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Calibration Software for Laboratory Instruments

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Laboratories have multiple devices that require maintenance and calibration performed on a regular basis. There are several standards concerning calibration of these devices and calibration is a fundamental part of good laboratory practice.

The objective of this thesis was to define the customer requirements for new laboratory instrument calibration software. The customer requirements were identified with a customer needs survey. The theoretical framework for this thesis is software requirements engineering, gathering and managing the requirements. After the identification of the customer needs they were converted in to the requirements for the software. The project is assigned by Sartorius Biohit Liquid Handling Oy.

As the result of this project the customer requirements for new calibration software for laboratory instruments were produced. These requirements can be used when requesting tenders and when creating technical requirements for the software.

Keywords	Laboratory, instrument, calibration, software, requirements

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Laboratorioilla on yleensä käytössä usean tyyppisiä laitteita, jotka vaativat tasaisin väliajoin suoritettavia huoltoja ja kalibrointeja. Näiden laitteiden kalibrointeja koskevat useat standardit ja määräykset. Tasaisin väliajoin suoritettu kalibrointi on myös tärkeä osa hyvää laboratoriokäytäntöä.

Tämän työn tarkoitus oli määritellä asiakasvaatimukset uudelle laboratoriolaitteiden kalibrointiohjelmistolle. Työn teoreettisena viitekehyksenä oli ohjelmiston vaatimusmäärittely, vaatimusten selvittäminen ja hallinta. Asiakasvaatimusten löytämiseksi suoritettiin laaja asiakastarvekartoitus, jossa haastateltiin useita laboratorioissa työskenteleviä ihmisiä. Kun asiakasvaatimukset oli selvitetty, niistä johdettiin ohjelmistovaatimukset. Työ tehtiin Sartorius Biohit Liquid Handling Oy:lle.

Työn tuloksena saatiin asiakasvaatimukset uudelle laboratoriolaitteiden kalibrointiohjelmistolle. Saatuja tuloksia voidaan hyödyntää tehtäessä teknisiä vaatimuksia kalibrointiohjelmistolle tai aineistona pyydettäessä tarjouksia ohjelmiston kehittämisestä ulkopuolisilta ohjelmistoyrityksiltä.

Avainsanat	Laboratorio, instrumentti, kalibrointi, ohjelmisto, vaatimus

Contents

Abbreviations

CFR	Code of federal regulations of the United States
FDA	Food and drug administration
GLP	Good laboratory practice
ISO	International organization for standardization
NFC	Near field communication
QR-code	Quick response code
RFID	Radio-frequency identification
SOP	Standard operating procedure
WLAN	Wireless local area network

1 Introduction

1.1 Sartorius Biohit Liquid Handling Oy

This thesis is commissioned by Sartorius Biohit Liquid Handling Oy which is a part of the Sartorius AG, one of the world's leading providers of laboratory and process technologies and equipment for the biotechnology and pharmaceutical industry [1]. Sartorius Biohit Liquid Handling Oy is focused on developing and manufacturing liquid handling products, such as pipettes and pipette tips.

Sartorius was founded in 1870 in Göttingen, Germany by Florenz Sartorius. Today Sartorius is present in 110 countries and employs more than 5300 people worldwide. In 2011 global sales revenue was 770 million euros. Sartorius is divided in three divisions, Bioprocess Solutions, Lab Products & Services and Industrial Weighing. Sartorius Biohit Liquid Handling Oy is part of the Lab Products & Services division. [3]

Sartorius Biohit Liquid Handling Oy develops and manufactures liquid handling products. The company's operations are based on goal-oriented, long-term innovations and patenting. Headquarters and Research and Development are located in Helsinki, manufacturing plants in Kajaani and in China. Sartorius Biohit Liquid Handling Oy also has a global pipette maintenance and calibration network, called Pipette Doctor.

1.2 Goals and scope

More than 20 years of experience in pipette development has led to a situation where Sartorius Biohit Liquid Handling Oy is the marked leader in electronic pipettes, most of the electronic pipettes worldwide are made by Sartorius Biohit Liquid Handling Oy. Precise and accurate pipetting is extremely important for achieving reliable results in laboratories. Sartorius Biohit liquid handling products are well known and comply with international standards and customer needs. [4]

Increasing customer requirements in the biotechnology and pharmaceutical industry as well as development of regulatory guidelines create increasing needs for extensive

quality systems. Laboratory instrument calibration is a very important part of quality systems as calibration is the only way to ensure the instruments' performance.

The goal of this project is to create requirement specifications for new laboratory instrument calibration software.

This thesis focuses on customer survey and requirements engineering. Project starts with an extensive customer survey which is carried out in Finland and in Germany and consulting calibration experts in France and the United Kingdom. Results from the survey are processed in to requirements. The collected requirements are called customer requirements. After all requirements are found the project is completed.

2 Marketing

2.1 Differentiation in the market

One of the basic principles of business is to differentiate from other competition operating in the same field. There are several methods to differentiate and they all have their advantages.

Two common ways to differentiate is to compete with price or quality. When differentiating with a low price, usually qualities, level of service or features are reduced. When differentiating with high quality the price is normally higher than in low quality products or services. Both methods can lead to success. [5]

It is possible to perform most of the laboratory instrument calibrations without computer software. But in today's industry focusing on highly standardized and effective solution world it is not reasonable. One way to differentiate is to create solution to fulfil all customer needs. When competing with a high quality products and service it is important to add value to the customer process in order to keep the customer bonded to the company [6].

2.2 Current situation

The very first task in this project was to assemble a team to consider if there is a demand for new calibration software. The team consists of heads of services, research engineers and marketing experts from Finland, France, Germany and the United Kingdom. The software would be used for internal work as a calibration company and also to be sold to external customers. Sartorius maintains currently three completely different calibration software programs in Liquid Handling division, and not one of them fulfils all calibration needs. The outcome of the meeting is that the current software is not sufficient enough and there is a demand for new software.

One stage to find requirements and features for the new software is to compare the current software. The calibration programs mentioned below are considered as the most serious competitors and therefore the following comparison chart (Figure 1) is created.

Classified information

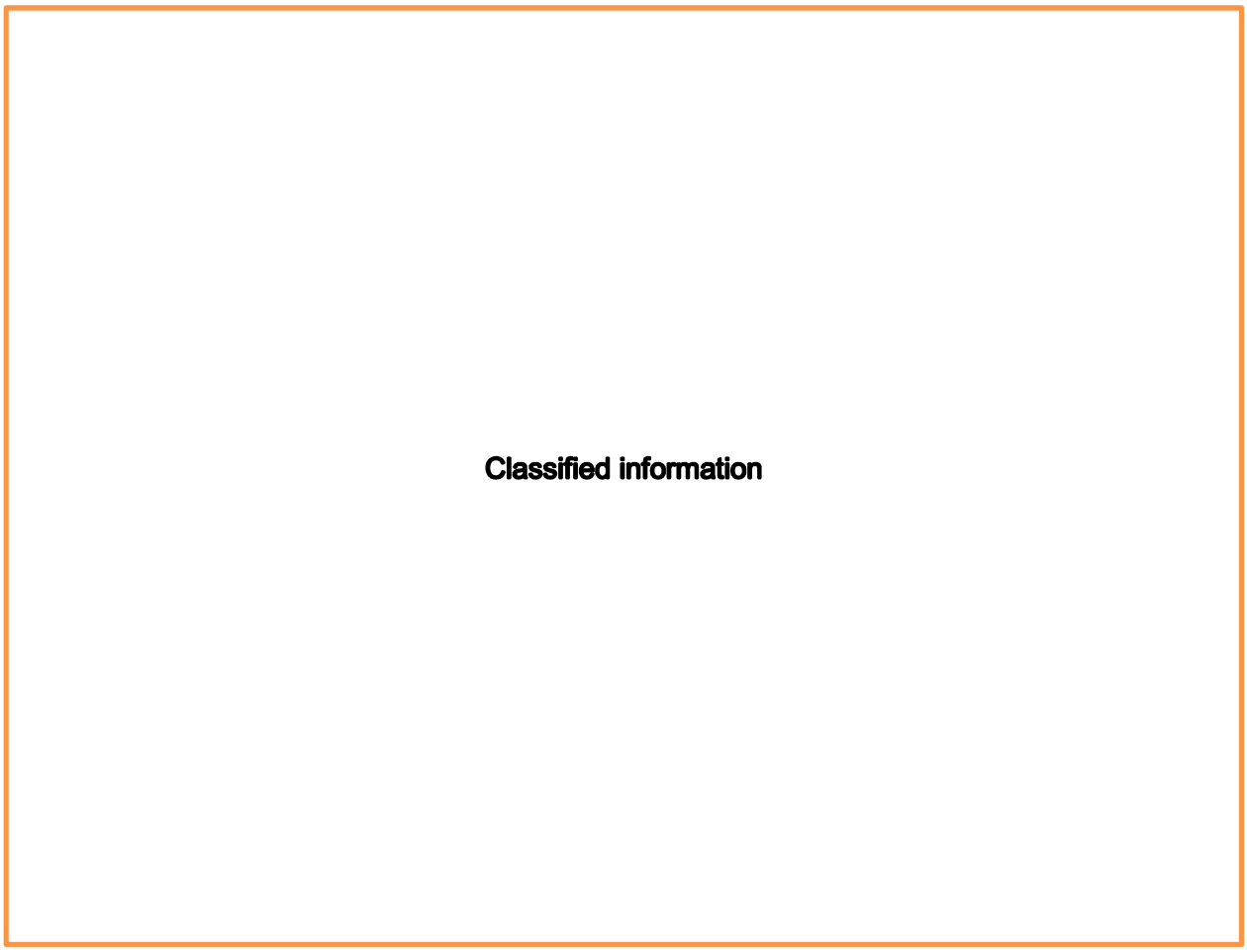


Figure 1. Software comparison.

In Figure 1 calibration programs are compared with a certain criteria and price. In the bottom left corner are software that are low priced and have only few features, and in the top right corner are high priced software with the most features. The criteria used to create the comparison include features such as compatibility to user computer architecture, language support, complying with standards and customer interface. All the criteria used to create the comparison are found in Figure 2.

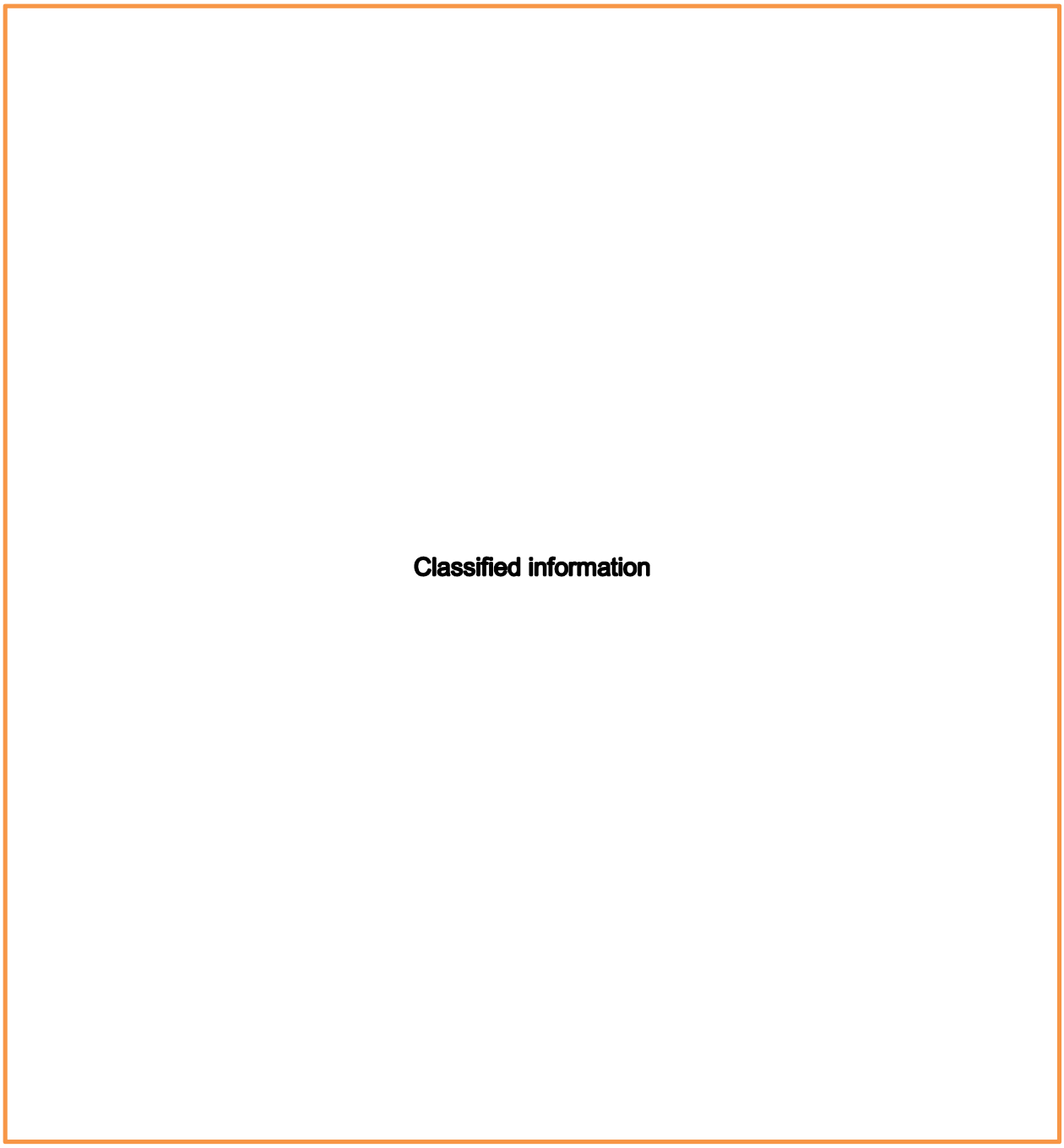
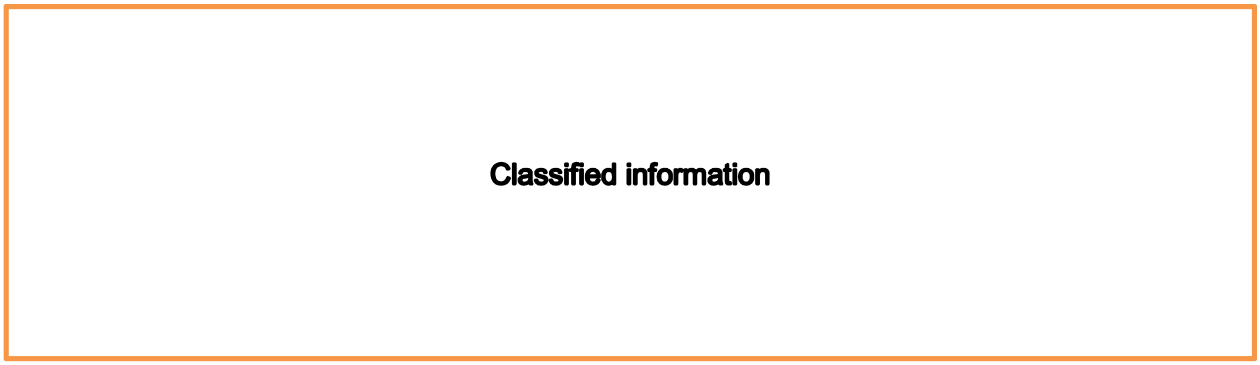


Figure 2. Criteria for software comparison.



3 Other research

3.1 Software development

Even though during this project not a single line of code will be written this is still a crucial part of the software development workflow. Discovering requirements properly is a basis to a good software project. I have adopted my approach to software development project from Karl E. Wiegers's book *Software requirements*. Wiegers deals with finding and analysing requirements in a way that was easy to approach and practical to implement [7]. Requirements engineering will be discussed later in this thesis.

3.2 Software quality assurance

Because this software is going to be a critical tool for the service organisation, it must be produced with high quality and a good support plan. Therefore, software quality planning is in an important role. A more accurate quality assurance plan is produced when the project is proceeding.

Points to consider when creating a quality assurance plan [8]:

- Must fit the business plan
    - It is not sensible to create software that does not fit into the company's business plan. Checking suitability for the business plan is essential for the project to succeed. This must be done in the pre-development phase.
- Requirements test plan
    - Suitability of all the requirements must be tested, all requirements must support the business plan and be executed with reasonable costs to ensure return of the investment.
- Design and production plan
    - If the work is not planned properly it is possible that the schedule fails and the outcome is not what requested.
- Architectural plan
    - New software must fit all the company's previous system and information systems.
- Software test plan

    - All parts of completed software are recommended to test to ensure quality.
- Support plan
    - After production support and manuals are vitally important in order to ensure fluent usage.
- Documentation plan
    - A good documentation is part of a properly executed project and is important for future modifications and adjustments.

3.3 Standards and regulatory requirements

Standards and regulatory requirements set multiple requirements for the calibration program. The program under development must comply with all relevant standards and regulations.

Standards associated with customer requirements:

- CFR 21 part 11 (USA Food and Drug Administration)
    - Describes how electronic records and signatures are created, modified, maintained, archived, retrieved and transmitted. [9]
- CFR 21 Part 58 (USA Food and Drug Administration)
    - Describes good laboratory practice for non-clinical laboratory studies. [10]
- ISO 17025 (International Organization for Standardization)
    - Specifies the general requirements for laboratories that carry out tests and calibrations. [11]
- ISO 8655-6 (International Organization for Standardization)
    - Describes gravimetric methods for the determination of measurement error for piston-operated volumetric apparatus. [12]
- GLP (Good Laboratory Practice)
    - Presents principles of good laboratory practice for non-clinical research. GLP itemizes responsibilities for persons in different roles and sets guidelines for quality programs, facilities, apparatuses, materials, tests, test systems, standard operating procedures, performance and reporting. [13]

In order to adapt to all these and more standards and regulations it was decided that consulting experts in a later phase will be the best solution.

3.4 Automatic identification of instruments

This calibration software is going to be modern high quality software, so all the ways to improve reliability, productivity and traceability must be taken into account. All instruments must be identified in the program before calibration. Automatically identified instruments reduce human error and increase productivity by always identifying instruments correctly and rapidly. Therefore it is required to include automatic identification research to this project.

Some of the common wireless techniques that are compatible with this purpose were selected for the research. In Figure 3 there is a comparison of wireless technologies that can be used to automatically identify instruments.

Criteria	Bluetooth	QR code	NFC tag	RFID tag	WLAN
Re-writable information	Yes	No	Yes	Yes	Yes
2-way communication	Yes	No	Yes	Yes	Yes
Passive device in instrument	No	Yes	Both	Both	No
Operation range (approximately)	10m	0,3m	0,1m	0,1m	150m
Bit rate	Moderate	Low	Low	Low	High
Set-up time (approximately)	5s	1s	0,1s	0,1s	10s
Price (per instrument, approximately)	1 €	>0,1€	>0,1€	>0,1€	5 €
Autoclavable	No	Yes	Yes	Yes	No
Type or reader	Radio	Camera	Radio	Radio	Radio
Strengths	Moderate data transfer speed	Easy implementation, passive device in instrument, size (printed on instrument cover alike serial number)	Rapid and reliable to use, passive device in instrument, size	Rapid and reliable to use, passive device in instrument, size	Fast data transfer speed, high range
Weaknesses	Requires operating voltage, high set up time, cost, size	Reading requires good lightning conditions and instruments must be stationary when reading, may worn out before instruments life cycle is over, limited amount of data and low data transfer speed	May require body modifications in order to fit the tag inside instrument, low data transfer speed	May require body modifications in order to fit the tag inside instrument, low data transfer speed	Requires operating voltage, high set up time, cost, size

Figure 3. Wireless technologies.

The technology solution used for identification of instruments is not yet selected at this stage of the project.

4 Requirements engineering

4.1 Theory

Documentation is a crucial part of all stages of a software development project. A document to describe project planning is called requirements specification. The requirement specification document is one of the first stages of a project and usually used when inviting tenders (Figure 4). [14]

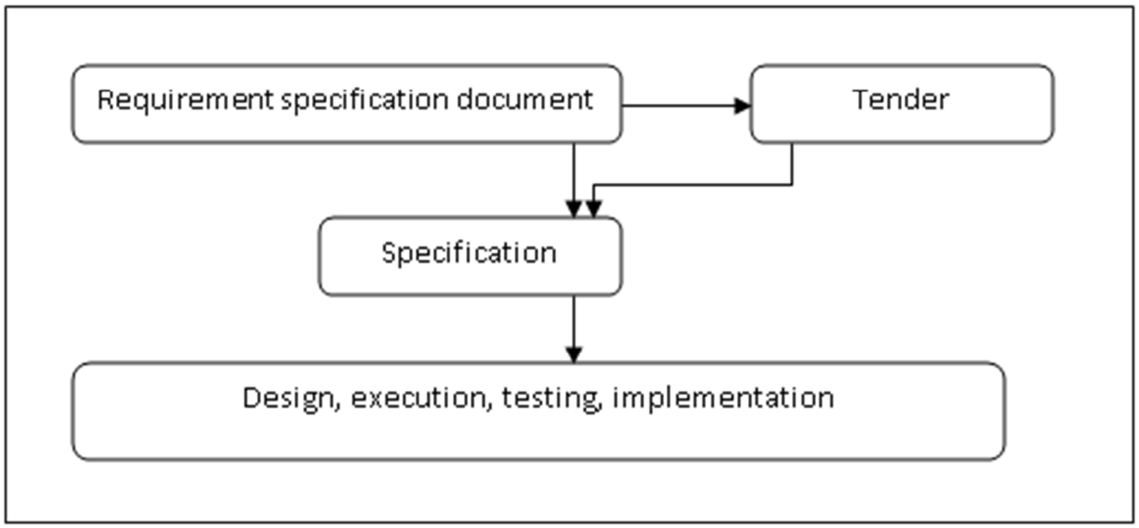


Figure 4. Use of requirements specification [14].

The purpose of a requirements specification is to describe the requirements for the planned system as accurately as possible. Requirements can be divided into functional and non-functional requirements. Functional requirements describe the operation of the system. Non-functional requirements describe other features, such as usability, performance and conformity to standards. [15]

For a supplier, it is very important that the requirement specifications are drawn up in such detail that the future development can be based on them. For customers, it is important that all the important requirements are drawn up in such detail that the supplier understands them correctly. [16]

The requirements specification document must include a precise description consisting of at minimum [16]:

- User requirements
- Old system
- Levels of requirements
- Technology limitations
- Resources, work and money
- Testability of requirements

4.2 Requirements elicitation

Finding requirements specifications is a process that must be planned well. When creating requirements specifications the following aspects must be considered:

- Scopes and limits of the system
- Roles and needs of participants and parties
- Duties and responsibilities of participants
- Workflow
- Structure of data

There are various methods to discover requirements. Different methods are suitable for different situations and complete each other. The suitable method or methods must be chosen for each project. Some methods for discovering requirements [17]:

- Indirect methods
    - Questionnaires
    - Use cases and scenarios
    - Old documentation
    - Prototypes
- Direct methods
    - Goal orientation
    - Interviews
    - Perception of the application
    - Group sessions

4.3 Documentation

All requirements must be documented so that there is no room to misinterpret them. Requirements should be documented in a form that they can be tested. Documentation should cover objectives, concepts, desired features, system- and software requirements, assumptions, responsibilities, and explanations. [17]

Traceability of requirements means that in each system feature it is possible to point out what user requirement is fulfilled. Traceability is a criterion for good software quality. Tracing can be performed both ways, from requirements to system features and from system features to user requirements. [15]

While creating requirements specifications, the need for amendments may occur. Changes may come while creating requirements, while creating the system or after the system has been completed. The need for change may be due to errors, changing objectives and priorities, or changes in the operating environment. To control changes in requirements specifications they must be traceable. Version control is used to achieve traceability. [17]

4.4 Requirement analysis

After requirements have been discovered, they must be analysed. Previously gathered information is still shattered, non-structural and may include unnecessary information. At this stage, conflicts must be resolved, risks identified, alternative solutions discovered and requirements must be prioritized [15]. Requirements are not always consistent because they are from several different sources. There are different types of inconsistencies, terminology-, designation- and structure clashes [17].

Quality assurance checks that the requirements fulfil the needs of stakeholders, considers all desired features and do not conflict with each other. Quality assurance techniques are inspections, reviews and computer-aided verifications. Validation should be performed continuously during the whole process [17].

Potential risks:

- Misunderstanding of requirements
- Customer not involved enough
- Misunderstanding of end user needs
- Requirement changes
- Conflicts between requirements
- Inadequate requirements

Each user requirement is processed to find reasons behind them. Simultaneously requirements are evaluated to determine how critical they are to fulfil. Prioritization ensures that the most critical parts will be completed. It is possible to determine which requirements are mandatory, desirable and which can be postponed. [17]

5 Survey

5.1 Customer needs mapping

The method of choice to find out customer needs is a survey containing multiple interviews. The survey is carried out as independent interviews one person at a time. The purpose of this survey is to find out requirements for instrument calibration software. The requirements are considered from the customer's point of view.

The first question to think about is what kind of customer is the right person for this survey. What area of business is important to research and who is the correct person to ask questions. Persons in different positions have different views and it is important to gain results from a wide perspective. Good persons for this interview are instrument users, the person performing the calibrations, lab managers, purchasers, calibration engineers, calibration managers and quality managers.

When interviewing, the customer workflow for instrument calibration must be found first. A good way to discover workflow is to guide the customer through the calibration process step by step. If there is no operating protocol for pipette calibration, the interviewer can ask the customer to think how calibration should be done. If there is operating protocol, can the interviewer ask the customer to think if there are any unmet needs and if there are some improvements to current calibration process. The interviewer must be sure to talk enough with the customer so he or she can understand their practice.

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5.2 Joining customer profiles

After an extensive survey a sufficient amount of customer profiles and requirements for each customer profile have been found. Customer profiles are found by listing the most common customer stakeholders and considering which of them are the most important to the project. The next step is to combine similar customer profiles in order to organize material to such a form that requirements can be processed to software features.

6 Results

6.1 Customer survey

The basic idea of this project was to find the requirements for new calibration software. The software will be used to interface with customers. Therefore it was important to find out the customer requirements.

An extensive customer survey was carried out, with both external and internal customers. The user profiles and combined user requirements found in appendices (Appendix 2). Derived customer profiles and requirements are given below.

6.1.1 Instrument user

Instrument users work with the instruments and are interested in the quality of their work. Instrument users may perform instrument quick checks.

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6.1.2 Laboratory manager

Laboratory managers manage work in the laboratory and are responsible for the instruments and the resources (personnel and financial).

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6.1.3 Laboratory quality manager

Laboratory quality managers are responsible for standard operating procedures, quality systems and supervising quality of work and are afraid of quality issues.

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6.1.4 Purchaser

Purchasers negotiate and take care of purchasing for the laboratory. Purchasers follow up performance of the vendor and performs vendor auditions.

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6.1.5 Service technician

Service technicians perform instrument maintenance and calibration for both internal and external customers.

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6.1.6 Service manager

Service managers manage the instrument calibration. They schedule work for service technicians and follow up the maintenance and calibration work.

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6.1.7 Service quality manager

Service quality managers are interested in maintenance and calibration quality. They are responsible for standard operating procedures, quality systems and supervising quality of the maintenance and calibration work.

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6.2 Users and use cases

As the result from the customer survey the user profiles and requirements for each user type were received. Service quality manager and laboratory quality manager profiles are so much alike that they are joined as one. As a new user group system administrator is created who installs and maintains the calibration system. The maintenance and calibration process and the use cases from the customer survey are found in Figure 5. The users are connected to the use cases they perform.

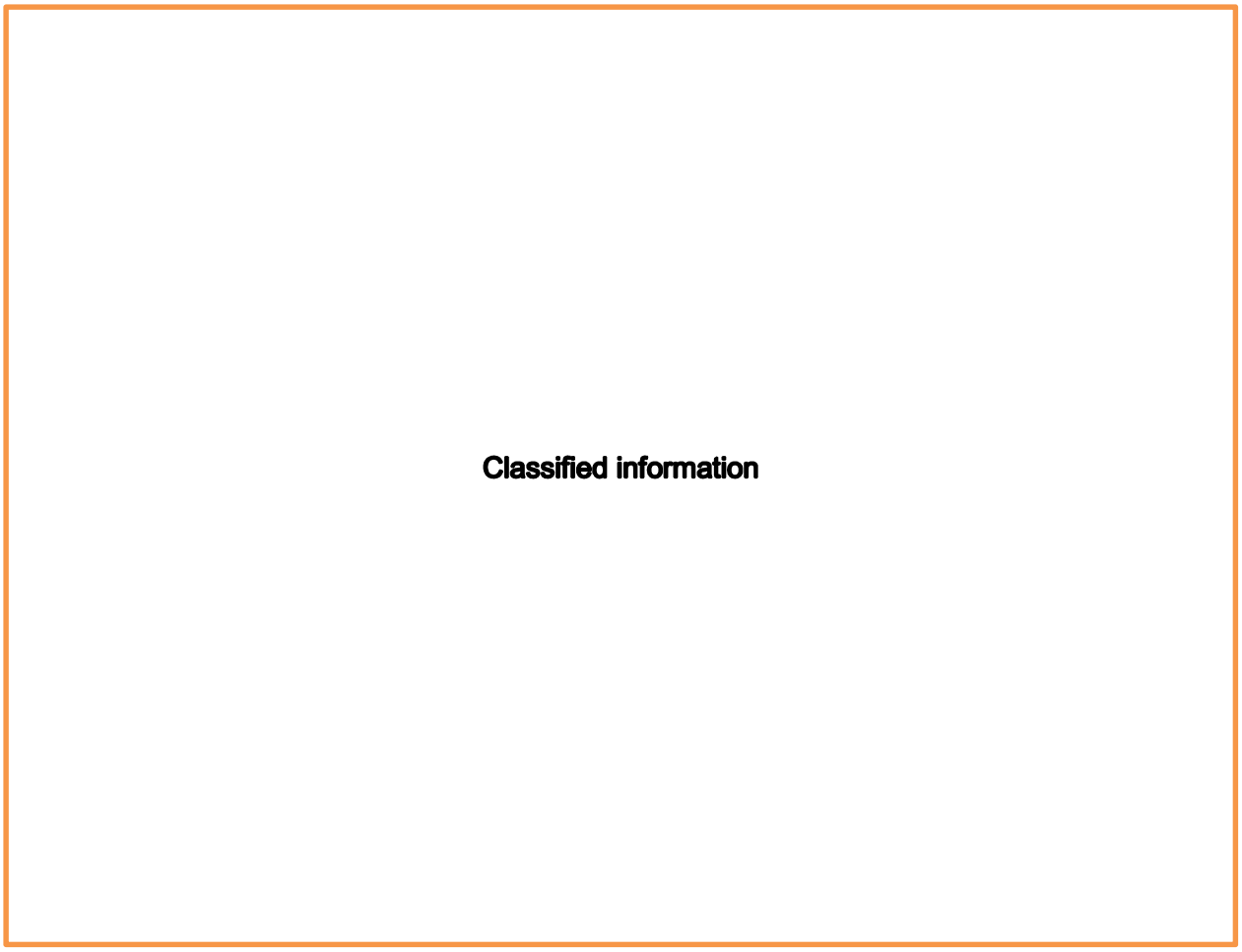

Figure 5. Users and use cases.

6.3 Functional requirements

Functional requirements are requirements that include some kind of an action from a user. A use case means actions that the user performs with a software and therefore are functional requirements. All the use cases are derived from Figure 5. To create the functional requirements all the use cases must be carefully thought. Detailed description for each of the use cases follows.

6.3.1 Use case 1, Help and guides

Actors

Pipette user, Service technician.

Description

A user needs help to use the program or guidance with quick check and calibration. There is also a link to a website where the user can find an additional help and contact information of the local Sartorius office.

Preconditions

The user is logged in. The computer is connected to internet.

Post conditions

The user has received guidance.

Normal Course

1. Select the help
2. Seek through the topics

Alternative Courses

1. Use the search function

Exceptions

If no help is found, the customer is asked to contact the local Sartorius office.

Priority

Medium.

Special requirements

Quick check and calibration help must be according to all relevant standards and regulations.

Rest of the use cases are classified information

6.4 Non-functional requirements

Non-functional requirements are the features that do not include direct user input, such as the quality and performance requirements. All the following requirements were highlighted by almost every person interviewed.

When creating new calibration software for an existing service organization, it is important to consider reviving the calibration and maintenance data from the old calibration system. Import and export features from and to certain software may ease some irregular tasks. An organization that has been in operation for a long time has valuable data that they will want to maintain. Importing data from other software eases with this issue. Exporting the calibration data to office programs like Word or Excel may help to complete special tasks that may occur with demanding customers.

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6.5 Customer requirements

The customer requirements consist of the functional and non-functional halves. Non-functional requirements contain requirements such as the quality and performance features and the functional requirements are contained in the use cases. Now that the functional and non-functional requirements have been discovered the objective of this project is reached. With the completed customer requirements the software project can be taken forward.

7 Conclusions

Most of the time used in this project went to interviewing people and gathering information about the instrument calibration procedure and the needs for new calibration software. During the interview period more than 100 people in Finland and dozens of people in Germany were interviewed.

In a very early stage of the project I noticed that the best way to find out requirements was to interview people in person and one person at a time. I visited some fairs but meeting the right person when there were hundreds of people around, turned out to be extremely difficult. Fortunately I was able to make some contacts during those fairs. I made appointments and interviewed in the privacy of an office. I also utilized contacts from our domestic sales team.

After the required amount of information was gathered, I started to compile them as user requirements. With a large amount of interviews there was a lot to go through. I divided the interviews to groups according to a person's position in the company, but

still compiling such a large amount of opinions into a single chart seemed challenging. Rather quickly I was able to see similarities in the answers and the compiling proceeded rapidly.

When all the requirements were compiled into the charts according to person's position in the company, I began the process to derive customer requirements into the software features. In this stage I consulted our software engineers in the Research and Development department. From them I received important information how the features should be presented.

The software features included both the functional and non-functional features. Functional features are presented in the use cases and non-functional features in the quality and performance requirements.

The outcome of the project was the user requirements for the laboratory instrument calibration software. The user requirements can be used in later phases of the software project. The achieved results cover user requirements comprehensively and they are a good starting point for the next phases in the software development project.

Some stages of the project went better than the others. Interviews started quickly after the project was launched and there was not much time to prepare. The interviews I did went well for the most part, and we received quality information. Briefing for interviews made by someone else did not go so well, and the results obtained were not as informative as they could have been. I should have prepared better instructions for the interviewers. The total results from the interviews are informative and cover the objective of the survey.

In the very beginning of the project I should have defined the technical environment and the other computer programs which interface with the new calibration software. I started this project with too many assumptions and because of that I had to revise some parts. I also should have explored the process to create software requirements earlier. After all, I think this project as succeeded because we kept the schedule and with the user requirements we are able to create the calibration software that will meet the customer requirements.

The weakest parts of the results are the non-functional requirements. They are not completely thought through and they must be processed further as the software project proceeds. If I would start this project now, I would do more research about software development and start the project with researching the company's information systems. The most successful part of this project was identifying the customer stakeholder profiles and mapping the needs. We have a comprehensive understanding of customer requirements for calibration software for laboratory instruments and we also understand the calibration and checking processes from the customers' point of view.

This was my first major project of this kind. I have previously performed only some small scale projects. During the project I have learned to focus on the essentials and how to manage large projects. I have also learned the importance of consulting and good ground work.

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Customer survey template

Classified information

Combined customer survey results

Classified information