, so we have a whole template of… Next step is you have to deliver that and control this and for example when you buy [ehhm] new instruments you have to go to different suppliers to figure out [eeh] what is cheapest and what is the best quality and so on and [Mark clears throat] then you have to say okay we have to make a review on what we should pick."

Linn: "okay so yes, and [ehmm] yes, how [whh] so some of these standards and some of these rules do you ever get like, do you ever feel influenced by the government and so on?"

Carsten: "By the government?"

Linn: "Yes, because of standards coming from the government and you have to change procedures or?"

Carsten: "No, not much from governments, but there is some [eeehh] fire safety [ehhm] regulations that changes ATEX for example as I have mentioned to you before, they can change

because they have been such and such for years ago and then they change it and we have to make new standards for that, but not directly from the government it is more from our customers and to for fill their, being compliance with their ideas on how things should be done."

Linn: "How would you describe the function of NNE?"

Carsten: "The function?"

Linn: "The purpose of the company?"

Mark: "The reason that it exist."

Carsten: "I think it is, it is very good [aaa] I am happy that, that these kind of companies exist because then there are some [eeehhh] high levels of [ehhm] security about how things are made in a, in [eeehh] in a company who makes [ehhm] pills or what, insulin whatever, our morality always focus on, not always, but think about who is in the end of the needle,"

Mark and Linn: "[mmm]"

Carsten: "they have to put it in your body or somewhere, you know, it is not just [eeehh] tires we are making or something, it is something that can effect people very much, so if we are not for filling all the requirements then somebody can be hurt in the end so it is [ehh] I think the purpose is very good."

Linn: "okay"

Mark: "what do you think that purpose is? Not how but the what? What kind of business do you think they are in?"

Carsten: "[eeehh takes a sip of water]"

Mark: "are you an engineering company or a design company or?"

Carsten: "engineering, we are consulting people more or less"

Mark: "okay"

Carsten: "Engineering consulting, they ask us we need a factory how do we do it and please we give you these kind of rules and [ehhh] [Mark: "mmm"] how much is the price. And then we

come up with a design and then they say yes or no and we take [ehh] we ask our working people, not our but we work together with the electri ehh what is it called… different kind of engineering, not engineering what is it called… [ehhh Carsten ask in Danish: "elektrikkere?"]"

Mark and Linn: "Electricians"

Carsten: "Yes yes"

Linn: "and other kinds of contractors?"

Carsten: "Yes contractors, yes exactly, and we control that they do it the right way"

Linn: "so [eeh] just to get back to the questions, are you involved in the '1001 ideas' initiative?"

Carsten: "Very much indeed I must say yes it is [ehhh] I was one of the first ones to come up with ideas and it was in the very early stage so I have been pushed forward all the time so"

Linn: "and what are your expectations for this process?"

Carsten: "Hopefully, hopefully it will end up with a product in the end or some products but but I have 1001 ideas is a lot 100 ideas is a lot still 10 ideas is still a lot I think one will be good in all of the so you know it is a kind of a lottery, I hope my idea the one that you are working with to will be the one but I don't expect more than one or two in the end."

Linn: "What about yourself? Have you experienced a process by working with this kind of development of ideas?"

Carsten: "the process?"

Linn: "Have you experienced some kind of processes some kind of ehh"

Carsten: "how the whole system works?"

Linn: "yes"

Carsten: "yes, very much because as I said I was one of the first to give in ideas and in the end there was, you know, it is the first time they do this, Finn is the man in charge of it, but it is the first time for a lot of things so that gives a lot of concerns but at the same time you are able to push things in directions so [ehh mmmm] it is evolving every day nearly it is something new

every day and that is good and frustrating at the same time, you see this confidentiality agreement we have I have been working on that even though I am not a what is it called?"

Linn: "a lawyer?"

Carsten: "a lawyer, but but you know as I am the contact person for you and so on it is [Mark laughs] I don't know how many hours I have used on it a lot"

Linn: "yes"

Carsten: "and I thought this should be in place long time ago and people ahhh do you think we need to? Off course we need to, you know, it is, it is a new thing everything "

Linn: "so it is a process and you know?"

Carsten: "I would say facility of the future version 2.0 next year will be so much different than this one"

Linn: "okay"

Loreta: "I have a question, so you want to say that it actually adds pressure to your normal daily activity work?"

Carsten: "[øhhh]"

Loreta: "how do you combine those two?"

Carsten: "It is difficult because I had [eehhh] before, before November, no before august it was pretty much you can use how much time you want because there is an amount of money for it and nobody took any of it because there was so few ideas in [mark: laughs] it was really, you know, then they put a deadline and suddenly I don't know 60-80 portent of all ideas just came [makes a bang] and suddenly they had to put up some times for each, you know you get five hours and this is ten and this is twenty and so on and suddenly you know, what, what do I only have this amount of hours to do it because we are very strict with hours, I have a project and this is the main thing and then we have this working together so I am sitting counting okay today I will use six hours with you I have to take that out of my equation so it effects it, I have a good, I have a lot of time now because the project I am on is on pause in a way but it will start up in two weeks and then it will be the different you know [ahhh], okay I can help you but it will

be short soo it effects a lot and a lot op people have [hmmm] you know complained about it because they want us to do it but yeah"

Linn: "what if we – is it important [referring to Mark]"

Mark: "yes yes, you mentioned that you were frustrated sometimes other people were complaining does this means that there is going to be a change required in how people work or does it just meae people will have to refocused with what they are doing?"

Carsten: "[mmmmm]"

Mark: "Change thinking as Andreas said"

Carsten: "Noo I don't think, I think people want to, to do the change but if there is no hours for it how to change it?"

Mark: "So it is all about budgets?[Loreta: "So it is a problem with the management?"]"

Carsten: "It is a lot about budget because [eehhh]"

Loreta: "and also management I guess"

Carsten: "exactly"

Loreta: "You should have thought about it a little bit more?"

Carsten: "I think they thought about it but, but suddenly it exploded."

Loreta: "mmm"

Carsten: "If I had, I came up with this idea in January or February and it just stood there for so long and when my manager he said shouldn't we go to Finn and present it and suddenly something started but we were only about, I don't know, 16 ideas I think until summer here and suddenly it [makes a bomb sound we all laugh] and suddenly we had to, you know, the amount of money they have to put it out to everybody soo"

Mark: "What do you think was the change?"

Carsten: "A deadline [Linn: "mmm"]"

Mark: "the deadline?"

Carsten: "for the ideas to come and the deadline for this event the 14th of November because it has been, later on we will do something, later on when? And then people go back to the projects and then work work work work and suddenly whoooa is there a date [Linn: "and then everybody had ideas?"] yes yes"

Loreta: "and it was compulsory, was it compulsory for every department to create an idea?"

Carsten: "I don't know how, Jan said that they had to come up with ideas every week, in my department they are not, I think [øhhhhh]"

Loreta: "It depends?"

Carsten: "Yes it depends very much and it is different on each department how they do it"

Mark: "yeah [laughs a little bit]"

Linn: "so what is your knowledge or experience of using XXXXX XXXXX?"

Carsten: "… not that much but I have come with the idea on not understood how it could be done without it so yes"

Linn: "so yes"

Carsten: "I don't use it that much once a month or so, so it is not that often"

Linn: "Do you see any issues with the procedures in preparing to enter and leave the 'XXXXX XXXX' at the moment?"

Carsten: "Yes, a lot I see, you sign something and you can do whatever you like afterwards"

Linn: "Okay"

Carsten: "you know it is like a driving licence you take it"

Linn: "so it is like the behaviour or [Mark: "this is really quite interesting"]?"

Carsten: "it is the behaviour and you know habits how are people doing it on daily basis, it could be anything and if they are in a hurry how do they do it then so"

Linn: "do you see any people who doesn't follow the rules when you go to the a XXXXX XXXX?"

Carsten: "[mmm] no because I don't come there that often so no, I have not seen anyone specifically, but I have, I have done it wrong because I was a bit ohh is it this or that way and suddenly someone said ohh you have to do it the other way [Linn: "okay"] you know what to do? Clean up afterwards or what?"

Mark: "this creates a question we maybe should have asked two questions ago – how did you learn about XXXXXXXXX procedures? Who was your teacher?"

Carsten: "[øhhh] the local [øhhh…] master I don't know what it is called but there is always somebody responsible at the specific site who instructs you how to do it and then you have to read some [øhhh] papers and then you have to sign that is how we learn it [Linn: "that is interesting"]"

Mark: "Are there any check procedures after you learn the first time?"

Carsten: "No [Linn: "hmmm"] I haven't seen it no, and nobody is controlling anything…"

Linn: "Okay"

Mark: "That is a interesting project as I [Carsten laughs] "

Linn: "so [ehm] what were your initial thoughts when like okay why when did you have the idea to [Mark: "Ohh no no go back to the first one that one is more interesting" all laugh] no I just need to know this when did you have the idea to incorporate XXXX technology in the intelligent XXXXX XXXX?"

Carsten: "[mmmmm] nearly a year ago, a year ago so I think, I think"

Linn: "and [Daniel open the door]"

Carsten: "ohh can you hang on for not much [to Daniel]"

Mark: "Have you had lunch?"

Daniel: "Yes I have thank you give me a call when you are ready"

Carsten: "It will be a few minutes"

Mark: "ten minutes"

Linn: "so back to the question, when did you have the idea to incorporate XXXX technology in the?"

Carsten: "a year ago I think"

Linn: "Yes and how did you came up with the idea?"

Carsten: "because I couldn't understand how can this be [ehhh] [ehhh] in compliance whit all the descriptions on how you should do it, it is so easy to not follow the rules"

Linn: "So maybe you were actually thinking about it while doing the procedure or?"

Carsten: "Absolutely, I started in Hillerød at the sight up there and I was so [eeehh] you know, there are so many rules everywhere but this is so easy just to sign something and you, you can say I just read and sign it"

Linn: "What do you see as the danger points of getting the procedure wrong?"

Carsten: "[eeeh] [eeeh]"

Linn: "What is the danger of not following the rules?"

Carsten: "Yes, contamination of some, some very expensive medicine we have medicine that cost 40.000 a milligram [Mark: "mmm"] you see, and somebody do this and it is destroyed [Linn: "yes"] so"

Linn: "I, we recently read a paper of contamination in a XXXXXXXXX [Carsten: "mmm"] with NCCE, or something [Carsten: "mmm"] but for my sake I think that people got sick because of the medicine was contaminated"

Carsten: "okay?"

Linn: "so the responsibility when I think about it is not only the cost but do you think?"

Carsten: "No, no I have not thought of that that much"

Linn: "When you make medicine for people it has to go out and people are sick taking medicine [Carsten: "hmm"]"

Mark: "I think you mentioned this about ten minutes ago when you mentioned that you liked the way the company was because you are injecting things into people [Carsten: "yes"] so I think we somehow covered this"

Linn: "okay"

Carsten: "the, the thing is that often the places where I have been is not, it is always in tanks, it is always with pipes it is not open it is not something out on the table, I can not get in direct contact with it, it should be a pipe blowing up in my face, then it is a problem, but "

Loreta: "no the thing is the end product [Carsten: "yes"] when it gets to the user, to the person particularly, for example the [Carsten: "yes"] vaccines that are contaminated?"

Carsten: "yes, yes that is a problem, but again they have so much control if this product is okay [Linn: "mmm"] before they put it on the market… so I am quite sure it will not, mostly not contain people but but"

Loreta: "That is the case, actually people died because of this this"

Carsten: "okay, okay but that is one part but the other part is that how much do they throw away because it is not clean [Mark laughs]."

Linn: "So [ehhm]"

Mark: "we can guess"

Carsten: "Yes we can only guess but but [ehhm] it is yes"

Mark: "I I"

Linn: "What were your initial thoughts when you were presenting, when you were presenting the idea of the 'intelligent XXXXX XXXX'?"

Mark: "I I think"

Linn: "yes, we have had that"

Mark: "sorry can we please refocus that. What were your initial thoughts when you were presented with our idea?"

Carsten: "[øhhh…] I think it was good work and I think you, you got my ground idea [øhh] correct from the start [ehh] and I was a bit surprised, not to take anything from your idea, but I was a bit surprised that you went so much in the same thought direction that I had [eehh] with how to solve it [ehhm eeii] I have been you know [ehhm] all the time focusing on less scanners… because they must be expensive.. but, but I haven't searched for any prices so I was, you know thinking of a simple one scanner and one scanner and your idea was in a you know a lot of scanners and it could be done absolutely."

Linn: "What, if any, concerns, what if, if any concerns did you have about the concept of the 'intelligent XXXXX XXXX'?"

Carsten: "[hmmm] Cost price, and how people will react on it or yes [øhh] this [ehhhmm] how much surveillance there will be from it and, and [ehhh] yes, I think that is [ehhh] that is the main thing"

Linn: "[øhm] and that is also leading to the next question, if there is any ethical issues [ehh] for you personally or for NNE Pharmaplan?"

Carsten: "… as long as it stays in a XXXXX XXXX area I don't think it will be a lot, but this could be expanded in every direction and this wristband could be used everywhere from when people meet in the morning until or even when they are at home so I think the there should be some kind of limitation where should it be used and where should it not be used [eeehhhh] but in a XXXXX XXXX area you identify your self with a card so they know you are there but yes [Linn: "okay"] but Brian's point whit this it is not a place you want to stay in for a long time so, so you know as we talked about the statistics thing [ehhh] you are so slow by changing clothes maybe it is not an issue at all because people just want to go take of fast"

Linn: "maybe that is also a problem?"

Carsten: "Yes it is ja ja"

Linn: "What do you know about XXXX?"

Carsten: "[Laughs] Not that much… I, I know [ehhh] I know it is an antenna and I know there is a chip and there is an active and [eehhh] a passive parts or kinds and [eehhmm] I haven't researched that much [ehhh] about it [ehhh mmm] ja it is it's more or less what you already knew but not, what we have talked about soo it is [ehhh] [Mark: "mmm"] off course I could go down into antenna details and so on but I haven't studied that much [ehhh] yes [Mark: "okay"]"

Linn: "so I am just curious because if you you, then how did you came up with this particular? Like applying XXXX [Mark and Carsten: "mmm"] in the XXXXX XXXX?"

Carsten: "[øhhh] just [ehhh] I think my way of think of creation is just [ehhm] take parts there is already existing somewhere an put them together in another combination because of course it could be nice to make aaa [ehhmm] something brand new but is always very expensive to come up with something new you know a car going on only clean water it is not easy to make but if you can come up with a combination of standard things to put together and then you have an idea I, I think that is always how I think about it so this XXXX is not my special [ehhm] knowledge area it is just some technology I know from you know a card or ski-areas where you [makes a bip sound] and that is it [ehhm] [Linn: "mmm"] you know."

Mark: "did you look at alternative technologies to come up with this kind of result?"

Carsten: "yes [ehhm] barcodes scanners"

Linn: "then why did you choose XXXX?"

Carsten: "Because barcode scanners are to complicated then you have to stand like this [Makes the bip bip bip bip sound and illustrates how he would use the barcode scanners] bip bip bip before you are in it is not, you cannot just walk through it, it should be, you know not complicated for the user."

Linn: "so these were the only two, did you do some research in other fields as well?"

Carsten: "Not much because I thought this was the idea, no?"

Linn: "Okay, and what about the process if this idea gets selected for further development what [Carsten: "mmm mmm"] how will you then out source it or?"

Carsten: "I will try to find companies who has specialised in this XXXX and figure out [ssyy] what's, what kind of scanners so and what kind of chip should we use, how long is the range, passive or active [ehhhmmm]"

Mark: "you will be soo happy about the results"

Carsten: "okay [Mark and Carsten laughs] it is good [hmmm] but but it will be research of the market or if there is something [emmm] like it already [emmm] yes and then try to start up some kind of [ehhh] you know, working together with a company and see if some kind of contract could be done and from there go on to our customers to present but but maybe it should be our customers who should be presented with the idea before and then figure out

Linn: "If you get this idea and you get, if this idea gets developed will you do some further studies in XXXX?"

Carsten: "[mmmmmnnnn] I would, I am not sure if I would go that much into it but I will get the knowledge from working together with companies who knows about it and I have the technical background to understand what is possible and not possible that is the main thing [ehhm] I am an engineer but I like the [thhhheee] concept developing part of it not the detailed that is that is a part of I understand the detail but I like the main idea and to make it [ehh] easy [ehh] for the user and that that is like apple who makes computers or IPhone's simple to use but the main [ehhm] what you use in the daily is what it is good at the rest is so what [Linn: "yes?"] yes."

Linn: "so you want, so you are thinking about user driven innovation? When you create something you are thinking of [Carsten: "yes"] a lot about how the users may perceive it?"

Carsten: "yes absolutely, I always take [ehhhh] take it from my own view and say why isn't it made? Like this, it this seams stupid or something like that, this with this idea I think it seems so [ehh] strange that nobody has done it. Why shouldn't it be controlled like this it is so easy in a way it is not brand new technology it is just to put things together to make a good system that's it."

Loreta: "This is more from company's perspective or from the users perspective?"

Carsten: "[eehhhh]"

Loreta: "Because they might be different"

Carsten: "yes yes I think this idea is from the company's perspective but but the idea came from my perspective as a user [Loreta: "okay"] I thought it was to easy to make a error soo"

Loreta: "so you are being responsible, and you think that people should be more responsible?"

Carsten: "yes yes that, that's how I think about it yes… but I, I think about ideas every day I come I say okay my little kid he is not a sleep but he is sleeping when I do this [takes his hand up and down] with the little [ehh] wagon he, why shouldn't I build a little engine that can do this [takes his hand up and down again] why not why not? Why shouldn't I then I can put it on for three hours and go up and rest – why shouldn't I do it? It it is like that [ehhhhh]"

Mark: "a food blender works well"

Carsten: "yes [all laughs]"

Mark: "but gear it down a little"

Linn: "Do we have any more questions?"

Mark: "I don't"

Carsten: "okay okay I just want to ask you, are you, did you think that I knew more about XXXX?"

Mark: "we weren't sure we thought you might know a little more than this"

Carsten: "yes, yes"

Mark: "we thought, I thought you might know about the…"

Carsten: "mmm, but in the main [eehhhm] I do, in a way but not specifically for XXXX it is you know digital thing [Mark: "yes"] antenna and so on but, but it seems so [ehh] heavy compared to what the idea is about at the moment"

Mark: "it doesn't have to be heavy"

Carsten: "No but if you are going into antenna design and so on is not easy"

Mark: "the antenna design is the simplest part from what I understand so far"

Carsten: "Okay"

Mark: "The problem appears to be the confirmation of the signals"

Carsten: "Okay, okay"

Linn: "okay"

Carsten: "so you know more than me [all laughs]"

Follow up questions by e-mail:

1; Hvordan og hvornår fandt dig og Camilla ud af at i kunne sammensætte ideerne?

2; Hvordan blev de 100 ideer udvalgt fra de 1001? Var det ledelsen eller en gruppe?

Answers:

1; Det var lidt tilfældigt at jeg kom til at tale med Camilla om hendes ide. Hun spurgte hvordan det gik med mine og så faldt snakken på hendes, og kort efter havde vi koblet dem sammen. Tilfælde.

2; Det her været nogle forskellige filtre undervejs fra de 1001 til 100. Jeg har selv været med i et udvalg i min afdeling hvor vi har sorteres hvilke der var bærdygtige nok til at komme videre. Derfra har Andreas og co. været inde og vurderer kvaliteten og potentialet i forhold til NNE, og har givet det nogle karakterer, som så er endt ud i nogle timer til at arbejde videre med. Hvordan de har selekteret i det må du forhøre Andreas om, for den proces kender jeg ikke til. Gav det mening?

Communities of Practice and Social Learning Systems

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articles

Communities of Practice and Social Learning Systems

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Abstract. *This essay argues that the success of organizations depends on their ability to design themselves as social learning systems and also to participate in broader learning systems such as an industry, a region, or a consortium. It explores the structure of these social learning systems. It proposes a social definition of learning and distinguishes between three 'modes of belonging' by which we participate in social learning systems. Then it uses this framework to look at three constitutive elements of these systems: communities of practice, boundary processes among these communities, and identities as shaped by our participation in these systems.*
Keywords: *boundaries; communities of practice; identity; knowledge in organizations; social learning systems*

You probably know that the earth is round and that it is in orbit around the sun. But how do you know this? What does it take? Obviously, it takes a brain in a living body, but it also takes a very complex social, cultural, and historical system, which has accumulated learning over time. People have been studying the skies for centuries to understand our place in the universe. More recently, scientific communities have developed a whole vocabulary, observation methods, concepts, and models, which have been adopted by other communities and have become part of popular thinking in various ways. You have your own relationships to all these communities, and these relationships are what enable you to 'know' about the

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earth's position in the universe. In this sense, knowing is an act of participation in complex 'social learning systems'.

This essay assumes this view of knowing to consider how organizations depend on social learning systems. First, I outline two aspects of a conceptual framework for understanding social learning systems: a social definition of learning in terms of social *competence* and personal *experience*, and three distinct *modes of belonging* through which we participate in social learning systems: *engagement, imagination*, and *alignment*. Then I look at three structuring elements of social learning systems: *communities of practice*, *boundary* processes among these communities, and *identities* as shaped by our participation in these systems. About each of these elements I use my conceptual framework to ask three questions. Why focus on it? Which way is up, that is, how to construe progress in this area? And, third, what is doable, that is, what are elements of design that one can hope to influence? Finally, I argue that organizations both are constituted by and participate in such social learning systems. Their success depends on their ability to design themselves as social learning systems and also to participate in broader learning systems such as an industry, a region, or a consortium.

The conceptual framework I introduce here is intended for organizational design as well as analysis. The questions I ask are meant to guide the inquiry of the researcher as well as the actions of the practitioner: what to pay attention to, how to give direction to our initiatives, and where to focus our efforts. As Kurt Lewin used to say, there is nothing as practical as a good theory.

Aspects of a Conceptual Framework

A framework for understanding social learning systems must make it possible to understand learning as a social process. What is learning from a social perspective? And what are the processes by which our learning constitutes social systems and social identities?

A Social Definition of Learning

In a social learning system, competence is historically and socially defined. How to be a physicist or how to understand the position of the earth in the universe is something that scientific communities have established over time. Knowing, therefore, is a matter of displaying competences defined in social communities. The picture is more complex and dynamic than that, however. Our experience of life and the social standards of competence of our communities are not necessarily, or even usually, congruent. We each experience knowing in our own ways. Socially defined competence is always in interplay with our experience. It is in this interplay that learning takes place.

Consider two extreme cases. Sometimes, we are a newcomer. We join a new community. We are a child who cannot speak yet. Or we are a new

employee. We feel like a bumbling idiot among the sages. We want to learn. We want to apprentice ourselves. We want to become one of them. We feel an urgent need to align our experience with the competence 'they' define. Their competence pulls our experience.

Sometimes, it is the other way round. We have been with a community for a long time. We know the ropes. We are thoroughly competent, in our own eyes and in the eyes of our peers. But something happens. We are sent overseas. We go to a conference. We visit another department. We meet a 'stranger' with a completely different perspective. Or we just take a long walk or engage in a deep conversation with a friend. Whatever the case may be, we have an experience that opens our eyes to a new way of looking at the world. This experience does not fully fit in the current practice of our home communities. We now see limitations we were not aware of before. We come back to our peers, try to communicate our experience, attempt to explain what we have discovered, so they too can expand their horizon. In the process, we are trying to change how our community defines competence (and we are actually deepening our own experience). We are using our experience to pull our community's competence along.

Whether we are apprentices or pioneers, newcomers or oldtimers, knowing always involves these two components: the *competence* that our communities have established over time (i.e. what it takes to act and be recognized as a competent member), and our ongoing *experience* of the world as a member (in the context of a given community and beyond). Competence and experience can be in various relations to each other—from very congruent to very divergent. As my two examples show, either can shape the other, although usually the process is not completely one-way. But, whenever the two are in close tension and either starts pulling the other, learning takes place. Learning so defined is an interplay between social competence and personal experience. It is a dynamic, two-way relationship between people and the social learning systems in which they participate. It combines personal transformation with the evolution of social structures.

Modes of Belonging

Our belonging to social learning systems can take various forms at various levels between local interactions and global participation. To capture these different forms of participation, I will distinguish between three modes of belonging.

- *Engagement*: doing things together, talking, producing artifacts (e.g. helping a colleague with a problem or participating in a meeting). The ways in which we engage with each other and with the world profoundly shape our experience of who we are. We learn what we can do and how the world responds to our actions.
- *Imagination*: constructing an image of ourselves, of our communities,

and of the world, in order to orient ourselves, to reflect on our situation, and to explore possibilities (e.g. drawing maps, telling a story, or building a set of possible scenarios to understand one's options). I use imagination here in the sense proposed by Benedict Anderson (1983) to describe nations as communities: it does not connote fantasy as opposed to factuality. Knowing that the earth is round and in orbit around the sun, for instance, is not a fantasy. Yet it does require a serious act of imagination. It requires constructing an image of the universe in which it makes sense to think of our standing on the ground as being these little stick figures on a ball flying through the skies. Similarly, thinking of ourselves as a member of a community such as a nation requires an act of imagination because we cannot engage with all our fellow citizens. These images of the world are essential to our sense of self and to our interpretation of our participation in the social world.

- *Alignment*: making sure that our local activities are sufficiently aligned with other processes so that they can be effective beyond our own engagement (e.g. doing a scientific experiment by the book, convincing a colleague to join a cause, or negotiating a division of labor and a work plan for a project). The concept of alignment as used here does not connote a one-way process of submitting to external authority, but a mutual process of coordinating perspectives, interpretations, and actions so they realize higher goals. Following the scientific method, abiding by a moral code, or discussing important decisions with our spouse can all become very deep aspects of our identities.

Distinguishing between these modes of belonging is useful for two reasons. First, analytically, each mode contributes a different aspect to the formation of social learning systems and personal identities. Engagement, imagination, and alignment usually coexist and every social learning system involves each to some degree and in some combination. Still, one can dominate and thus give a different quality to a social structure. For instance, a community based mostly on imagination such as a nation has a very different quality from a community of practice at work, which is based primarily on engagement. I would in fact argue that these modes of belonging provide a foundation for a typology of communities.

Second, practically, each mode requires a different kind of work. The work of engagement, which requires opportunities for joint activities, is different from the work of imagination, which often requires opportunities for taking some distance from our situation. The demands and effects of these three modes of belonging can be conflicting. Spending time reflecting can detract from engagement, for example. The modes can also be complementary, however. For instance, using imagination to gain a good picture of the context of one's actions can help in fine-tuning alignment because one understands the reasons behind a procedure or an

agreement. It is therefore useful to strive to develop these modes of belonging in combination, balancing the limitations of one with the work of another. For instance, reflective periods that activate imagination or boundary interactions that require alignment with other practices around a shared goal could be used to counteract the possible narrowness of engagement (Wenger, 1998).

Communities of Practice

Since the beginning of history, human beings have formed communities that share cultural practices reflecting their collective learning: from a tribe around a cave fire, to a medieval guild, to a group of nurses in a ward, to a street gang, to a community of engineers interested in brake design. Participating in these 'communities of practice' is essential to our learning. It is at the very core of what makes us human beings capable of meaningful knowing.

Why Focus on Communities?

Communities of practice are the basic building blocks of a social learning system because they are the social 'containers' of the competences that make up such a system. By participating in these communities, we define with each other what constitutes competence in a given context: being a reliable doctor, a gifted photographer, a popular student, or an astute poker player. Your company may define your job as processing 33 medical claims a day according to certain standards, but the competence required to do this in practice is something you determine with your colleagues as you interact day after day.

Communities of practice define competence by combining three elements (Wenger, 1998). First, members are bound together by their collectively developed understanding of what their community is about and they hold each other accountable to this sense of *joint enterprise*. To be competent is to understand the enterprise well enough to be able to contribute to it. Second, members build their community through mutual engagement. They interact with one another, establishing norms and relationships of *mutuality* that reflect these interactions. To be competent is to be able to engage with the community and be trusted as a partner in these interactions. Third, communities of practice have produced a *shared repertoire* of communal resources—language, routines, sensibilities, artifacts, tools, stories, styles, etc. To be competent is to have access to this repertoire and be able to use it appropriately.

Communities of practice grow out of a convergent interplay of competence and experience that involves mutual engagement. They offer an opportunity to negotiate competence through an experience of direct participation. As a consequence, they remain important social units of learning even in the context of much larger systems. These larger systems are constellations of interrelated communities of practice.

Which Way is Up?

Communities of practice cannot be romanticized. They are born of learning, but they can also learn not to learn. They are the cradles of the human spirit, but they can also be its cages. After all, witch-hunts were also community practices. It is useful, therefore, to articulate some dimensions of progress.

- *Enterprise: the level of learning energy.* How much initiative does the community take in keeping learning at the center of its enterprise? A community must show leadership in pushing its development along and maintaining a spirit of inquiry. It must recognize and address gaps in its knowledge as well as remain open to emergent directions and opportunities.
- *Mutuality: the depth of social capital.* How deep is the sense of community generated by mutual engagement over time? People must know each other well enough to know how to interact productively and who to call for help or advice. They must trust each other, not just personally, but also in their ability to contribute to the enterprise of the community, so they feel comfortable addressing real problems together and speaking truthfully. Through receiving and giving help, they must gain enough awareness of the richness of the community to expect that their contribution will be reciprocated in some way.
- *Repertoire: the degree of self-awareness.* How self-conscious is the community about the repertoire that it is developing and its effects on its practice? The concepts, language, and tools of a community of practice embody its history and its perspective on the world. Being reflective on its repertoire enables a community to understand its own state of development from multiple perspectives, reconsider assumptions and patterns, uncover hidden possibilities, and use this self-awareness to move forward.

The three dimensions work together. Without the learning energy of those who take initiative, the community becomes stagnant. Without strong relationships of belonging, it is torn apart. And without the ability to reflect, it becomes hostage to its own history. The work associated with each mode of belonging can contribute to these criteria. Table 1 illustrates how the modes of belonging interact with community elements.

What is Doable?

When designing itself, a community should look at the following elements: events, leadership, connectivity, membership, projects, and artifacts.

Events. You can organize public events that bring the community together. Obviously, these may or may not be attended, but if they are well tuned to the community's sense of its purpose, they will help it develop an

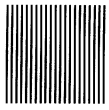

Table 1. Community Dimensions

	Enterprise: learning energy	Mutuality: social capital	Repertoire: self-awareness
Engagement	What are the opportunities to negotiate a joint inquiry and important questions? Do members identify gaps in their knowledge and work together to address them?	What events and interactions weave the community and develop trust? Does this result in an ability to raise troubling issues during discussions?	To what extent have shared experience, language, artifacts, histories, and methods accumulated over time, and with what potential for further interactions and new meanings?
Imagination	What visions of the potential of the community are guiding the thought leaders, inspiring participation, and defining a learning agenda? And what picture of the world serves as a context for such visions?	What do people know about each other and about the meanings that participation in the community takes in their lives more broadly?	Are there self-representations that would allow the community to see itself in new ways? Is there a language to talk about the community in a reflective mode?
Alignment	Have members articulated a shared purpose? How widely do they subscribe to it? How accountable do they feel to it? And how distributed is leadership?	What definitions of roles, norms, codes of behavior, shared principles, and negotiated commitments and expectations hold the community together?	What traditions, methods, standards, routines, and frameworks define the practice? Who upholds them? To what extent are they codified? How are they transmitted to new generations?

identity. A community will have to decide the *type* of activities it needs: formal or informal meetings, problem-solving sessions, or guest speakers. It will also have to consider the *rhythm* of these events given other responsibilities members have: too often and people just stop coming, too rare and the community does not gain momentum. This rhythm may also have to change over time or go through cycles.

Leadership. Communities of practice depend on internal leadership, and enabling the leaders to play their role is a way to help the community develop. The role of 'community coordinator' who takes care of the day-to-day work is crucial, but a community needs multiple forms of leadership: thought leaders, networkers, people who document the practice, pioneers, etc. These forms of leadership may be concentrated on one or two members or widely distributed, and this will change over time.

Connectivity. Building a community is not just a matter of organizing community events but also of enabling a rich fabric of connectivity among people. This could involve brokering relationships between people who need to talk or between people who need help and people who can offer help. It is also important to make it possible for people to communicate and interact in multiple media.

Membership. A community's members must have critical mass so that there is interest, but it should not become so wide that the focus of the community is diffuse and participation does not grab people's identities. Including those who are missing can be very helpful in consolidating the legitimacy of the community to itself and in the wider organization. Conversely, realizing that the membership is overextended allows the community to split up into subgroups. Finally, devising processes by which newcomers can become full members helps ensure access for newcomers without diluting the community's focus.

Learning Projects. Communities of practice deepen their mutual commitment when they take responsibility for a learning agenda, which pushes their practice further. Activities toward this goal include exploring the knowledge domain, finding gaps in the community practice, and defining projects to close these gaps. Such learning projects could involve, for instance, assessing some tools, building a generic design, doing a literature search, creating a connection with a university doing research in the area, or simply interviewing some experts to create a beginner's guide.

Artifacts. All communities of practice produce their own set of artifacts: documents, tools, stories, symbols, websites, etc. A community has to consider what artifacts it needs and who has the energy to produce and maintain them so they will remain useful as the community evolves.

Boundaries

The term boundary often has negative connotations because it conveys limitation and lack of access. But the very notion of community of practice implies the existence of boundary. Unlike the boundaries of organizational units, which are usually well defined because affiliation is officially sanctioned, the boundaries of communities of practice are usually rather fluid. They arise from different enterprises; different ways of engaging with one another; different histories, repertoires, ways of communicating, and capabilities. That these boundaries are often unspoken does not make them less significant. Sit for lunch by a group of high-energy particle physicists and you know about boundary, not because they intend to exclude you, but because you cannot figure out what they are talking about. Shared practice by its very nature creates boundaries.

Yet, if you are like me, you will actually enjoy this experience of bound-

ary. There is something disquieting, humbling at times, yet exciting and attractive about such close encounters with the unknown, with the mystery of 'otherness': a chance to explore the edge of your competence, learn something entirely new, revisit your little truths, and perhaps expand your horizon.

Why Focus on Boundaries?

Boundaries are important to learning systems for two reasons. They connect communities and they offer learning opportunities in their own right. These learning opportunities are of a different kind from the ones offered by communities. Inside a community, learning takes place because competence and experience need to converge for a community to exist. At the boundaries, competence and experience tend to diverge: a boundary interaction is usually an experience of being exposed to a foreign competence. Such reconfigurations of the relation between competence and experience are an important aspect of learning. If competence and experience are too close, if they always match, not much learning is likely to take place. There are no challenges; the community is losing its dynamism and the practice is in danger of becoming stale. Conversely, if experience and competence are too disconnected, if the distance is too great, not much learning is likely to take place either. Sitting by that group of high-energy particle physicists, you might not learn much because the distance between your own experience and the competence you are confronting is just too great. Mostly what you are learning is that you do not belong.

Learning at boundaries is likely to be maximized for individuals and for communities when experience and competence are in close tension. Achieving a generative tension between them requires:

- something to interact about, some intersection of interest, some activity;
- open engagement with real differences as well as common ground;
- commitment to suspend judgment in order to see the competence of a community in its terms;
- ways to translate between repertoires so that experience and competence actually interact.

Boundaries are sources of new opportunities as well as potential difficulties. In a learning system, communities and boundaries can be learning assets (and liabilities) in complementary ways.

- Communities of practice can steward a critical competence, but they can also become hostage to their history, insular, defensive, closed in, and oriented to their own focus.
- Boundaries can create divisions and be a source of separation, fragmentation, disconnection, and misunderstanding. Yet, they can also be areas of unusual learning, places where perspectives meet and new possibilities arise. Radically new insights often arise at the boundaries between

communities. Think of a specialization like psychoneuroimmunology: its very name reflects its birth at the intersection of multiple practices.

In social learning systems, the value of communities and their boundaries are complementary. Deep expertise depends on a convergence between experience and competence, but innovative learning requires their divergence. In either case, you need strong competences to anchor the process. But these competences also need to interact. The learning and innovation potential of a social learning system lies in its configuration of strong core practices and active boundary processes (Wenger, 1998).

Which Way is Up?

Not all boundary processes create bridges that actually connect practices in deep ways. The actual boundary effects of these processes can be assessed along the following dimensions.

- *Coordination.* Can boundary processes and objects be interpreted in different practices in a way that enables coordinated action? For instance, an elegant design may delight designers but say little to those concerned with manufacturability. Across boundaries, effective actions and use of objects require new levels of coordination. They must accommodate the practices involved without burdening others with the details of one practice and provide enough standardization for people to know how to deal with them locally.
- *Transparency.* Do boundary processes give access to the meanings they have in various practices? Coordination does not imply that boundary processes provide an understanding of the practices involved. For instance, forms like US tax returns enable coordination across boundaries (you know how to fill them out by following instructions line by line), but often afford no windows into the logic they are meant to enforce (following instructions often tells you little about why these calculations are 'fair').
- *Negotiability.* Do boundary processes provide a one-way or a two-way connection? For instance, a business process reengineering plan may be very detailed about implementation (coordination) and explicit about its intentions (transparency), but reflect or allow little negotiation between the perspectives involved. Boundary processes can merely reflect relations of power among practices, in which case they are likely to reinforce the boundary rather than bridge it. They will bridge practices to the extent that they make room for multiple voices.

Table 2 explores how the three modes of belonging affect these qualities of boundary processes.

What is Doable?

Boundary processes are crucial to the coherent functioning of social learning systems. A number of elements can be intentionally promoted in

Table 2. Boundary Dimensions

	Coordination	Transparency	Negotiability
Engagement	What opportunities exist for joint activities, problem-solving, and discussions to both surface and resolve differences through action?	Do people provide explanations, coaching, and demonstrations in the context of joint activities to open windows on to each other's practices?	Are joint activities structured in such a way that multiple perspectives can meet and participants can come to appreciate each other's competences?
Imagination	Do people have enough understanding of their respective perspectives to present issues effectively and anticipate misunderstandings?	What stories, documents, and models are available to build a picture of another practice? What experience will allow people to walk in the other's shoes? Do they listen deeply enough?	Can both sides see themselves as members of an overarching community in which they have common interests and needs?
Alignment	Are instructions, goals, and methods interpretable into action across boundaries?	Are intentions, commitments, norms, and traditions made clear enough to reveal common ground and differences in perspectives and expectations?	Who has a say in negotiating contracts and devising compromises?

an effort to weave these systems more tightly together. Here, I will talk about three types of bridges across boundaries: *people* who act as 'brokers' between communities, *artifacts* (things, tools, terms, representations, etc.) that serve as what Star and Griesemer (1989) call 'boundary objects', and a variety of forms of *interactions* among people from different communities of practice.

Brokering. Some people act as brokers between communities. They can introduce elements of one practice into another. Although we all do some brokering, my experience is that certain individuals seem to thrive on being brokers: they love to create connections and engage in 'import–export', and so would rather stay at the boundaries of many practices than move to the core of any one practice. Brokering can take various forms, including:

- *boundary spanners*: taking care of one specific boundary over time;
- *roamers*: going from place to place, creating connections, moving knowledge;
- *outposts*: bringing back news from the forefront, exploring new territories;

- *pairs*: often brokering is done through a personal relationship between two people from different communities and it is really the relationship that acts as a brokering device.

Brokering knowledge is delicate. It requires enough legitimacy to be listened to and enough distance to bring something really new. Because brokers often do not fully belong anywhere and may not contribute directly to any specific outcome, the value they bring can easily be overlooked. Uprootedness, homelessness, marginalization, and organizational invisibility are all occupational hazards of brokering. Developing the boundary infrastructure of a social learning system means paying attention to people who act as brokers. Are they falling through the cracks? Is the value they bring understood? Is there even a language to talk about it? Are there people who are potential brokers but who for some reason do not provide cross-boundary connections?

Boundary Objects. Some objects find their value, not just as artifacts of one practice, but mostly to the extent that they support connections between different practices. Such boundary objects can take multiple forms.

- *Artifacts*, such as tools, documents, or models. For instance, medical records and architectural blueprints play a crucial role in connecting multiple practices (doctors/nurses/insurers, architects/contractors/city planners).
- *Discourses.* A critical boundary object is the existence of a common language that allows people to communicate and negotiate meanings across boundaries. This was an important thrust behind the quality movement, and it was typified by the six sigma discourse at Motorola.
- *Processes.* Shared processes, including explicit routines and procedures, allow people to coordinate their actions across boundaries. Business processes, for instance, are not just fixed prescriptive definitions. At their best, they act as boundary objects that allow multiple practices to coordinate their contributions.

Boundary objects do not necessarily bridge across boundaries because they may be misinterpreted or interpreted blindly. Rethinking artifacts and designs in terms of their function as boundary objects often illuminates how they contribute to or hinder the functioning of learning systems. An organizational structure, for instance, is often considered as an overarching umbrella that incorporates multiple parts by specifying their relationships. But, in fact, it is more usefully designed as a boundary object intended to enable multiple practices to negotiate their relationships and connect their perspectives.

Boundary interactions

- *Boundary encounters.* These encounters—visits, discussions, sabbaticals—provide direct exposure to a practice. They can take different

forms for different purposes. When one person visits, as in a sabbatical, it is easier to get fully immersed in the practice, but more difficult to bring the implications home because the very immersion into a 'foreign' practice tends to isolate you from your peers. GM, for instance, has had difficulty learning from people sent on sabbatical at its more experimental units such as NUMMI and Saturn because their transformed perspectives could not find a place back home. When a delegation of two or more people visit, as in a benchmarking expedition, they may not get as fully immersed, but they can negotiate among themselves the meaning of the boundary interaction for their own practice, and therefore find it easier to bring their learning back home.

- *Boundary practices.* In some cases, a boundary requires so much sustained work that it becomes the topic of a practice of its own. At Xerox, as in many companies, some people are charged with the task of maintaining connections between the R&D lab and the rest of the corporation. They are developing a practice of crossing these boundaries effectively. Of course, the risk of these boundary practices is that they create their own boundaries, which can prevent them from functioning as brokers. It is necessary, therefore, to keep asking how the elements of the boundary practice—its enterprise, its relationships, its repertoire—contribute to creating a bridge and how the community deals with its own boundaries. And, sometimes, a new practice in its own right does develop at these boundaries, which is worth paying attention to in its own terms.
- *Peripheries.* Communities often have to take steps to manage their boundaries to serve people who need some service, are curious, or intend to become members. Many communities have found it useful to create some facilities by which outsiders can connect with their practice in peripheral ways. Examples of such facilities include lists of 'frequently asked questions', visitors' rooms on websites, open houses and fairs. Some communities have even established 'help desks' to provide access to their expertise in a more efficient way. The idea behind many of these facilities is to provide for some boundary activities without overwhelming the community itself with the task of accommodating outsiders' demands. For newcomers, some communities organize introductory events, mentoring relationships, or even formal apprenticeship systems.

Cross-disciplinary Projects. In most organizations, members of communities of practice contribute their competence by participating in cross-functional projects and teams that combine the knowledge of multiple practices to get something done. Simultaneous participation in communities of practice and project teams creates learning loops that combine application with capability development. In these double-knit organizations, as Richard McDermott (1999) calls them, the learning and innovation that is inherent in projects is synthesized and disseminated through the home

communities of practice of team members. The new knowledge can then be applied and expanded in new projects, and the cycle goes on.

Such a perspective brings up a different way of thinking about these projects. From the standpoint of the task to be accomplished, these projects are cross-disciplinary because they require the contribution of multiple disciplines. But, from the perspective of the development of practices, they are boundary projects. Indeed, participating in these kinds of projects exposes practitioners to others in the context of specific tasks that go beyond the purview of any practice. People confront problems that are outside the realm of their competence but that force them to negotiate their own competence with the competences of others. Such projects provide a great way to sustain a creative tension between experience and competence when our participation in a project leverages and nourishes our participation in a community of practice.

Identities

As I said, you probably know that the earth is round and in orbit around the sun. Of course, it is not a flat plate in the way it appears to be at first glance. You actually want to make sure you know this. It is part of your identity as the kind of well-educated adult you probably are if you are reading this article. You may even know that the orbit is not an exact circle, but a slight ellipse. Chances are, however, you do not know the exact distance between the earth and the sun or the precise difference between the apogee and the perigee. This kind of ignorance, your identity can accept without existential angst because your relationship to the communities where such knowledge matters is very peripheral at best.

I am not trying to make you feel self-conscious about your knowledge of astrophysics. There will be no test at the end of this article. (Did I hear a sigh of relief? No, no, you are perfectly OK just knowing the earth is round, and many of our fellow human beings have lived very good lives not even knowing that.) My point is that, if knowing is an act of belonging, then our identities are a key structuring element of how we know.

Why Focus on Identity?

Knowing, learning, and sharing knowledge are not abstract things we do for their own sake. They are part of belonging (Eckert, 1989). When I was working with claims processors in an insurance company, I noticed that their knowing was interwoven in profound ways with their identities as participants in their community of practice. Their job did not have a high status in the company (and in their own eyes, for that matter), so they were careful not to be interested in it more than was absolutely necessary. What they knew about their job, what they tried to understand and what they accepted not to understand about the forms they had to fill out, what they shared with each other, all that was not merely a matter of necessity to get the job done, but it was also a matter of identity. Knowing too much

or failing to share a crucial piece of knowledge would be a betrayal of their sense of self and of their community (Wenger, 1998).

In the landscape of communities and boundaries in which we live, we identify with some communities strongly and not at all with others. We define who we are by what is familiar and what is foreign, by what we need to know and what we can safely ignore. You are a cello player, but not the conductor who signals your entry, or the dancer who dances the ballet you are playing, or the lawyer whom you saw this afternoon about your uncle's estate. We define ourselves by what we are not as well as by what we are, by the communities we do not belong to as well as by the ones we do. These relationships change. We move from community to community. In doing so, we carry a bit of each as we go around. Our identities are not something we can turn on and off. You don't cease to be a parent because you go to work. You don't cease to be a nurse because you step out of the hospital. Multimembership is an inherent aspect of our identities.

Identity is crucial to social learning systems for three reasons. First, our identities combine competence and experience into a way of knowing. They are the key to deciding what matters and what does not, with whom we identify and whom we trust, and with whom we must share what we understand. Second, our ability to deal productively with boundaries depends on our ability to engage and suspend our identities. Learning from our interactions with other practices is not just an intellectual matter of translation. It is also a matter of opening up our identities to other ways of being in the world. Third, our identities are the living vessels in which communities and boundaries become realized as an experience of the world. Whenever we belong to multiple communities, we experience the boundary in a personal way. In the process, we create bridges across communities because, in developing our own identities, we deal with these boundaries in ourselves.

Which Way is Up?

Our identities are not necessarily strong or healthy. Sometimes, they are even self-defeating. In fact, a whole self-help industry has flourished by offering advice for building healthy identities (Giddens, 1991). Navigating the social landscape defined by communities and their boundaries requires a strong identity. Progress can be described in terms of a few crucial qualities that must coexist to constitute a healthy social identity.

- *Connectedness.* Where are enduring social relationships through which an identity gains social depth? An identity is not an abstract idea or a label, such as a title, an ethnic category, or a personality trait. It is a lived experience of belonging (or not belonging). A strong identity involves deep connections with others through shared histories and experiences, reciprocity, affection, and mutual commitments.

- *Expansiveness.* What are the breadth and scope of an identity? A healthy identity will not be exclusively locally defined. It will involve multimembership and cross multiple boundaries. It will seek a wide range of experiences and be open to new possibilities. It will identify with broad communities that lie beyond direct participation.
- *Effectiveness.* Does an identity enable action and participation? Identity is a vehicle for participating in the social world, but it can also lead to non-participation. A healthy identity is socially empowering rather than marginalizing.

There are potential tensions and conflicts between these qualities. How 'big' can your identity be and still be engaged as well as effective (not merely an abstract kind of identification)? Can you really think globally and act locally, feel like a citizen of the earth without losing your ability to connect with specific communities? Can you live on the Internet and still have a good marriage? In other words, it is the combination of these qualities that matters. Table 3 explores how each mode of belonging contributes to these three qualities.

Table 3. Identity Dimensions

	Connectedness	Expansiveness	Effectiveness
Engagement	Is there a community to engage with? How far back do you go? What kinds of interactions do you have? What do you do together? Do you trust and are you trusted?	Is there enough variety of contexts and identity-forming experiences, such as logging on the Internet and chatting with strangers, going on a blind date, or visiting a foreign country?	Do you have opportunities to develop socially recognized competences by participating in well-established practices? Are your communities ready to embrace your experience into their practices?
Imagination	Do you have good conversations? Do you talk about your deepest aspirations? Do you listen well?	Can you see yourself as a member of large communities, for instance, a world citizen, the heir of long-lived traditions, the pioneer of a world to come?	Do you understand the big picture well enough to act effectively?
Alignment	Do you keep your commitments to your communities? Do you uphold their principles? Do you give and receive feedback?	Do you follow guidelines that align your actions with broader purposes, such as saving energy or recycling for the sake of the planet?	Do you know the regimes of accountability by which your ideas, actions, and requests will be judged? Can you convince others of the potential of a new idea?

What is Doable?

To help identities achieve simultaneously high degrees of local connectedness, global expansiveness, and social effectiveness, here are some design elements to consider:

Home Base. Identity needs a place where a person can experience knowing as a form of social competence. Think of a project-based organization, for instance, where people go from one project to the next, spending a few days in-between on the 'available' list. The learning that they do in their projects does not have a social 'home', unless they can also belong to a community of practice. In such a community, they are not only recognized as competent for the sake of a project, their need to develop their competence is also part of their belonging. Their professional development and the development of the practice go hand in hand: the identity of the community as it evolves parallels the evolution of their own identity. They can talk with peers who understand the way they look at a problem, who appreciate the potential value of a half-baked idea, and who know where the cutting-edge of the practice lies. With such a 'home base', people can engage in a diversity of projects and in interactions with other communities without becoming uprooted.

Trajectories. Identity extends in time. It is a trajectory in progress that includes where you have been and where you are going, your history and your aspirations. It brings the past and the future into the experience of the present. Apprentices in traditional apprenticeship, for instance, are not just learning skills, they are exposed to possible futures. By observing and working with journeymen and masters, they develop a sense of trajectory that expands their identity in time (Lave and Wenger, 1991). Members of a community embody a set of paradigmatic trajectories that provide material for newcomers to construct their own trajectory through a community and beyond. In the generational encounter between newcomers and established members, the identities of both get expanded. Newcomers gain a sense of history. And old-timers gain perspective as they revisit their own ways and open future possibilities for others (Wenger, 1998).

A good way to develop identities is to open a set of trajectories that lead to possible futures. The engagement of one's identity then incorporates imagination and alignment: envisioning these possible futures and doing what it takes to get there. These trajectories can be of various types. Inbound trajectories invite newcomers into full membership in a community. Peripheral trajectories allow a person to interact with the community without making a commitment to becoming a full member. Outbound trajectories, such as the ones offered by schools, point to forms of participation outside the current communities.

Multimembership. Identity extends in space, across boundaries. It is neither

unitary nor fragmented. It is an experience of multimembership, an intersection of many relationships that you hold into the experience of being a person, at once one and multiple. It is not something we can turn on and off. When we go to work, we don't cease to be parents, and when we go to the theater, we are still an engineer or a waitress. We bring these aspects of our identity to bear to some extent in everything we do. Even though certain aspects of our identities become more salient in different circumstances, it would be an oversimplification to assume that we merely have a multiplicity of separate identities. Such a view would overlook the extent to which our various forms of membership can and do conflict with, influence, complement, and enrich each other. The work that we do in attempts to combine, confront, or reconcile various aspects of our identities has a double effect. It is a source of personal growth. It is also a source of social cohesion because it builds bridges across practices. As a result, our identities shape the social structures we live in. The work of identity constantly reshapes boundaries and reweaves the social fabric of our learning systems.

Combining concurrent forms of membership in multiple communities into one's experience is a way to expand an identity. Of course, we can only combine core membership in a limited number of communities, but we can also have more peripheral forms of participation, or even transitory one, such as visits, sabbaticals, immersion, or one-time projects. Communities that can include in their forms of participation a large portion of the multimembership of their members are more likely to engage their whole identity. If I do not have to pretend that I am not a parent when I am at work, I am more likely to put my heart into what I do.

Fractals. Identity extends across levels. You are having dinner with your family, ensconced in an intense discussion of international politics with your teenagers, living—in the local context of the dinner table—your sense of identification with the global environmental movement. Similarly, you may belong to a local church, but this belonging is usually an expression of your belonging to a religion that includes many other people in many other churches. Engaging at the local level of your church is a way to belong at the broader level of your religion by combining such engagement with imagination (you can picture many other churches with people very much like you expressing similar beliefs, even though you have never met them) and with alignment (in your church you follow rituals that conform with liturgical formats adhered to by all other churches). Note how the three modes of belonging complement each other. Engagement is enriched by the awareness that others share the same beliefs and follow the same guidelines. Conversely, imagining the whole community and understanding the value of its rituals and norms gains concreteness by the ability to engage in a local group.

Combining modes of belonging this way creates 'fractal' layers of

belonging. More generally, if a community is large, it is a good idea to structure it in layers, as a 'fractal' of embedded subcommunities. If a community is large and does not have a fractal structure with local subcommunities in which people can engage actively, then it can easily happen that beyond a small core group various segments of the community feel disconnected. Subcommunities could be defined regionally as local 'chapters' of a global community. Some representatives of these local communities then form a global community among them, whose purpose is to connect the local subcommunities into one large global one. This is how some global communities of well engineers have structured their forms of participation at Shell Oil. Subcommunities could also be defined by subspecialties as engineering communities are at DaimlerChrysler, where engineers can join communities specialized in specific components (e.g. wipers, seats, or dashboards) but clustered into broader communities defined according to systems (e.g. body or powertrain). With such a fractal structure, by belonging to your own subcommunity, you experience in a local and direct way your belonging to a much broader community.

Conclusion: Participation in Social Learning Systems

The perspective of a social learning system applies to many of our social institutions: our disciplines, our industries, our economic regions, and our organizations. This view has implications at multiple levels.

- For individuals, this perspective highlights the importance of finding the dynamic set of communities they should belong to—centrally and peripherally—and to fashion a meaningful trajectory through these communities over time.
- For communities of practice, it requires a balance between core and boundary processes, so that the practice is both a strong node in the web of interconnections—an enabler of deep learning in a specific area—and, at the same time, highly linked with other parts of the system—a player in systemwide processes of knowledge production, exchange, and transformation.
- For organizations, this perspective implies a need to learn to foster and participate in social learning systems, both inside and outside organizational boundaries. Social learning systems are not defined by, congruent with, or cleanly encompassed in organizations. Organizations can take part in them; they can foster them; they can leverage them; but they cannot fully own or control them.

This paradox could be bad news because the organizational requirements of social learning systems often run counter to traditional management practices (Wenger and Snyder, 2000). The currency of these systems is collegiality, reciprocity, expertise, contributions to the practice, and negotiating a learning agenda; not affiliation to an institution, assigned auth-

ority, or commitment to a predefined deliverable. But there is also good news. The knowledge economy will give more primacy to informal systems. In a traditional industrial setting, the formal design of a production system is the primary source of value creation. Think of an assembly line where value derives from the quality of the design of the formal process. Informal processes still exist, but they produce value to the extent that they conform to and serve the formal design. In the knowledge economy, this relationship is inverted. The primary source of value creation lies in informal processes, such as conversations, brainstorming, and pursuing ideas. Formal organizational designs and processes are still important, but they contribute to value creation to the extent that they are in the service of informal processes.

This framework suggests two directions for organizations. On the one hand, they must learn to manage themselves as social learning systems and develop such systems internally. This means:

- giving primacy to the kind of informal learning processes characteristic of communities of practice and designing organizational structures and processes that are in the service of the informal;
- placing a lot of emphasis on the meaningfulness of participation in the organization, on the possibility of building interesting identities, and on community membership as the primary relationship to the organization (Handy, 1989);
- organizing for complexity, working to link the various communities that constitute the learning systems in which the organization operates; offering channels, shared discourses, processes, and technology platforms by which local forms of knowledgeability can have global connections and effects; and providing coordination among practices to create complex knowledge beyond the purview of any practice.

On the other hand, organizations must learn to participate in broader learning systems in which they are only one of many players. Companies have learned to participate as one of many players in economic markets to sell products and services to customers taken as individual decision-makers. In the knowledge economy, however, they must learn to participate in learning systems as well. Knowledge production is becoming more distributed, complex, and diversified, in disciplines and industries (Gibbons et al., 1994); in regional economies such as Silicon Valley (Saxenian, 1996); and among consumers who have the potential of forming communities (Snyder, 1999).

In these learning systems, organizations find the talents they need, new ideas, technological developments, best practices, and learning partners. The rules of participation in social learning systems are different from those of product markets. You don't simply compete; in fact, your most threatening competitor may be your best partner when it comes to learning together. If you hoard your knowledge in a social learning system, you

quickly appear as taking more than you give, and you will progressively be excluded from the most significant exchanges.

In a knowledge economy, sustained success for any organization will depend not only on effective participation in economic markets, but, just as importantly and with many of the same players, on knowing how to participate in broader social learning systems.

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Transcription of interview with Daniel

People in the room: Daniel, Carsten (leaves the room shortly after the start of the interview), Loreta ,Mark and Linn

Mark: "We errr have a format of basically short list of questions for you [Daniel] which are specific to your background. Oh, no. Don't let him see the questions in advance. No. No. No. He can't jump ahead. And errr…more questions that are specific to your area of expertise."

Daniel: "Okay."

Anders: "How long do you think it will take?"

Mark: "10 minutes."

Carsten: "10 minutes."

Mark: "10 minutes, maybe 15. For the interview. Let's say 20."

Linn: "What is your education/background? We really have to speed up."

Daniel: "BSc, MSc, PhD."

Linn: "That was in…"

Daniel: "The PhD was in yeast microbiology. Beer specifically."

Linn: "What is your role within the company?"

Daniel: "General expert, process stuff. The actual process by which we…biological medicines are manufactured."

Linn: "Okay, and what is your main responsibility in your everyday work?"

Daniel: "Ooo, I don't know. Erhm…well I basically work projects for customers. Erhm…I generally have and my role ideally should be erh as an expert in those areas that have a biological process area. So it's discussion with the customer to understand their needs and also relating that back to the people at NNE."

Linn: "How do your main responsible…contribute to the NNE Pharmaplan, do you know about CSR?"

Daniel: "Well, no, which, perhaps answers the question. I'm not overly evil. So that's quite good."

Linn: "How would you describe the function or the purpose of NNE Pharmaplan as a company?"

Daniel: "It's erh…It specialises in bio-pharmaceutical engineering. So that means erhm everything from advising the customer to planning for example a facility from scratch, understanding the process and understanding how that relates to that hardware in the field."

Linn: "Okay."

Daniel: "That's quite good that."

Linn: "Are you errr involved in the '1001 ideas' initiative process?"

Daniel: "Yes, yes I am."

Linn: "And, how did you erhm"

Mark: "You have to expand on that."

Linn: "How you created ideas."

Daniel: "I have. One of which, the last one I came up with is when I got a call from a chap called Mark Hewson. And he suggested he had some…he asked me something about XXXXs and I said I sought of knew a way that could be incorporated, that was 1001 ideas, erhm that was erhm and I submitted a few ideas myself for risk analysis and a couple of other various ones. There's about a thousand and I think I can claim about 1% of them."

Linn: "Okay. And what about…we have been discussed about Carsten. How did you…how did the contact established with Carsten? How did you realise he was working on something with XXXX?"

Daniel: "Well…I had a meeting with these lovely students in the Black Swan, I don't know if you know it? Have you been there yourself? After that I contacted the erhm the heavenly bodies in the 1001 and said I had this idea and that we should move quickly. All they asked for was an expert in XXXX. And we looked up who the expert was in XXXX and it turned out to be Carsten. And errr there we are."

Linn: "Okay and what are your expectations for the process of 1001 ideas?"

Daniel: "Errr…I mean… for an idea to become a commercial reality you probably need a few thousand ideas, so it's about 50/50 whether any of them will be actually covered in the field. A few of the more modest ones actually that will definitely be useful. There could be a big one, but a thousand is not many for a big one…you know a breakthrough idea. But, erhm, there are a lot of ideas that could certainly move but needs understanding, by looking at areas we haven't looked at before."

Linn: "How do you see the 1001 ideas, do you see it as like a process for you as errr as a pross…as a process for you as a employee?"

Daniel: "I think the main use for it is to boost morale. To get people engaged and thinking and excited about NNE Pharmaplan and the work here again. It sounds quite cynical but it's not meant to be, it's quite a good idea. You know, to wake people up and use their imagination and get them excited about this kind of thing."

Linn: "Have you worked here for a long time?"

Daniel: "About 6 and half years."

Linn: "And, have you…can you feel a change with this?"

Daniel: "That's hard for me to say because I was here for about 2 and half years then I moved to Belgium for nine months then I moved to USA for two years. Errhm, so then I worked for Bio-Igen in Hellerup, so I wasn't actually in Nyborvej for that time so I can see a difference from the time I left, but that's about 3 years since I've been away. So I wouldn't like to say, it's hard for me to say."

Linn: "Okay, because you said that it…I could understand it you said that it's mainly just going one way, so it needed some change, it needed spark or."

Daniel: "I think it's always, I think every organisation does. You can't erm…no organisation is going to stay lively and engaged. That's always a challenge. I mean, when a company goes from a start-up to a medium-sized it becomes a little more erm quieter and then then spark goes. So, I think that anything that can rekindle the spark is a good thing."

Mark: "Do you see…NNE as a start-up when you left and do you see it as a more mature company now?"

Daniel: "No. I see it as medium-sized then and medium-sized now. I think I do see it as though… erm…less lazy and less fat…and a lot leaner…erm.. they weren't capitalising on their advantages, they were slightly complacent before…erm…for example, I mean there was very

little in the way of word of mouth of there is a huge amount of expertise in this building and erm globally, there wasn't…no real effort was made to capture it and build the efficiencies. And I must say when I was here…and…the job in NNE often do could have been done by a much looser organisation without the overheads and employ people on a semi-independent basis. There's a few companies doing that now and erm they're better at that than NNE is, were as NNE has it's got procedures, it's capitalising on the expertise of everybody in the building who is salaried, that's where it's improved, that's where it's a lot better now. It has erm procedures and tools in place for actually for building on expertise and developing expertise."

Mark: "Do you see the 1001 ideas as facilitating this or as being the cause of this?"

Daniel: "Facilitating it."

Linn: "Um…and erm, to get to the clean rooms."

Daniel: "Yes."

Linn: "What is your knowledge and/or experience of using 'clean rooms'?"

Daniel: "I've used them…pretty well…I first…moved used into a clean room, I think I was 19. That was class 100 and almost all my work has been around them since then."

Linn: "Okay. So…Do you see any issues with the procedures in preparing the gowning procedure and de-gowning procedure at the moment…when you in a XXX XXXX?"

Daniel: "Errr it's a frightening thought that there's people in this company that weren't alive when I first started doing it. [laughter] That's a…yes. Erm…yer, it's a pain in the arse actually…to do the procedure to on and off. Gowning is messy, it's time consuming, particularly if you just need to nip in and do something. People often put that job off because the actual process is just so a pain in the bum. Erm…there's also the huge possibility to mistakes. Of course it's gowning it a real pain in the arse. Erm there's a great movement to reduce gowning levels wherever possible. But there's also the erm [cough], there's also the problem which is…risk analysis is very good in this industry, because you have to look at the… errr…there's some risks that are very apparent. The most apparent risk is you don't gown up enough. And if we say, okay, we don't want to take risks we got to do it properly, you can justify gowning up more. The dangers…err…the risks associated with the higher level of gowning up more are vaguer, it's a bit more time-consuming, people might not do things because, it's all very wishy-washy. Which means that this…erm…to gown up more and more is a much easier case to argue, it's much more solid. And so it tends to happen so gowning levels tend to increase over time in facilities."

Linn: "Okay."

Mark: "So, you say…that there's perhaps too many procedures."

Daniel: "No, there's…I think the gowning level."

Mark: "If it was done properly."

Daniel: "Yer, I think…erm…if we don't represent clean room classified, if you don't' do clean room classified, we can say put on a hair net or beard cover and shoes covers your pretty much, that's fine. Because the vast majority of your debris is going to come your hair, or from your shoes. So, for a clean room classified, most of the time that will be it. Of course, there will be an argument, people are touching things, just gloves, that seems feasible. Maybe a lab coat, okay, do a lab coat, and when you have this argument, particularly if you take it to policy how you argue against a lab coat and gloves? How do you come up with a strong, convincing argument against such things. It's very hard to do. Whereas, technically, I'm not saying this…it's a quick action you can take to show that, yes, look, we've reacted, we've done something it. We've increased the gowning levels, then the problem should go away. And…erm…that's why it's always going to be very, very tempting…and then the facility is clean room classified, when you get into actual places, such as a grade D, well now what I is called described is basically pretty much a grade D environment, but… and you end up to make sure your grade D is of a high enough level you end up making putting on a full body suit, gloves, and you end getting a very highly suited, even for a class environment. And…erm…I think what I would do to justify my argument perhaps… that there is too much emphasis on gowning and doing more and more gowning, rather than doing gowning well. And, of course erm…first of all, there is very little emphasis on doing gowning well because that is invisible, it very harder to see. You can show the procedure, a picture and say this is our gowning, and say this is very pretty. How well people do gowning you can't show on a picture. Erm…also when you go in there's all soughts of habits. I mean…it's not uncommon for someone in a class 100 and run, jog along a bit. Jogging is appallingly bad for particle distribution. But erm…clamping down on that sought of thing is going to be a much lower priority, because it's less visible and harder to measure."

Questions specific to Daniel:

Linn: "So, ya….what were your initial thoughts when you were presented an idea to design intelligent clean rooms?"

Daniel: "Errr, hmmm…my initial thoughts on XXXX was likely, still, look, this was a solution looking for a problem."

Linn: "How did you."

Daniel: "It is still a solution looking for a problem. Errr and have to say when I saw the last meeting I thought, well hopefully we'll something that's presentable. I was actually quite impressed. It's very well thought through and I liked the errm…there are lots of little aspects that I thought suddenly thought that very…were actually killer items. Well, do you remember…the called Mark…I suddenly got very excited, logistics for example. I suddenly got excited about."

Mark: "Yes. Supply logistics. Reducing costs."

Daniel: "Yes. One of the worst things about suits is that they don't fit. And I made a joke about the extraordinary large hood I have to put on. Errm I didn't realise it didn't fit, until I saw this freakishly large hood I put on, and I think this is comfortable. Until then I was very, very uncomfortable. And I just thought that was the same for everyone. It is the same with the gloves, I didn't think I had large, particularly large hands until I."

Linn: "Ca."

Daniel: "Until someone, I saw size 9 gloves and thought what kind of freak has these, let's try them on and oh, they fit. And then my comfort level rocketed and it made it much more easy to work. Err, it's a small factor but it's, again, it's not as well measured. People, okay they've got a suit on, but actually having it fit particularly if you're going to be in there all day is very important."

Linn: "And…what, if any, concerns did you have about the concept of the intelligent clean room?"

Daniel: "When we first saw the errrm. I when I first saw the initial idea, I was slightly, which was presented by Carsten, I was worried it was…slightly over-engineered for which was a small benefit. Erm, of course it has been [?] idea first. My initial concern was…it was over-engineered for small benefit. As I saw this idea being developed, I actually thought no, what your producing is more and more benefits from it, which makes it increasingly feasible."

Linn: "Okay, and errrm…if you should come up with another idea then this to improve a clean room, what would it be?...Have you thought about it in this process?…That there might be other techniques."

Daniel: "One thing that we have is the…what if there is an alternative to a bench? Because benches are, I think. Benches are very, very awkward. They are fiddly things. Errm, and they actually take up a lot of room. Errm, a hole in the wall for example for items, a little hatch,

for items you can pass through is much more practical than, a few people held up waiting for someone to get over bench. So, maybe if there's a very small step over it would make it much easy for people to err change their clothing, this is just an idea. I think."

Linn: "But this is, errr, this is also from the user's perspective."

Daniel: "Yer."

Linn: "And we're using clean rooms, we need to, we are doing, we need to know what is good and what is bad."

Daniel: "I think this is very true. Errm, the other problem is the errm…there generally are procedures on the wall to show you the pictures are very useful. No-one reads the actual procedure, it's in gobbly-gook. Because SOPs are made to cover peoples' arses and to show we have proper procedures. They're not really designed for the operator to read and understand. It's basically, it's legally nonsense to say, look we've told the operator. It's not, it's not to show that the operator understood, the operator just has to sign. One of my other ideas is to abolish normal standard operating procedures because they, they're useless. Errr, umm, yes."

Linn: "To change your procedures."

Daniel: "Change the format, the way procedures are written. Take away the procedures. Which I think the SOPs should just be a database and the relevant bits presented to the operator as and when they need them."

Linn: "Okay. And, errm, does, does the concept raise any ethical issues for you personally or for NNE as a company?"

Daniel: "I think the ethical issues are I imaging are mainly about staff tracking and invasion of where you are. I think those issues are essential covered by the present ID badge, because, at the moment, we are tracked…effectively by an ID badge and lots of the time particularly in erhm some areas there will be cameras. Particularly, for example, I mentioned when I packaged-up dia-morphine, there were cameras on you the whole time. Erhm, so we tend to get those ethical issues…it would not raise further ethical issues than are already there."

Linn: "Uhm. What do you know about XXXX?"

Daniel: "Not much. Erhm…it's I think. It's bar codes with a touch of class."

Linn: "And, erhm…so you said that it may not raise any more ethical issues but…do you think it is because the environment or maybe the people working in this environment have a way of thinking, so they already accept it?"

Daniel: "Yes, exactly. It's not to say there aren't any. I, it's just that…there argu [cough] you badged everywhere you go, they errr because the nature of the regulative environment it's badge access on doors and decodes on doors erhm you'll allowed to go out through some and not through others. It's very highly monitored and you are essentially monitored very closely anyway. So, it's not that there aren't any issues, it's just that they're already there."

Linn: "And, you have already accepted them."

Daniel: "Yes."

Linn: "And do you think it is within the culture or think it is because of responsibility of the firm or the place where you work in?"

Daniel: "I'm not sure. I think, I think those lead on to each other."

Linn: "Yes."

Daniel: "I think because it has to be that way people accept it and becomes part of the culture. I think, in a way, how can I put it? That the requirement. I think initially culture acceptance came because of the necessity. Oddly, if the necessity disappeared the culture would remain."

Linn: "Okay. Do…what do you want?"

Mark: "How many XXXX tags do you think you have…in your life exposure at the moment?"

Daniel: "[laugh] Well, that's a very good question. I'm not really aware, the only thing I can think of is perhaps those tags awkwardly stop me from shoplifting are probably XXXX."

Mark: "Are you aware that your ID badge is XXXX enabled?"

Daniel: "Only because heard it at the last meeting. The truth is, I hadn't. I wasn't aware beforehand. Errr you raise a good point. I was pretty much obvious. I didn't know until quite recent what XXXX was and my notion of it is still vague."

Mark: "What would comment be to the following quote: The limitations of XXXX applications are limited mainly by development engineers."

Daniel: "Well, that's a bit harsh to be quite honest. Erhm [cough] I think, first we can say that for most. There are very few technologies were that wasn't the case, and I think you can argue that has been the case for any single advanced technology. So, I think it's strong…but yes it's true I think the erhm what's limits it mainly is erhm…errr people looking for it as a solution."

Linn: "Uhm."

Daniel: "Cause how it, when the development we come up with a problem that we want solved. And when start to look for possible solutions do we consider XXXXs. Now, development engineers are certainly part of that, but they're not the whole thing. XXXXs have been around for a long time, they're about to revolutionise the industry, and they've been about to revolutionise it for about 20 years."

Linn: "And what about…now…when you think about it…I'm just…thinking, maybe it's also about the customers."

Daniel: "Arrh."

Linn: "The limitations."

Daniel: "I think the industry is erhm peculiar I mean, in that it's errr most industries if you can give an extra 1% of yield, an extra 1% of you know, 1% of yield of up-turn, turnover bite your hand off. In this industry there would be slightly scared. That's because the erhm, they're on a good thing. But, erhm, the one thing that could jeopardise it that they try something that isn't allowed. Technology they go for isn't accepted."

Mark: "Accepted by whom?"

Daniel: "Oh, the regulatory authorities and also there's another strange thing here, often we have erhm the way decisions are made, there's a balance between quality and production. And errr production want to do things faster and make, you know, make more, more, more. And that's one powerful force. The other force is…well that is the ego maniacs-side of the industry. Then you have the conscience-side or the slightly more neurotic side which is represented by quality, which say hold on there. Is it okay, do we know, and then you have the engineers and the development people. Who are, perhaps, on the back of the seat, steering, these two are on the front. Then erhm, first of all the production will, of cause, want to do what they do faster and will be quite excited by new technologies. Not as excited as the development people will be. The quality will say, and we have, [breath] this is where risk analysis is going to big in the industry. We have a very, very, very old fashioned model of risk. We erhm…the car industry is balancing both sides of risk, positive risk and negative risk.

So you would look at also…so as well as looking at the risk you would look at the risk of not doing something. At the moment errr, if, if the way you're doing it has a 20% risk then you know is, so, there'll be problems one to two. If we say we can do it a different way, we eliminate problems one to two, we'll only have problem 10, it is clearly better. You're, you know, eliminating two risks and only getting one, and they say they're all equal and that's going to be twice as good. The car industry would jump at it. The pharmaceutical industry would reject it. Because there is still that extra risk. You're taking on a risk, how can you justify that? They're taking on 10 that wasn't there before. We've lifted one and two but not prepared to live with number 10. You then have a very complex argument. And…this is changing but hugely embarrassingly slowly. It's noticeable that most of the progress, most of the advancement is erhm, particularly in terms of risk and process understanding, is being made in penicillin not in a very high through-put cloud one anti-bodies. The main for this, I would say is that it is a penicillin has become a commodity. A commodity product has many making it, there's no patent protecting it, and it's made in such large quantities. This is actually brilliant because people suddenly have to look at those risks properly. I realise that, okay, what's better, how do we develop, how do we make our process better? So they have to understand the process a lot better, therefore they understand the risks a lot better and a lot more safely."

Mark: "Are you saying that development is linked to market forces?"

Daniel: "Yes, absolutely. And I think the erhm at the moment when the pharmaceutical can just make what they're doing it's fine as long as they don't bugger it up and as long as they don't ruin it fine. There are not going to take any risks."

Mark: "So there's no more development."

Linn: "No. But. You're saying there is a patent on a medicine there, you develop one way and you stick with that because that's good enough."

Daniel: "Yer."

Linn: "And when the patents go off you have, you have so many competitors companies making this so you have to do, you have to really think about how to make the best product."

Daniel: "Exactly. But errr erhm I mean, it's also frightening that one of the big threats the industry has is you know bio pharmaceuticals is 10 years you know there is no patent and any can come along and do it more cheaply because they haven't had the development costs. But…this is embarrassing, you've been doing this product for 10 years and you still don't know enough about it so that someone else can come along and do more cheaply.

That's preposterous. That should not happen. And that's urrr hmmm the reason for that is because basically it was developed and then frozen. Now the reason for that is the fault originally of the regulatory authorities. Because they would say, okay, tell us your process for making it. Now they're shifting to say, okay, now let's understand your process parameters, let's see you continuingly improve. Which is, obviously, far better."

Linn: "Uhmm."

Daniel: "I've seen erhm, I was actually involved in a process where erhm, we, we had a process and in a couple of years we massively increased yield and massively increased the understanding, used different technologies, so it's much purer. We could show it's much purer errr much better quality, far higher yield and production time went from natural processing, once you got the product, which was almost halved. We don't do that, because the original submission on how we do it was the old way. And so we would have to go through a complete resubmission. The very lazy authorities would erhm tell that of cause is for another window. They want risked based approach looking at it and show process understanding errr but also first of all most of the people in the industry are stuck in the old days. And that's the industry's fault and don't' trust the regulators to come through this, and that's the regulator's fault because there's political pressure. Congress, for example, recently said… I'm going on, you're right."

Mark: "That's fine. I know all about this but it's totally new to you guys [the other interviewers]."

Daniel: "But the Congress said come on we want to show you getting value for money. So they went bloody hell, we better get a few more people. What can we get them for? And it's the old thing like you did a change. I'm not convinced. And then you can start to get them on offences that don't matter. And then you have this pressure, which is represented by the Quality Department. Many, many fine quality in quality and many idiots and in any group there are going to be lots of idiots. Say about a third. One in a third will be shaky in their job and you know that's just the bottom third. Well, they're the ones who…the FDA for their credit have never actually penalise anyone for making a spelling mistake. Quality do. There is still a tendency in Quality Departments to penalise you badly because of a spelling mistake in a document. Regulative authorities don't care about spelling mistakes they never have. But, if your job is to look for a fault, and you have powerful bodies whose job is just to look for a fault what you get is they managed, unwittingly, is a hugely conservative industry."

Linn: "Can we have a last question for [Daniel]?"

Loreta: "Should there be some form of psychological way to introduce people, to make them feel comfortable [with introducing new procedures]?"

Daniel: "we are talking about the old system, were you would, perhaps, put on a gown so unless you knew people you wouldn't be able to recognise them anymore and you're walking around in a completely sterile environment with washed down white walls, white everything apart from what is stainless steel. Erhm…it's such a bizarre environment to work, that I think the concern of having you access computers screens is, frankly, minimal. I don't see it has a big issue."

Loreta: "I didn't mean computer screens. You all know that you have to follow the system or, perhaps, you know that you have signed a document, you signed a document that no-one really checks and you feel more relaxed. I don't know."

Daniel: "I'd say there is a culture of no you didn't spoil the book, that's how strong they [?]. That's not the case. There is a certain case of having worked globally, there are a set of culture which do take a more relaxed approach. Erhm…they're not actually generally ones you might erhm, ya, I would say the ones that take the most relaxed approach are those companies that, for example, have erhm badly run, where there's no pressure, you've got the market sewn up and they don't dare stop your product. Then you know erhm then you see some frankly shocking."

Linn: "Do people try to cheat the system? Would you try to cheat?"

Daniel: "No. I'm a good boy. No I wouldn't. It's just not worth it."

Mark: "I think, as a visiting expert, everywhere you go, you, perhaps, pay more attention to new SOPs. Everywhere you go is going to be a new SOP for you, isn't it?"

Daniel: "Yer."

Mark: "So, you're going to pay more attention than perhaps a regular user."

Daniel: "The errr the main problem with SOPs actually often is they're very hard to read, they're very hard to understand in the context because they're technical instruction documents rather than user documents. And erhm you may arrive one day and find you have here please read these 120 of them. Well, who is going to read them? So, in a way, it's not the case of how willing someone is, it's just a case of got a 120. If you, before you got to a play with your video recorder or anything like this you had read manual of the video recorder you'd learn nothing. You wouldn't learnt much from it unless you're sitting down with the video recorder at the time."

Linn: "So errr you don’t think it would be an, an issue for people who have, who have been and would use the same routine for 20 years to change to a new routine with XXXX wristband."

Daniel: "No. No. Because the environment is already bizarre."

Linn: "So you think people would adapt."

Daniel: "Yes."

Linn: "Okay."

Mark: "Here are the list of questions posed. It is just for your reference."

Transcription of interview with Edward

People in the room: Edward, Loreta ,Mark and Linn

Mark: "ge, which basically examines the role between aaaa developers of technology and the users of the technology aaand then try to create aaaa we analyze the best fit. So we don't always come up with the conclusion, but we analyze the processes also so aaam and we come up we're analyzing aaaa basically from your point of view we analyzing how people use XXXXX XXXXX, aaand we looking at perhaps how they could be improved for the process and we come up with the list of aaaa questions and in two areas. One is the general background aaam exercise which we gather we want to listen how do you think about certain things. And then the second one is more related to the users of the XXXXX XXXXX, so...but you won't notice the difference really. But we need to understand the mind of the user aah it is really quite important aaam."

Linn: "Ok and I ask the questions?"

Mark: "Yeah, please"

Linn: "What is your education, what is your background?"

Edward: "By default I'm aa chemical engineer, process engineer"

Mark: "Sorry, your first name again"

Edward: "Edward"

Mark: "Edward...sorry, my memory is not what it used to be."

Linn: "So you are process engineer..can you..and e what is your role within the company?

Edward: "I am OSD and containment specialist as oo tablets, everything that has to do with aa yeah, solid production: sashes, tablets, epavesense, aaamm the non biotech part basically, everything that is traditionally pharmaceutical products and then containment."

Mark: "Containments"

Edward: "Meaning if you have very high potent drugs, aahm protect the operators, the people in there. Aehm so if you produce the pharmaceutical products that you don't kill people while you produce them."

Linn: "Mhhm"

Edward: "Would be a benefit. [laughing]"

Linn: "Sometime yeah. And what is your eehm main responsibility in your everyday work?"

Edward: "My main responsib I am the head whatem of the head, I am the the specialist ouhm one of the top specialists globally for for the tablets, OSD and containment parts, so basically advising on how is the production layouts, how are the rooms layouts, how is the air-lock principles setup, how is the process flow [Linn:"yeah"] in the facility like that, aso I basically design how our XXXXX XXXX area looks like in where the consecutive process taking place."

Linn: "Ok."

Mark: "How would you define your main concerns with with regards to responsibility, what are your main concerns in responsibility?"

Edward: "What you mean concerns in responsibility? "

Mark: "What are you main worries or priorities?"

Edward: "Related to the XXXXX XXXXX? No?"

Mark: "Yeah, with the containment design."

Edward: "Eeeem one part of it [Interrupted by Mark asking]"

Mark: "Personal safety?"

Edward: "Person safety is definitely the highest concern because it is containment and the other one is gmp aspect, it is about hygiene."

Mark: "Which would you say normally takes priority in your experience?"

Edward: "Weeell hm, sometime working mainly with containment I would say the containment part. Because I am drown in if there is potent or poisoned or toxic ingredients involved, then is where people draw me in."

Linn: "Are are you involved in this 1001 idea process or development?"

Edward: "Pretty much, I am in the advisory board of it."

Linn: "Ok. And ehh what are your [Marks voice] expectations for the process?"

Edward: "Can you stop the tape?"

(Everybody laughing)

Edward: "No, just kidding. Eeeh I hope that we get some valuable aa ideas out of that. And I've seen some of them, they are actually quite nice, to enhance basically mmh the future and how we aso the facilities, how they are set up."

Linn: "What is your knowledge and experience using XXXXX XXXXX?"

Edward: "I've been working in pharmaceutical industry couple of years back, since I'm designing them I was also having projects where we were going into aso where we implemented process equipment and process within XXXXX XXXXX and then doing the start up and testing we have been in XXXXX XXXXX. So I've been there a little bit I would say."

Linn: "So yeah"

Edward: "I've I've done my share of gowning I would say." (slight laughter)

Linn: "Okey.And eh.."

Mark: "Question four."

Linn: "And yeah, do you do you are you ehmmm how do your main responsibility contribute to the NNE Pharmaplan CSR resp ehhh program?"

Edward: "CSR program?"

Linn: "Ehh.."

Mark: "Aaaa, that's the secret!"

Linn: "Corporate social responsibility, do you inc, do you intake that in your[interrupted by Mark]"

Mark: "It was just something I knew"

Edward: "I can give clear answer to that what no"

Linn: "Ok."

Edward: "I've never heard about that until now." (laughing)

Mark: "Ok."

Linn: "Ehh do you see any issues eh with the procedures in preparing to enter, the XXX XXXX procedures to enter and gowning and degowning procedures?"

Edward: "Yeah yeah"

Linn: "Which which is these are you main concerns?"

Edward: "Uuu depends where we look, what country we look, basically eeehm I would say the highest risk factor always an operator and operators always wanna take shortcuts, I learned that and if you consider that entering the XXXXX XXXX area that can be a problem for the productions, because it can actually harm your products. Meaning you can contaminate products and on the way out if you walking in containment areas, ehh it can be or in sterile areas even. It's depending what do you define as XXXXX XXXXX. What class do we talk, do we talk sterility? Do we talk only a class D? Or.."

Mark: "Mmm"

Edward: "Or we talk a class B? I mean there is different levels of it"

Linn: "But if we talk ..like the highest level as well."

Edward: "Then I would say it's hygiene is definitely an issue and eh doing the gowning properly."

Linn: "Yeah."

Edward: "And if we taaaalk.. that that I would say."

Linn: "And then then if we talk."

Edward: "Entering the facility, if we talk my containment area, is it degowning or using the proper gowning, but then it should be also closed units."

Linn: "Have you experienced and issues of people, have you seen people now following the procedure correctly?"

Edward: "No, I've seen companies not having the right procedures in this industry."

Mark: "It's interesting."

Linn: "And what about eh you ehm, have you had any difficulties during the procedures, lied while being a user?

Edward: "No, I never did that actually."

Linn: "No."

Edward: "I was sometimes you as a consultant you only go in there once or twice, you telling to them if they change it, it's up to them, if just visit them as well."

Linn: "But but have you had, eh do you find as a user did you find the procedures ehhh difficult to follow?"

Edward: "No not when we I was working in pharmaceutical company when we saw flows we tried to change them aso we adapted."

Linn: "Yeah."

Edward: "Because of course it was once a green field aah you needed to adapt to come to the right approach that when there wasn't order everything is in place sooo we adapted at the levels ferelight. "

Mark: "In your opinion when people were not following correct procedures in your view, was this gen down to the lack of training or was it bad practice on the case of individuals?"

Edward: "Both. You could find both."

Mark: "Ok."

Linn: "Can you present..yeah"

Edward: "You could find"

Linn: "with the idea"

Mark: "Ahm"

Edward: "You could find people who are basically as I said trying shortcuts and the other [mechanical sound] ones, they didn't have this official training"

Mark: "Ok."

Edward: "Or retraining is actually also very interesting problem."

Linn: "Yeah."

Edward: "I think a lot of companies lacking ehm I would say a retraining. "

Linn: "What about the we we have heard something about the actual size and the actual equipment in the clean clean in the XXX XXXXX, do you see any issues with them? "

Edward: "Yeah, I think most of the time the XXX XXXXX are too small."

Linn: "Yeah."

Edward: "That is the common problem, especially when I go to China, Asia and so on it's quite obvious they do not understand the purpose of it and the need or the space requirements to these items and they mainly design these things too little. But you see also here in Denmark to small"

Linn: "Yeah."

Edward:"air-locks, but in generally I see it quite often in in Asia."

Mark: "So is the is the actual companies not understanding the issues rather then perhaps"

Edward: "Yeah"

Mark: "physical constrains or financial constrains?"

Edward: "Yeah, it's not only the companies I would say it's even the engineering companies, even my own colleges do not understand eeeh the reasoning behind it sometimes. Because they do not understand what do you really have to do in these areas."

Linn: "Ok."

Edward: "And how much space you need, how you behave in these areas."

Linn: "So so they don't really look at yeah at the standards when they design."

Edward: "Well this is the problem, we do not get from the company specific sops when we design, and then as I said ehhm if something like that is designed, people sometimes lack these kind of informations and also do not fully know the full picture, how to what is the full operation in these rooms. And this is why usually it's getting to small, suddenly it's much

much more is happening or has to be put in the room and then proper behavior is difficult because you are just squeezed in."

Mark: "Ok. We have a a very quick presentation on a concept."

Linn: "If you have the time."

Mark: "It'll take 2 min. to run through this. Ok [clears the throat] emhaa ."

Linn: "Just aaa, just this eee"

Mark: "Yeah yeah."

(sound on as knocking on the table, most likely from the computer being made ready to show the presentation)

Linn: "me..to find my side"

Loreta: (inaudible)

Mark: "Ok. ...Really don't know how to do this."

Loreta: "(inaudible) have to go out of this big"

Linn: "Ok, just aaa."

Mark: "Ok. It's fine, it's going through page by page so that's fine [clears the throat] Ok, we have a suggestion that's going through 1001 ideas aaaa competition."

Edward: "Oh I know that one. The hygiene scanner."

Linn: "Yeah"

Mark: "And well that's one bit to this which we hoping to integrate."

Edward: "When I was I was basically the would say the sparings partner of the other one."

Mark: "Ok, aaam the scanner [interrupted by Linn]"

Linn: "It's a combination between two ideas actually."

Edward: "I know idea two and I did"

Linn: "Oh ok"

Mark: "Ok, have you seen this presentation from, ok, aahm a typical XXXXX XXXX, lockers, bench, supplies, gloves, clothing, wash area [clears the throat] so into the XXXXX XXXX and this point, wash hands."

Linn: "You enter with your with your ID badge."

Mark: "ID secure type badge, eehm, wash your hands, you check it for in the hygiene scanner, after that, if it is ok, get issued with an XXXX bracelet, which will identify your personal needs: a clothing sizes for example aahm you only get issued with this once you pass the hygiene scanner for your hands. And if it's ok you go through to display and this will tell you the SOPs for getting gowned. So it will be just simple list, using a display similar to this. So, oh initially all being red [Interrupted by Edward]"

Edward: "This is what I brought into the idea, said they should keep doing in case if someone [Interrupted by Mark]"

Mark: "Yeah...it's"

Edward: "intrude the gowning procedures [Interrupted by Mark]"

Mark: "Yeah"

Edward: "it was basic my idea"

Mark: "Aaand at e section here you'd have short range scanner, which will be activated by the wrist band"

Edward: "Mmhm"

Mark: "So when you take it out at this point you will be given a number, a a because you not be different size, so each size could be given a different number."

Edward: "Mmhm"

Mark: "So"

Linn: "So"

Mark: "So you it direct you to the exact size of gown or hat."

Linn: "Yeah, bit personalized within the ,

Edward: "Mmhm"

Linn: "within your card."

Mark: "So in the end you should have all green, because you come through at the end before you allowed to enter the door you find the scan, which is all green and then you are allowed through. Aahm [noise from the table surface] presentation, very very quikly. Do you want to ask the questions?"

Linn: "Yeah there will also, yeah there will be like, yeah screens telling you what to do, what is the next step."

Edward: "Mmhm"

Linn: "When you have scanned your hands."

Mark: "You could have a big television, and you could have multiple people"

Edward: "Mmhm"

Mark: "on one display."

Loreta: "Have you actually been working talking about it with Carsten, perhaps you were collaborating?"

Edward: "No, but I was given to Camilla, who was idea 98 the hygiene scanners."

Loreta: "Ok."

Mark: "Mmhm"

Edward: "I was ehm how would you call it, ...while she came up with the idea and then she gave it to me to review, I gave her some input and so on."

Mark: "Mmhm"

Edward: "Ehm because I was there is a problem when people entering the gown, the system does not know how many people are in there, when you go out, meaning when you open the door with your card scanner

Mark: "Mmhm"

Edward: "five people can go in the system only detects the first card. The next thing is also when you open on the outlet, eehh the first person opens the door and five people can go out."

Mark: "Mmhm"

Edward: "So that is the hole in the system. The it's also that you can basically eehm hygiene is not only washing hands, it's a disinfection step you have to consider.

Linn: "Mmhm"

Mark: "Yep"

Edward: "That disinfection step should be a validated version how you do it and ehm I was recently at the company in Southern Europe oh it's the Southern Eastern Europe, and ehm they didn't have the similar system for scanning but they had aahm disinfection systems, so you basically put your hand into a box and you get similar amount of disinfectant, so you don't use to much or too little."

Linn: "Mmhm"

Edward: "So more or less and then."

Mark: "Mmhm"

Linn: "And you use it proper."

Edward: "Yeah that's the next thing...mmm"

Linn: "And what about.. ehm, so we were also thinking about that you actually you take your card through then you press a code before entering, so you actually limit that, ... but ok then five people can of course just follow you."

Mark: "No is there always way around this."

Linn: "Yeah"

Mark: "Eehm at least it's not really for this situation on this interview, aahm"

Linn: "What were your initial thoughts when you were presented for this idea?"

Edward: "That's quite a good idea, otherwise I would have not made some"

Mark: "Ok."

Edward: "review marks and would not be [Mark laughing] ready to do it [Mark laughing], it came sort of natural because eehm when I it was presented I said yeah, I take care of this and"

Mark: "Mmhm"

Edward: "this disinfection thingy and so on, I think they I also heard in this company they actually a scanner, they knew how many people were in the XXX XXXX, so until everybody had used it, door didn't released, so."

Mark: "Yeah"

Edward: "Because they need to check"

Linn: "Mmmh"

Edward: "how many people are in, how many people do wanna go out and so on."

Mark: "This is very it's technically simple thing to get around."

Edward: "Yeah yeah but you still people still need to invest the money to do it."

Mark: "Yeah"

Edward: "It's the problem."

Linn: "And and it's also some of the ideas we haven't presented now. What if any, did you have any concerns when you were presented with this idea?"

Edward: "Mmmh"

Mark: "No, it's just ones he just covered, eehm.."

Linn: "That's the.."

Mark: "Twelve."

Linn: "Does the concept raise the ethical issues for you as a user?"

Edward: "Yeah, I know the last sentence in this idea it stated that people could be traced and blah blah and so on and I think it's a little over the top, I mean they are in production, everybody knows if you use this scanner to come into the building, you are in the building and of course you should be doing that, aso I don't have any ethical eeeh, issues of the tracing within the facility, I think this section obsolete to discuss in my mind. Because you are at work and it's not tracing your private life anyway"

Mark: "Mmmh"

Edward: "just so you are doing proper procedures."

Mark: "Ok."

Linn: "Do you think people will try to get around or to cheat the system?"

Edward: "No, I don't think so."

Linn: "Ok."

Mark: "Mmmh"

Edward: "Well it would iiit it's say if you have the XXXX technology eeh for the gowning, for the bracelets, for the door, etcetera, eehm also you should have it on the scanners if you ask me, so you know who has actually disinfected himself."

Linn: "Oh, we would have that, I didn't understand.."

Mark: "Yeah yeah, that would that's part of it as well, eehm we been advised that maybe they actually before people they get washed they might be putting on the head gear in which case that would have a passive chip and above the wash basin there could be a scanner to prove they actually already got their head gear on one example."

Linn: "Before you, when you enter you you have your you take your card and you press now I'm going to and then it activates the water or you take your your this on and then and then it activates the water and then when you have scanned your fingers afterwards for the content if there is any bacterias then the wrist band so it's will come so you haven't and then your hand are clean, you take this sterile wrist band on and and then so it's actually."

Edward: "Yeah but then your drawing doesn't fit."

Linn: "Yeah but that's."

Edward: "Your presentation doesn't fits."

Mark: "Yeah."

Linn: "But then but then"

Edward: "You have to wash to cross over to the clean barrier and so on."

Linn: "But eehh"

Mark: "Yeah do you have any issues with regard to this clean barrier, the the so called bench? Or did you have any issues with that?"

Edward: "Not inside."

Mark: "Ok. Eehm ok, eehm, question thirteen."

Linn: "Eeh what do you know about XXXX?"

Mark: "In general terms."

Edward: "Do you want a technical description what it does or just that I know what it is?"

Mark: "Well if you have got the background to describe technical description that would give us some information."

Edward: "Well you have a little chip, it's more like an antenna while anything, it can be encoded with whatever information and when you "

Mark : "Mmmh"

Edward: "pass by in a certain distance of a reader in second this information can be read."

Mark : "Are you aware of the different classes of chip?"

Edward: "I'm not that deep in it, but I know there different classes with the different level of eehm memory so to say."

Mark : "Yeah"

Edward: "Eeh different level of information aso how much you can store."

Mark : "Ok."

Edward: "I know that."

Linn: "Do you do think that would be better ideas to improve that this process? This process. Or have you come across?"

Edward: "I think the idea generally is quite good, I think it is a little overkill if you wanna have an XXXX on a on a on a head cover and so on, because I would just say that is follow the picture and just do it, but on the gowning and eeeh the hands and so on I would have it and on the wrist band maybe, but eehm, yeah, for the head cover, beard cover and so on I would not really have an XXXX, that would be an extreme running costs related I would say also."

Mark : "Sorry on the.."

Edward: "Running costs opex."

Linn: "On on the he is eeh"

Edward: "On the beard cover and"

Linn: "The beard and the head cover."

Edward: "I'm only temporarily, that it's just I'm lazy [Linn laughs], and I am training up for the November." (referring to his beard)

Linn: "Yeah"

Edward: "Eeeh no eeeh."

Mark : "Haven't you mentioned clean shave and first November for that?"

Edward: "No no, it's only that one stays."

Linn: "Yeah"

Mark : "Aaaaa"

Edward: "Normally I am, [Mark laughs] it just last few weeks I've been lazy. I noticed that when I was eehm last week in a production area and I had to put the full thing and I eehmmh [Edwards laughs]"

Mark: "So you in general terms you think that the passive chips might not be required on all clothing?"

Edward: "Yeah"

Mark: "Ok."

Edward: "It's depending I mean a beard cover and I had cover, this is not what you really wear when you go there first, but that is to thin"

Mark: "Mmmm."

Edward: "to small eehm equipment I would say."

Mark: "How how would you explain this to the auditors, who would need complete ehmm traceability on how people follow the procedures?"

Edward: "That is a good argument. Could say they are definitely retrained and trained permanently and these things are checked. That could be an argument. Until now nobody is doing this with traceability of XXXX."

Mark: "Mmmm."

Edward: "Soo and say ok, that is ... just checking my training, or checking by ... ehm spot-checks, but in generally if you go into a class B"

Mark: "Mmmm."

Edward: "I would say having the beard cover on is the least, not on is the least problem, since in class B you have so much other gowning on top of it, you cannot see it anyway, but of course they would be cheating, but I think people would not really forget it, aso that is I've never seen somebody not."

Mark: "But if we go back to one of your earlier comments, that ehmm people often take shortcuts."

Edward: "Yeah, but I've never seen in the pharma production that somebody is not taking the head cover or the beard cover, that is always on."

Linn: "But maybe take"

Edward: "That is to visual."

Linn: "taking it in to the eeeh, maybe following the eeh, not following the correct order?"

Edward: "No, it's more like these things, how do you wash your hands. Have you been in the sterile environment before?"

Linn: "Yeah"

Mark: "I have."

Loreta: "I haven't."

Edward: "You know how you wash your hands and so on, how you follow the procedure, and some people just, that is something that I take short cuts. Or when you take your sterile gowning on"

Mark: "Mmmm"

Edward: "I mean this is a nightmare, you know what you come from D to C, strict and then you go from C to B, and B, how you touch the glows, how you touch your gowning, that you do not touch the outer side and all the stuff, I mean."

Mark: "So think it's really"

Edward: "if people do not wash just put it on."

Mark: "Yeah."

Edward: "That can happen."

Linn: "So you you don't that it is a problem for the people to do it in the correct way? You just"

Edward: "I think on the small things like eeh the mal the very very visual aspect of a gowning I think people are not tending to do a shortcuts, because everybody can see it in a split second, it's more these not direct visible things where they take shortcuts. Taking do not take the shoe cover it's night shift do not take shoe cover out go over the bench, go to the toilet, go in again, stuff like that, or.."

Mark: "Yeah."

Edward: "That's how"

Mark: "Yeah, how do you think people would react if they were forced to do eehh these things more carefully?"

Edward: "Mmmm I think only those who permanently cheat would be a little bit annoyed, but they would accept it.."

Mark: "Ok."

Edward: "Because there is no other way around it, at the end."

Linn: "Ok."

Edward: "It's a little a mixture I would say, what is the behavior, you would definitely see difference in day shift and night shift."

(Mark is laughing)

Linn: "That is quite funny."

Edward: "No, it's natural."

Linn: "Yeah..yeah, but I think it is quite funny that you think differently now there aren't many people to to see me or look at me."

Edward: "Well, I have seen people going at night shift with chewing gums into aaa class D."

(Mark is laughing)

Linn: "Yeah"

Edward: "I have seen women going with make up into a class C ..., sooo I even seen or heard, I haven't seen it life, but I've heard after an audit that the woman who took the medical audit refused to take her makeup off."

Mark: "The one conducting the audit?"

Edward: "Exactly. ... And that was just here, in Copenhagen area."

Mark: "No way! "

Edward: "Yes, way, and that was from, I don't know actually where she was from, it was from eeeh, not this continent, but yeah. She refused, and then they and to find basically for class C, they put her into class B gowning, fully masked, everything. ... That's happens here, I mean, I can tell you other things. "

Mark: "She is just doubled or tripled cost for the inspection."

Edward: "If I would have been the HAC or the responsible, yeah, not gonna happen, you do not come in if you do not follow the procedures."

Linn: "Mmmm"

Mark: "So she worked for a company like Lloyds or"

Edward: "No no, she was a medical agency ... from a country."

Mark: "Oooooh" (whispering in big surprise)

Linn: "Yeah"

Edward: "Talking about trying going around and cheating, or whatever. ... and that's not made up, I mean that's foot serious."

Mark: "Aaah no, I could believe e that we are all aware that different cultures operate different practices."

Edward: "Oh China is funny in that one"

Linn: "But if, problem is that people we people don't always these maybe don't see the con, they can't see the consequences of their behavior"

Edward: "But if you are medical"

Linn: "Yeah yeah"

Edward: "auditor, you know all the consequences [laughing]"

Linn: "But that's, that's the scary thing"

Edward: "Yeah"

Linn: "that you might just see it as a job or something you don't ehh look at, we we just, we have been researching about why you should eehh why it's also important, why are the contaminations risk and how may it affect, and there are, actually when you are doing or making medicine, you can kill people."

Edward: "Yeah, I know."

Linn: "And that is very scary [laughing]"

Edward: "I know. Trust me, especially with the things I work with. I have things when you see grain of solt and that would be an API when you throw it into a"

Mark: "Mmmh"

Edward: "Olympic swimming pool"

Mark: "Eeeh, you have to explain API to my colleagues."

Edward: "It is pharmaceutical ingredient, aso the row material"

Mark: "Mmhm"

Edward: "that makes as basically"

Linn: "Yeah"

Edward: "You take one grain of salt and you throw it into a Olympic swimming pool"

Mark: "Mmhm"

Edward: "dissolve it in that one, that equals to two and a half thousand cubic meters of water. If you would jump into that water, after words you would have an overdoses."

Mark: "Hhmm"

Edward: "The grain of salt of, something like in this one you see."

Linn: "What that's crazy."

Edward: "That strong are ingredients in our days."

Mark: "This is why it's so expensive per gram."

Edward: "Gold is cheap."

Mark: "Yeah yeah... Do you want to copy the questions we just asked you?"

Edward: "No, that's ok."

Mark: "Ok."

Linn: "Ok."

Mark: "Thank you very much for your time."

Transcription of the interview with Freya

People in the room: Freya, Lene, Loreta ,Mark and Linn

Mark: "What is your education/background?"

Freya: "I have a master in errr I am a biologist, Master in biology from the university in Copenhagen, 25, 26, 27 years ago. Actually I am a botanist, not many of them left…but I am. And then I have errr a quality management errr system auditor education too. Way back in the 90s, 1960, 1996 I think. And then I have errr, errr what do you call it in English? en diplom i ledelse, diploma in management."

Line: "Management."

Freya: "Management. Errr conducted by something called UCC. UCC?"

Line: "Uhmmm."

Freya: "And a lot of other management courses and so."

Mark: "The second question. What is your role within the company?"

Freya: "I'm the stream leader of HSE and errr sustainability and I've just been employed from the first of June, this year. So only a few months."

Mark: "If I can ask a follow-up question on here. What is meant by Stream Leader?"

Freya: "It is the streams in…I'm employed in the global consulting. You know our organisational diagram. Have you seen that? Or you should ask errr what's he called? [tapping on table] Anders for that. And you'll see that our part of NP is called Global Consulting errrm and Global Consulting is quite different from the other part of the Company. Which is a more traditional engineering company. Errrm and a part of all the departments in Global Consulting is called streams. So that's why."

Mark: "Ok. Question…"

Freya: "I think that it is important that, that you try to distinguish between the consulting part of the firm and the engineering part of the firm. That's why, that's why…I think that maybe I act differently cause I'm in the consulting part. I think. You'll…maybe you can…ya… use [?]"

Mark: "What is your main responsibility in your everyday work?"

Freya: "I'm a stream leader, I'm department leader. I hire and errr…when I took over the department errr this Summer we were only two, three employees and now we're 10, 11, 12. So errr most of my time I do interviews and errr con errr participate in conferences and you knows classes [?] and our services. To…the biotech and pharma sector."

Mark: "How do your main responsibilities contribute to the CSR programme?"

Freya: "Now you, yo, yer talking about the CSR programme. Our CSR programme because we haven't…we…haven't a dedicated CSR programme."

Mark: "On the Company website."

Freya: "Ya. Ya."

Mark: "There is a mention of a CSR programme."

Freya: "Ya. That is an over-statement I think. Ya. We have errr one of the things that I would go to tell you about later maybe for 2014 I have planned to do a more errrm a more sophisticated CSR strategy. So, that's why. [laughter] So, errr ya. But, but my main responsibility now is that I have taking over the COP reporting, as a reporting con…in relation to the UN Global Compact. That's my responsibility and actually tomorrow we, we start up that process for this year."

Mark: "Just to clarify for us. COP programme, do you mean committees of the parties in this case?"

Freya: "Ya."

Mark: "Thank you. Ok. How would you describe the function/purpose of NNE?"

Freya: "Errm…I think that, that our slogan or, or mission statement, that we errr we do engineering for a healthier world says it all, says it all. Errrm…I've been employed in various companies in Denmark in Grontmij – Carl Bro and in Birk and Krogboe now called Alectia and I've never been, never, been to a company like NP. They're…were the standard…the… is so extremely high errr and where the people are so extremely dedicated."

Mark: "Okay. I'm sorry to interrupt you. The last company you mentioned, just for the tape."

Freya: "Ya. Birk og Krogboe it's now called Alectia."

Freya: "Electric."

Line: "Hmmm."

Freya: "Alectia. It’s an engineering."

Line: "Company."

Freya: "Ya."

Line: "Hvad laver de ellers?"

Freya: "Øhh nu. Det er en almindelig rådgiver tror jeg."

Line: "Ya."

Freya: "Ya."

Line: "I think it's, er det rådgivende ingeniører?"

Freya: "Ya."

Line: "Ya, advisering engineers."

Mark: "What skill sets do you prioritize within your area of responsibility?"

Freya: "What do you mean about skill or skills sets?"

Mark: "Errr…what kind of skills are most valuable to…within your department?"

Freya: "Competences or."

Mark: "Yes."

Freya: "Competences. Errm…that's a good question…errr…referring to the discussion about the consulting part and the engineering part because…errr...arrh...erhm...how should I explain it. I think they're…one of the main skills…errr…errr…my employees have to have arrh consulting abilities. The ability to listen, to perform, to…errr…errm…deliver to promise and so on and so on. And it might seem…errr…easy for some of us but errr you know that there's 1500 engineers out there, and some of them couldn't dream of taking a sales…attending a sales meeting or conference or something like that. So, consulting abilities and the…errr…aim to thrive to be a, very, very sharp consultant. That's a…then you know, you can be an engineer or biologists or…and that's…you, you…you never get near NP if you

haven't your, your bases…errm…competences…errr…tick, tick, tick. Forstår du hvad jeg siger? It's difficult to explain in English."

Line: "Mmmm. But that's alright."

Freya: "Okay."

Mark: "What is your role within the '1001 Ideas' competition?"

Freya: "I have errr…two of my ideas…erhm…errr…went through from 1000 to 100. So, so I have two ideas which I'm going to have errr…errr…two workshops actually. One about…errr…change in the reception area erhm and one about sustainability. And then I'm stream leader and in this context stream is not a department but a collection of people. Erhm…I'm stream leader for errr 14 or 15 ideas concerning sustainability."

Line or Loreta: "Uhmm."

Freya: "Oh…so I'm very busy…on Thursday."

Mark: "How do you see the competition contributing to NNE?"

Freya: "What? Why do you call it a competition?"

Mark: "It was explained to us that is was a competition."

Freya: "Ya. That, that's real, really hvad hedder det interesting. You should errr elaborate a little bit about that because. I don't see it, and I will not see it as a competition. Because it's about innovation, and innovation hights. I don't know if you can say that in English. In, in Danish it would be, we talk about innovationshøjder. Errr…erhm…and it's about getting ideas with no constraints. No errr…so it's not a competition. And, and I think it's really important, it's not a competition. We do not compete."

Mark: "What are your expectations for the outcome?"

Freya: "[light laughter] Errm…I'm looking very much forward to Thursday. To the day, because…I think there will…errr…experience…erhm…you know laughter and errr curiousness. Nysgerrighed. We will see errr engaged people who will feel wibes in the building errr, ahhh…I hope…I'm a little bit concerned the time afterwards, and I have talked to Finn Dyrhus. Do you know him? About that. Because I think that we have not been able to communicate the time after Thursday. Good enough and that's the point. So…erhm…maybe that's errr not to be taken down to paper, but, but quite a lot of people har trukket mig til side and said that what are we going to be doing afterwards? What about our ideas, what if

my idea, my idea do not survive? What then? Is.. Did I waste my time or…so…if we are going to do it again, then we, we have to have a kind of timeline, so you can see, well now, what's next step, what are we going do? What is uhmm, and so on."

Line: "What is your ideas for the time after Thursday?"

Freya: "Errm…I know that Finn has now called us into a errr whole day meeting on the 16th of December. Errr…a more classical evaluation and talking about what was good and bad. But it's only the project managers which have been invited to that errr they…and I think that's wrong in a way. If you really want to, to errr work with new innovation methods, new ways of thinking, if you…altså NP wants to be outstanding. Errr and if you want to be outstanding then we have to errr develop outstanding methods toooo…conduct or plan these kind of processes. Forstår du hvad jeg mener, jeg kan godt høre det er lidt uldent, men... I don't have the answer and the fact is, but I think that's a major drawback in this process. You don't have this visualisation of the time line."

Mark: "Thank you. Errr, now the set of questions we erhm did not post to you."

Freya: "Uhmm."

Mark : "What is the prime driver for the CSR programme at NNE? What is your main concern for implementing a new CSR programme?"

Freya: "A new strategy, ya. Erhm…I think…erhm…it has everything to with this outstanding ambition. Because…it is obvious that you can't be outstanding if, and then not have a CSR strategy or not cope with in errr…not be in compliance with so and so and so and so. So it's more like errm, errm…implicit, do you call that in English? Altså, det ligger implicit."

Line: "Ya."

Mark: "Who prepares and approves the sustainability reports produced by NNE?

Freya: Errr…I…have very little history on that but, but errm before I was errm employed, erhm I think that's classical thing. If there was HR department errr which took care of errr together with errr the errm accountant. Revisor, what's the name for revisor, accountant?"

Mark: "Accountant."

Freya: "The external accountant."

Mark: "The auditor."

Freya: "Ya. Ya."

Mark: "How are the reports distributed to the stakeholders?"

Freya: "I don't know actually. Yes. I don't know. And through the website, of our external website. I don't know how. Errr I think that I'm going to change that. [light laughter]"

Mark: "How do the ISO standards that NNE follow impact on the management of NNE?"

Freya: "Erhm…you have been introduced to our errm QMS…model. QMS?"

Mark: "Not in any detail."

Freya: "No. No."

[papers being rustled]

Mark: "Should we stop the tape at this stage?"

Line: "No. No."

Freya: "No. Because…if I take…[papers being put on table]…errr…ya…actually we have, we have errm…arrh…we have a QMS system in errr con, as a errr, which errr consists of QMS how to do errr, errr what to do and then errr and so-called our model…what to do and if you're, if you're in doubt or need example the we have our wiki. Erhm."

Line: "And what is QMS?"

Freya: "Quality management system."

Line: "Oh ya."

Freya: "And as part of every project, and it is every project, you are errr obliged to go through a HSE errr check list. And errr the check list errr is the way that we erhm implement ISO 14001 and ISO 18000. Erhm, so, you can tell, you can say erhm, we don't make such a fuss about that we are certified according to 14001 and 18001 because it is an integrated part of our QMS system and… but the systems…we, forces us to make that continuous improvements that we are obliged. So errr ya."

Mark: "How many XXXX tags do you come into contact with in your daily life?"

Freya: "Once again, please."

Mark: "How many XXXX tags do you come into contact with in your daily life?"

Freya: "RFI what?"

Mark: "Tags."

Loreta: "Do you know…"

Line: "XXXX."

Freya: "No. What's that?"

Mark: "Do you know what XXXX tags are?"

Freya: "Tags? Sig det lige på dansk, er der noget dansk ord."

Line and Loreta: "XXXX."

Line: "Tags, chips."

Freya: "Chips. Okay. None I think. I don't know."

Mark: "Okay."

Freya: [light laughter]

Mark: "What if I was to say that your ID badge is XXXX enabled, what would be your response?"

Freya: "Ya, maybe."

Mark: "Okay."

Freya: [light laughter]

Mark: "Okay. Final question. Do the tags, the chips."

Freya: "Uhmm."

Mark: "Raise any ethical issues for you personally, in your daily life?"

Freya: "So now, I'm not speaking as…stream manager but I'm speaking as Freya?"

Mark: "Yes."

Freya: "Okay. Ethical issues!"

Line: "We are thinking a little bit about the awareness. Why you weren't, wasn't aware that you have XXXX tags in your card."

Freya: "No. No."

Line: "Ya."

Mark: "You don't see any concerns with carrying these things around with you?"

Freya: "Nooo. No."

Loreta: "For instance, tracking, the data security such aspects?"

Freya: "What, what is the alternative?"

Mark. "Okay."

Freya: "Because I want to be in the building with, which, where in the seven or eight o'clock at night and not meet you [laughter]. Errr. And that's… Nooo. Sorry. No. No."

Line: "That's alright."

Mark: "I don't have any more questions. Do you have some questions?"

Line: "Is there something you want to tell us? Or have you thought about something when you saw the questions?"

Freya: "You will participate on Thursday? All."

Line: "Yes."

Mark: "Yes."

Freya: "Maybe I can just errr think about, altså elaborate a little bit. And if I will see you on Thursday and then I might just oh…"

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MEET YOUNG PROFESSIONAL MARK HEWSON

Mike McGrath

Sometimes projects don't turn out as originally planned. That is the case for Mark Hewson, who is in the process of completing his Master's thesis. The conversations he had with ISPE Members, among others, took his research in an unexpected direction. However, these conversations also revealed an area in which there is tremendous potential for career development gains for pharmaceutical engineers.

Mark Hewson is completing his Master's degree in techno-anthropology at Aalborg University, Department of Learning and Philosophy, in Denmark. He set out to examine the mechanisms that allow a novice pharmaceutical engineer to progress and be recognized as an expert in the industry. To move his research forward, Hewson, an ISPE Nordic Affiliate Student Member, reached out to fellow Members at ISPE events and even started a discussion on the ISPE LinkedIn page (www.linkedin.com/company/ispe).

"I tried to network with as many people as possible at events and get my question to them during the break times," says Hewson. "I found that I had to get people when I could because I never knew when I'd be able to get them again. People are very busy working on projects, which is a good thing for them, but it made it difficult to pin them down for an interview. But it was very useful, enlightening and helpful."

It was in those interviews that Hewson discovered a lack of clarity in the industry.

In setting out to define how an individual could move from being a novice to an expert, Hewson first had to define what a novice is, which was simple. He then had to define what an expert is before he could determine what it takes to move between the two.

That proved more difficult to define. "When I tried to dig deeper into this, I didn't get a consistent answer," says Hewson. "It appears to be largely dependent on the individual company concerned. This means that a subject matter expert (SME) for one company can be a complete novice for another company. How can I ask the original question when no one can really define what an expert is? So, my focus became how to define an expert in the industry."

According to Hewson, the ability to clearly define what it takes to be an SME could have wide-ranging benefits within the industry. The first definition would benefit the engineers themselves. "I see this as a way to encourage potential employees who see a structure for promotion and development," he says.

ISPE Members' input takes Mark Hewson's research in a new direction.

The second definition would benefit companies, both through recruitment of a broader range of talent and by establishing a competitive advantage. "By doing this, I think they're going to attract potential employees who might have overlooked the industry, because if employees can't see how their skills might be used, or a career path for them, they might look elsewhere," says Hewson. "I think it's also a tool when bidding for a contract. Companies can say 'We've got this way of proving our expertise; have our competitors got this?' I think customers will have more faith in the skills as they apply to the contract. So, it could be a competitive plus for companies to develop something."

After he submits his thesis in August, Hewson says that he would be open to continuing his research via the PhD route or participating in the development of industry-accepted definitions of SME skillsets.

Just as the ISO has set standards for quality, Hewson sees something similar applying to SMEs in pharmaceutical engineering. "I would like to see some kind of structure or framework in place that pharmaceutical engineering companies can develop," he says. "Even if it varies from company to company, it could fall into a larger framework that allows for some kind of support or validation of skills in the workplace."

Despite the change of direction, the experience has been good for Hewson. "I have attended network events and spoken to participants on a range of issues such as sustainability, chemistry – a whole range of subject matter. It has been quite enlightening and very informative."

Hewson intends to present his findings to ISPE committees in Denmark and Scandinavia, who have shown interest in his research. Anyone wishing to contact Mark Hewson regarding his research can reach him via his LinkedIn page (dk.linkedin.com/pub/mark-hewson/2a/139/636).