# CHALMERS

# System tools at Pharmadule

*An investigation of the interaction of system tools in project phases*

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# SUMMARY

Pharmadule AB is a leading global provider of modular facilities for biotech and pharmaceutical industries. The company recently finished a mapping of the company's activities and it has been connected to upgrading. It has appeared a need to identify how system tools are integrating the various processes. The company wants to investigate whether their system tools support their processes or if they are forced to work in ways that are not described in their processes.

This thesis deals with the mapping of system tools related to the processes and how the system tools provide employees with support for their work. In addition to this, there has been performed a part of a gap analysis due to the  information management system ISO 27001.

The aim of the thesis was to see if the company's system tools support their processes or if the employees are forced to work in ways that are not described.
The analysis is based on interviews of employees, a survey the employees were asked to complete and the investigators personal experience of job in the department for Document Control on Pharmadule AB.

The result of this study is that employees work with IT tools in ways that are not described. The company must develop its processes and ensure that all process descriptions are implemented in the business. The part of the Gap-analysis that has been made is an indication of what remains before Pharmadule AB can implement the information management system ISO 27001. To get a better view the company is recommended to fulfill a complete Gap-analysis according to the book "Mät din informationssäkerhet -Gap Analys."

# Table of context

# 1 Introduction

Pharmadule AB is a world-leading supplier of modular production facilities for pharmaceutical and biotech industries. Since the start in 1986 Pharmadule has produced over 50 facilities for clients like Eli Lilly, Merck, GSK, Astra Zeneca and Shering Plough.

## 1.1 Background

Pharmadule is a line organisation and gets competence from the line to the projects. The company's projects are all parts of the clients' projects which result in that the company complies with clients' desires to a very large extent. This is an underlying cause of the need of a review and standardisation of the processes of the company.

From 2001 to 2007 Pharmadule AB was a part of the Pharmadule Emtunga group where Pharmadule was intended for the pharmaceutical industries and Emtunga intended for offshore industries. A decision was made that the company should be certificated according to ISO 9001 and ISO 14001, and the implementation of well documented management system began. During the implementation of the management system, a lack of interest for these issues within the organisation was discovered. Besides the common system there was a compromise as to both parts of the organisation. In 2007 the company was divided into two separate organisations; Pharmadule AB and Emtunga Offshore AB. As a result of this separation the interest in upgrading the management system increased. The upgrading was based on ISO certification and the target was an integration of quality- and environment management systems.
The mapping of the company's activities has recently been finished and connected to upgrading. There has appeared a need for mapping the Information System/Information Technology tools to see how they interact in the different processes. It is also in the company's interest to find which tools that are used in the processes. The company wants to investigate if their system tools support their processes or if they are forced to work in ways that are not described in their processes.

## 1.2 Purpose

The aim of this bachelor thesis is to map and describe the company's usage of IT tools and to relate and to verify the tools to the company's process description. This will result in an overview of the processes and which systems they are depending on, in other words; to further develop their processes. During the process of mapping the system tools, an overall picture that shows, if Pharmadule has an adequate basis to fulfil ISO 27001, should emerge. This will give the possibility of a standardisation of the company's working procedures based on the interaction of the processes with the system tools. The aim of standardisation is to create a frame for how the work within Pharmadule shall proceed and a way to incorporate an IS/IT management system. A standard like this will give the clients a better view of what is being offered, and client requirements in addition to the standard will increase the client's costs.

## 1.3 Delimitations

The processes within Pharmadule are divided in a way that describes the different phases of the projects. There will be focus on two of the company's project phases; Project Execution Pharmadule and Project Execution Site. All processes in both phases will be investigated and evaluated according to the system tools used in the different processes. The aim of the Project Execution Pharmadule phase is to have pre-produced modules ready for set-up at the client's site. At the site the modules are set and the facility is assembled, started and tested. When all criteria for final approval in each system are fulfilled, the system is handed over to the client. When all systems are approved and handed over (one by one), the whole facility and documentation are handed over to the client. Pharmadule's remaining phases and processes will not be investigated or described in this bachelor thesis because of time limitations. Delimitations of system tools are defined according to the definition below.

"A system is one or more programs that solve an issue, i.e. create invoices, calculate salaries or control an expedition into space. In a simple way a system may consist of only one program where the aim is to calculate a certain task. Normally it will consist of several programs (maybe more than a hundred), depending on what kind of tasks the system will perform and the size of the computer/server." (Det store norske ökonomileksikon)
A division of small and large systems has been made where small systems have 1 to 24 users and large systems have a user group consisting of 25 persons or more. The large systems will be the most relevant and will therefore be the main priority.

## 2 Methodology

This chapter describes the procedure of this Bachelor thesis. The methods that have been used and how they have been preceded. Further it describes how the data was gathered and analyzed, and also the validity and reliability of this thesis.

### 2.1 Research Method

The research method used in this thesis is Case Study. "In general, case studies are the preferred strategy when "how" or "why" questions are being posed, when the investigator has little control over events, and when the focus is on a contemporary phenomenon within some real- life context." (Yin, 2003)

### 2.2 Data Gathering

Before writing this case study some literature regarding how to write reports and how to define case studies were studied. The literature was found at the internet through gigapedia. Key words for search were "case study". Literature about interviews and good interview practice were also studied before the writing started. It was gathered at the Chalmers Lindholmen library and at the library of the University of Gothenburg. All other data have been gathered during the research process. Pharmadule´s own intranet have been the main source to information since it contains descriptions of system tools, processes and project phases. The theories regarding organisations were gathered at the Chalmers Lindholmen library. The ISO standards 9001 and 27001 were ordered from SIS by Pharmadule and handed to me through Elisabet Lindberg.

### 2.3 Research Process

In order to get a complete overview of the project some questions were designed before the research process started. This resulted in a better understanding of the complexity of the project.The questions pointed out where to start the research, what to be investigated and in which order. They may be considered as a guideline for the research process and they are listed in an own chapter; research questions. After making the questions, which also helped to define the project, a work breakdown structure was made. This work breakdown structure resulted in a Gantt scheme. The theoretical framework was collected and red - in front of and during - the research process. After identifying all the guideline questions, a study of the Pharmadule intranet gave answers to the questions regarding the processes in the two project phases. To identify the system tools the Pharmadule intranet was helpful as well as an open dialogue with Robert Velén who is information system manager and an acting system manager for AutoCAD, Comos and Navis Works. The aim of the dialogue was to guarantee that the system tools were correctly connected to each of the processes. To map and investigate the system tools a comprehensive question- battery were developed. Elisabet Lindberg, supervisor at Pharmadule took an active role in development of the questions to ensure high quality

and that the company's interests were covered. This was done through mail conversations and meetings between investigator and supervisor. The results of the mapping of the system tools were directly inserted into a tool, Qualiware, which is the system tool that Pharmadule use to describe their processes. The system tool consists of a database (input) and a generator that publish the results on the intranet (output). The system tools were connected to respectively process in the two project phases. Some of the system tools were used in a larger extent, among them Pro Arc and DePlan.

Working at the department Document Control, the investigator gets a good overview regarding all engineering disciplines and knowledge about the importance of using the system tools in a correct way. ProArc is the system tool used at Document Control together with the Microsoft Office Package. When the investigator started to work at Document Control, a short introduction course in the basics on how to use ProArc were participated. The duration of the course was tree hours and the scope included basic functions in document profiles and ProArc explorer. During the time working at Document Control, the investigator noticed some issues regarding ProArc that is useful to mention in this case study. During the time as an employee, the investigator was speaking to the ProArc support and got explanations regarding most of the issues.

As a part of the job the investigator was sent to site in a project where the investigator worked as a document controller, helping the discipline Test to make system binders. At site problems regarding system tools occurred frequently and the investigator got useful experience on how stress affects the way of working with the system tools.

**Interviews**

The interviews had mostly an open structure and aimed at receiving qualitative information from the respondents. An open interview is a scenario where the interviewer asks wide and open questions where the respondent can answer with considerable freedom of choice. The interview includes questions like how something is or what sense something makes (Lantz, 2007). The questions were unstructured which means no standardized answering alternative, but some of them were more leading than others. A lot of the issues that were under discussion in the interviews were already a common knowledge within the company. Some of the questions had a more leading character because there were issues that needed to be confirmed. Questions should be formulated so it becomes naturally for the respondent to express him/her- self in detail and with his/hers own vocabulary. It is often suitable to open the interview with interrogatives such as why, how, where, who.... but it is also possible to achieve same results with introductions like: please tell about, please describe... etc. (Gordon, 1977). The questions were also simple and direct which promoted complex answers with a lot of substance, i.e. "How do you work with the system tools, please describe!"
A few questions were of little more complex characters. "The aim of asking a more complex question is i.e. it could be valuable to achieve information of how a person reacts on a more unclear question, what kind of information this person describes and how he or she describes the information. This requires high ability of sensibility and interpretation of the interviewer. A more unclear question can sometimes be described

as a projective question i.e. the question is specifically asked because the respondent shall project some, perhaps unconscious ideas to the answer. The projective technique is an example of an indirect way of asking questions. "The interviewer is not primarily interested in the answer of the direct question but uses this to learn about the outlook of the respondent."(Gordon, 1977 ).

A few questions were asked according to the quotation above to give an indication to the respondents' ability to see solutions to the issues they considered as problems. Mostly the questions were standard for all the interviewees, but some were specifically designed to each of the interviewees' role in the organisation. The selection of interviewees was done on recommendations from Elisabet Lindberg because she has a better understanding and overview of the organisation. Aspects like organisational position, project role and experiences were substantially. Before the interview took place a mail was sent to the respondents. The mail contained a short presentation of the bachelor thesis and the aim of the interview. "It is easier to receive reliable information if the interviewee can identify with the aim of the interview and thus the questions asked" (Gordon, 1977). Four of the interviews were preformed face to face and the rest of them had to be preformed electronically in lack of time.
According to the project financial controller the employees working at Front End were quite unhappy with the "create cost estimates"- function in Prima, the system tool of financial control. Due to lack of time it was not possible to follow up that question with anyone at Front End.

**Survey**

A survey was made to get a quantitative perspective of the system tools. "The survey is a completely structured interview where the interviewer asks questions that are pre - formulated and in a certain order and the respondent choose its answers among answering alternatives that are made in advance."(Lantz, 2007). The survey had 37 questions where 31 of them were fixed questions with fixed answer alternatives. Five of the questions had not any answer alternatives which means that the respondent had to use own words. The reason why these questions were asked was to get a qualitative perspective on some quantitative information. As a result of this it was easier to see relationships between some common issues.
The survey was inserted into InSurvey, a system tool used to create surveys, and sent to the employees within the company. The survey was sent as a link attached to an email. The selection of participants of the survey was done by Elisabet Lindberg and the investigator. The relationship between the respondents and the investigator was established while the investigator worked as a Document Controller at Pharmadule. Supervisor Elisabet Lindberg also took an active role in informing the respondents about the survey and its purpose. InSurvey is disposed by the director of sales development, Ola Skoglund. He was very helpful in the process of creation, distribution and collection of the survey. In InSurvey the answering alternatives got different values according to a scale. Most of the questions were yes/no questions where yes had the

value 1 and no had the value 2. Some questions had four answering alternatives that were scaled from the most positive alternative to the most negative.

**Gap- analysis of ISO 27001**

The aim of the analysis is to develop a basis for checking that the organisation has implemented safeguards that are applicable to the business. The analysis results in evidence on how effective the safeguards are implemented, a comprehension of the quality of the safeguards and important information on how strong or how weak the existing safeguards are today. In lack of time the investigator did not preformed a fully Gap-analysis. The investigator selected some chapters from the book "Mät din informationssäkerhet – Gap-analys" written by Jan-Olof Andersson. The chapters were chapter 2- Personnel, chapter 3- Accessibility/Reliability, chapter 9- System security, chapter 10- Network/ Communication, chapter 11- System development/ System changes and chapter 12- Personal computers/ Workstations. The chapters in the book contains of pre-populated questions that were answered with "yes", "no" or "do not know". The questions are belonging to a main question for each chapter. All questions were valued between zero and three according to the investigator's own opinion due to risks. Zero represented unacceptable risk and three represented a minimum risk. The three answering alternatives to the questions were valued as well. "No" had the value zero and "yes" had the value one. "Do not know" were considered as negative answers and got the value zero, as well. The values of the answers were multiplied with the values of the questions and finally divided with the amount of questions for each chapter. That value became the value of the main question of the chapter.

The respondents of the questions of the Gap- analysis were picked due to their competence of the areas represented in the chapters. Supervisor Elisabet Lindberg was very helpful finding respondents to the Gap-analysis. The respondents were employees from the IT/IS department, Human Recourses department and the receptionist of the Pharmadule Nacka office. Three of the interviews were performed face to face and two of them were sent by email.

## 2.4 Reliability and Validity

The interviewees were picked because they have a special place in the organisation and work a lot with the current system tools. Especially the system tools that Pharmadule use to monitor and manage their activities. All the interviewed wanted to participate, and all interviews were conducted. Some interviews resulted in follow-up questions that were answered retrospectively. Some of the interviewed, I met again for a short "second round ", some responded to supplementary questions by email and some responded to the follow-up questions over the phone.

The respondents of the survey are from seven different disciplines within Pharmadule. These disciplines are Architectural, EIT/Automation, Structural, HVAC, Piping,

Biopharma & API and Secondary Processes. These disciplines are using the engineering tools every day, therefore their opinion about the engineering system tools, must be the most valuable. The number of respondents is 14; two persons from each discipline. The number of respondents was chosen to limit the scope of the study but the investigator is aware of that the reliability would be even better if the number of respondents would have been increased. Not all the respondents that got an email were willing to participate in the survey which is a factor that decreases the reliability. The validity of the study is assured by choosing respondents that have long experience within Pharmadule and the use of the system tools.

Interviewees to the Gap- analysis were chosen due to their knowledge about the different areas of the analysis. All the interviewed participated, some of them filled in a questionnaire by email. The valuations of the risks were performed by the investigator, which has limited knowledge regarding some of the topics. This results in decreased reliability and validity.

## 3 Research Questions

The questions were designed before the research process was started. The aim of the questions was to get an overview of the project and they also contributed to define the research process.

The questions are as follows:

Identify the system tools.

- Which are the system tools?
- Which system tool belongs to which process in which phase?
- Who are the users of the system tools in the different processes?

Identify the processes in the two project phases.

- Which are the processes?
- Are all processes described?
- How do the processes work?
- Who are the internal clients of the processes?

Mapping of the system tools.

- How are the processes described today?
- Are the same system tools being used in the same type of processes in both project phases?
- How are the system tools being used in the processes today?
- In which extent do the system tools interact with the processes today?

Identify relevant requirements to the standard ISO 27001

- What are the requirements in the standard?

Furthermore a hypothesis was defined:

If the system tools interact with the processes a GAP- analyze to ISO 27001 can be preformed.

# 4 Theory

This chapter contains theories that describe different types of organisations, individuals in the organisations and the management systems ISO 9001 and ISO 27001.

## 4.1 Working organisations

**Process- based organisation**.

A business process is a chain of activities that result in a product the customer wants to pay for. The customer is either internal or external. Business processes can be described by two characteristics

- It has customers, and there are recipients of the outcome of the process.
- It runs across the (traditional) organisational boundaries, both internally between functions and externally between organisations that work together. (Willoch, 1994)

The organisation's processes involve many different activities. These activities are performed by different departments and functions within the organisation. Often every unit and feature solves his part not seeing how it is related to the integrity and the customer. "Nobody has the responsibility of the whole, but each one takes care of its part". According to Willoch the business processes of many organisations, have many units involved, but no single named unit responsible for the entire process. Willoch also believe that the units are invisible i.e. they are not visible on the organisation chart.

Organisations that organize activities along the process will easier maintain and improve its competitiveness. To take base on the processes when the organisation is designed, intend to raise the efficiency regarding time and cost and improved productivity, quality, and service levels. It would also simplify management. For results to be achieved, a number of parameters must be satisfied. These parameters are more extensive training of the employees, that employees are organized in teams that achieve continuously learning, main focus on customer values and a working organisation containing of more horizontal flows among others.

**Learning organisations**

"Organisational learning is created when the organisation gives employees wide latitude and individual development budgets" (Charles Handy, 1989). Other important methods include: mentoring, training and seminars, acceptance of mistakes, project, question times, quality circles, study circles, horizontal career paths, brainstorming sessions and concern for the individual. These methods should create a learning culture in the organisation but they must also be added to the right persons, so that barriers to continuous learning can be eliminated. Examples of such barriers according to Handy: "The fact that the organisation sees problems as signs of failure

That ideas coming from the bottom of the organisational hierarchy regarded as less valuable just because they come from the bottom
That decisions on important changes in the organisation are taken in silence and presented to the employees on short notice and without warning
The dissemination of information is blocked or prevented in the organisation."

The learning process of learning organisations is organized within the organisation for it to be as efficient as possible. All the employees who plan and make decisions should also implement the decisions and follow up the consequences. This will give employees important information about what works and what does not work. It will result in reflection and genuine learning. Many of the principles that apply to process-based organisations, is also true for learning organisations. It is important to identify and organize around business processes so that the learning process can be related to something that is understood, influenced and developed by the individual employee. It is important that the employee is given powers to make decisions and take responsibility for decisions taken.

## 4.2 Individuals in the organisations

**Competence**

The right skills are essential for employees to perform their duties satisfactorily. To achieve the right skills, training is required. It can apply technical skills (i.e. how to use an IT tool) or interactive skills (i.e. how to deal with customers). Knowledge within organisations can be divided into individual-bound and bound structure of knowledge. The individual-bound knowledge is individually among employees, while the structure of knowledge is bound within the company consisting of concepts, information systems, administrative procedures, networks, contracts, etc. Together with knowledge skills are also experiences, values, attitudes and networks. In order to maintain good skills in the organisation, the organisation must constantly grow, evolve and change.

**Changes - Resistance to change**

Borer resistance change varies extremely from case to case and from person to person. How the of new changes.
Positive attitudes to change requires a focus on transformation, transparent strategies, that the purpose of change is well-defined and that everyone in the organisation understand the purpose. If everyone in the organisation feels that they are involved in the decision to change and that they are involved in the change process new ideas and changes will be easier to implement.
company handles both the introduction and implementation of changes are important factors at play. Resistance to changes increases when it takes a lot of energy to implement them, and when they are significant. When the changes are unexpected for a certain group of people or when they are more advantageous for some in the organisation the resistance will increase among the displeased.
Increased resistance to change appears also when the changes are unclear. It becomes

difficult to understand why the changes will be implemented and what the organisation may benefit from them.

If anyone have negative experiences from previous changes it will be more difficult to have a positive view


## 4.3 Organisational learning

Attitudes and practices are often entrenched within the organisation. Before the entire organisation can learn new things in a good way, it has to be set to zero. The individuals within the organisation have to "forget" all previous working methods. The aim of the reset is to provide individuals a fresh start and create more openness to embrace new ways of working and creating new attitudes. In order to have a positive climate for organisational learning, it is important that the individual is seen. That individuals receive feedback on what they do and that there is room for making mistakes. If the error is considered to an opportunity to further understanding rather than a failure, it will result in employees who dare more and it will create a positive environment for organisational learning. But it requires that everyone is communicating their experiences and insights and that the organisation quickly apply what they have learned.


## 4.4 The Quality Management system SS-EN ISO 9001:2008 (E)

ISO 9001:2008 is a further development of the earlier versions of the ISO 9001 series. Some of the requirements in the standard include:

- To identify all key processes in the organisation and ensure procedures for each and every
- To monitor the processes to ensure their efficiency
- To keep sufficient records
- To check process outputs for failures, with the aim to perform corrective actions
- To keep working on continual improvements

Chapter 6, Resource Management contains requirements regarding provision of resources, competence, training, infrastructure and work environment. The organisation shall ensure the resources to implement and maintain a quality management system. Sufficient resources shall also be provided to continuously improve operations in terms of efficiency. The purpose of the requirements of Chapter 6 is to meet costumer requirements and increase customer satisfaction by improving internal aspects. The claims shall define how the organisation will develop personal skills, define and maintain the infrastructure and working with the clients requirements.

People who work in relation to product requirements shall have proper training, qualifications and experience. The company will ensure that everyone have the right skills to perform their duties to the satisfaction of the clients requirements. If knowledge is missing the company has to provide adequate and relevant training so that the right skills are obtained. The standard also requires that the company keeps records on

education, skills and experience. The employees shall always know how their actions affect the quality management system.

The organisation shall determine, provide and maintain the infrastructure necessary to meet the requirements of the production down to business. The infrastructure includes both hardware and software. The company shall also determine and manage the work needed to considered satisfactory requirements for their products.


## 4.5 The Information Security Management System SS–ISO/IEC 27001:2006

The aim of the standard is to establish, implement, operate, monitor, review, maintain and improve an Information Security Management System (ISMS).  The establishment and implementation depends of the surroundings of the organisation. Visions, goals and requirements of the organisation will affect the interaction of the standard in the organisation. If there is already an effective management system within the organisation, for example ISO 9001 or ISO 14001, it may be more appropriate to comply with the existing standard.

The process approach for information security management submitted in the standard requires that the users

- understand the requirements of information security and the need of maintain policy and vision due to information security

- implement and maintain necessary security to manage the risks regarding information security within the context of the organisations overall business risks

- monitor and review the performance and effects of ISMS

- continuously improve the standardisation based on objective measurement

Chapter 4, Information security management system, contains requirements regarding establishment, introduction, operation, monitoring, review and improvement of ISMS. It also contains requirements regarding documentation and document management. The management of the organisation shall establish procedures that ensure that all documentation is relevant, updated according to latest review, have valid revision and that the latest valid revision is available. The documentation shall also be distributed, stored and if necessary destroyed according to the classification of the documents. Further, the management shall ensure that all external documentation are identified, prevent misuse of obsolete documents and mark these if they are aimed to be stored. The management shall also assure the document distribution flow.

## 5 Processes and System tools

Below a short description of the system tools and the processes are presented. The system tools are connected to the processes as they are on Pharmadule's intranet.

### 5.1 System tools

Some of the system tools have a complete presentation on the intranet where the reader easily understands how the system tool works and how it interacts in the organisation. However some of the system tools need a better description.

**The server of Pharmadule**

The server is located in Bromölla in Sweden. All of Pharmadule's offices are connected to this server which means that all of Pharmadule's system tools work through this external server.

**The interaction between system tools at Pharmadule**

To understand the interaction between the system tools you have to understand what a tag is. Pharmadule divides their facilities into areas. Each area contains a various number of modules. They are classified to what kind of equipment they contain and how they are hooked up at site. The design, the production and the hook up is preformed per area. Each module contains a various number of articles. To keep track of the articles Pharmadule use tags. Each tag contains description and information about the location for a specific article. Further information about the creation of tags is found in the description of Comos.
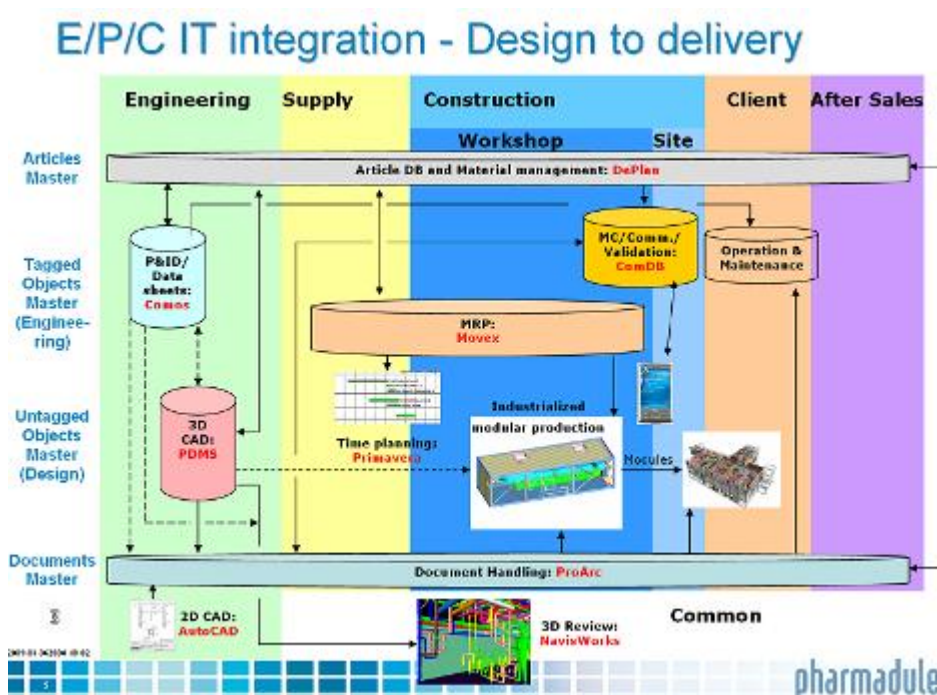


*Figure 5.1. Chart showing the interaction between the system tools of Pharmadule.*

**The system tools**

AutoCAD – 2D
AutoCAD is used for general CAD tasks, mainly 2D detail drawings. AutoCAD is used by the engineering disciplines and production.

ComDB - Commissioning and validation
ComDB is a database that interacts with DePlan. From DePlan the system tool gets all information regarding tags. It contains the components article numbers and tag numbers. ComDB helps Pharmadule to validate projects to make sure that they fulfil the quality demands of the customers.

Comos - System engineering
Comos is Pharmadule's tag handling system. It is a database controlled program and it interacts with DePlan. Objects are created in Comos which gives each object a tag. When Comos synchronizes with DePlan articles from DePlan are imported into Comos and it is possible to connect the articles to the tags.

DePlan - Material management
DePlan is the application for engineering and material handling. It is the master database for all articles used by Pharmadule. DePlan is the integration platform used by PDMS and Comos, sends tags to the commissioning database (ComDB) and sends articles, purchase order proposals and manufacturing orders to Movex. Some information i.e. the status of the articles is also transferred back into DePlan from Movex.

Movex – Financial management
Movex is a business system that is used primary for financial management, manufacturing and supply chain planning. Movex receives information from DePlan : which articles to order and what quantity. The purchaser puts the articles together in an order. When the articles arrive at the Pharmadule production site the production team controls that the order is received correctly. The production team report back to the purchaser that then uses Movex to control invoices.

NavisWorks - 3D viewing
Navis Works is a 3D tool which is easy to use by non designers. It is used at meetings with clients to review the plant and also in production. Navis Works shows the whole plant, or each module, in a very detailed way. You are able to see detailed views of pipes, equipment, walls etc.

PDMS – 3D
It is a3D CAD tool, where Pharmadule build their 3D model of the plant.
PDMS is a database that handles placement of objects (Area, Block, Batch, Module, and Room). It handles materials and other types of project information. The system produces drawings and reports and transfer material data to other systems, i.e. DePlan.

PDMS integrates with ProArc where registration card in ProArc are filled in directly from PDMS.

Prima – Cost management
Prima is used for following up costs in the projects and in the line organisation. Also used for making budgets in the projects and for doing the cost estimates. Prima creates a large amount of reports to see the costs in alls sorts of ways.

Prima Web – Time Report
Prima Web is an internet site where the employees report their working hours. The employees can also get a complete overview of their working time during a whole year.

Primavera - Time planning
Primavera is the main tool for time planning. The project scheduler make schedules for the project so the project management is able to control activities compared to time. The schedule is communicated to the project team at continuously meetings.

ProArc - Document management
ProArc is an electronic document management system. Pharmadule use it to archive all documentation, both documentation produced in projects and documentation used to manage the company. In the projects the engineers and project management produce a lot of documents in native files witch are uploaded in ProArc. ProArc generate PDF copies of the native files. The documents are distributed external to client or internal to project team or production. All distributions generate transmittals helping Document Control to control the distribution flow. Pro Arc interacts with the Microsoft Office Package and PDMS.

## 5.2 Processes

Not all the processes are fully described on the intranet. They are all named and "the steps" in the processes are described to a certain extent but you have to know the organisation very well to get a complete overview. The internal clients of the processes are the project management and the project team members. The system tools are mapped to the processes due to answers from interviews, the survey and the investigators understanding and own knowledge about the projects.

**Phase: Project Execution Pharmadule**

Project Execution Pharmadule: The Project management conduct internal and external meetings, Document Control distribute information and documents and Quality Assurance perform monitor and training.
System tools in use: ProArc

Initiate: The project roles are initiated , budget is established, document archive and document structure are established and engineering tool set up are updated.
System tools in use: ProArc

Monitor and control: The disciplines report their project performance to the project management who collect the information and conduct monthly meetings informing the project about the progress.
System tools in use: Not found

Plan Project Execution Site: The site scope is clarified, plans and site cost estimates are updated and resources are planed.
System tools in use: Prima and Prima Vera

Close Project Execution Pharmadule: The project financial controller reports Key Performance Indicators according to Pharmadule standard procedures and closes the project phase in financial systems. The project management conducts lessons learned from the project phase.
System tools in use: Prima

Plan Project Execution Pharmadule: The project management has meetings with the client, where the scope is defined, and the project management makes plans for the project phase.
System tools in use: Not found

Design before facility layout freeze: All disciplines design their systems.
System tools in use: Auto Cad, Comos, Navis Works, PDMS, ProArc

Area design Area-N: All disciplines prepare and develop Area design. The multi discipline design coordination is performed for design acceptance procedure.
System tools in use: Auto Cad, Comos, Navis Works, PDMS, ProArc

Fabrication Area-N: The production fabricates each module before assemble the area, they outfit and install modules before internal review of fabricated modules are performed.
System tools in use: Navis Works, ProArc

Client walkdowns : The client have a walkdown at the facility. They summarize the walk down in a report.
System tools in use: Not found

Transport modules and materials: The transportation from the production site to the clients' site are planned and performed.
System tools in use: Not found

Engineering before facility layout freeze: The multi discipline engineering is coordinated and performed. A package for requirement acceptance procedure and facility layout freeze is compiled before an internal design review of the package is performed. Design stability risk analysis is compiled.
System tools in use: Auto Cad, ComDB, Comos, Navis Works, PDMS, ProArc

Develop Project Execution Site proposal: The Project Execution Site proposal is developed, reviewed and compiled.
System tools in use: Prima

Negotiate Project Execution Site: The client performs a review of the Project Execution Site proposal. Then Pharmadule compile and assess the clients' comments.
System tools in use: ProArc

Requirements approval procedure: A package for Requirement acceptance procedure and facility layout freeze is compiled and distributed to the client. Requirement Acceptance procedure per system is performed, facility layout freeze is performed, and lessons learned are performed.
System tools in use: ProArc

Supply management long lead equipment: Request for quotation is prepared and planed. Purchase services and contractors are planed and evaluated. Purchase of vendor equipment is performed. Follow ups of fabrication, building equipment and component classification is performed.
System tools in use: Movex, Prima, ProArc

Engineering after facility layout freeze: The system engineering documentation is developed and updated. A multidiscipline engineering coordination is performed before all disciplines perform engineering after facility layout freeze.
System tools in use: Auto Cad, ComDB, Comos, Navis Works, PDMS, ProArc

Design after facility layout freeze: Multidiscipline design coordination is performed before all disciplines design after facility layout freeze. Requirement acceptance procedure is compiled and then an internal review of the package is performed. Constructability reviews are performed and hook up layouts are developed.
System tools in use: Auto Cad, Comos, Navis Works, PDMS, ProArc

Supply management tagged material:  Estimated standard material is planed and purchased. Request for quotation is performed. Services and contractors are planed, evaluated and purchased. Vendor equipment, tagged objects and standard material are purchased.
System tools in use: DePlan, Movex, Prima, ProArc

General engineering: Articles and material in engineering tools are created, all disciplines perform general engineering, plans for commissioning, turn over package, fabrication and site are compiled and building permit package is developed.
System tools in use: Auto Cad, Comos, Movex, Navis Works, PDMS, ProArc

Pre- production engineering Area-N: Drawing production of structural and architectural drawings.
System tools in use: Auto Cad, ComDB, Navis Works, PDMS, ProArc

Supply management untagged material: Estimated standard material is planed and purchased; services and contractors are planed, evaluated and purchased.
System tools in use: DePlan, Movex, Prima, ProArc


**Phase: Project Execution Site**

Initiate Project Execution Site: Project key roles are initiated, it environment at site is ordered and turn over package and site budget is established.
System tools in use: Prima, ProArc

Plan Project Execution Site: Meetings with client where the site scope is defined and planned. Other activities are also planned, like meetings, project communications, and schedule etc.
System tools in use: Prima Vera, ProArc

Management: The Project management conduct internal and external meetings, Document Control distribute information and documents and Quality Assurance perform monitor and training.
System tools in use: ProArc
Monitor and control: The disciplines report their project performance to the project management who collect the information and conduct monthly meetings informing the project about the progress.
System tools in use: Not found

Plan after sales: Preparation of hand over to after sales is performed.
System tools in use: Not found

Close Project Execution Site: The project financial controller reports Key Performance Indicators according to Pharmadule standard procedures and closes the project phase in financial systems. The project management conducts lessons learned from the project phase.
System tools in use: Prima

Assemble modules: Modules are stripped and lifted on to the foundation before they are welded and protected against the weather. Finally architectural work on the inside of the roof is finished.
System tools in use: Not found

Hook Up of modules and systems: Hook-ups for all disciplines are coordinated.
System tools in use: Navis Works, ProArc

Start Up of systems: All process systems are started.
System tools in use: ComDB

Hand over system to client: Before the final hand over of systems to client, a transfer of control of systems to client and a provisional hand over to client is preformed.
System tools in use: ComDB, Pro Arc

# 6 Results

The aim of this chapter is to give a relevant description of the use of the system tools today based on the investigators own experiences, some detailed interviews and the survey. This chapter together with the theory will be the base for the analysis and discussion in chapter 7.

## 6.1 Results from observations and lessons learned made by the investigator from working as a Document Controller at Pharmadule

Sometimes ProArc do not create PDFs of native documents made in Word or Excel. This problem often depends on the native documents, not Pro Arc as a system tool. The natives are often "misused" which means that the users copy contents from similar documents used in earlier purposes. By performing this action it result in a lot of error in the new document and ProArc is not able to create a PDF. Sometimes the document front page crashes when updating/ raising revisions in ProArc. This can depend on the same issues described above.
ProArc can crash when actions regarding large size documents are preformed. Often the mail import function does not respond. This leads to inconsistent storage of e-mails related to the distribution flow in the projects.

At site the same problems as described above occurred besides that ProArc crashed a lot in general. That depended on slow connections at the site office. In general, the investigators' understanding is that every site office has slow connections. At site the stress often affects the way of working with the system tools. The clients are always in the same location as the employees and often demand quick solutions to upcoming problems. This is not always compatible with slow internet connections and an IT support with response hours based on Swedish working hours.  This leads to site workers coming up with own solutions which differ from standard working procedures. Transmittals i.e.: standard working procedure is to create every transmittal in Pro Arc before hand over of documentation to client. The client shall sign the transmittal as soon as the documentation is received from Pharmadule. When it is really stressful at site this procedure has been missed and transmittals have been created and signed by client after document hand over. Another observation from site is that the engineers often update documents and drawings in the engineering system tools but this action is not described in neither of the processes at the Pharmadule intranet.

**Questions to Petter and Jan at IT/IS - 30/6 2009:**

Why does not TAG data work in ComDB?

People do not have enough knowledge about how to work and how the flow should be. It is often a lack of responsibility regarding the system tools.
Pharmadule's system tools and systems have to be described. Today they are not fully described.  Pharmadule have to build in systems to avoid manual inputs. Better continuous controls of the flow between the system tools are needed. Tag names or tag

manual controls are not performed. Often the users work with the system tools in a wrong way, therefore a control function that verify the way of working should be implemented. Also a better training of the organisation and a more extended training of consultants is needed to make them understand the organisation.

Which mistakes/defaults does the IT support often register regarding DePlan? What mistakes do the users do?

The users do not have any control of transmissions between the systems. They do not always understand the ordering list and in which order the actions are preformed. As soon as a tag is received from Comos, the integrator in DePlan is checking whereas the system exists. If the system does not exist, DePlan creates the system. If the systems have to be modified, the change has to be done per tag, but this action can be preformed as a mass update. The changes have to be updated in the system where the tags were created at first. The tags are always connected to the systems, but they do not have to share the same name.

The system lists are not always cleaned automatically because this action is complicated to perform regarding technical issues. It would be better to have one responsible person in each project that clean the list.

## 6.2 Results Interviews

**ProArc**

Interviewee : Head of QA, Document Control Manager, Test Manager and Project Manager

ProArc interact with the Microsoft Office package. The mail interaction does not always work but when it works it works well. The combination Word- ProArc-Adobe is not always optimized and it is the generation of PDF documents that often causes failure. Today every ProArc user have more editing rights than necessary which results in different document layouts as each employee ticks different boxes. This results in a great variance in quality. Some of the functions are not necessary and should be removed. Making the rights in ProArc more specified for each user will ensure that it will only be possible to perform actions that belong to that specific task/ role. This should make the appearance and layout more homogenous and result in a higher document quality.

Document approval: those who check, QA-check and approve documents can make changes during the review without informing the document creator. This means that the document creator has less leads to less control over his/her documents. The reason why these changes can be made by other than the document creator him/herself is that the documents are in native format in ProArc. The problem can be solved easily by generate PDF copies direct into ProArc and eliminate the natives from the system. Those who

review the documents in this case would have to send their comments and changes back to the document creators who perform the changes on documents in ProArc.

Store large files/documents: ProArc is not adapted the need for storing large, heavy documents/ files like videos for example. They require long "check-in" and "check-out" time at the Pharmadule office and at site it can take up to 30 minutes just to "check out" a single document. This depends on a very slow ProArc in a combination with slow internet connections at site.

Limits regarding this system tool comprise the internal communication flow which is not optimized. A function called Activity list needs to be more efficient regarding to search out documents. Today the users have to search for documents one by one which is very time consuming. It can also be difficult to give internal comments. Users can write comments in the document profile but it is hard to find if the users do not know where to specifically look and it is too easy to erase comments written by others. To search out results of distributed documents is another function in ProArc that can be improved. The folder "Approved but not distributed", as soon as documents are distributed, either internal or external, they will automatically disappear from this folder even if the same revision of the documents should be distributed external later on. This result in less overview over distributed documents.

Functions that improve and ease the work methods for some of the project roles:

Head of QA:    Some of the functions are not necessary and should be removed. Making the rights in ProArc more specified for each user will ensure that it will only be possible to perform actions that belong to that specific task/ role. This should make the appearance and layout more homogenous and result in a higher document quality.

Project Manager: A management tool! Today issues have to be discussed by mail which is a time consuming process. An issue management tool that is able to filter questions/issues by subject will make it easier to see the history of discussions and make the discussions more efficient.

Document Control Manager: It should be easier to collect a T.O.P. list from ProArc. There should be a T.O.P. list that the system tool supports, which means that the indexes are done as usual but ProArc should be able to generate a sorted T.O.P. list. It should be easier to search out many documents at the same time.

Test Manager: A kind of Review task. It should ease the work if it is possible to get a list over documents that are ready for check and approve. ProArc should have a function that makes it easier to see what have been sent to client and an easier way to see the T.O.P setting.

ProArc is both needed and used at site!

There is a difference in use at Site vs Pharmadule office and the reasons of the differences are slow internet connections, ProArc does not always interact with other systems at site (like scanners for example) and the scanners are not always satisfactory. The team members at site have not always the same opportunity to the same communication with support than the team members at home. ,

These differences are first and foremost time consuming and bad scanning affect the quality of the documents which result in a lot of rescanning. When the client is close and continuously demanding progress, the employees are often forced to work outside ProArc and have a tendency to create their own solutions. The risk of failures increases. It is often a lack of Document Control resources at site. Sometimes it is a local temporary person that acts as a Document Controller or the responsibility of the documentation is on the Validation discipline. A Document Control resource at Site should make it easier to work more consistently with scanning and documentation and ProArc in general.

There is no 24 hours support for ProArc. At site when ProArc crash, often because of slow internet connections, the site workers do not have time to wait for support. The environment is more stressful than at Pharmadule office and the connections and interactions are slower. The site server works very well at site but not at Pharmadule office and the X folder works very well at the office but not at site. This causes difficulties to send larger amounts of files between site and Pharmadule office. Everybody should have access to the FTP server. To work with ProArc through VDM makes ProArc extremely slow.

**Prima**

Interviewee : Project Financial Manager

Prima is used for pre-project calculations, project follow-ups, forecasting of final cost, change order handling, both external and internal invoice support and user register maintenance in the projects of  Pharmadule. It is almost an optimized system tool but some functions could be more automatic to improve the user-friendliness. Functions that can be improved or added to Prima according to project financial controller are improved user friendliness regarding follow up of actual costs and integration with resource and time planning.

Prima is both needed and used at site. It is no difference in the use of this tool at site vs. at Pharmadule Office but the use is affected by these different environments.

**Prima Web and Movex**

Prima Web is not always working in an optimized way because of the interaction with Movex. The employees have to time report electronically in Prima and physically in Movex. It is very complicated to do corrections if the employees somehow forget to report their time.

Prima Web is both needed and used at site. Movex is only used at the PHD office. Instead of using Movex the business trips are registered before the employees leave home and then they report as usual in Prima Web. At site Prima Web works very well. It is only an internet site and not heavy which means that the impact on internet connections is relatively small.

**Prima Vera**

Interviewee : Project Schedule Controller

Prima Vera is used to make schedules for Pharmadule projects. Besides using this system tool the project financial manager use currently Microsoft Project to test if Primavera can be replaced and if MS Project schedules can be imported into Primavera without losing any data. It is an optimized tool with regard to create schedules. The interviewee believes that the new version P6 has all functionality they will need. At site they use Prima Vera in the same way as at the Pharmadule office, they have some problems with the existing version P3 but the interviewee has not responded what kind of problems.

**ComDB**

Interviewee : Test Manager and Test Manager Estonia

The interviewees answered that ComDB had all desirable functions but that some of them can be improved.  They want a more intelligent way to filter data so that tags with no status attached will be exposed in a search, the  possibility to report status to several tags at the same time (in case of batch RV) and the ability to assign tag attributes to a created dummy tag, such as module data, system data etc.
Both of the respondents thought that they have enough training to work with this system tool in an optimized way but neither of them could confirm that this training have been given by Pharmadule. One of the interviewee thinks that he/she got some basic training but had to learn the details by him/herself and the other one answered that he/she has learned to use ComDB mostly by him/herself.
In the projects the users of the project team get a short introduction course to the usage of ComDB but there is no extensive training like there is for ProArc.

Regarding ComDB some occasions of system failures occurs from time to time. There are functions that are not working quite correct or they are not accessible. System failures are called "bugs" and these failures are usually solved together with the software company but that process is rather time consuming.
The interaction between ComDB and other system tools works, but it is not optimized. A complete overview regarding the data flow is difficult to achieve and sometimes the import of data from other systems is too slow.
A common issue is the data quality since there often is a lack of data in ComDB. This depends on confusion among the employees regarding what tag data needed in ComDB

and where this data should be typed. Whether it is in Comos, DePlan or PDMS. When tag data is missing the printed check records from ComDB will lack data.

Another complication that appears during big projects is the synchronizing of the pocket PC: s with the database.  If there is a large amount of data the process takes too much time.                                                   To improve or completely eliminate these complications in the future, it requires an improved effort in the start up of a project in ComDB. Also a more extensive training of the employees using ComDB will make a contribution to improve the issues. The training shall put more emphasis on the important tag data in the project. Another commitment is to improve the cooperation between Pharmadule and the software developer. It is also suggested to replace the pocket PCs but the respondent has not any concrete suggestion of replacement.

Sometimes the respondents have communication problems with the project team: "One example is the interpretation of the Check Lists in ComDB. It is not always communicated how to interpret them, this is a discussion between production and design. Another example is the punch description text; it is not always as informative as it should be. "(Emilia Zettergren) According to Mart Torsus there can be issues when other users need some extra advice.

ComDB is both needed and used at site! The difference in use at site vs Pharmadule office is that at Pharmadule Office a project test manager uses ComDB for follow ups and progress reports. In Estonia pocket PC:s are also used and at site they use a combination of both. It is more time consuming when the Pocket PC:s are used. The internet connections at site and Pharmadule's own networks do not always serve as intended.  ComDB works slowly when the connection with the server failures.  Other issues that affect the way of working with ComDB at site are stress and lack of time.

## 6.3 Results Survey

The survey was sent to seven disciplines and two employees within each discipline.  All disciplines participated at least 50% except Piping which did not answer at all. Biopharma & API and Secondary Processes had 100% contribution.

Do the system tools that you use support the work and your way of working?
6 of 8 answer yes and 2 of 8 answer no!

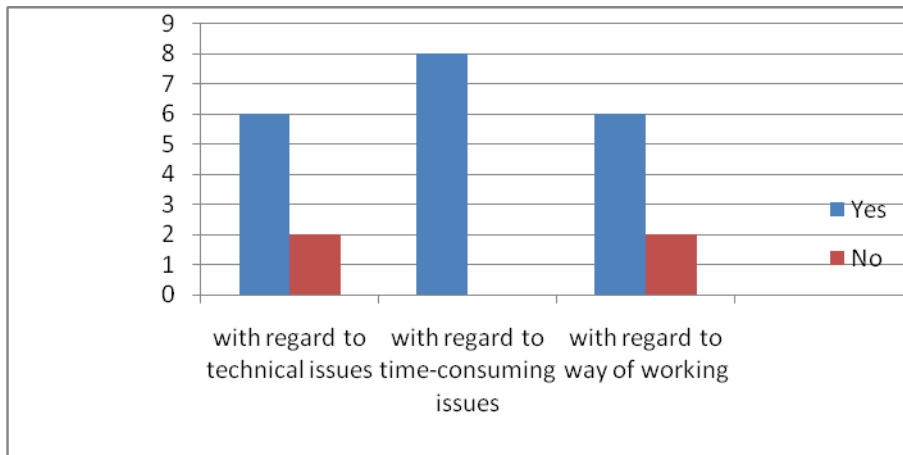Are there any limits regarding the use of the system tools?



*Figure 6.1.Diagram showing how many that answered yes/no to the question "Are there any limits regarding the system tools?"*

Are there other/more limits regarding use of the system tools at site?
4 of 8 answer yes and 3 of 8 answer no. 1 of 8 did not answer this question!

1 of 8 thought that technical issues were limiting the use, 5 of 8 thought that the limits depended on time-consuming issues and 3 of 8 thought that the way of working is the problem. Employees representing the disciplines EIT/Automation and Biopharma & API thought that all three factors were limiting the use of system tools.

Does the interaction between the system tools serve as intended?
2 of 8 answer yes and 6 of 8 answer no!

The respondents got the opportunity to describe why the interaction between the system tools do not serve as intended. Some want to optimize the interactions between PDMS-Comos-DePlan-Movex-Proarc, others have good believe in the progress the IT/IS department has regarding the system tools. Quotation from the survey: "Not yet (if the interaction between the system tools serve as intended…). When IT/IS department is finished, it will be great!", "Lack of data integrity. Data is often manually copied between different sources so the same data can exist at several locations. A unified definition of data is missing. Issue is that data between the system tools get lost." How the data get lost is not described.

Is there any lack of access to any system tool?
5 of 8 answer yes and 3 of 8 answer no!

Most of the respondents think that ProArc often has error regarding access. To check out protocols the employees have to work through the VDM server. Comos does not work correctly unless if it is ran through the VDM server. The VDM server is not reliable besides it does not keep personal profiles or settings. DePlan has a host of bugs and crashes a bit too often and it also has limitations regarding the handling of many

tags and causes slower searches. Biopharma & API are requesting a 3D tool that can handle design of skids. PDMS is very time-consuming and not intended to use for detailed construction design of process skids. According to the respondent from Biopharma & API Process Piping has the same issue. Structural wants a material ordering system tool. They do not use DePlan.

Approximately, how long does it take to log on the computer at site vs at Pharmadule office?

3 of 8 think it takes between one to five minutes, 3 of 8 think it takes between five to 30 minutes, less than one minute and more than 30 minutes, respectively. Two respondents did not answer this question.

Training – is there any need for supplementary training regarding system tools at site?
2 of 8 answer yes and 4 of 8 answer no. 2 of 8 did not answer this question!

Was/is this training available?
6 of 8 answer no. 2 of 8 did not answer this question!

Is every computer ready for use when the project team arrives at site?
3 of 8 answer yes and 2 of 8 answer no. 3 of 8 did not answer this question!

Does it take some time to establish the system tool package at site?
4 of 8 answer yes. The other 50% of the respondents did not answer.

It can take from a couple of hours to a day to establish the package. The employees have to contact Service desk to add system tools. 3/8 of the respondents mean that it takes from one hour to one day to wait for problems to be solved regarding system tools at site. 1/8 thought it takes more than a day and 1/8 thought it takes a week. All of the five respondents who answered this question feel that the time to wait affect their work. 2/5 thought it affects very much.

Other infrastructure like server, printers and faxes, how do they work at site?

3/8 respondents says that everything is available at site when the project team arrives. 2/8 says that it is not and 3/8 has not answered this question.

1/8 respondents says that the support of server, printers and faxes are local, 3/8 means it is not four respondents have not answered this question.

Among they who answered all of them say that there is more than three persons per device/machine and 2/4 says that it is more than 20. Nobody among them think that the capacity is sufficient.

How often do you consider that the system tools perform as you wish?
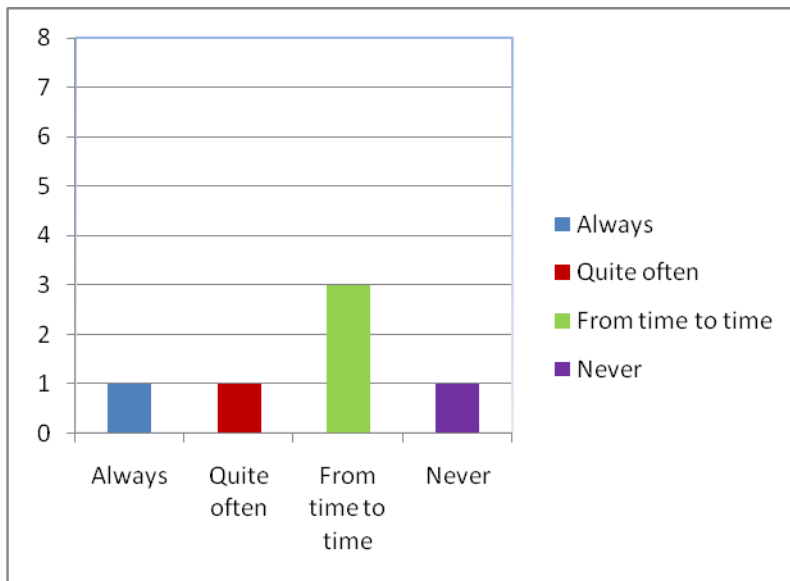


*Figure 6.2. Diagram showing how the respondents answered at the question "How often do you consider that the system tools perform as you wish?".*

Your way of working – do you feel that you have necessary support from the system tools to do your work correctly?
3 of 8 answer yes and 2 of 8 answer no. 3 of 8 did not answer this question!

The respondents want to improve the access of ProArc, Comos and DePlan at Site. They want a more reliable VDM connection and a ProArc without bugs like that page number change without a change request and PDFs that not generate, ect. Do helpdesk understand the site requirements? One of the respondents opinion is that training of Pharmadule staff is not the matter, training of system owners is the real concern.

Do you know if there is any other system tool that would support your work better?
1 of 8 answer yes and 5 of 8 answer no. 2 of 8 did not answer this question!

Respondents from the discipline EIT/ Automation want EPlan, Darwin and SAP. They think that these programs will support their work better.

5/8 of the respondents agreed that a supplementary training in use of the system tools is necessary.

7/8 of the respondents agreed that an easily accessible manual for each system tool is necessary.

7/8 of the respondents agreed that super-user tips and tricks are valuable and will ease the work.

The office package:

6/8 of the respondents agreed that they are a component user of the package.

2/8 have a professional training course in the package, 6/8 have not.

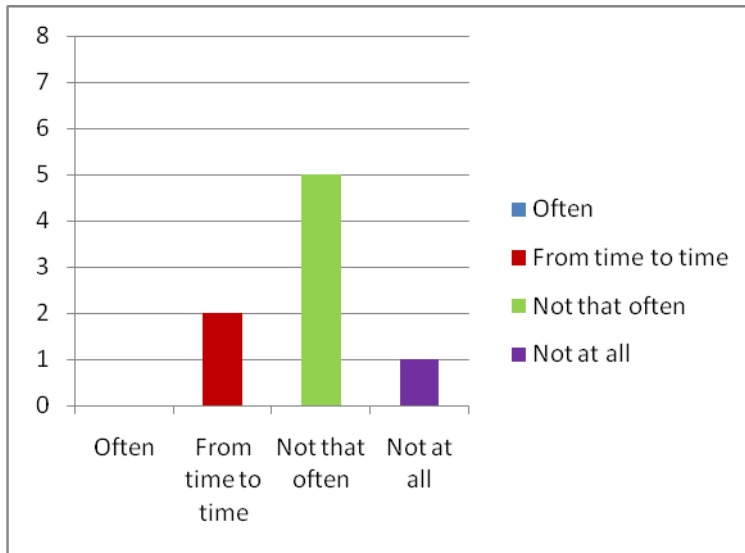Do you have error in any office program?



*Figure 6.3. Diagram showing how the respondents answered to the question "Do you have error in any office program?".*

## 6.4 Results of Gap – Analysis to ISO 27001

The results of the selected chapters of the Gap- Analysis are represented by charts. Each staple represent the main question of the sub chapters. The value of each main question is based on a several questions that were weighted due to a risk. Zero is unacceptable risk and three is a minimum risk. The sum of the main questions were divided due to the amount of main questions of each chapter, which resulted in the mean value of each chapter. There is also a summary of the deficiences of each chapter.

**Personnel - Chapter 2**

Chapter 2 contains questions regarding if there is any guidance of safety assessment of recruitment of employees, if there are established rules for how an employee should be treated, if the responsibility to end or change an employment is clearly defined, if the company is aware of where in the organisation there are people that hold the key positions, if access to facilities and systems are regulated, if the employees have sufficient IT competence and if the consultants are used in a way that do not affect the company's safety. The mean value of the chapter is 0, 71.
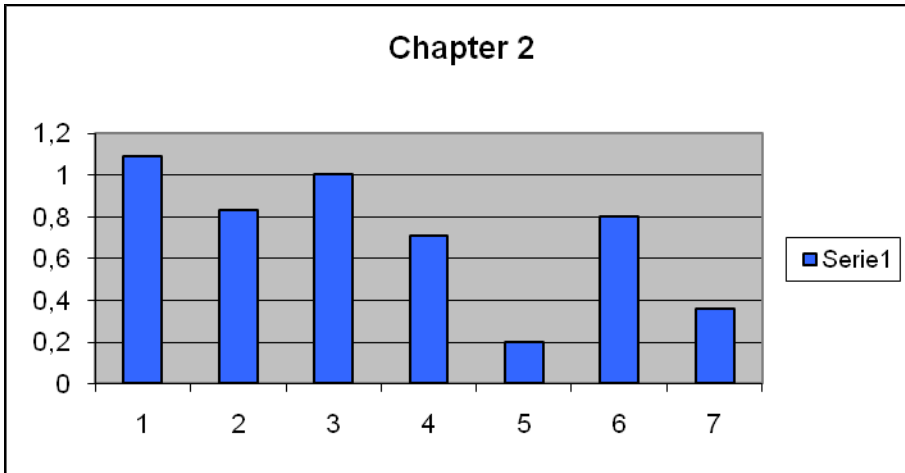
*Figure 6.4. Staple one to seven represents the subchapters of chapter 2:*

1. *Before employment*

2. *During employment*

3. *Responsibility when employment are changed/ended*

4. *Key positions/ persons*

5. *Permission*

6. *Competence*

7. *Utilisation of consultant*

**Deficiencies of chapter 2:**

2.1 - Before employment

There are no routines of how employees are checked due to security issues. The authenticity of the references of an employee related to a new employment is not checked. Previous criminal burdens of employees are not checked due to a new employment. Information on credit history is not checked.

2.2 - During employment

The proof of confidentiality is not audited every year.

2.4 - Key positions/ persons

Key positions in the organisation are not fully identified and documented. It is possible that external persons/suppliers have key positions. The organisation has not taken any special protective measures for key personnel. There is no plan on how replacement personnel shall be provided.

## 2.5 - Permission

There is a pass to enter the offices and there is an access code into the server room. The respondent does not know if the IT department has access to information on employees who have received complaints regarding security issues. Consultants have limited access to premises. The respondent does not know if employees who have security objections may have access to computer systems, limited or no access to computer rooms and archives.

## 2.6 - Competence

The respondent does not know if there is a continuous development of skills within the organisation.

## 2.7 – Utilisation of consultant

The respondent does not know if the consultants only have access to the premises/information needed to perform their job. It is not always set up a consultancy agreement.

## Availability/ Reliability - Chapter 3

Chapter 3 contains questions regarding monitoring of the functionality of the production, if there is any reports or documents that shows average response time and amount of transactions during maximum loaded hours. If there is any schedule or plan that reports production planned per day, week and month. Further the chapter contains questions regarding rules, routine and resources according to use of the existing systems, service of all IT- equipment and safety guidance adapted to protect the company of all types of malware. The chapter also contains questions regarding validation of all inputs and outputs of the systems and issues due to safety from third part participants. The mean value of the chapter is 0, 64.
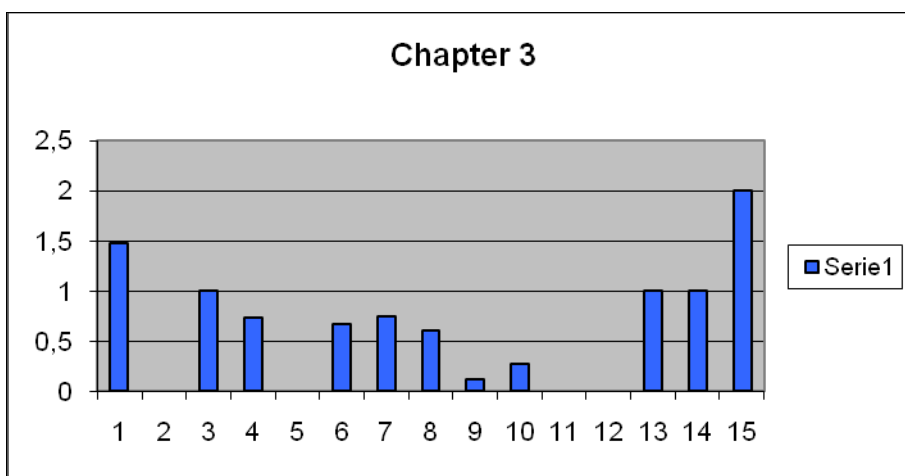


*Figure 6.5. Staple one to fifteen represents the subchapters of chapter 3:*

1. *Shutdowns*

2. *Response time*

3. *Imposition*

4. *Planning of continuously production*

5. *Production to come*

6. *Use of system*

7. *Maintenance*

8. *Security precaution due to harmful code*

9. *Validation of input*

10. *Controlling of internal arrangement*

11. *Integrity of communication*

12. *Validation of output*

13. *Provision of service*

14. *Monitor and control of services of a third part*

15. *Handling of services of a third part*

**Deficiencies of chapter 3:**

3.1 - Shutdowns

There are no clear limits when malfunctions shall be recorded. Availability measurements are not carried out. Instructions on when to registry errors exists only to a certain extent. A plan of action when disturbances occur is not developed.

3.2 – Response time

Statistics of response time are not done.

3.3 - Imposition

Critical periods are not identified and they do not constitute as basis for operational planning.

3.4 – Planning of continuously production

The total product chain is not scheduled due to time. The respondent does not know if rules for planning of personnel are established. Service and support – contracts for each system are not established. Systems/ routines for change management do not exist. Production planning is not documented. Security instructions for handling of manual input/output do not exist. The operators do not write any logs due to their activities.

3.8 - Security precaution due to harmful code

There is no formal policy of protection against risks associated with downloading files or software through/ from external networks. There are no management practises and responsibility regarding protection of malware in the system. There is no appropriate business continuity plan for recovery after attack caused by malicious code, including back up of all necessary data, programs and processes required for restoration.

3.9 - Validation of input

The respondent does not know if controls on the input of business transactions, fixed data and parameter tables apply. Regular review of key fields or data files to confirm their validity and accuracy are not considered. Reviews of paper- bound input documents to detect any unauthorized changes are not done. The company takes no procedures in place to respond to any validation error. The respondent does not know if procedures regarding reasonableness tests of input data are considered. Guidelines governing the definition of the responsibilities of persons involved in processing of inputs are ignored. There is only a log of activities in the input processes on some of the systems.

3.10 - Controlling of internal arrangement

Protection against attacks that use excess of permissible data/ field size is an area not considered in the design and implementation of application systems. A checklist of the sessions or batch controls for reconciling file balance after transaction updates is not made. A checklist for updates of totals and programme aimed for controls of programmes is not established. A checklist for the inspection to ensure that applications run at the right time is not established. A checklist to ensure that programs are run in the right order, ended if errors occur and continuously processing stopped until the problem is solved is not established.

3.11 - Integrity of communication

The company does not assess security risks due to determine the importance of the accuracy of messages and establish the most appropriate protection method to import.

3.12 - Validation of output

The validation of the outputs does not contain any probability controls, enough information to determine the accuracy of the information, routines to retroact on validation tests, definition of responsibilities and creation of a log of activities.

3.14 - Monitor and control of services of a third part

The process due to the management of services between the organisation and a third party does not include examining the third party's audit trails and reporting of security

incidents, operational problems, etc. No knowledge about the technical skills of the third party.


**Security of system - Chapter 9**

Chapter 9 contains questions regarding an authorization control system, if there are resources allocated for administration of authorization and incident tracking, if there are routines that ensure that permissions in the systems always are up to date and if there are routines of follow ups and controls of how the employees use their authorizations. It is also questions regarding how each user are identified in the systems, how the authorization control system applies to the systems and if the company has an encryption policy. Further there are questions regarding the operational systems, the introduction of these systems, access, the possibility of making changes to the operational systems, antivirus, handling of applications and to which extent information in data bases is secured. Finally chapter 9 contains questions regarding logs of activities and service of the operational systems. The mean value of the chapter is 0, 33.
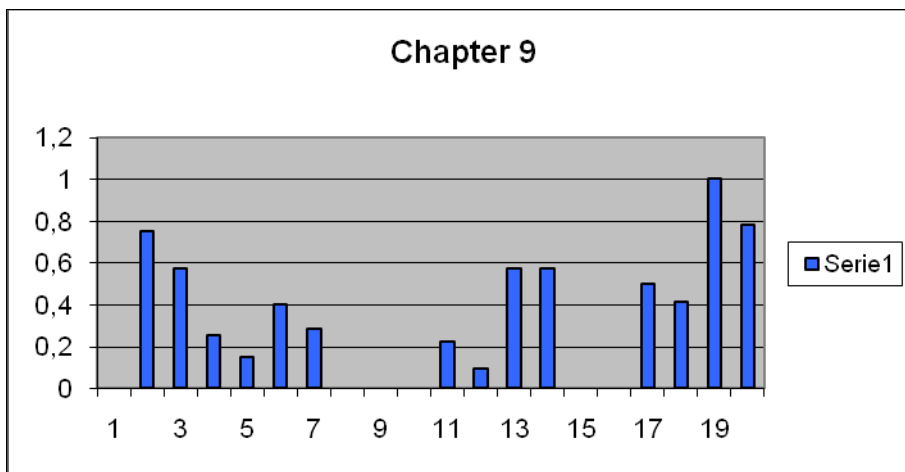


*Figure 6.6. Staple one to twenty represents the subchapters of chapter 9:*

1. *Authorization Control – Introduction*

2. *Authorization Control – Organisation*

3. *Authorization Control – Update*

4. *Authorization Control – Control actions*

5. *Authorization Control – Follow- ups*

6. *Authorization Control – Identification*

7. *Authorization Control – Access control*

8. *Authorization Control – Reporting/Analysis*

9. *Authorization Control – Policy of encryption*

10. *Authorization Control – Key management*

**Deficiencies of chapter 9:**

9.1 - Authorization Control – Introduction

There is no complete documentation of the system configurations and no policy regarding the system security. The respondent does not know if the authorization control system regards the policy of system security and if the authorization control system is installed according to the suppliers' instructions and routines. Nor the respondent knows which functions the authorization control system has, how it is built and configured and if the authorization system supports the system of information classification.

9.2 - Authorization Control – Organisation

The respondent does not know if the line organisation follows up the permissions of the employees and if there actually is resources in the line organisation to follow up such issues. The respondent does not know which criteria that must be fulfilled to have permissions to the system tools.

9.3 - Authorization Control – Update

The company does not perform any safety assessment before implementing new software in the systems; neither do they perform any safety assessment before installing new hardware.

9.4 - Authorization Control – Control actions

There is no prescriptions regarding incoming and out coming deliveries of data. There is no routine that regularly controls users' accesses to data and IT-systems. The IT department does not perform any evaluation of changes if the information classification needs to be changed.

9.5 - Authorization Control – Follow- ups

The respondent does not know if the authorization control system automatically controls that the employees change their passwords according to affirmative procedures, that they do not change back to recently used password to soon and that the passwords are complicated enough to maintain the security. There is no routines and organisation to monitor the use of IT- resources/ systems. There is no function of authorization that monitors unauthorized attempts to enter the systems.

9.6 - Authorization Control – Identification

The respondent does not know if all authorized users are defined in the authorization control system. The company does not use any other method of verification than a password and the respondent is not sure how many and what characters the password shall contain. There is no reinforced identification regarding users nor internal or external.

9.7 - Authorization Control – Access control

Access to system tools, software and data bases are not regulated due to time on the day. It is possible to login after three failed logins. The time for automatically logout can be set by the user and it is not always limited to five minutes due to unused applications. Not all classified information is cryptal (end to end). Unauthorized persons are not warned to use the systems due to login and the users in general are not aware of that their activities are logged in the system.

9.8 - Authorization Control – Reporting/Analysis

Not all changes are logged in the authorization control system and the logs are not saved any long (two years). Changes in time are not logged. There are no routines on how the log is supposed to be used. There is no alarm when the requirements of the log are fulfilled and there is no responsible person that monitors the logs and alarms. There is a several issues that is not logged like login/log out, failed operations, deleting of data, print outs. The logs are not analysed every week.

9.9 - Authorization Control – Policy of encryption

The questions regard development of an encryption policy. Since Pharmadule has not created any encryption policy, all the answers to the questions are negative.

9.10 - Authorization Control – Key management

The questions regard a system aimed to support the use of encryption within the organisation. All answers to the questions are negative.

9.11 - Operating System – Introduction

The operational systems are not installed and maintained by Pharmadule's own personnel. The operational system is not security classified. There is no routine that ensures that all passwords that have been delivered with the operational systems are changed due to installation.

9.12 - Operating System – Access

There are more than five persons that are super users/ administrators of the systems. Not all systems are protected nor the terminals that are used as operator consoles. It is possible to restart operational systems from unprotected terminals. All possible opportunities to perform operational commands from lines are unlocked. Sensitive data/ media that contain information about the operational system are not secured. Login which has the highest root is not locked to any specific console or working station. The integrity of the operational system is not maintained due to TCB, Trippware etc.

9.13 - Operating System – Changes

The operator/ system administrator can change the system log due to start up of systems and it is not impossible for the vendor to make changes in the operational systems even if the client is not aware of it. The operational systems integrity regarding security does not update due to installation.

9.14 - Operating System – Virus/ Harmful programmes

Pharmadule does not use several anti virus programs.

9.15 - Operating System – Use of system/program

Logs regarding the users of a system and how the system is used do not exist.

9.16 - Operating System – Applications

The questions regard an archive of the logs. All answers to the questions are negative.

9.17 - Operating System – Databases

Data dictionaries are not specially protected.

9.18 - Log function – Logging

There are no documented regulations regarding how to follow up logs and who that should do it. The logs do not show from which computer/ working station the change has been performed or which programmes that have been used to perform the changes. Neither do the logs show which users that have opened certain files nor at what time did the users have access to the files. The respondent does not know if it is possible for the administrators to change what have been logged. Neither does the respondent know if

the company's own logged programmes are documented and protected due to access. Functions that erase all logs when changes are performed do not exist. The respondent does not know if new logs are created when erasing an existing log.

9.19 - Log function – Archiving

There are no routines that secure logs to be saved at least six months and there are no routines on how data should be moved, i.e. from a hard disk to another media.

9.20 - Maintenance – Service

Pharmadule has no alternative to original vendor of hard ware.


**Network/ Telecommunication - Chapter 10**

Chapter 10 contains questions regarding error – handling, documentation, availability, planning of stops and redundancy of network administration. The chapter also contains questions regarding identification and access due to authorization and protection of transactions in the network. Finally the chapter deals with questions regarding firewall and electronically security. The mean value of the chapter is 0, 43.



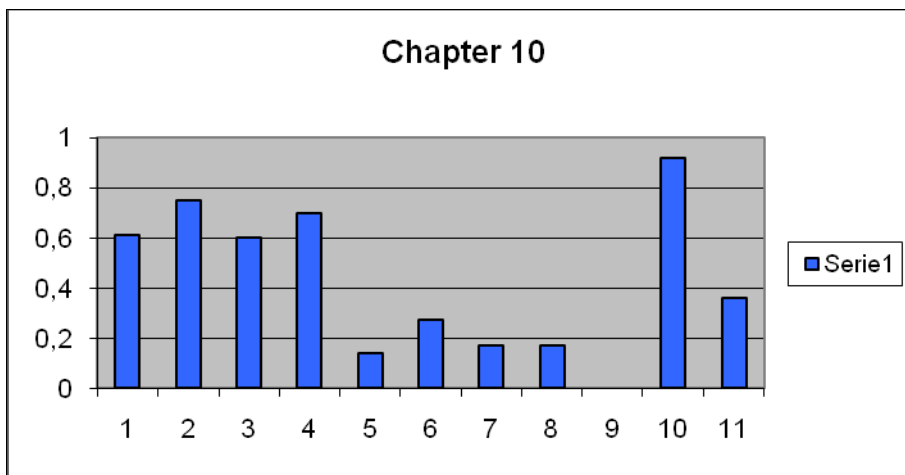*Figure 6.7. Staple one to eleven represents the subchapters of chapter 10:*

1. *Network Administration – Bug tracking*

2. *Network Administration – Documentation*

3. *Network Administration – Availability*

4. *Network Administration – Business continuity planning and redundancy*

5. *Access – Identification*

6. *Access – Accessibility*

7. *Protection during translation – Physical protection*

8. *Protection during translation – protection due to unauthorized connection*

9. *Protection during translation – protection due to interception and change*

10. *Connection to the internet – Firewall*

11. *Use of electronically services – Safety*

**Deficiencies of chapter 10:**

10.1 - Network Administration – Bug tracking

Failures in the network are not logged. It regards: type of failure, the extent of failure, the reason to failure, responsibility person(s) to supply the failure and which actions those were taken to supply the failure.

10.2 - Network Administration – Documentation

No documentation regarding physically cable installations exists.

10.3 - Network Administration – Availability

There is no local responsible person to each remote node. The respondent does not know if it is possible to access the network even if the network has foundered.

10.4 - Network Administration – Business continuity planning and redundancy

Back up alternatives for important systems like replying of data bases and mirroring of servers do not exist. The mean time between failures (MTBF) for each component in the network is not known. Which clusters and lines to prioritize during error search and disaster change-over is not clearly defined.

10.5 - Access – Identification

The respondent does not know if the authorization systems regarding input nodes/ computers in the network are compatible and synchronized. Neither does the respondent know if all components in the network only are accessible for authorized persons, if the part that sends information can verify that the receiving part is the authorized receiver and the other way around. The respondent does not know if a new identifying of the user is required due to communication from i.e. a local network (LAN) to another or that all incoming accesses in the network via "proxies" etc. are identified and removed.

10.6 - Access – Accessibility

The respondent does not know if all activities in the network are logged. Neither does the respondent know if the equipment where changes to the configurations can be performed, is regulated to any authorization, or if there is any alarm function due to unwanted coincidences. There is no regulations of how bugging of data communication is allowed to happened and by who. Further there are no regulations of how

communication equipment is allowed to be used per information range; fax, mobile telephone, radio transaction, telephone and electronically post.

10.7 - Protection during translation – Physical protections

Incoming and out going information of the company are not documented. There are no physically security actions to prevent unauthorized access due to remote connections regardless the location of the equipment or type of the physically network. The respondent does not know if there is any detection of physically manipulation of cables.

10.8 - Protection during translation – protections due to unauthorized connection

The respondent does not know if there are functions to prevent bugging of the network, if there are any password controls in the modem due to dialled connections, if closed user groups are used where possible, if the risk of unauthorized access decrease due to call backs, if the logs of computer-to-computer communication via i.e. gateways are performed in a way that makes the transactions traceable, if encrypted passwords are used regarding connections where the authorization are controlled by the authorization control system only, if the number to the modem is taken from other number series than the telephone numbers, if any log analyze of the modem connections is performed and if there are regulations regarding the use of the modem.

10.9 - Protection during translation – protection due to interception and change

The risk of unauthorized access via the network is not minimized due to encrypted transactions. The encryption is not performed with a legal crypto. The unencrypted information that is sent within the organisation is not sent in cables that are possible to inspect, neither are the cables alarmed. An encrypted check sum i.e. "sigillet" is not used.

10.11 - Use of electronically services – Safety

Information that is allowed to be sent through e-mail is not described in any policy or regulations. Electronically signatures are not used as protection to changes. The electronically post is not encrypted. The respondent does not know if EDI-transactions are protected. Neither does the respondent know if an agreement regarding exchange of information and programmes with other organisations is made or if the electronically trade is protected against deception, contract deficiencies and changes of information.

**System development/ System changes - Chapter 11**
Chapter 11 contains questions regarding supply of systems, programming, environment of development, testing, documentation, security aspects, deployment and change management of system development and system changes. The mean value of the chapter is 0, 56.
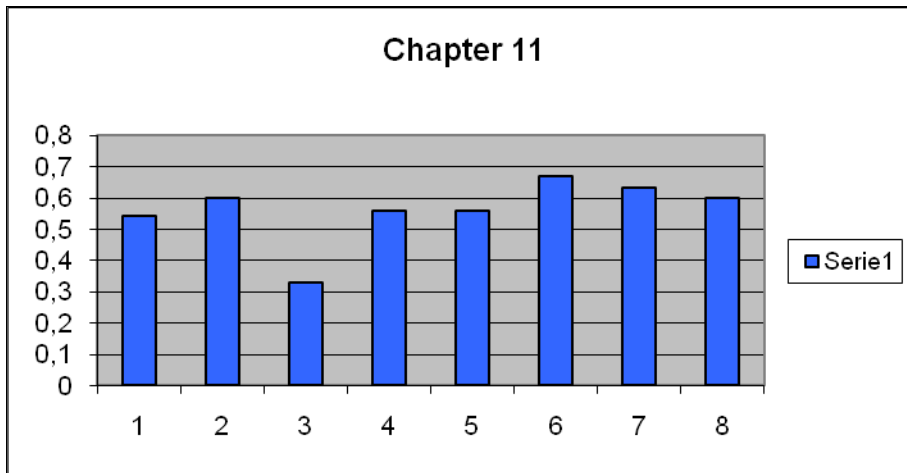
*Figure 6.. Staple one to eight represents the subchapters of chapter 11:*

1. *Design/Supply*

2. *Programming*

3. *Development environment*

4. *Testing*

5. *Documentation*

6. *Safety Aspects*

7. *Deployment*

8. *Change management/ Amendment Procedures*

**Deficiencies of chapter 11:**

11.1 - Design/ Supply

It is not clear who should approve the bid of changes of systems/ programmes. The principles of the several control functions are not included in the description of the aims. It do not exist any special security features when the development is performed by a third part. The information security is not a governance requirement due to procurement. The purchaser does not always confer with the security function when purchasing IT- systems aimed for handling classified information. During the projects, plans of actions are not created to catch absences as a part of further improvements.

11.2 - Programming

The respondent does not know if the programming modules are constructed with the aim of testing or if the modules can be compiled and handled separately.

11.3 - Development environment

A clear separation of the operational business, the department of development and the department of maintenance is not made. It is not secured that the programmers and the

operators are able to affect the inputs and/or the control parameters in the production. A programmer may use his/ her personally computer/ terminal as an operational console/terminal.

11.4 - Testing

It is not secured that the programmer of the actual programme executes the test of approval. A change is not signed by at least two persons regarding the acceptance test. The programmes/systems are not free from "patches" due to delivery controls. There are no formal routines regarding change management.

11.5 - Documentation

Documentation regarding systems, programmes and operational procedures is not archived satisfactory. The documentation is not updated due to all changes performed at the systems, not classified and not archived due to fire security.

11.6 - Safety Aspects

File- and/or catalogue encryption is not used. A continuity- or disaster plan for applications is not always performed.

11.7 - Deployment

The routines are not secured in a way that guaranties that no authorized person will be able to perform changes to the data of any application. Back up intervals and restart times are not agreed with the system owners. Systems and applications are not reviewed regarding start up.

11.8 - Change management/ Amendment Procedures
Strictly formal routines regarding change management do not exist. No controls regarding hidden functions in applications/systems are performed by testing.


**Personal computers/ working stations - Chapter 12**

Chapter 12 contains question regarding responsibility, authorization, function, back-up and malware related to personal computers/ working stations. It also contains questions regarding routines and security of equipment the employees use outside the offices. The mean value of the chapter is 0, 61.
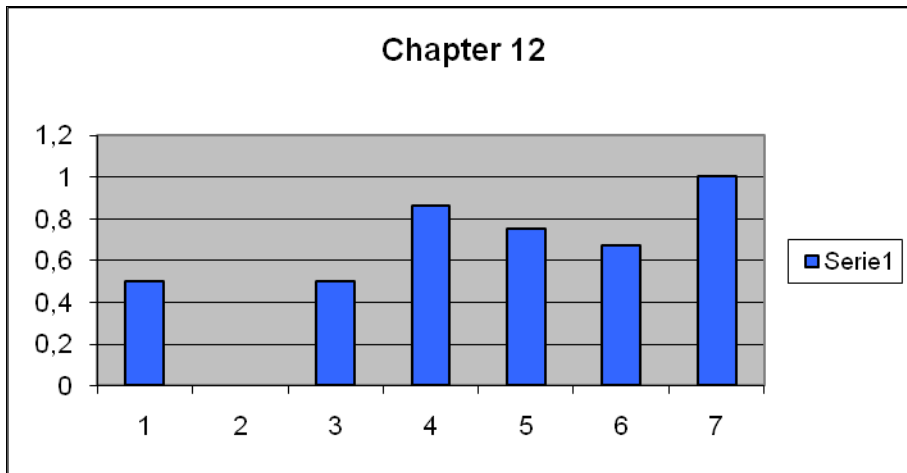
*Figure 6.7. Staple one to seven represents the subchapters of chapter 12:*

1. *Responsibility*

2. *Permission*

3. *Function*

4. *Backup*

5. *Virus/ Harmful programmes*

6. *Safety protection due to equipment outside the business*

7. *Teleworking*

**Deficiencies of chapter 12:**

12.1 - Responsibility

The employees are allowed to bring their lap tops home. No education/ training courses have been performed regarding personal computers/ lap tops due to security. The respondent does not know if any notifications due to personal register have been received by the responsible of the register.

12.2 - Permission

The personal computers have not any authorization control systems. The users own passwords are not kept safe.  There are no routines of storage of personal keys, codes etc. Information on the drives is not encrypted. Routines regarding handling of data to avoid unauthorized access of registers or other important/ sensitive information do not exist.

12.3 - Function

Neither mechanically nor manually logs, regarding how the equipment is used and how it works, are performed. Not any considerations are taken regarding placement of

equipment, statically electricity and quality of electrical supplies. The equipment is not secured due to the thief risk.

12.4 - Backup

Classified information is not managed on separate disks or magnetic tapes.

12.5 - Virus/ Harmful programmes

The users are not informed of which actions to be taken if viruses should occur.

12.6 - Safety protection due to equipment outside the business

There are no routines or regulations regarding handling of equipment and data media during travelling. No personal computer that is brought outside the office has any authorization control systems or encrypted information on the drives. The insurance for the equipment that is brought outside Pharmadule's offices is not regulated.

# 7 Analysis and discussion

By combining the theoretical framework and the results from the interviews and the survey, this chapter analyzes the problems that have been discovered.

## 7.1 The system tools

The problems regarding the system tools are many. We can classify the problems into two main categories; technical issues and human failures. The issues within these two categories leads to the most frustrating issue of them all; the time consuming issue which result in stress and inconvenient working environment.
75% of the respondents of the survey think that the system tools that they use support the work and their way of working, but only 1 of 8 consider that the system tool perform as they wish! The system tools used at Pharmadule are adapted to the tasks that they are aimed for. The users may have a lack of knowledge how to use the system tools correctly. The description of the processes at the intranet does not reveal any close interaction with the system tools.

**ProArc**

ProArc is mainly used in most of the processes in the two project phases. In the beginning of the phase "Project Execution Pharmadule" the document archive and structure are established in ProArc. All project specific procedures and documents are stored in ProArc during the project. The disciplines insert their produced documents into ProArc and the Document Control division distributes them either internal to the production team in Estonia or external to the client. In the end of "Project Execution Site" the Turn Over Package is collected from ProArc. The description of the processes has a lack of information regarding ProArc as an archive. All Pharmadule documents are stored in ProArc either as project related documents or in other archives that manage the company. It is the source of all information within the company and should be part of nearly all of the process descriptions. Today there is no description on the Pharmadule intranet how the use of ProArc is executed through the project phases. A more detailed description may increase the interest among the engineers and the management regarding correctly use of the system tool.

Technical issues:

At Pharmadule, in general, a management system tool is missing. By adding a function like that to ProArc, the follow ups of discussions in projects will be much easier and less time consuming. Today all discussions are preformed by email conversations. The discussions will be more structured if ProArc get such a function. Then the users will be able to connect their discussions directly to the project archives which result in a more efficient way of working. Besides, the mail interaction between Microsoft Outlook and the ProArc mail import does not always work as intended. Often the mail import

function does not respond. This leads to inconsistent storage of e-mails related to project specific discussions and distribution flow in the projects. Why this function works inconsistently is hard to say. An option is to look at other technical solutions regarding a mail archive. Is it possible to keep an archive outside ProArc? As far as the investigator is concerned, the archive has to be in ProArc! Pharmadule tries to obtain archives based on each project, which ease the process of finding documentation from earlier projects. It will work best in ProArc because the emails will then be connected to documentation within the different projects.

A function that can achieve further improvements is the Activity List. Today the function does not cause any directly technical problems but can be very time consuming to use. The users have to search for documents one by one which can take time specially if there is many documents. A technical solution might be to put the documents in packages sorted by the time when Activity list receive the distribution.

Another problem occurs when actions regarding large size documents are preformed. Large size documents are often videos, protocols or document profiles with a lot of files attached. ProArc often "crash" because the files are too heavy and ProArc is not adapted for that. Today storing documents/ files like videos for example, requires long "check-in" and "check-out" time. According to Head of QA it can take up to 30 minutes just to "check out" a single document at site. To check out protocols the employees need to work through the VDM server which also is a time consuming alternative. This issue has to be solved because any issue that result in delays will cause frustration and stress among the employees.

Human failure:

Those who check, QA-check and approve documents can make changes during the review without informing the document creator. This means that the document creator has less control over his/her documents. Many believe that the reason why these changes can be made by others than the document creator him/ herself is that the documents are in native format in ProArc. A suggestion is to generate PDF copies direct into ProArc and eliminate the natives from the system. Those who review the documents in this case would have to send their comments and changes back to the document creators who perform the changes on documents in ProArc. A major problem will then occur when it is time to update new revisions. It is not possible to copy contents from a PDF because "Adobe Reader is a stand-alone application that you can use to open, view, search, and print PDF files." (www.adobe.com).Another issue is employees that disappear from projects. If they are the document creators it will be difficult to make changes because the documents will then be locked and the document creator is the only person that will be able to unlock the documents. Pharmadule needs to improve working instructions and working procedures when dealing with changes in documents. Some function in ProArc that monitors changes in documents would be helpful. One option is to make a review task that lists the documents that are ready for check and approve with a built-in function that monitors changes in documents.

To give internal comments on documents can be difficult. The document profile has a function where users can write comments. It is hard to find if the users do not know where to specifically look and it is too easy to erase comments written by others. This function is not told in the ProArc basic course. A ProArc basic course that cover more functions and dig deeper into each and every function will ensure that the employees will have knowledge about such function as mentioned above.

To search out results of distributed documents is not a function that causes problems but it can be improved. An improvement of this function will definitively make document distribution more effective and improve the overview over documents ready for distribution. Another option is to improve the users' way of working by teaching them how to work with ProArc in a more efficient way. It is quite simple; documents that are not in the folder "Approved but not distributed" have already been distributed and the users need to search for them one by one. The users often get distribution assignments on email; maybe it is possible to get a mass search function in ProArc?

Sometimes ProArc do not create PDFs of native documents made in Word or Excel. A common attitude among the employees within the company is that they throw the blame on ProArc. The problem generating PDF: s often depends on the native documents, not Pro Arc as a system tool. The users do not work with natives in a correct way. They often "misuse" the natives by copy contents from similar documents used in earlier purposes. By performing this action it result in a lot of error in the new document, because when a document is copied, hidden Meta - data always follow and will also be pasted into the new document. ProArc will then have difficulties to create a PDF with a Pharmadule standard front page because the section breaks are moved. Sometimes the document front page crashes when updating/ raising revisions in ProArc. This can depend on the same issues described above but it can also depend on bugs in the users computers or that the users do not perform correct print settings before document approval. The reason why users work in a wrong way is that they have insufficient knowledge about the integration between ProArc and the Microsoft Office package. Some of them also have more or less lack of knowledge regarding the office package in general. According to the survey 6 of 8 of the respondents agreed that they are a component user of the office package but only 2 of 8 have a professional training course in the office package. If the employees change their attitude when working with changes in documents in ProArc, problems regarding generating of PDF's are solved in no time. The company needs better descriptions of the working procedures and the employees need more training in following them! As far as the investigator is concerned there is a culture among some of the employees that they do not accept the working procedures. Some of them need to take a more active interest in their working tools and how they interact with processes and procedures. By including the employees in the work of describing the procedures it will result in increased interest among the employees.

Documents often have variance in quality. Users have more editing rights than necessary which results in different document layouts as each employee ticks different boxes. Some of the functions are not necessary and should be removed. Making the

rights more specified for each user account will ensure that it will only be possible to perform actions that belong to that specific task/ role. Another solution is to train the project team more than once. Because of the complex, long term projects some in the project team may be replaced during the project. A review of the project procedure is preformed in the start up of the projects. The project will save a lot of bother by repeating the procedure during the project and focus on more training specified for each project role.

**Prima**

In both phases in the process "Initiate" Prima is used to establish the budget. All project costs are reported, updated and closed in Prima in both project phases.

Technical issues:

Prima has not any problems that somehow affect the processes in the projects but it is a couple of functions that can be improved. According to project financial controller functions like; "follow up of actual costs" and "integration with resource and time planning" can be improved to increase the user friendliness of Prima. There is no urgent matter but it is mentioned and should be investigated as a part of the work of continuous improvements.

Human failure:

Not any human failure is pointed out during the interview. The system tool is both needed and used at site which means that the environment at site will affect the use of the system tool. Unfortunately there is no explanation from the interviewee on how the site environment affects the use.

**Prima Web and Movex**

Prima Web and Movex are used as time report tools in all processes through all project phases. Every project team member report their working hours regardless which project phase it is. The different project phases have different codes where the employees are supposed to report their working hours.

Technical issues:

The interaction of Prima Web and Movex can cause difficulties if employees for some reason forget to report in Movex. Prima Web allows corrections regarding time report after some time but Movex do not. Because of the interaction it makes corrections in Prima Web far more complicated. Besides it is only permanently employees that have to report in Movex. Employed by the hour and consultants do not. This makes the use of Movex inconsistent and the company needs to investigate if they need Movex in

purpose to time report at all. If they find out that they do, they have to look at the possibility to include all types of employment into the Movex time report procedure. Then the time report procedure will be consistent and equal for all.
Human failure:
As described above. Human failures result in a technical issue.


**Prima Vera**

Prima Vera is described in the processes "Plan Project Execution Pharmadule" and" Plan Project Execution Site" but it should also be described in the process "Monitor and Control" as a system tool that manage the overview of time.

Technical issues:

The Project Financial Manager use currently Microsoft Project to test if Primavera can be replaced and if MS Project schedules can be imported into Primavera without losing any data. It is an optimized tool with regard to create schedules; the new version P6 has all functionality they will need.

Human failure:

No human failures are found from the interview.


**ComDB**

ComDB is not fully described in the processes at the intranet. It is confusing when ComDB is used and how it is used in the processes. There is no description regarding Receipt Verification or Installation Verification, two very important activities in the project phases. Both RV and IV are essential for the use of ComDB and client requirements.  How does ComDB help Pharmadule to validate projects? A more detailed description of the system tool is required to increase the understanding of the system tool, its function and importance through the projects.

Technical issues:

A complication that appears during large projects is the synchronizing of the pocket PC:s with the database.  If there is a large amount of data, the process takes too much time. To improve or completely eliminate these complications in the future, it requires an improved effort in the start up of a project in ComDB. Also a more extensive training of the employees using ComDB will make a contribution to improve the issues.
Some occasions of system failures occurs from time to time. There are functions that are not working quite correct or they are not accessible. System failures are called "bugs" and these failures are usually solved together with the software company, but that

process is rather time consuming. A solution is to improve the cooperation between Pharmadule and the software developer.

Human failure:

Today only some basic training in how to use ComDB is given. The system tool is a complex tool that interact with a several other system tools and it can be complicated to achieve all the requested knowledge by yourself. They who work at Validation have the knowledge to work with it in an optimized way. They use the system tool constantly but the disciplines need more training. In the projects the users of the project team get a short introduction course to the usage of ComDB, but there is no extensive training like there is for ProArc. The training shall put more emphasis on the important tag data in the projects.

A common issue is the data quality since there often is a lack of data in ComDB. This depends on confusion among the employees regarding what tag data needed in ComDB and where this data should be typed. If it is in Comos, DePlan or PDMS. When tag data is missing the printed check records from ComDB will lack data. Another example is the punch description text; it is not always as informative as it should be. To solve these issues the project team needs more training in how ComDB interact with other system tools and what kind of information that is required. The most important is where to type the information.

If the system tool gets a more intelligent way to filter data, the tags that lack data will be exposed in a search. The project team and the disciplines also need a better understanding of the flow of the system tools through all processes in the projects. They need to understand the consequences of their own way of working. If they type something wrong or type information at wrong locations, it will affect the entire project. Sometimes communication problems with the project team occur: One example is the interpretation of the Check Lists in ComDB. It is not always communicated how to interpret them, this is a discussion between production and design. The communication between different units within Pharmadule must be improved.

**De Plan**

Technical issues:

The system lists in DePlan that interacts with ProArc are not always cleaned automatically because this action is complicated to perform regarding technical issues. Today the cleaning of the list is quite random and not consistent. If each project make one person responsible for cleaning up the list it will improve the quality of appreciating method and system in the projects because all systems that is not in use will be removed systematically. According to the respondents of the survey DePlan has bugs and crashes a lot. Unfortunately there is no further description in the survey regarding this bugs but

there is an issue that the IT/IS department shall investigate. Maybe there is an issue that is rather easy to solve regarding a technical solution?

Human failure:

According to the IT-support the users do not have any control of transmissions between the systems. They do not always understand how the ordering list works and they do not understand in which order the actions are preformed. The users need to understand that changes within a system have to be preformed as changes per tag which mean that all changes have to be updated in  the system tool where the tag were first created. According to the respondents of the survey DePlan has limitations regarding handling of many tags but changes regarding tags in DePlan can be preformed as a mass update. The users need more training in how DePlan interacts with other system tools.

**The system tools at site**

50% of the respondents of the survey think that there are more limits regarding use of the system tools at site. The respondents want to improve the access of ProArc, Comos and DePlan at site and they want a more reliable VDM connection. Almost half of the respondents of the survey think that every computer is ready for use when the project team arrives at site. 4 of 8 think that it takes some time to establish the system tool package at site. It can take from a couple of hours to a day to establish the package. The employees have to contact Service desk themselves, to add system tools. Time spent on communicating with service desk to establish network and computers cause frustration. Network, computers and system tools shall be ready to use when the project team arrives at site. When an engineer arrives at site without functional system tools, it is the same as a carpenter arrives at work without a hammer! Not so many think that there is any need for supplementary training regarding system tools at site, but they want helpdesk to have a better understanding of the site requirements.

At site the system tools crashes more often than home at the Pharmadule office. It depends on slow connections. As far as the investigator understands, every site office has slow connections. Nearly half of the respondents  of the survey think it takes between one to five minutes more to log on the computer at site than at the Pharmadule office, and the other nearly half think it takes between five to 30 minutes more. Internet connections are slow because of weak line quality. Better internet connections require higher line quality. An increase of the costs in the site budget is not to avoid, but in long terms the projects and Pharmadule will take advantage of such investment.

Stress often affects the way of working with the system tools. The clients are always in the same location as the employees, and often demand quick solutions to upcoming problems. This is not always compatible with slow internet connections and IT support with response hours based on Swedish working hours.  Sometimes it takes up to one day to solve simple issues regarding the system tools.

Non- solved issues regarding the system tools often leads to that site workers come up with own solutions that differ from standard working procedures. These solutions are usually not described in any of Pharmadule's procedures or any project procedures. All actions preformed outside the project procedures breaks the agreements made with the client.

Another observation from site is that the engineers often update documents and drawings in the engineering system tools but this action is not described in neither of the processes at the Pharmadule intranet.

Nearly half of the respondents say that site server, printers and faxes are available at site when the project team arrives. Scanners at site have often lack of performance. They do not always satisfy the requirements according to Pharmadule working procedures. A common problem is the interaction with ProArc. Issues regarding scanners results in a lot of rescanning which increases the possibility of double documentation in ProArc. In worst cases the scanned documentation are inserted as blanch documents into ProArc. The stressful environment at site does not allow checking each document, as the users should, before inserting into ProArc. In the end of the projects Document Control discover the faulty scanned documents, but then it is too late to rescan because the scanned documentation is originals that are handed over to the client at site. Among the respondents who answered the question all of them say that there are more than three persons per device/machine and some says that it is more than 20. Nobody among them think that the capacity is sufficient.

At site there is often a lack of Document Control resources. Sometimes a local temporary person acts as a Document Controller, or the responsibility of the documentation is on the Validation discipline. Document Controllers must attend the Pro Arc basic training course to achieve their administration rights. Neither the local person nor the people from the Validation discipline have fully administration rights, which result in inconsistent use of ProArc. Some documents have to be scanned at site and then inserted into Pro Arc. If the user does not have the administration rights, scanned documents have to be inserted to the document profiles instead of at the right revisions. This result in incorrectly document profiles which confuse the engineers. A Document Control resource at site should make it easier to work more consistently with scanning and documentation and ProArc in general.

The site server works very well at site, but not at the Pharmadule office and the X folder works very well at the office, but not at site. This causes difficulties to send larger amounts of files between site and the office. To work with ProArc through VDM makes ProArc extremely slow. The explanation is that Pharmadule's server is located outside the office. If the server was located in the same buildings as the offices, the problem would be solved.

**(The impact of the system tools on the organisation and its people)**
The interviews and the survey point at many issues regarding the system tools. All of the respondents in the survey thought that limits regarding the way of working depended on time consuming issues. Time consuming issues are results of technical issues or human failures or a combination of both.

Technical issues regard both specific system tools, but also the interaction between the system tools. Only 25% of the respondents of the survey thought that the interaction between the system tools served as intended and the rest thought not. Some of the respondents want to optimize the interaction between PDMS – Comos – DePlan – Movex – ProArc, others want improved data integrity. When the employees manually copy data between the different system tools, it results in data existing at several locations. If the interaction between the system tools were optimized there should not be necessary to manually copy data. The system tools should have a built in function that made it possible to transfer any data from any system tool to another.

Human failure can be both individual and organisational. The individual issues can either be lack of interest or lack of knowledge. Basically, the interest depends on the knowledge. It is important that the employees have some basic skills but it is the company's responsibility to provide proper training for employees so they can perform their tasks satisfactorily. According to ISO 9001 the company shall ensure that everyone have the right skills to perform their tasks. If they have not, the company shall ensure that the employees get the necessary training. By increasing the individual knowledge, the employees will have a better understanding of their work, and they will be more able to work on their own and according to the procedures.

The organisational issues can be divided into lack of process descriptions and lack of management. At the intranet the description of the processes does not reveal any close interaction with the system tools. The system tools are only listed together with the processes, they are not described. To the investigators' knowledge there is no document within Pharmadule that actually describes the flow of the system tools trough the processes. A more fulfilled description is required to maintain the certification of ISO 9001 and if Pharmadule intend to; implement the information management standard ISO 27001.
Pharmadule needs to review their management. During the time working at Document Control the investigator got the interpretation that decisions were made higher up in the organisation without consulting the employees further down in the organisation. In order to maintain a good environment for learning it is important that everyone in the organisation is heard.

**7.2 Gap – analysis to ISO 27001**

The mean value of the analysis is (0+1+2+3)/4 = 1,5 but 3 is the best value and should be the value that the company are aiming for, regarding most of the issues. None of the chapters have a mean value over 1,0, which indicate that the security of Pharmadule is not optimized. Below improvements required for each chapter, are described.

**Personnel - Chapter 2**

The mean value of the chapter is 0, 71. Pharmadule needs to perform some improvements regarding permission, competence and utilization of consultants.

**Availability/ Reliability - Chapter 3**

The mean value of the chapter is 0, 64. Some issues have high scores which mean that there is a very little risk or no risk at all. Still there are some issues that need to be improved. They are security precaution due to harmful code, validation of inputs, controlling of internal arrangements and integrity of communication.

**Security of system - Chapter 9**

The mean value of the chapter is 0, 33. Pharmadule needs to make considerable improvements to reduce their risks. Issues regarding the use of operating systems and archiving the log functions are satisfactorily, but all other issues in the chapter need improvement.

**Network/ Telecommunication - Chapter 10**
The mean value of the chapter is 0, 43. Issues that have an almost unacceptable risk are identification due to access of systems and network, and protection of unauthorized connections. However, all the issues in the chapter need improvements to increase the information security of Pharmadule.

**System development/ System changes - Chapter 11**

The mean value of the chapter is 0, 56. The issues of the chapter need to be part of the work regarding continuous improvements.

**Personal computers/ working stations - Chapter 12**

The mean value of the chapter is 0, 61. The issue with the lowest score and highest risk is permissions. To install an authorization control system on the personal computers will decrease the opportunity for unauthorized persons to access the computers.

## 8 Conclusions

This chapter presents the conclusions of the analysis and discussion.

Pharmadule needs to provide for more training. The employees need more training regarding the use of the system tools, but they also need a better understanding of the interaction between the system tools. To work with ProArc in a correct way they have to work with the Microsoft Package in a correct way. Some of the employees do not have sufficient knowledge about the MS Package and they need a course.

To eliminate a lot of error in documents in ProArc, the employees need to understand the impact of their native documents on the system tool, and the entire document flow. Some need more training in how to use native files and how to use templates in ProArc. Others need to understand how their own computer affects their documents. Some employees have viruses on their computers and the company/ IT support should be more consistent in reformatting the computers.

The employees need more knowledge of how the system tools contribute to the processes. This knowledge should be maintained through training and a better description of the system tools and the processes at the intranet.

The interaction between system tools and processes must be fulfilled. The intranet does not give a satisfactorily description of how the use of the system tools is applied through the processes.

Descriptions of working procedures need improvements. The employees need to take a more active interest in new and improved working procedures. To fulfil that requirement the company needs to welcome their employees in the work of changes. A more open dialogue and discussion between employees and management regarding existing procedures will clarify the situation today. When the employees have a complete overview they easily understand and are able to identify with, the motivation to perform changes increases.

The Gap- Analysis to ISO 27001 is not completed in this thesis. There were only a few chapters that were investigated and the investigation was not performed by the book. If Pharmadule wants to complete the analysis, the company needs to set up an investigation team containing an investigator, a single point of contact at the IS/IT department and individually selected persons who are able to answer specific questions.

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