Laboratory Information Management System (LIMS) – software acquisition for Quality Management (QM) in plastics manufacturing

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EXAMENSARBETE	
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Utbildningsprogram:	Plastteknik
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Författare:	Sebastian Peltola
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Handledare (Arcada):	Valeria Poliakova
Uppdragsgivare:	Plastavdelningen på Orion Oyj

Sammandrag:

Detta är ett arbete vars syfte är att skaffa en ny programvara för plastavdelningen på Orion Oyj. Programvaran är inte vilken som helst, utan skall användas för kvalité hanteringen som dessutom följer de amerikanska Food and Drug Administrations standarder. Kvalitén i plast produkterna inom plast avdelningen är oerhört viktigt, på grund av att produkterna är i kontakt med läkemedel vid en senare fas. Plasten kan inte återvinnas för att det skall vara så rent som möjligt. Den huvudsakliga meningen med programvaran är att allt skall vara spårbart, varenda stege som sparas innanför programvaran skall vara elektroniskt signerat, vilket betyder att när någonting är ändrat eller skrivet i programvaran, vare sen kvalitén av en produkt eller mätningar, skall det förekomma en elektronisk signatur. Via detta, kommer personalen att få så snabbt som möjligt reda på vad för fel kan förekomma i produkterna, vilket leder till en effektiv produktion med så lite misstag som möjligt. Detta arbete kommer att innehålla processen bakom ackvisitionen av programvaran samt de relevanta teorierna som skall tas i beaktan innan skrivningsprocessen av programvarans kravspecifikation. Syftet är att hitta ett lämpligt företag som erbjuder programvaran samt uppfyller alla de krav som behövs, men samtidigt är lätt att använda och går snabbt att lära sig.

Nyckelord:	Orion Oyj, Laboratory Information Management System (LIMS), kravspecifikation av programvara (SRS), Food and Drug Administration (FDA), kvalité, plast
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Abstract:

The aim with this thesis is to research the relevant theory in Laboratory Information Management System (LIMS) software for the Plastics Department, to be able to write a proper Software Requirement Specification (SRS). The purpose of the software is to use it within the quality management and the requirement for the software is that it has to fulfill the standards of Food and Drug Administration (FDA). The quality of the plastics products are important, because they will be in contact with medical devices. The plastics material cannot be recycled because it has to be as pure as possible. The main reason of the software is going to be traceability. This means that, when something is saved, the program will leave an electronic signature. With this function, it will be easy to have a full control of the procedure, and the personnel will easily be able to avoid error, which leads to a more effective production. This thesis will contain the process of the acquisition of the software as well as the relevant theory that needs to be taken into account before writing a software requirement specification. The meaning is to find a suitable company that offers this kind of software that fulfills the necessary requirements, but also is easy to use and easy to learn.

Keywords:	Orion Corporation, Laboratory Information Management System (LIMS), Software Requirement Specification (SRS), Food and Drug Administration (FDA), quality, plastics
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Toimeksiantaja:	Orion Oyj

Tiivistelmä:

Tämän työn tavoitteena on kuvata uuden ohjelmiston hankintaprosessi Orion Oyj:n muovituotannolle. Kyseessä on ohjelmisto, jolla varmistetaan tuotantoprosessin laatu. Lisäksi täyttää amerikkalaisen Food and Drug Administration:in (FDA:n) vaatimukset. Muovituotteiden laatu on todella tärkeää Orionin muovitehtaalla, sillä tuotteita käytetään lääkevalmistuksessa. Muovi raaka-aineen täytyy olla puhdasta ja tämän takia tuotteita ei kierrätetä sisäisesti. Tulevan ohjelmiston päätarkoitus on jäljitettävyys, mikä tarkoittaa sitä, että kun jokin kirjaus tallennetaan, sähköinen allekirjoitus tulee automaattisesti. Tämän avulla tuotannon työntekijät saavat nopeasti tietoa mahdollisista virheistä ja virheitä voidaan välttää, jonka seurauksena saadaan tehokkaampi tuotanto. Tämä opinnäytetyö sisältää ohjelmiston hankinnan sekä teorian, mitä kannattaa huomioida kun ohjelmiston vaatimusmäärittely laaditaan. Tarkoitus on löytää sopiva yritys, joka tarjoaa kyseistä ohjelmistoa sekä täyttää määritellyt vaatimukset. Kuten esim. ohjelmiston täytyy olla helppokäyttöinen ja helppo opettaa muille työntekijöille.

Avainsanat:	Orion Oyj, Laboratory Information Management System (LIMS), Ohjelmiston vaatimusmäärittely (SRS), Food and Drug Administration (FDA), laatu, muovi
Sivumäärä:	40
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CONTENTS

Figures

Tables

ABBREVIATIONS

LIMS – Laboratory Information Management System

FDA – Food and Drug Administration

FDS – Functional Design Document

GMP – Good Manufacturing Practice

CFR – Code of Federal Regulations

GxP – Good (Anything…) Practice

SRS – Software Requirement Specification

SAT – Site Acceptance Test

PQ – Performance Qualification

IEEE – The Institute of Electrical and Electronics Engineers

FOREWORD

This project is done for the Plastics Department at Orion Corporation so I would like to thank all the workers at the department, especially the Factory Manager Erki Suortti for giving me the great opportunity to work with such a huge project. I would also want to thank my supervisor Valeria Poliakova for giving me guidance with this thesis.

A big thank you belongs to my family, for all the support and trust that I have got from you.

1 INTRODUCTION

1.1 Orion Corporation (Oyj)

Orion Corporation (Oyj) is a pharmaceuticals and diagnostic tests developing company that was founded in 1917 by three chemists: Onni Turpeinen, Eemil Tuurala and Wikki Valkama.

Orion manufactures both human and veterinary pharmaceuticals and develops new drugs and treatment methods all the time.

Orion has around 3500 employees and had net sales of 1,015 million Euros in 2014. [1]

Figure 1: Onni Turpeinen, Eemil Tuurala and Wikki Valkama [1]

1.1.1 The history of Orion Corporation

Before Finland's independence in 1917, Orion OY (later Oyj) got its start by three chemists Onni Turpeinen, Eemil Tuurala and Wikki Valkama. Back in those days, Finland had a majority of Swedish speaking Finns, which was the main language in most companies. These three chemists wanted to start a company where Finnish would be the number one language and this is how Orion got its start. The share capital was in the beginning 1000 Finnish Marks (FIM), which is nowadays around 1000 EUR. The share capital today is over 92 million EUR.

The beginning of Orion was very humble. It was located on Mariankatu 24 in Helsinki in a previous butter plant. “Due to poverty and lack of capital, Orion was forced to operate in a small building that I now wouldn’t hesitate to call a dump.” – Dr. Arvo Ylppö, a member from Orion’s Management Board wrote back in 1925. The first major products that Orion made was not pharmaceuticals, they were the artificial sweetener dulcine, Lysol, ammonia and Bellistol, which were used as rifle cleaning oil. The oil was a very popular and well sold product during wartime.

In 1920s, Orion started to sell pharmaceuticals and the typical products those days were acetylsalicylic acid pills, eye creams, rhubarb tablets and Nutrol, fish liver oil and malt extract containing nutritional supplement.

Orion changed its location in 1934 to a bigger factory in Vallila, Helsinki. Via this, Orion became the biggest pharmaceutical company in Finland. The factory was located in Vallila until 1961, when it moved to Mankkaa, Espoo, where the factory is located also today. [1]

1.1.2 Plastic department’s history

The Plastic department was founded in 1956 in Vallila, Helsinki. In 1970’s, the department was moved to Espoo, where it is also nowadays located. Back in 1970’s there were only 9 machines, both injection- and blow molding machines. The manufacturers of the machines were Krauss Maffei, Engel and Bekum.

Today the Plastic department has 21 plastic machines and the manufacturers are Engel, Ferromatik Milacron, Uniloy Milacron, Meccanoplastica and Arburg. Most of the plastic machines are made by Engel and they are injection molding machines, but there is also some injection blow molding machines (Meccanoplastica and Uniloy Milacron).

There are around 60 plastic products made in the Plastic department. The plastic machines operate continuously for 24 hours for five days a week, because the employees work in three shifts (day, evening and night). The plastic department has 24 employers and 12 of them work in three shifts. [2]

1.1.3 Aims and Objectives

The aim with this thesis is to research the relevant theory in Laboratory information management system (LIMS) software for the Plastics Department and related Food and Drug Administration (FDA) requirements to be able to write a proper Software Requirement Specification (SRS). It is also important to analyze the specific requirements for the LIMS-system at Orion's plastics plants laboratory, to be able to understand the importance of each requirements.

The quality of the plastic products made by the Plastics Department in Orion Corporation has a significant role. Therefore every product that is tested is documented and errors that occur are transferred into digital format, with additional information depending on the error. Nowadays all the documentation takes place in Excel and all the information about the products are listed there. This method does not follow the regulations of Food and Drug Administration (FDA).

When writing in Excel, even though the file is saved and the personnel have put their signature, everything is changeable. Only adding or deleting a small symbol can make a big difference in the final report. The desire is to get software which fills the regulations of FDA but, at the same time, has a simple layout, a layout that looks like the files already existing in Excel. To find the right software that achieves these requirements can be challenging, following all the requirements, standards and other regulations that has to be taking into account. Major improvements with time savings in documentation, reporting and working process will be achieved with the software. This leads to fewer error made by personnel and via that, minimizing the plastic waste can be achieved.

2 BACKGROUND

2.1 Quality Requirements

The quality of the products made in the Plastic department has a high importance when using for medical purposes. The appearing plastic waste cannot be recycled, because it has to be as pure and bacteria free as possible. All the waste that the machines produce are thoroughly sorted, so that the raw material store keeper knows precisely how much waste has come from each raw material. The waste is put in different scrap cages. These different cages are named, depending on what they contain, some examples of scrap cages are: Polyethylene and Polypropylene cage, Polystyrene cage, a cage for Plastic jars and jar closures, etc. When a cage is full, it is removed from the production line and moved to the weighing area, where each cage is separately weighed. After the weighing procedure, the score is written down in an Excel file where all the information about the total scrap is documented. Through this, the total amount and the percentage of the scrap can be strictly followed.

Figure 2: An example of a scrap cage containing PE and PP scrap (Sebastian Peltola, 2015)

There are several methods done to different products to check the quality. The most common way to check the quality is visual checking. This means that a sample collector collects products from all the running machines and takes them to a different room for visual control that takes place every hour. Some examples of errors are flash, the plastic is burnt, scratch marks, stained etc. (an error list in appendences). To avoid further errors in the plastic products, the molds are cleaned and some changes may be done to the plastic machines. In case of problem being observed there are five severity classes which are used:

- AA = Major problem requiring immediate action and detailed review, as well as rejecting earlier products.
- A = Severe problem requiring immediate action and possible rejection of products.
- B = Small problem requiring action (mold cleaning, adjustment of the machines) but no need for rejection.
- C = Minor problem only to be informed forward and observed.
- D = Minor problem, no need for actions.
  (More detailed explanation in the appendences)

After the visual control, more advanced checks are done to some products. Some of these advanced checks are for example sealing tests. This means that liquid is put into a product, then closed with a closure and then the whole package is shaken to test if the product is seal. This is where the quality is very important, because inside these products, human blood can be stored. It is important that the products are seal and no bacteria can enter inside the product into the liquid.

2.1.1 Implementing the quality requirements to LIMS

Because everything is written in Excel, there is the small chance to make changes to the results. For example dimensions of the products can vary because of a wrong click on the mouse. This is one of the reasons why the software has to be changed into LIMS. In LIMS everything is traceable and the user's signature comes automatically when saving a file.

A person has to use one's own username and password which leaves an automatic electronic signature when saving the file. If, however, something is misspelled or a decimal of a number is wrong, it can be corrected, but it is demanded that the reason for this change has to be explained, i.e. a "miss click" with the mouse, or a typing error etc.
Another helpful feature, which comes with the program, is the structure. All the documents about the quality records, instructions, list of raw materials and the different test methods, with several equipment, are in one place, which will help the working procedure and save time.

3 LITERATURE REVIEW

This chapter will contain a more detailed explanation of what LIMS is and also cover information about FDA and its regulations.
There will additionally be explained the meaning of software requirement specification (SRS), how it's written and what needs to be taken into account when writing an SRS.

3.1 Laboratory Information Management System (LIMS)

Laboratory Information Management System, or LIMS, is a software-based program that is often used within a laboratory environment and gives the opportunity to support a modern laboratory's operations. The software is used to trace and handle data and different materials, as in equipment, workflow, reports, invoicing etc.
There are different ways to build up the software, depending on the demand. Some might want a simple layout and just a narrow use of the software, whereas others might want a more complex system, a system where everything is possible. The definition "LIMS" is often used within pharmaceutical and petrochemical analysis.
LIMS was introduced in 1982 in a form of a single centralized minicomputer that gave the laboratories the first opportunity to put to use automated reporting tools. Before LIMS, up until 1970s, all the reporting in laboratories where done manually, which was a time-consuming process. [3 pages 31 – 32]

Sample management has been the basis function of LIMS. It is typically set up when a sample is collected in to the laboratory, at which point it is registered in the LIMS. The LIMS system then tracks the samples location, which means that the system assigns the sample to a special location, for example a box, row or a column.
LIMS also provides a large amount of instrument and application integration. The system can feed files into the instrument and direct its operation on an item, such as a jar or other container. Afterwards the LIMS imports the results from the instrument and extracts the data for quality control assessment. [3 page 34]

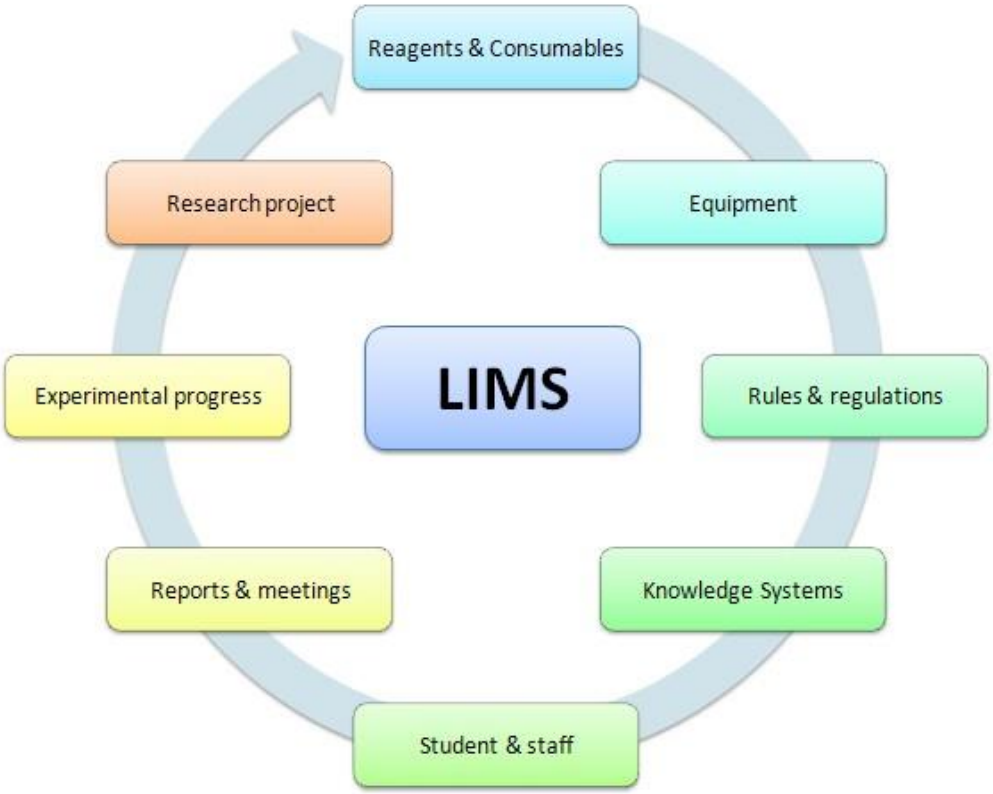

Figure 3: The cycle of Laboratory Information Management System [15]

3.1.1 21 Code of Federal Regulations (CFR) Part 11

The 21 CFR Part 11 contains regulations considering issues and securities with electronic signatures and electronic records.
"§11.1 Scope: (a) The regulations in this part set forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to

paper records and handwritten signatures executed on paper."(U.S. Government publishing office – Electronic Code of Federal Regulations)
The regulation ensures security, integrity and confidentially of electronic records. The electronic signatures are as legally binding as hand-written signatures.
This regulation demands manufacturers of pharmaceutical products to implement validations, audit trails and documentation for both closed and open software as well as systems that are involved in manufacturing specific electronic data. [7, 8]

3.2 Food and Drug Administration (FDA)

Food and Drug Administration (FDA) is government agency of the United States Department of Health and Human Services founded in 1906, which makes the administration the oldest consumer protection agency in the U.S. The administration is responsible for approving, managing and auditing medical products, including pharmaceutical drugs and medical devices, as well as responsible of protecting the public health. They are also responsible for making medicines more effective and more affordable but also responsible to help the public to get more science-based information how to improve the health in medicines and foods. [4]

3.3 Good Manufacturing Practice (GMP)

GMP is a system, declared by the Food and Drug Administration of the U.S, for guaranteeing that products are manufactured repeatedly and supervised according to quality standards. These standards, which have the force of law, demands the suppliers, processors, and packagers of medical devices, drugs, food and blood-take proactive steps to ensure that their products are safe, pure and effective. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated though testing the final product.
GMP takes all the productions conditions into account, but the conditions are not tested in a batch of product, namely every single step is tested separately. Everything from the

starting materials (such as raw-materials in plastics) and equipment that is in use, to the well-being of the staff, such as their personal hygiene and their training.
Most of the requirements that are associated with GMP are very broad, which grants the manufacturers to choose freely the perfect implementation method. [9]

Figure 4: The GMP guidelines [14]

3.4 Software requirement specification (SRS)

A Software requirement specification (SRS) is a document that defines how a software system is expected to work, from the user's perspective and has a list of all the customer's requirements of the system. It is a two-way project to ensure that both the customer and the supplier understand each other's requirements and that it will be possible to satisfy both participants.
The document states in precise and correct language the functions and proficiencies a software system shall contribute. To acquire the needed requirements, the participants

need to have a clear and a full understanding of the product being developed. When the document is completed and accepted, changes are still accepted, but, the changes must be strictly controlled. [10 page 1, 11]

3.4.1 Different Software requirements

The software requirements can be put into two major sections, user requirements and system requirements.
The user requirement normally describes the needs, goals and tasks of the user. The user requirements document defines the end-user, which means that any measurements of, for example, quality will be taken into account from the end-users point of view.

The system requirement has two definitions. It can refer either to the software requirements that describes the competence of the system with the functioning of the product, or, it can refer to the requirements that define the product, which means that the product is a system. Furthermore, there are two types of system requirements, namely user- and software requirements. The software requirement indicates the obligation of the system, whereas the user requirement indicates the acceptance level of the user performance and the system satisfaction.

There are also other requirements, such as functional requirements. It describes the functions at the implementation level, which are typically used to build the system exclusive of the Graphical User Interface (GUI). This means the design of the page, such as an e-mail section, shopping cart page, and navigation components etc. [10 page 2, 11]

Software Requirement		
User Requirement	System Requirement	Functional Requirement
• Needs • Goals • Task	• Capabilities of the system • Description of the product itself	• Function at implementation • Design of the page

Table 1: A chart describing the different software requirements (Sebastian Peltola, 2015)

The figure below shows the various types of SRS requirements.

Figure 5: Diagram of various types of requirements [12]

3.4.2 Features of a good SRS

A good SRS should be

1. Correct
2. Unambiguous
3. Complete
4. Consistent
5. Ranked for importance and/or stability
6. Verifiable
7. Modifiable
8. Traceable

1. *"An SRS is correct if, and only if, every requirement stated therein is one that the software shall meet."* [13]

Correctness is not something that can be guaranteed with neither a procedure nor a tool. The SRS should be compared with another appropriate preferable specification to ensure the correctness of the SRS. The changes done in an SRS makes the traceability process easier and error free. [13 page 4]

2. *"An SRS is unambiguous if, and only if, every requirement stated therein has only one interpretation."* [13]

The importance of the software life cycle requirements process is in an SRS. The SRS is used within design, validation, verification, implementation, project monitoring and training, and this is why it is important to have a clear understanding of the SRS, both for the user as well as for the developer.

It is typical to write an SRS in native language, e.g. English, which makes the language unclear (see next paragraph). Therefore the specification should be reviewed by an independent group to identify unclear use of language and followed by correction of the specification.

To prevent the unclear, natural language in an SRS is to write it in a particular requirements specification language. Language processors automatically detect many syntactic, lexical and linguistic errors. A disadvantage with such language is that a nontechnical user may find it incomprehensible, and to understand the language may take some time. [13 pages 4-5]

3. In order for an SRS to be complete, it has to include some elements. Firstly, all the important requirements need to be listed, whether it is issues about performing, design, external interfaces or functionality. Secondly, a relevant list of the responsibilities concerning the software, whether it is valid or invalid input values. Finally, a full description to all tables, diagrams and figures as well as definition of all terms and measurement units. [13 pages 5-6]

4. *"Consistency refers to internal consistency. An SRS is internally consistent if, and only if, no subset of individual requirements described in it conflict."* [13]

An SRS is not correct if it does not agree with some higher-level documents, e.g. as a system requirement specification. Some conflicts may appear in a wrong written SRS. These conflicts are, e.g. that someone requires a product to be a specific color, while another one requires that the product should be color free, or that the format of the SRS is tabular instead of textual. Another conflict may be that a number of requirements are described in the same way but different terms for the descriptions are used. This might lead to an SRS that repeats itself many times. [13 page 6]

5. An SRS document is classified for importance and/or stability if every particular requirement in the document has an indicator for its importance of stability.

Requirements for a software product have a different importance, some are more important than the others. This is why it is valuable to state which requirements are important, to get a clear understanding of the differences between the requirements.
There are some clear ways of classing a requirements importance, e.g. essential, conditional or optional. With this can the supplier easily see the importance class of a requirement for the system. [13 pages 6-7]

6. If each requirement in the SRS is stated as valid, then the SRS is verifiable. There has to be some definite cost-effective process where a person or a machine can check that everything fulfills the requirements. There can be non-valid requirements if words as "good", "usually" or "well" is included in the original specification. Requirements that include these words cannot be verified because it is not possible to define the terms. In case it cannot be determined, if the software meets specific requirement, then the requirement will be removed or edited. [13 page 7]

7. If an SRS has a structure that is easy to modify and make changes to the requirements, but still keeping its structure and style, then an SRS is modifiable. Some requirement for a modifiable SRS is for example: an understandable structure with a table of contents, an

index and some cross-referencing. The requirement should not be repeated, and every requirement should be individual, instead of mixing the requirements together. [13 page 8]

8. If the originality of each requirement is understandable and clear, then the SRS is traceable, meaning that each requirement has to have a source or a reference number, to make it easy to find, both for the supplier and the customer, in what section does the requirement belong. There are two types of traceability, namely backward and forward traceability. The backward traceability means that each requirement should refer to a source, which often can be found at the very end of an SRS, while forward traceability means that each requirement should have an exclusive name or a reference number and by referring to the specific reference number, both participants can easily find the section where the requirement is stated. [13 page 8]

A good example of the structure of an SRS can be found on the next page, which follows the Institute of Electrical and Electronics Engineers (IEEE) standards.

IEEE Standard SRS Template

1. Introduction
- 1.1. Purpose
- 1.2. Scope
- 1.3. Definitions, acronyms & abbreviations
- 1.4. References
- 1.5. Overview

2. Overall description
- 2.1. Product perspective
  - 2.1.1. System interfaces
  - 2.1.2. User interfaces
  - 2.1.3. Hardware interfaces
  - 2.1.4. Software interfaces
  - 2.1.5. Communications interfaces
  - 2.1.6. Memory constraints
  - 2.1.7. Operations
  - 2.1.8. Site adaptation requirements
- 2.2. Product functions
- 2.3. User characteristics
- 2.4. Constraints
- 2.5. Assumptions and dependencies
- 2.6. Apportioning of requirements

3. Specific Requirements
- 3.1 External interface requirements
  - 3.1.1 User interfaces
  - 3.1.2 Hardware interfaces
  - 3.1.3 Software interfaces
  - 3.1.4 Communication interfaces
- 3.2 Specific requirements
  - 3.2.1 Sequence diagrams
  - 3.2.2 Classes for classification of specific requirements
- 3.3 Performance requirements
- 3.4 Design constraints
- 3.5 Software system attributes
  - 3.5.1 Reliability
  - 3.5.2 Availability
  - 3.5.3 Security
  - 3.5.4 Maintainability
- 3.6 Other requirements

4. Supporting information
- 4.1 Table of contents and index
- 4.2 Appendixes

Figure 6: An IEEE standard SRS template [13]

4 METHOD

This section is going to contain the proceeding and the implementation process, how to begin the process and what should be taken into account when describing the company's requirements for the upcoming software to the Plastics Department.

4.1 Interviews with the Candidates

On 18th of March, Chemistry Fair at the Fair Center in Helsinki took place. There were two companies presenting a LIMS software-based program that drew the attention. After going through the Plastic Departments needs and explaining them the production method including the current sample recording method, some meeting dates was arranged with the companies, to be able to go through the offered software in more details.

Two companies are not enough to get valid bids, because it is not accurate and competitive enough, therefore a minimum of three companies have to be involve, so more company research has to be done. After some research and asking co-workers, two additional companies came up.

The following task was to contact the selected companies and present them the Departments demands, as well as introduce them to the current activities. The most effective way of contacting the companies is by e-mail, because more persons can be involved in an e-mail discussion, rather than using a phone. Another valid reason for the use of e-mails is that you have a permanent prove of the discussions, so no-one can blame one other for lying. Subsequently, when discussions through e-mail were done, meetings had to be arranged. The agenda in the first meetings with the companies was to get the representatives from the companies acquainted with the plastic production line and with the sample recording, containing introductions to the different equipment that are in use for several measurements to the products.

The suppliers prepared a simple demo version of what their software looks like, when customizing it for the Departments purposes. This way a good picture of each companies offer can be achieved and that will help the process in writing a proper offer request, along with the final decision that has to be done.

The demos contained examples of different test methods for several products. The test methods that were presented were directly examples of the daily procedure, which made

the whole presentation easy to understand from the Departments point of view. Some of the candidates gave the opportunity to create a product from the beginning. This means that they gave the opportunity to try out the software that will be used by the production personnel later on and that helped the understanding of the function of the specific software.
The suppliers showed different layouts in the software for different users. For example, the layout for the production workers was very simple, as demanded. The only thing a production worker needs to see is the products process and a few test methods that will be done to the products, e.g. measuring the diameter of a product, or weighing the product etc. The reason for a simplified layout for the production workers is to prevent extra time consumption with searching for the right task within the software. The point is to have everything accessible for them only by a few clicks.
They also showed what the quality controllers will see when they log in to the program, which is a wider range of options. They will have the access to all the test methods done to the plastic products. Last layout that the candidates showed was the manager's layout. The manager will have access to everything, and by everything is meant that the manager will be able to create a new product, decide which tests will be done to the specific product. The manager will also have the ability to choose, who has access to what.

The candidates visited the plastics department a couple of times, and every time showed an updated version of the software, when they got a better understanding of what the process within the plastic department.

4.2 Writing the LIMS offer request

After getting together with the companies and going through how the offered software looked like, an offer request has to be done. In this offer request, detailed information and request has to be listed. The offer request has to contain the Departments needs and examples of today's method.
The first version of the offer request is written at the beginning of June. This version is only a preliminary version of the upcoming one. The point of this first version is to send the companies an overview of the Departments demands. The reason for this first version

to be preliminary is that it doesn't contain any GxP (Good [anything...] Practice) standards or any other regulations, only the situation at this point and what is hoped to get from the software. There are also lots of examples on the current records of how it is written down when something unexpected happens and how the personnel mark it when it's fixed. The version also contains all the equipment that the software has to be able to cooperate with. The two main subjects are the general technical requirements and the requirements for the program.
There is still a problem with the preliminary version, it is not detailed enough. The point with an offer request, especially a reasonable one, is that anyone can understand it, even without seeing the functionality of the process in real life, but still has an understanding of the criticality of some requirements. This leads into a new, improved and more detailed version of the offer request. To understand and to be able to have the knowledge for writing a proper offer request, some meetings have to be arranged. The task is to be in contact with the application manager and go through what to take into account when designing the request, what standards has to be read, the layout of the request etc.

A few meetings are held and the content of the meetings are to go through some valid examples of different specification. Afterwards, the offer request has to be rewritten into a new, improved specification template. The new version is more detailed and more standard requirements are listed. The big difference between these two versions is the traceability and the electronic signature feature. With traceability is meant that every log-in, saving, change etc. is electronically signed by the person who is logged in on the computer. If something unexpected happens or misunderstandings in communication appear, a full, detailed history of what has happened is possible to go through. If someone makes a typing error or another mistake, it can be change by another user as well but, the only thing is that the person has to leave a comment why there are changes from the original one and it will leave the persons signature as a mark, so afterwards when going through the history, it can easily be seen who has done what.

4.2.1 Benefits for the Plastics Department

There are several expected benefits that the Plastic Department will gain from the new software. The biggest benefit is to get the production to be more efficient. To achieve a more efficient production, some time-consuming steps need to be cut. One step is to get more things automated, to get fewer manual steps in the working process. Already automated time & date saves working time. To get all the reports automatically filled by choosing the right product will save lots of time. The profit with the software is to minimize errors done by the people working at the production line, which leads to better control of the products. By better control of the products is meant that, flaws in products can be noticed earlier, which on the other hand leads to maintaining and fixing the machines earlier that leads to less wastage and finally leads to saving money.

Another major benefit with the new software is to get a program that follows the right regulations within pharmaceutical industry.

One goal with the software is to make the layout as easy-using as possible. Meaning that the program is easy to use and things are easy to find. There will be different kinds of user-levels in the program, which means that depending on your working level, the structure and layout of the program will change. The production workers will have the easiest layout and structure of the program, only showing the products that we make and the required tests that need to be done to the products. The quality controllers will have a more comprehensive structure with more test methods. Finally, the managers will have a full access to the program, meaning that they can do changes within the program and add new products etc.

4.3 Decision

A meeting considering the offers is held on 12th of October with the IT- and procurement department with the purpose of going through the offers and discussing which one would be the most convenient for the Departments purposes. There are some unclear information and statements in the offers, considering concurrent licenses, the number of users and a future support of the software, including updates of the software etc.

The task is to gather all the unclear statements and pose questions, where asking for clearer answers.
The decision-making is a long lasting and well-thought-out procedure. Which of these companies fulfills the Departments desire the most, and will most likely supply, in the future, with the most comprehensive support. The layout of the software is also a big issue to take into account. The meaning is to have a program that is easy to use, and more important, easy to teach for the blue-collar workers.
Further decisions were made on the 9th of November and on this day a candidate had to be eliminated to get closer to the final result. The reason for excluding this particular company is that they are located in Sweden, so quick support can be a challenge and there were a big trouble to get the program to look the way that was wanted. Now that one company have been excluded, there can still be some polishing done the other offers to make it more competitive, so further meetings will be held with the companies. This is the reason why making the decision takes a long time, to get an offer that satisfy both participants.

5 RESULTS

This is the part where we go through the results. All the different companies have now presented their offers. There are many different points that effect on the final result, e.g. price, future support, the stability of the company, company location etc.
Orion has expertise in some of the programs that have been offered, which make a huge significance in the final result but does not exclude the others. If a new offer is bought by a company that has never collaborated with Orion, extra work has to be done, such as validation of the company and the program etc., but if the price and every requirement fulfill our desires, the company is still a valid option.

The result of this thesis is the offer request presented by the Plastics Department and how it differs from the IEEE standard template. In this particular offer request, some statements are referred to the standards presented by the IEEE, such as the forward traceability

and the structure of the offer request. Each requirement written by the Plastics Department has a unique reference number, which makes the offer request valid.

The current offer request has the following statements:

1. *Introduction* - A presentation of what the demands are and what the purpose with this new system is. It is also listed who has the responsibility of what, e.g. the supplier is responsible of the installation and has to provide adequate training for the key users.

2. *An overview of the application area*– An explanation of the expected benefits getting from the system and how many users will approximately be using the new system, therefore the number of concurrent licenses that are needed.

3. *Operation requirements* – This section contains an explanation of the current method, as well as a description of the main functions of the system, what is expected to get from the new system, how the Department want it to look like etc.
   Other operation requirements are for example, compatibility, access control (who has access to what), interfaces with equipment and other systems, reporting (getting automatically filled reports from the system and be able to obtain clear printed copies of electronically stored data), traceability, electronic signatures, etc.
   Access control also requires that users password must be encrypted for local user accounts, which means that the users can log in to the system with their given windows accounts, therefore it must be possible to set the system to periodically force the change of passwords.

4. *Technical requirements* – Explanation of protection against harmful attacks, e.g. by firewalls, automatic virus control etc.

5. *Validation requirements* – The system has to be legitimized internally.
   The system shall be Computer Science (CS) legalized according to Orion's Standard Operation Protocols (SOP). To keep the state of validity, some maintenance actions are required, such as the technical support for application assistance and the people who use the program should have a mandatory training for it.

6. *Quality and documentation requirements* – Specific certificates should be easy accessible, for example the user and administrator manuals for the software, or the installation instructions.

7. *Procedure of acceptance* – The acceptance action, such as explaining the Site Acceptance Test (SAT) and the Performance Qualification (PQ). With SAT is meant that the program will be checked if it fills all the requirements and after that follows the PQ, which means that the system will be in a trial use for a period of eight weeks. During this time, the user will define whether the system is functioning as specified, if not, then the time-period might be extended. When the trial period is completed, the system will receive its final acceptance.

8. *Terms of payment* – This is the part where the agreement of payment is defined.

9. *Contact and attachments* – Describing who the contact person for this project is, but also containing the list of all the attachments that are needed. The attachment is a separate file containing examples of the excel files that are currently in use at the Plastic Department. This way it is easier to show the supplier how it is done in the production line nowadays and how the upcoming system is expected to look like.

6 DISCUSSIONS

This section is going to contain the thoughts of what needs to be taken into account when making the final decision, is the price the only crucial matter or is there something else that need to be considered.

6.1 Price comparison

When deciding the best candidate, the price has naturally a significant role. It is not only the total price that counts, but also the yearly fee, such as yearly support and updates. Some candidates offer cheaper implementation and licenses but a greater yearly fee, as others have a cheaper yearly fee. Another factor that the price depends on is the time that the implementation will take. There are candidates that say that the implementation will take months, whereas other candidates offer an implementation that only will take a few weeks.

Another thing that effects on the price is the cost of licenses. We need four concurrent licenses and as we already have one candidate's software within Orion Corporation, the Plastics Department doesn't have to pay for the licenses, only the yearly support fee for them. This naturally effects on the total price, but for some reason the total price for this particular candidate is extremely high, despite the fact that the license fee is excluded from the quote. This is yet a part worth some negotiation with the company, because they still are a valid candidate for our purposes.

6.2 Other things to take into account

There are several things to take into account when making a decision, is the offering company stable, how does the future of the company look like, are they offering support in the future such as software update? These are questions that need to go thoroughly through before making a decision, because it is a major investment for the Plastic Department, and our whole process control relies on this particular software program.

It is important to know how fast the offering company can supply their support, is it hours, days or weeks. Therefore, the location of the company is important and their support level.

An easy way to have a clearer vision of a company is to check how big the company is, and is it well known. The amount of existing customers has also an important role. With the customers we can clearly see who has already applied the offering company's program. If there still is some hesitation and questions about the company, there will always be the option of calling one customer and ask their satisfaction with the company. An easy way of seeing the validity of the company's software is to see if their existing customer is a company like Orion that does pharmaceutical products. This way we can see that the software will be able to handle same parts as we demand, and is compatible with the same standards that Orion is dealing with.

7 CONCLUSION

The importance of writing a proper and comprehensive software requirement specification is high. To make it clear already in the beginning, what is wanted and the role of each participant, is recommendable. When thinking about my effort and the proceeding method, some steps could have been done in a different way. I should have done more research in an earlier state, and write our requirement specification thoroughly one single time. The way I preceded took simply too long, because many different people had to be included, to get the specification written in a right way. Major time savings could have been done if I firstly would have contacted the right persons, went through the proceeding method with them and then contact several candidates to get an offer from them.
This project is a very long-lasting process and therefore did not come to an end. There will still be some meetings with the candidates, discussing about their price and offer. It is important not to hesitate with the decisions but think and go through options thoroughly. Although this project did not give any results, decisions and conclusions can still be done after reading this thesis. The aim today is to make the final decision by the end of this year, so that the implementation phase can start by the beginning of next year and the new software will be running at fullest no later than next summer.
The objective with this thesis was to write a proper offer request, following IEEE standards and Orion's standards. This part gave results, because the final offer request was accepted by different application managers and persons in charge of purchases.

The interesting part will be in the future, what did this new software bring to the plastics department, was it only to fulfill the required statements or did the production increase via the program, i.e. did the plastic waste decrease with the program? This was an aim for the Plastics Department to achieve and only time can tell us what will happen.

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APPENDIX 1 ERROR CODES

The Plastics Plants error codes

A = Short Shot

B = Stained

C = Flash

D = Plate section bent

E = Spindle section bent

F = other failure, e.g. color error

G = Hole at the hub/bottom

H = the hub has a sink mark

I = the bottom is broken, spindle broken

K = Air bubbles, the thickness is uneven

L = Flaw at the side of a pipe

M = the bottom is faulty

N = There’s a fracture in the product

O = Flattened

P = Too tight, too loose

Q = Flash, a spike at the injection point

R = Fault in thread

S = hole is plugged

T = suction

U = scratch mark

X = burnt

APPENDIX 2 ERROR CLASSES

List and explanation of error classes:

D-class: The product is good.
The error is not concerning and there is no practical meaning with the error. Example of errors: a small flash, scratch or a single dirt dot.

C-class: The product is good.
The error is being monitored and observed where the situation is going to go but no further operations is going to take place. Informing the production workers about the error, e.g. a number of dirt dots in the plastic product.

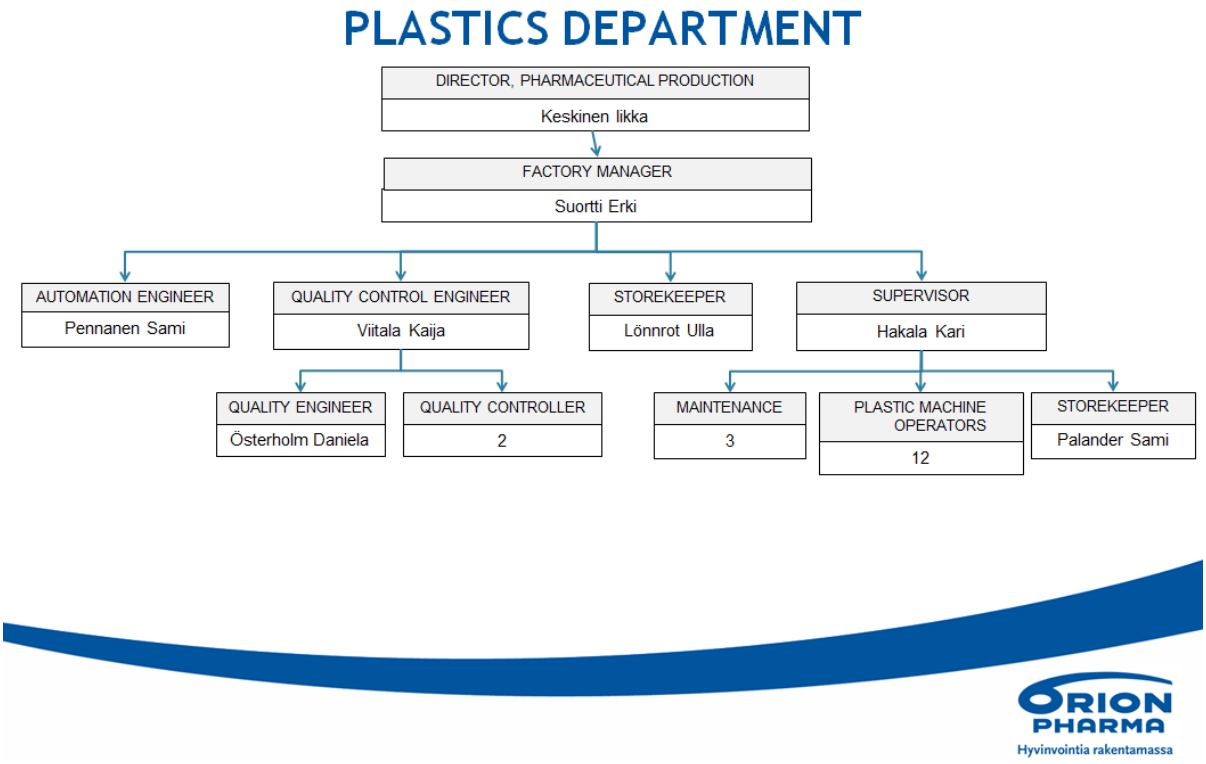
B-class: The product is good and the packaging is continuing.
The product is still good, but some changes in the machines will take place, or cleaning the mold. The production line will be informed about the error. Errors can be: the product is a bit oblique, small spikes at the injection point, small start of dirt at the ejection points etc.

A-class: The product is bad, not to be packed. The packed products will be checked and the bad ones will be removed. Adjustments in the machine will be done, e.g. changing parameters, cleaning etc. or stopped in worst case scenario. The production line will be informed about the error in the products. Examples of errors in this class are: short shots, some serious flashes, bad scratch, color error, very dirty product etc.

AA-class: Same as A-class but the quality controller does a wider and briefer check of the product. The quality manager decides if an A-class will be changes into an AA-class. The production workers will not be using this class. A statements report will be written including the check of the packed products, a clearance of the seriousness of the error and the removal of the products.

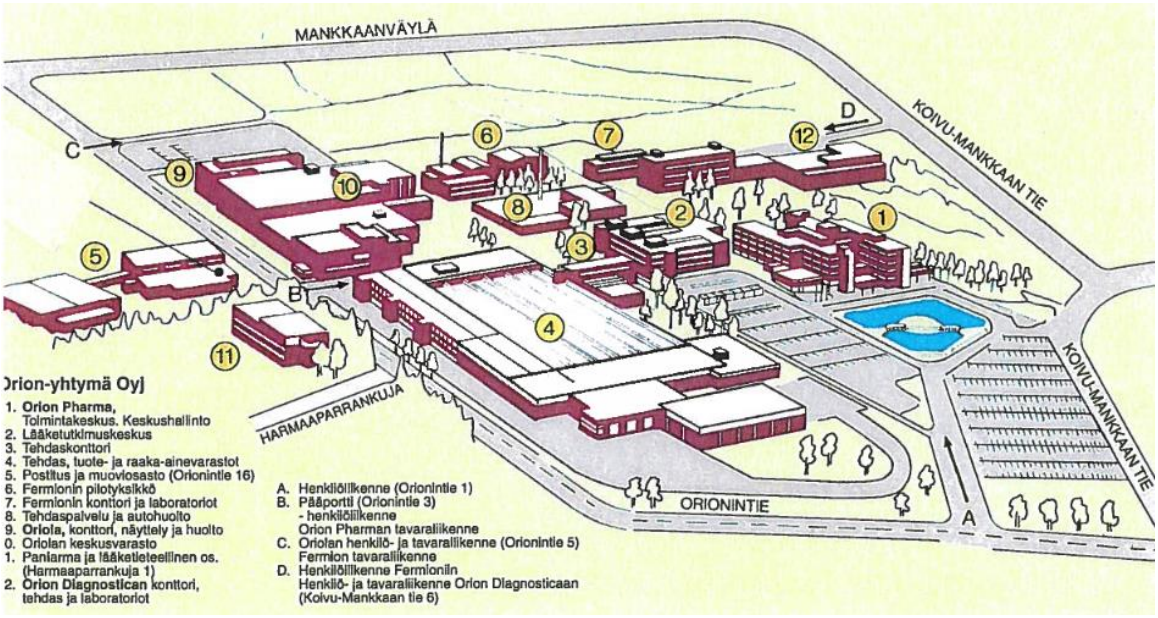
APPENDIX 3 ORGANIZATION

A map over the organization

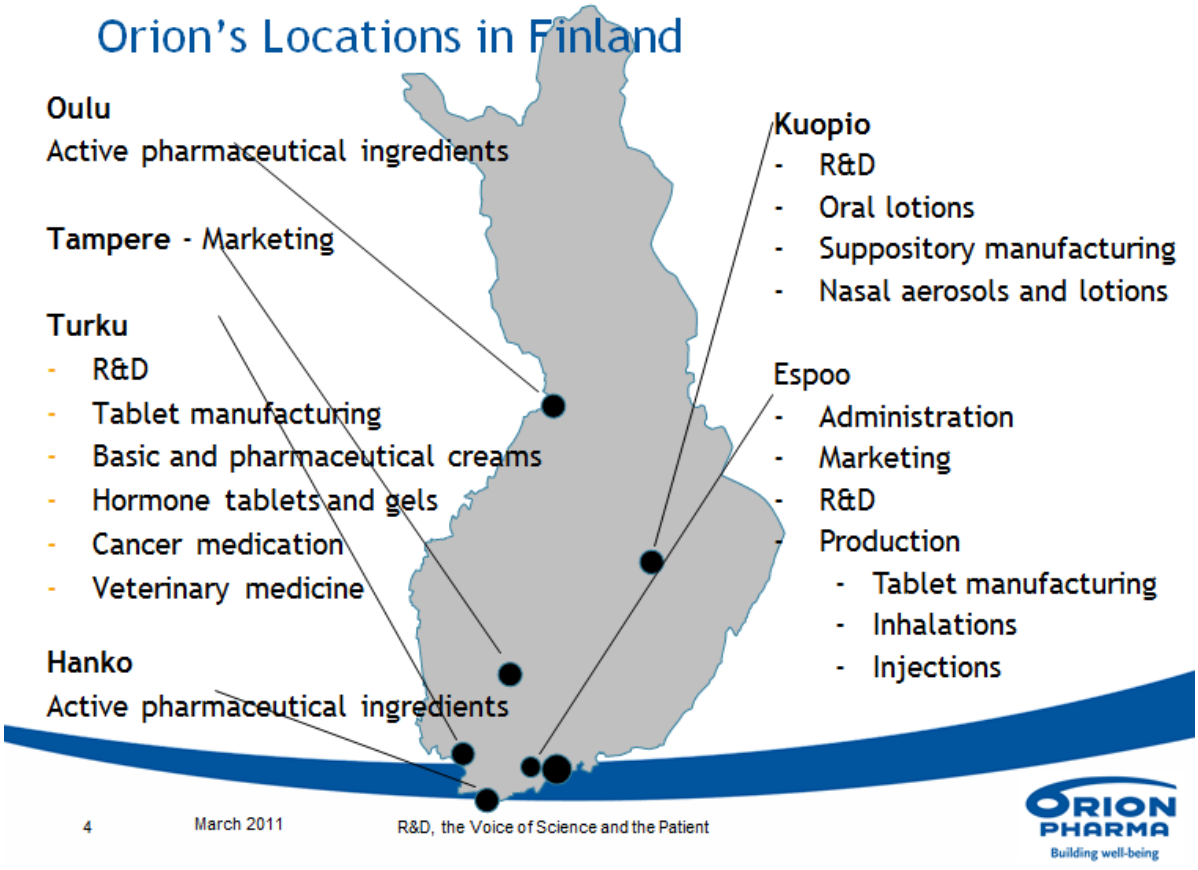


APPENDIX 4 MAP OVER ORION CORPORATION

A map over Orion Corporation in Espoo



1. The Headquarters
2. The R & D Department
4. The Pharmaceutical Factory
5. The Plastics Department


Orion's Locations in Finland
Oulu
Active pharmaceutical ingredients
Tampere - Marketing
Turku
- R&D
- Tablet manufacturing
- Basic and pharmaceutical creams
- Hormone tablets and gels
- Cancer medication
- Veterinary medicine
Hanko
Active pharmaceutical ingredients
Kuopio
- R&D
- Oral lotions
- Suppository manufacturing
- Nasal aerosols and lotions
Espoo
- Administration
- Marketing
- R&D
- Production
  - Tablet manufacturing
  - Inhalations
  - Injections
4
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