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Agile challenges within regulated healthcare environments

Master's thesis in Software Engineering

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Abstract

Agile methodologies has had an increasing popularity within healthcare software development due to many advantages over more traditional waterfall-like methodologies. However, there are still many challenges and uncertainties facing practitioners working with, or wanting to adopt an agile methodology within the regulated domain. In this thesis we perform a case study to identify challenges perceived by practitioners when working with, or adopting agile within the regulated healthcare environment. This is done through interviews with a total of 9 practitioners from 5 Sweden-located companies. The interviews produced a set of 37 challenges, summarized into 10 challenge categories based on similarity. The challenge categories are put into three areas indicating where the cause for the challenges lie: either at the practitioners; at the regulatory bodies; or somewhere in between the two. Given the encountered challenges, this study investigates if they are common to all software healthcare companies and further try to resolve the challenges while still keeping to an agile approach. This study, however, finds no literature which treat the challenges caused by the regulatory bodies, and as such many challenges are missing suggestions for solutions. This study concludes by identifying three needs in order for companies to be able to work with agile in regulated healthcare environments. Firstly, there needs to be more research done in the field. Secondly, there is a need for more resources and guidelines explaining how to work agile in regulated healthcare environments. Lastly there is the need for an improvement of the existing regulatory documents to better emphasize support for the agile way of working.

Keywords: Challenges, Agile, Healthcare, Regulations, Regulated environment, Practitioners, Regulatory bodies, Development methods, Software, FDA, Läkemedelsverket.

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1
Introduction

Healthcare is important in order to improve quality of life and in recent years there has been a large increase in the interest of developing software for the healthcare industry. The life sciences industry has increased its ratio of software engineers more than other industries (Brown, 2012). With the expansion of software and products that can run said software, such as smartphones, there is a need to be able to keep up with the development of such software. Software development is an area that is constantly being updated with new ideas and ways of working including development methods such as agile software development. Agile methodologies has had an increasing popularity within software development due to many advantages over more traditional waterfall-like methodologies (State of Agile Survey, 2015). Many practitioners, both new start-ups and old industry giants, therefore strive to adopt agile development.

In contrast to hardware development, within software development there is a larger allowance in how finished the delivered product may be due to software being able to be updated or replaced easily at a later point in time. Certain industries are more sensitive to change though and examples of these are the healthcare sector, the car industry and the military. Within these areas, a flaw in the software could be a great risk for the user client or patient and therefore regulations exist in order to prevent any problems with systems. Regulatory bodies create these regulations and control that they are complied with by industry practitioners. However, the strict regulations posed on practitioners in regulatory environments can be perceived to be ambiguous and difficult to understand when trying to apply them to a specific work methodology (Mehrfard and Hamou-Lhadj, 2011). Furthermore, looking into the agile methodology there are also reports that practitioners perceive barriers towards the adoption of agile (McHugh et al., 2012) signifying potential difficulties in combining an agile methodology with a regulated environment.

1.1 Purpose of the study

The implementation of agile in regulated healthcare environments has had some research and testing but the field is still reported as unexplored (Hajou, 2014). The purpose of this study is to identify the challenges that are facing individual companies, as well as the industry at large when looking to work with, or to adopt agile

development methods within regulated healthcare environments. The study aims to investigate the challenges perceived by companies and to propose resolutions to these challenges. This study will focus on companies within the healthcare sector. The results of this study aim to help provide an understanding of how software healthcare companies can approach, and work with, agile development while adequately meeting regulations, as well as enlightening the regulatory bodies of the challenges faced by these companies.

This study has been delimited in two aspects; Firstly, the challenges sought for in the study are perceived challenges by the participants in order to see the difficulties in not only adopting agile methodology but also practising agile. Thus a delimitation has been made to not validate said challenges against literature but rather against the companies included in the study. Secondly, challenges included in the study need to have both agile and regulatory aspects . Challenges with only one of the two aspects are not included.

1.2 Research questions

Based on the purpose of this study, the following research questions have been posed.

1. What challenges are encountered when developing with agile work methods within regulated healthcare environments?
2. Are the encountered challenges common to all software healthcare companies?
3. How can the challenges be resolved while still keeping to an agile approach?

1.3 Thesis outline

CHAPTER 2	Summarises previous literature within the field and compares it to this study and how the study complements or differ from their approach and findings.
CHAPTER 3	Describes the process used to collect data, analyse the data and form suggestions for challenges resolutions. It also describes how the data was validated against the companies.
CHAPTER 4	Provides a description of the challenges iterated from the interviews and a motivation for the challenge categories based on the interview data. For each category, there is also a reflection based on relevant literature and information from the interviews.
CHAPTER 5	Presents results from the questionnaire sent to companies to inquire their thoughts on our presented challenges and solutions.
CHAPTER 6	Provides a discussion on the results reached in this study, the effectiveness of the chosen research method, possible threats to the validity of the study as well as suggested future work.
CHAPTER 7	Summarises the conclusions of this thesis.

2
Background

The following section will present definitions and explanations for terminology that is used within the report and also describes previous literature within the field and compares it to this study and how it complements or differ from findings and conclusions in the literature.

2.1 Definitions

This subsection contains clarification for definitions that are specific to the scope of the study or could possibly be ambiguously interpreted.

Medical device

Medical device means (according to Global Harmonization Task Force, 2005) any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination by and, for human beings for one or more of the specific purposes:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Medical device classification

Within the Medical devices regulations, devices are classified into one of several levels depending on how much risk of harm the device pose to a patient or a user of the device. Different regulatory bodies have different classifications, including varying levels and varying criteria for which level a medical device is regarded as.

A paper by Kaushik et al. (2013) explains the approval process of a medical device and illustrates the major classifications that apply in China, the E.U., India and the U.S. Japan has 4 levels of classification while the rest classifies medical devices within three levels. Common for all areas is that a level 1 classification, Class I, indicates a product with the lowest risk of harm, while a Class III medical device (Class IV in Japan) constitutes medical devices associated with the highest amount of risk.

Regulations

When speaking about regulations in this thesis, there are two concepts that are relevant. Regulations - or external regulations - refers to the guidelines and rules needed to be fulfilled by a medical device posed by a regulatory body. Internal regulations refers to the guidelines set by a company itself on their development process.

Regulatory body

Regulatory bodies are the agencies that oversee and control regulations for specific regions. In order for a product to be sold in such a region, the regulations posed by the governing regulatory body has to be followed. Examples of regulatory bodies include the Swedish Medical Products Agency which regulates the medical device market in Sweden and the Food and Drug Administration, FDA, which regulates the North American market.

Regulated environment

A regulated environment points to an area within industry where companies, and their products, have to deal with regulations.

2.2 Related work

The content of this subsection contains related work from current research that has related parts to this study's context. For each related work: their study is summarized; the results from the study is presented; and a discussion is made on how the study and results are connected to this thesis. When applicable, there will also be a motivation for how this thesis tries to complement the study.

How the Pharmaceutical Industry and Agile Software Development Methods Conflict

Hajou, A., Batenburg, R. and Jansen, S. (2014) performs a systematic literature review of the research field of agile methods in the pharmaceutical industry. In the review, the final selection of appropriate literature consists of 49 articles; from where 10 articles handle the application of agile methods, 15 articles handle quality assurance in software development projects, 14 articles handle improving software

development projects and 10 articles handle software development in the pharmaceutical industry. From the selection they identify three main conflicts between the pharmaceutical industry and agile development: The regulatory complexity of software development in the pharmaceutical industry; Differences between the agile and the highly documentative approaches; and Lack of attempts to be agile in the pharmaceutical industry.

Within the first conflict they identify that projects done within healthcare are subject to strict regulations and legislation which increase the cost of development and therefore make them more expensive. The regulatory requirements can change fast and the changes are usually opposed by country-specific laws. Within the second conflict, their results point to difficulties in adopting agile work methods in healthcare environments and an incompatibility of existing agile methods with aspects of healthcare software development. Within the third conflict, the literature review results points to that there is a lack of attempts to be agile in the pharmaceutical industry and also a lack of material such as published case studies, experiences and scientific articles on the domain. However, they mention that the pharmaceutical industry still is actively searching for alternatives to traditional plan driven software development methods.

The results found by Hajou et al. (2014) point to the desire and need within the field to adopt agile methodologies within the development. They mention that the collected articles vary in topics which do not always correspond with each other which is exemplified and discussed within the review. The aim of the literature review correspond well with the intent of this research. As such the found conflicts in the literature review will be taken into account when eliciting challenges during this research and in the final discussions when comparing findings in related work to findings in this research. As mentioned by Hajou et al., there is a lack of published research material in the domain. This study will further increase the amount of research based on industry experience.

The Impact of Regulatory Compliance on Agile Software Processes with a Focus on the FDA Guidelines for Medical Device Software

Mehrfard & Hamou-Lhadj (2011) examine how well the agile methodology of Extreme Programming (XP) supports the requirements posed on medical device software by the FDA. This is done by analysing the FDA regulations and - recognising the challenge of interpreting these - provide a mapping of the regulations onto possible development artefacts and activities. The paper then proceeds to address how well these activities would fit into an XP methodology by comparing the mapped development activities with development activities supported by XP.

In the paper, Mehrfard & Hamou-Lhadj (2011) present tables showing in which

aspects XP supports or does not support the demands posed by the FDA. They show that several regulatory requirements are not supported by XP, mainly many of the documentation related activities. The paper then finishes by suggesting introducing new activities, roles, and artefacts into the XP methodology to be able to be compliant towards the regulations. The authors mention, however, that this action should be done carefully as to not remove any of the positive aspects of the original XP methodology.

While Mehrfard & Hamou-Lhadj (2011) examine how well XP supports regulations, the lack of which possibly indicates the presence of an agile related challenge. Our research differs in the intention of identifying what practitioners perceive the challenges of agile to be within the regulated healthcare domain.

Barriers to Adopting Agile Practices When Developing Medical Device Software

McHugh et al. (2012) have conducted a questionnaire in order to identify the barriers to adopting agile practices when developing medical device software as well as provide recommendations on how these barriers may be overcome. The questionnaire was sent to twenty Irish pharmaceutical companies where 75% of the included companies were developing software in accordance to agile methodologies and the remaining 25% had other development lifecycles such as the waterfall and iterative combined with incremental approaches. The barriers identified include: lack of documentation; traceability issues; regulatory compliance; lack of up front planning; and managing multiple releases. From the identified barriers, recommendations on how to overcome them are made which include agile methodologies or tools to use in order to still keep to an agile development.

The results provided by McHugh et al. (2012) suggest and show that agile can be implemented in a healthcare software environment. However, from the perspective of the practitioner, and its perceived challenges, some of the recommendations given are lacking. An example is the barrier lack of documentation where they just state that there is no barrier due to agile being able to provide documentation. Another example is regulatory compliance where they state that a solutions will be provided by Advancement of Medical Instrumentation (AAMI) in the near future.

The presentation of the challenges and the recommendations on how to overcome them are a bit vaguely described in the paper. However, the perceived barriers found serves as a good comparison between found challenges in Irish companies within the healthcare sector to the challenges found in our research with companies within the healthcare sector in Sweden.

Agile in an FDA Regulated Environment

Kappe (2013) claims that the healthcare industry are facing unprecedented challenges and that current waterfall methods are ill suited to deal with the pace of

change and uncertainty that product development organizations are facing. It lists the problems with current development methods and why the problems are important to look at. They bring up aspects such as waterfall not matching reality based on different changing factors in development and establish why the cost of change is unnecessarily high. Kappe (2013) then addresses the shortcomings of waterfall with the help of agile with a focus on cost of change. He brings up agile together with FDA regulations and examine if agile is a suitable approach in regulated environments. Kappe (2013) then proceeds to list common misconceptions with agile and healthcare and goes through these misconceptions to show how to deal with them in an agile manner. There are three major principles that are processed: Risk management; quality management; and software engineering. The conclusion is that agile methods can, when properly adapted to the FDA's quality systems regulations, provide better results than waterfall development methods.

Kappe (2013) brings up interesting aspects of common development methods within the healthcare sector and a view that agile methodologies can be used as a way of working within regulated environments. These aspects give a line of thought that can be applied to the challenges iterated within this study where companies' challenges are brought forth and a view on how an agile solutions could look is provided.

Agile development methods for space operations

Trimble and Webster (2012) look into how NASA has successfully adopted agile methodologies and shortened their software release cycle from months to weeks within one of their projects, The Mission Control Technologies (MCT) project. They introduce why agile developments was chosen by providing the benefits gained from switching from waterfall processes such as: Replace Predictions with Actuals; Manageable Deliveries; Development Team/Customer Interactions; Fast Response to Change; and Team and Organizational Culture. They then present delivery cycles on the MCT project through examples on how to implement agile software development in a mission operations environment. The iteration and release cycle is made of four iterations where each iteration is three weeks. There are three development iterations and one testing iteration for bugs and usability. In the paper it is also presented what the core lessons learned when working agile are, and that the core lessons should be adaptable to most situations.

Trimble and Webster (2012) bring up an interesting view on how NASA, who work in another sector which is strictly regulated, handle their development methodologies and successfully adapt agile. They reach a conclusion that there are a lot of benefits with changing development methodologies to agile such as better results at lower cost, more effective and unified customer-developer teams, and a better solution for the customer overall. This insight will be valuable to consider when proposing solutions for the challenges found in our study.

Scaling Agile Methods to Regulated Environments: An Industry Case Study

In a paper from 2013, Fitzgerald et al. performs a case study on an Irish software healthcare company, collecting data via semi-structured interviews. The aim of the study is "to investigate how an agile development approach can meet the rigorous standards required in regulated environments", which Fitzgerald et al. proceed to do by first examining the case company's agile work methodology and then its approach to regulatory compliance. The regulatory compliance activities are inspected within five areas: Quality assurance; Safety and security; Effectiveness; Traceability; and finally, Verification and validation.

After examining how the case company reaches regulatory compliance in their agile methodology, Fitzgerald et al. (2013) conclude that tailored versions of agile are well suited to software development within the regulated case domain, however, they also mention that it is important to have a good set of tools in order to facilitate this. They further proceed to highlight found aspects of the studied agile approach which provide added benefit towards working within a regulated domain.

In comparison to the study by Fitzgerald et al. (2013) the intent of our study is to examine agile challenges over several companies to investigate if there are any differences or similarities depending on the kind of company studied. While Fitzgerald et al. seek to answer what activities are necessary to implement in order to achieve a regulatory compliant agile methodology, our study instead focuses on the more general question of what challenges practitioners perceive related to working with agile in a regulated domain.

Conclusion

The related work found provide several insights into the research domain for this study. Firstly, several papers mention perceived barriers to working agile, such as the belief that regulatory bodies promote waterfall methodologies. However, many papers also acknowledges that this is not the fact, and that bodies such as the FDA do indeed promote agile. This inconsistency between practitioner belief and literature findings hints at the existence of challenges for practitioners in understanding posed regulations. As such, there exists a motivation to perform further research into these challenges.

Secondly, several papers in related work also investigate how the standard agile approach can be adjusted to suit the regulatory healthcare domain. However, they either do this without the background perspective of currently perceived challenges towards already using agile, or they do not further investigate what new challenges can come from working with the adjusted agile methodology. To thus expand the research field, this study intends to include challenges perceived both from trying to adopt agile and when already working with an agile methodology.

Lastly, the 2014 systematic literature review performed by Hajou et al. indicates that there is a lack of research investigating the relationship between the agile methodology and the regulated healthcare domain. This study intends to broaden that field in a way that complements previous research by trying to identify perceived challenges regardless of whether a company is already working agile or not, and to provide a comparison on the companies that mention said challenges and provide views from both small and large companies within the healthcare industry.

3
Method

The intent of the study is to find challenges that are affecting agile adoption and practise within healthcare as well as find potential resolutions for found challenges. Due to the research question being open minded, this study took an exploratory and qualitative approach on finding challenges. Looking at research methods, an exploratory case study was chosen as defined by Runeson and Höst, 2009.

The research process they present includes five major steps; Case study design was done by looking for related work, setting up related research question, methods on how to collect data and what companies to include in the data gathering. Preparation for data collection was done by creating an interview guide based on domain knowledge. Collecting evidence was done through interviews. Analysis of collected data was done on the data collected from the interviews. Finally, reporting is contained in the challenge reflections and discussion section. All of the five steps is further described in the sections where they are presented.

When conducting a case study in collaboration with companies, it is important to look into ethical aspects. There are several factors Runeson and Höst (2009) brings up that were included in the design time of the case study; In the study, interviews were held and the participants gave their informed consent both on the collection of data as well as for how the data will be used within this report. To make sure that the interpretation of the interviewees was as accurate as possible, the interviews were recorded and the challenges found using the data was double checked by both researchers. Regarding the confidentiality of the participants, it was decided that all collected data was to be stripped of identifying factors and that no companies or participants names would be included in the report.

3.1 Procedure

The plan for conducting this research, which can be seen in Figure 3.1, was divided into three main stages. Firstly, interviews were held in order to gather data for identifying the challenges that occur when developing with agile work methods, or trying to adopt an agile methodology within regulated healthcare environments. Secondly, an analysis on the collected data was conducted where the results needed in order to answer our research questions were derived. Thirdly, given the set of challenges

that was found, their causes were identified and suitable solutions were suggested. To help with identification of these causes and solutions literature was studied in conjunction with the collected data.

After the analysis, in order to assess the validity of the found challenges and proposed solutions, a questionnaire was presented to the previously interviewed companies where they were asked how much they agreed the challenges were applicable to their company.

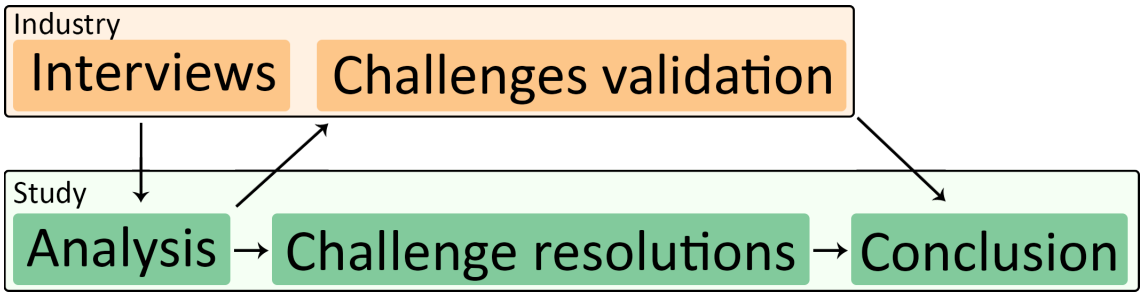

Figure 3.1: The research process. Interviews were held which were then analysed to elicit challenges. After the analysis a reflection was held to find solutions to these challenges. A questionnaire was also constructed to validate the challenges with the case companies.

3.2 Interviews

Data was collected by conducting semi-structured interviews with employees from healthcare software companies. Since this study was of an exploratory nature, it was difficult to know what information that could be of interest; In the case of inquiring practitioners about their perceived challenges, it seemed likely that a few misunderstandings could occur or that new interesting questions could arise from the practitioners' explanations. To make sure that this would not be an issue, it was decided that interviews with the practitioners would be conducted, where direct contact was had and it would be natural to ask follow-up questions or ask for clarification in the case something was not fully understood. The reason for having a semi-structure of the interviews was to allow an exploratory view on posed interview topics while still being able to keep a key interview structure intact.

For the semi-structured interviews an interview guide was created that outlined the questions that should be asked during the interviews. The interview guide had two translations used depending on the preferred language of the interviewee (see Appendix A for the English version and Appendix B for the Swedish version). When creating the interview guide several tips were followed from DiCicco-Bloom and Crabtree (2006) to promote trust between interviewers and interviewee and to help get better qualitative information out of the interview. Firstly, the beginning of the interview guide was designed with open-ended and non-threatening questions, with the aim of introducing the interviewee to the research topic and to get the

person talking, creating a relaxed atmosphere where the interviewee would feel safe about sharing information. Secondly, to enable more exploratory interview sessions where new information could be learnt and inquired about without prior relevant knowledge of the interviewees, all main questions of the interview guide were kept open-ended. Lastly, in order to catch more detailed information where needed, more specific questions were evolved from the dialogue between interviewers and interviewee.

To aid with the note taking and to make sure that all important parts of the interview were more likely to be interpreted correctly, the interviews were recorded using a recording software. In order to be able to process the interviews by coding, all audio recorded interviews were transcribed and content that could prove to be identifying factors of the participating companies or interviewees were anonymised to protect all participants' identities.

3.2.1 Case study participants

According to DiCicco-Bloom and Crabtree (2006), interview participants should be selected by purposeful sampling that seeks to maximise the depth and richness of the data to address the research question. The selection strategy was to select healthcare software companies that were developing medical devices. The companies included in the study should also vary in size and their offices' geographical location should be in Sweden. However, richness in the data, as discussed by DiCicco-Bloom and Crabtree (2006), was provided through a variation sampling for company size, employee role, product type and medical device classification. This study includes 9 interviews with employees from 5 separate companies shown in Table 3.1.

Company	Size	Interviewee	Role
Company 1	Start-up (employees < 10)	Interviewee 1	CEO
Company 2	Start-up (employees < 10)	Interviewee 2	Developer
Company 3	Medium (50 < employees < 500)	Interviewee 3	Software manager
Company 4	Very Large (20,000 < employees)	Interviewee 4	Section manager
		Interviewee 5	Agile coach
		Interviewee 6	Project manager
Company 5	Large (500 < employees < 20,000)	Interviewee 7	Software manager
		Interviewee 8	Section manager
		Interviewee 9	Interaction designer

Table 3.1: Study participants. The table shows the size of the 5 companies that were interviewed. It also shows the 9 interview participants, what role they had and which company they were from.

There are two companies that are in the phase of a start-up with few employees and three companies with larger sizes, where the largest ones are globally working within the healthcare sector. For employee roles, there was a broad selection. The products that are developed by the companies include pure software products that are developed off the shelf and on customer order as well as software that is included within hardware that the companies also deliver. Thus, there are work processes that both include and exclude the hardware part within the development of the companies. The companies have different products with medical device classifications ranging from not yet classified as a medical device (but aiming for it) to classified as Class III (Japan Class IV).

3.3 Analysis

When analysing the interview data, challenges that the interviewees perceived were identified and listed. In order to provide a base for identifying potential resolutions for the challenges, a grouping of the challenges was introduced in form of challenge areas and challenge categories. To find good candidates for challenge categories with a similar abstraction level, three challenge areas were defined: “Internal challenges”, “External challenges” and “Interlocated challenges”. Internal challenges are challenges within companies making it more difficult for them to work with, or take steps towards agile development. External challenges are challenges with external regulations making it more difficult for companies to work with, or adopt agile work methods. Interlocated challenges are challenges where it is unknown where the prohibiting factor lies in between the companies and the regulatory bodies when working with, or adopting agile methods. The different challenge areas and challenge categories are presented in table 4.1 in the Challenges chapter.

3.4 Challenges validation

In order to validate that the elicited challenges were relevant to the companies that participated in the study, an online questionnaire was created and distributed to the companies (see Appendix C). In order to create an effective questionnaire, the paper by Iarossi on survey design (2006) was followed. Iarossi (2006) brought up two important rules that are important to consider when creating questionnaire questions: relevance and accuracy. Relevance is obtained *"when the questionnaire designer is intimately familiar with the questions, knows exactly the questions' objectives, and the type of information needed"*. In order to achieve high accuracy, larossi (2006) brings up that *"the wording, style, type, and sequence of questions must motivate the respondent and aid recall."* Relevance and accuracy was taken into account in the design of the questionnaire.

In the questionnaire, the categories were described together with examples of challenges in order to improve the participant's understanding of the questions. There were input fields where respondents had the potential to suggest solutions to the challenges. These were however not mandatory and therefore the participants were free to skip it if they did not wish to answer. Regarding the main questions, the respondents were asked to grade how well they agreed to each challenge category. The answers were given in a range going in five stages from "strongly disagree" to "strongly agree". There was also a "Don't know" option available. Each participant of the questionnaire had to choose one value for each of the ten categories elicited during the study.

3.5 Challenges resolution

In order to address the third research question - how to resolve the challenges - the answering discussion was held on two levels: Firstly, solutions were discussed on a challenge category level by looking into literature and what had been said about possible solutions during the interviews. Secondly, solutions were discussed on a higher level covering the challenge areas, again based on literature and what had been said in the interviews.

4

Challenges

This section will present the challenges, challenge categories and challenge areas (shown in table 4.1) elicited from the 9 interviews held at the 5 different companies. Throughout this chapter, companies and interviewees will be referred to as named in table 3.1 in the Method chapter. Due to the problem formulation of this research, only challenges where regulatory aspects are interfering with the capability of practitioners to adopt, or work with agile are considered and listed here. During the interviews challenges were mentioned that either involved agile or involved the regulatory side, but did not involve both. These challenges are outside of the scope of this research, and are not considered.

This chapter is structured as follows. Firstly, the challenge areas defined will be introduced and explained. Secondly, within these area sections, the challenge categories elicited from the interviews will be introduced and explanations of them will be given by providing examples of individual challenges raised in the interviews. Lastly, within each category, a reflection will be held that speaks about the challenges and the category and discusses potential solutions or mitigation strategies for the challenges based on related literature or what has been said in the interviews.

Several quotes provided within this chapter have been translated from Swedish to English by the interviewers.

Area	ChA	CA	IA	Category	ChC	CC	IC
Internal	5	2	3	Internal agile competence	2	1	2
				Internal work processes and internal regulations	2	1	1
				Communication within the company	1	1	1
External	18	4	4	Regulations are difficult to comprehend	6	3	3
				Regulations are not up to date with current software evolution	5	3	3
				Regulatory instructions are missing agile definitions	6	1	1
				Regulations do not follow industry conventions	1	1	1
Interlocated	14	5	8	Regulatory certification	2	4	4
				Software quality control	10	3	5
				Customer expectation	3	2	2

Table 4.1: The elicited challenges. Contains the produced challenge categories together with the areas they have been sorted into. For each category and area a listing is done of the amount of challenges contained in said category or area, how many different interviewed companies mentioned a challenge within the category or area, and how many different interviewees that mentioned a challenge within the category or area.

The following are explanations of the abbreviations used in table 4.1:
ChA: Number of unique challenges found in the area
CA: Number of unique companies brought up a challenge in the area
IA: Number of unique interviewees brought up a challenge in the area

ChC: Number of unique challenges found in the category
CC: Number of unique companies brought up the category
IC: Number of unique interviewees brought up the category

4.1 Internal challenges

The internal challenges area includes challenges within companies preventing them from working with, or taking steps towards, agile development.

Internal agile competence

Agile development has had an increasing impact in software development but in the industry of healthcare it has not been as prevalent. As mentioned in interviews performed during this study, companies that have been in the software healthcare market for while are still mainly working in large parts with waterfall-like processes and agile-waterfall-hybrid processes. It is first in later years that agile has started making its way into companies developing medical devices. In the interviews, the

interviewees were asked when they started working with agile methodologies and it was answered that the companies that had been in the industry for over a decade started looking into agile methodologies around the years 2006 to 2010. However, some of the interviewees from those companies mentioned that it was not until 2013 to 2014 that they started incorporating agile methodologies fully into their software development. Regarding the challenges in this challenge category, two interviewees at Company 4 mentioned aspects related to internal agile competence and two interviewees at Company 5 mentioned that they had challenges within internal agile competence. These challenge aspects are explained in the following paragraphs.

During the interviews, one interviewee at Company 4 mentioned a perceived challenge in that the company's middle management were not mature enough to adopt agile development. The interviewee also mentioned that employees working within the hardware sector claims that agile methods are only applicable in the software sector. Another interviewee mentioned that when wanting to adopt agile in parts of the company, there is a will amongst middle management to change current work processes since they are perceiving complications with today's situation. However, many employees have been working non-agile for a long time and are opposed to the change.

One of the challenges that was mentioned by the interviewees from Company 5 was that agile methods had not been accepted fully throughout the company which resulted in a regulatory department that did not provide support for an agile process. *"it is truly only the development process that follows more of an agile methodology. Is it not something that has been accepted as a standard operating procedure for all groups so most companies will have specialized resources for regulatory. That is typically where we don't incorporate the regulatory aspects into the development sprints"* (Interviewee 7). Another challenge mentioned was that there was a differing understanding throughout the company whether agile was applicable or not in a regulated environment due to interpretations of the regulations.

Reflection

By the companies having less exposure to agile methodologies and having a non-agile work process, there seem to be less experience and acceptance with agile and therefore less of an agile competence. Kappe (2013) mentions that medical devices typically have long product development cycles, from 3 to 5 years. This is compared to non-medical software development cycles which, according to Kappe (2013) tend to be much shorter and whose speed have even been accelerating in many industries. The longer development cycle-length could be a reason why there is less agile used for medical devices, and why the developing companies have had less agile exposure.

When it comes to agile competence, Saboo (2014) mentions that one of the biggest strategic mistakes organisations make is not getting professional training at the start of the change. It is crucial that middle management participates in training since they hold the keys to the success of the agile adoption and that they create all of the procedures and policies necessary. He also mentions that if the middle management

is not on board, transformation will be shunned and by having middle management properly trained they can be influential in mentoring the team and demonstrate the value of agile to higher management. Relating this to the interviews, It was mentioned that the usage of agile methodologies did not really take hold until top management decided that the company was going to take an agile direction, and that the primary obstacle was to get middle management to embrace and promote agile methodologies.

Internal regulations and work processes

When defining a new internal work process, the companies in this study report that they base the new process on the external regulations that are in effect for them, and some of the companies also define internal regulations as guidelines for the development process. Internal regulations and work processes is one of the aspects that differed the most between the companies that were part of the study: The start-ups based their work process purely on agile from the start, while looking at the larger companies the amount of agile included in their processes depended on whether the same processes included development of hardware or not. A common factor with the larger companies was that they all followed internal processes and internal regulations defined by a previous waterfall process. Regarding this challenge category, an interviewee at Company 4 brought forth two challenges.

It was mentioned in the interview that companies are much more thorough with activities such as requirements, testing and traceability within software development due to the indication that there are very strict audits applied on the companies and due to the consequences posed when not fulfilling regulations. The first challenge mentioned was being able to add this thoroughness without also having to add a lot of time needed to complete projects, or adding a lot of error prone manual steps to the company's processes. In order to ensure that external regulations were complied with, the company had created rigorous internal regulations with a wide safety margin towards the external ones. The second challenge was that these internal instructions were not fully supporting agile, and the strictness of them had put the company in a position where they had difficulties updating them to fit an agile methodology.

Reflection

In regards to this challenge category, Saboo (2014) mentions that when adopting or expanding agile the largest challenge is cultural transition. Going towards an agile methodology changes the command and control structure from a top-down approach to a bottom-up approach. Saboo (2014) also mentions that in order to transition smoother and improve adoption, the process transition should be slowed down and made into a long-term commitment and a strategical consideration should be held over where the transition would be most effective to start with in the company. Examples on how this transition can be done is presented by Regan and Wynn (2015) in their material on regulatory change management where they present regulatory

change management models together with key phases within regulatory change management and roles and responsibilities.

One of the challenges mentioned in the interview was the difficulty of maintaining a good enough delivery pace when regulations added many activities to the work process that had to be done manually, and as such, was reported to being fault prone. One solution to this issue, reported in the interviews, was to introduce more automation into necessary activities, as that can reduce the risk for faults as well as increase the possible delivery frequency.

Communication within the company

Internal communication affects how well information is shared between employees within a company as well as how well information is shared between different departments. When working with a project, communication between all parts of the project is important for its success and lack in communication may easily lead to problems that could be avoided. Regarding the challenge in this challenge category, one interviewee at Company 5 mentioned that they had a challenge with communication between development and regulatory departments that could affect their agile work process.

In order to be compliant with regulations, the interviewee mentioned that they had a department that handled external regulations and set up company policies and processes. The development and regulatory departments were separated and communication was needed between them in order to make sure that regulatory compliance was fulfilled. The challenge mentioned was based on a lack of communication between these departments leading to an uncertainty of what was needed in order to be compliant to the regulations set by the company. This lead to more work being done than needed.

Reflection

Communication and collaboration is important in any organization. Saboo (2014) mentions, in a chapter about allowing teams to communicate across methodologies, that agile teams often become insulated from the rest of the organization and rarely interface with other teams or departments. This corresponds well with what an interviewee mentioned, that a further step in expanding their company's processes would be to have a more consistent flow through the organisation where required information would be seamlessly transferred between groups. The company's departments were not working within the same process and this caused interruptions to appear in the communication chain where sharing of information did not spread further. Saboo (2014) mentions that to have an effective mixed-methodology enterprise, communication is needed. The solution he mentions, in order to make hybrid organisations more productive, is to enable visibility and communication across distributed teams as well as managing the entire work lifecycle within one tool. He further mentions that developing standard processes for organising requirements and cross-team development could help a company reach this solution.

When communicating between departments that work with different methodologies (e.g. agile communicating with waterfall), Saboo (2014) mentions that it is important that a common language is used that everyone understands. Regardless of the methodologies chosen by the departments or teams, the work must be visible to the organisation's management. Saboo (2014) further mentions that since management tend to focus on waterfall-centric metrics, it is important that teams that work with agile methodologies can translate their result and progress into understood terminology. Shown from interviews in the study, it is equally important that the work performed by the rest of the company is translatable into the agile terminology and that also applies for regulations which determine how the agile work process is formed.

In order to reduce cross-department communication issues, one interviewee mentioned that it was important that agile methodologies were accepted throughout the company. In the interviewee's scenario, management had accepted that the organisation needed to adopt agile methodologies but the change was slow within the organisation due to employees being accustomed to the old work methods.

4.2 External challenges

The external challenges area includes challenges with external regulations making it more difficult for companies to work with or adopt agile work methods.

Regulations are difficult to comprehend

Regulatory documents are in place to guarantee patient safety and are made to cover a large variety of products. Interviewees from several companies found it difficult to correctly interpret these documents and there existed a lack of understanding on what parts applied to the development at hand. *"The challenge is when entering the medical device market, it is to understand, interpret all these regulatory things and to do enough but not too much"* (Interviewee 8). Regarding the challenges in this challenge category, one interviewee each from companies 1, 3 and 4, mentioned issues with comprehending regulatory documents.

From the interviews it was made apparent that the companies found that there was a challenge in understanding both what regulations that applied to them as well as correctly interpreting the regulatory documents. There was also a challenge in knowing how to proceed in order to interpret the regulations which often lead to turning to external services as explained in one of the interviews: *"Yes, well it's not easy to find that in some document where it says you should follow these steps to comply with this certification or regulation, rather it is, we are using external companies"* (Interviewee 8). There also existed a challenge in finding the right balance of interpretation of the regulations, e.g. how strict to enforce the guidelines provided. Another challenge was to determine what kind of documentation was needed, to find the right amount of documentation to include and to decide on what to archive

and what can be removed.

The interviews also brought forward that the necessity of understanding the documentation requirements was not only limited to the developers. It also extended to other stakeholders such as the customers that used the products that were delivered since they in turn put demands on what documentation needed to be included with the product. These customer demands were based on the regulations applying to the customer, so another challenge with developing using agile methods was customers' understanding of the regulations and their interpretation. If a company's customers did not have a clear understanding of their regulatory requirements on documentation, it fell on the company to convince the customer of what documentation was enough. *"There can be customers requesting documentation but then you sometimes have to understand why they're asking for that documentation to know if you can replace it with some other way to do things or if you can skip it; that they're only asking because it's been provided before."* (Interviewee 4)

Reflection

Regulations are mainly written very generic in order to match a wide market that develops medical software products, as Mehrfard & Hamou-Lhadj (2011) comments: *"FDA guidelines and requirements for software development are defined in a way that is too generic to be applied to a development process, which often causes ambiguities for software developers since no specific development methodology can abide by the provided guidelines."* This statement fit well with the challenges explained during the interviews, that it was difficult to interpret what requirements applied for a certain company, process and project, and to know whether you were doing enough to fulfil them or if you were doing too much, leading to an increased workload.

Due to the difficulty of fully understanding the regulatory documents and how to develop a work process that fully complies with the requirements while still being competitive in the market, some companies hire external help, or have separate regulatory divisions. These parties help with interpreting the regulations and validating the company's work process in order to make sure that it stays compliant. This help relieves the issue of comprehending the regulations but instead introduces other issues at hand which are also brought up in the interviews in form of communication issues and agile competence. It is of importance that the organisation responsible for interpreting the regulations or constructing the company's work processes has an agile competence in order for the company to develop a company-wide agile adoption.

When it comes to the challenge of conforming to regulations posed on the customer, Hajjdiab and Al Shaima Taleb (2011) mentions a similar challenge with agile development called *"A lack of business knowledge among developers"* which amongst other things refers to developers missing knowledge about their customers' needs. As suggestions for solving this challenge Hajjdiab and Al Shaima Taleb (2011) recommends the customer running training sessions on topics within the business domain. This could, in the case of regulations, help the company better understand

the demands faced by its customer.

Regulations are not up to date with current software evolution

Mentioned in the interviews was that software development is a field that is in constant change and processes and methodologies are replaced with alternatives that are more appropriate with increasing demands. However, companies participating in the study mentioned that the process of regulations does not keep up due to the limitations inherited in changing regulations. This creates a rift between how practitioners would like to work, or the needs they see, and how the authorities regulate this work. Interviewees mentioned that even though regulations were slowly adapting, there was still a gap which hindered productivity and it was still some way to go until the regulations fully supported agile methods. One company expressed that this was a challenge and that the regulatory bodies were aware of it, but had not solved it yet (Interviewee 1). Regarding the challenges in this challenge category, one interviewee each from Companies 1, 3 and 4 mentioned challenges with regulations not being up to date with current software evolution.

A challenge that was mentioned in the interviews was that it was difficult to interpret what part of the documentation that was mandatory and how much documentation that was required to be provided with the delivery of the product. A lot of focus was put on user experience and software was designed to be self-explanatory and contain in-use help functionality such as tooltips. One interviewee said: *"They [(the FDA and European bodies)] are viewing it a bit like hardware. When you buy one of these [hardware products] that are packaged, you get an included user manual, but it is very seldom you are using a [physical] user manual for a computer program since you [already] have it inside the program in some form."* (Interviewee 3). This requirement on user manuals pushed the need to finish the requirements engineering activities earlier, since the user documentation had to be formulated, designed and sent off for translation, which had to be certified before any release. Additionally, the regulatory demands on physical user documentation put even more strain on releases since those had to be printed before any product could be shipped. This made agile work more difficult and to alleviate the issue, the regulatory bodies would have to review how the need for user documentation looks in the modern world, and redirect regulatory demands towards the context where end-users are actually learning how to use the software.

Another challenge mentioned in the interviews was the need for documentation used for the validation of a company's work process. One company used system tools that provided a good format for traceability, requirements engineering and other documentation. This information was very useful to the company but was not formated in a way that was easily converted into a document based format. Regardless, the company still had to convert the data and store it as text in physical documents in the end. An interviewee at another company reported that they would have liked to have more of their requirements, testing specifications and other documentation

put inside systems instead of provided as physical documents, but even though they were using large requirements databases, they still needed to be able to withdraw printable documents.

Through the interviews, the companies also present a challenge with the regulatory bodies still expecting traceability to be done in ways which were not relevant any more. One interviewee reported that the company had been struggling with the regulatory bodies over the demands for code traceability. That regulations asked for traceability of feature requirements down to code level, even single lines of code. The interviewee argued that this was just not possible anymore. The regulatory bodies seemed to not grasp the concept of object oriented programming and how that kind of traceability was no longer relevant (Interviewee 4).

Reflection

The challenges included in this challenge category has not been found treated by related work and therefore no suggested solutions to the challenges have been identified. The challenge category is however still relevant since it provides an insight into challenges perceived by industry practitioners, which is the focus of the study. This is also supported by the answers to the validation questionnaire which is further discussed in Chapter 5.

Regulatory instructions are missing agile definitions

This challenge category encompass challenges perceived by companies on how regulatory instructions are lacking agile definitions or described in ways that are easy to understand from a waterfall, or sequential perspective, but that introduce added effort when working with agile. Challenges within this challenge category were reported by one interviewee in Company 4.

When trying to understand how to adapt the regulations to an agile environment the interviewee reported that the descriptions in the regulatory documents were based on sequential methodologies, such as waterfall, or otherwise not using an agile terminology. It was said that this introduced challenges for the company when having to interpret and translate the regulations. Specifically, it created difficulties when having to map the regulatory terms to agile terms in order to understand how to correctly apply the regulations to agile methods. The interviewee also report that it was felt that due to regulations being constructed around waterfall processes, there was a challenge in explaining and proving to the regulatory bodies how the agile methods complied as it had to be done to show that they complied equally well as the waterfall processes.

It was also mentioned that the regulatory instructions often presented demands that fit sequential processes well; that all requirements had to be finished to a certain level at one point, then development should be done for a while followed by verification, etc. This made the adaptation of the regulations to an agile environment difficult. Additionally, this issue also introduced the need for companies to

map and translate their agile work methods and process artefacts into a language that fit sequential definitions. As one interviewee stated: *"all detailed instructions that are describing how to work are constructed from the notion that everything is done according to this waterfall principle. So that is where complications arise, so there is a need to be able to describe this agile way of working and to show that it brings about these quality improvements that we [believe it does]"* (Interviewee 4). This lack of an iterative view in the regulatory instructions would further make it difficult for companies trying to adopt agile to update their own internal regulations.

Reflection

Regarding the challenge category of missing agile definitions in regulatory instructions, there are very few guidelines found during the study that suggest solutions to the challenges. However, in 2012 the Association for the Advancement of Medical Instrumentation (AAMI) produced a guidelines document for how to work agile with medical device development called TIR45:2012 (AAMI, 2012). These guidelines have been recognized by several regulatory bodies, such as the FDA, as an approved way of being compliant to their regulations. Kappe (2013) mentions that TIR45:2012 covers: *"several key topics such as documentation, evolutionary design and architecture, traceability, verification and validation, managing changes and 'done' criteria"*. Kappe continues to to mention that the key topics of the TIR45:2012 document are presented at both a conceptual level and a level practical for implementation. However, he also mentions that TIR45:2012 misses to specify how to integrate risk management activities within agile methods and instead, Kappe provides alternatives in his paper (2013).

Regulations do not follow industry conventions

This category collects challenges that are based on a discrepancy between how industry works and the activities supported by the regulatory bodies. It also covers aspects where regulations demand use of development artifacts in a way that is contrary to how industry wish to use them. There was one challenge reported by interviewee 3 within this challenge category.

Within the interviews, interviewee 3 mentioned that their company had a challenge regarding version numbering. The company used the same build number within their internal process for certification as they did for their distribution of the software which resulted in that a new certification was needed every time the build number was updated. When publishing an app onto, or updating an app already on a mobile application store there was a need to provide a description of the product or the change. If this provided information contained any errors, the application store could demand a republishment of the app. In this act, a new build number had to be provided to the app store. However, since the build number was changed, a new regulatory certification was required even though nothing essential had changed within the software of the product.

Reflection

The challenge of *"regulations do not follow industry conventions"* is described on a higher level, but contains one very specific challenge. The challenge category brings up an interesting aspect of new technology that increases ease of access for customers, and which regulations needs to adapt to. When studying related literature in the field, we have not found any that treat this challenge category. However, when looking at the answers provided in the validation questionnaire a majority agrees that this category is relevant.

4.3 Interlocated challenges

The interlocated challenges area includes challenges where it is unknown where the prohibiting factor lies between the companies and the regulatory bodies when working with, or adopting, agile methods. The challenges in this area are caused by actions or factors belonging both to the practitioners as well as the regulatory bodies, and needed resources for solving these challenges are located at both parties.

Regulatory certification

The regulatory certification challenge category consists of challenges that have arisen based on the requirement, or willingness, of companies to be certified in order to guarantee their customers a safe product. The challenges within certification are mainly concerned with the lengthy and costly process of going through a certification check, and the strictness of how little a product can change without having to be re-certified. This is an important factor when looking at agile methods and can seem to not function well with regulatory approval processes due to the introduced long delays. One interviewee each from Company 1, Company 3, Company 4 and Company 5 mentioned challenges within this category.

Several of the interviewed companies pointed towards a challenge in that even small changes in software impose re-certification: *"For example if a piece of firmware changes in its medical device has to be re-certified. It doesn't matter what it is in the firmware that's changed (...) It's not very agile if you're not able to do such things (..) to your firmware without having to re-certify yourself since it takes time and costs money."* (Interviewee 1). With this in mind, given a lengthy certification process product release can be extended by several months. If for example a bug is identified in the software it can be of interest to get a fix released as soon as possible, but that is difficult for medical companies: *"The same with bug fixing, it's pretty difficult to know what is a large change and what is not a large change. You often want it released pretty fast, a quick fix. That can be hard for medical companies"* (Interviewee 3).

Reflection

The interviewed larger companies cope with the issue of heavy certification activities by keeping an agile process during development but keeping the other parts of the

project structure in a more linear-like process in order to reduce the cost and time associated with getting certified frequently. While this helps the companies not having to worry as much about certification, it also limits the company's possibility of using agile to its full ability. This type of compromise is also included in the hybrid agile models described in papers such as Bose et al. (2013).

Software quality control

During development within regulated environments such as healthcare, it is important to ensure that a software product meets its quality goals. There are added aspects such as quality assurance and audits that are in place in order to make sure that there is a compliance to the regulations. However, these aspects also add increased work difficulty. Challenges within software quality control was mentioned by one interviewee at Company 3, one interviewee at Company 4 and three interviewees at Company 5.

A challenging part of software quality control which was mentioned by many companies was validation and verification, which includes the strict validation and verification activities posed by regulations onto software development. Mainly, these challenges are about a difficulty in staying agile or making fast deliveries. One interviewee said: *"For example, the validation that we're doing has to be [on] the finished product with documentation (...) and the released software and training material, and you can't do that iteratively. We're putting three man-months into that activity (...) and it always has to be the finished launched product, which like makes it no alternative to have the acceptance phase in that [iterative] process"* (Interviewee 9). Reported in the interviews was also that the regulatory bodies demanded very detailed traceability which increased the documentation needed to be done and complicated iterative agile work.

The issue with verification and validation cycles is also reported in other interviews. It is mentioned that the issue causes external release cycles to become longer which goes against the agile interest of having frequent releases and being able to quickly adapt to customer needs. Since deployment has to pass through an acceptance process first which is slow, continuous deployment is more difficult if not impossible. *"We can't do continuous deployment in a reasonable way. It doesn't work. You've got to have things accepted before you can deploy it, there you've got your hands tied a bit"* (Interviewee 3). There is also a brought up challenge in that customers have to keep their systems validated in order to meet regulations. Whenever an update would be delivered to the customer they would have to re-validate the updated system, which is a costly and lengthy process so customers tend to prefer less frequent deliveries.

Another challenge mentioned by one interviewee was that you must provide evidence that a feature is well devised before designing it which does not function well in iterative loops. The interviewee explained the needed evidence: *"It's a user evaluation, that is, you're looking for objective evidence, that you can do a run-through*

of the functionality together with the users, and then you need a certain sample of a certain amount of users. And to get that evidence in place before you develop, or design it, that's the challenge" (Interviewee 9). The challenge of involving users continued to be described within the strict need to validate a product's usability. This was reported as difficult in an iterative work process since each release needed a new validation which would require involvement of end users. Such an activity, however, was very time consuming and needed to involve people closely representing the actual end users. So if the product was to be released in another region, end users from that region might have needed to be included.

When developing globally within healthcare, a company reported that there was a requirement for the product and documentation, such as user manuals, to be localised to the native language of the country where the product was to be released. Supporting different languages is a process that takes time and adds a challenge to agile development due to the need to plan and define most features requiring user documentation at the start of development. This was so that the lengthy translation process can begin and since there was a validation process involved when all translations were finished, it was very difficult to introduce new features at a later stage of development if they had a need for localisation. This new feature would then be subject to a new lengthy translation process which would delay the point of validation heavily. One interviewee explained the situation as follows: *"The more time we have, and the better we are, the more features we can include and the more things we can do, but then you're sometimes limited by the language already being accepted. All text and all mandatory material must be finished already, so it's still difficult to extend our software or remove things at the end because we have to support our documentation. That's a drawback for a medical device"* (Interviewee 3).

This challenge of localisation also extended to include a second aspect mentioned which was that even though many countries may speak english well, the documentation still needed to be localised into the country's native language instead of it being possible to initially provide a global english version and later on, complement with localised versions since that would have had less effect on an iterative development method.

Reflection

The challenge category of software quality control processes is the one with most challenges associated with it and was mentioned by all three large companies. When it comes software quality control, there are many aspects hindering the adoption of complete agile methods. One of the mentioned aspects was that it was hard to change the linear process due to factors such as translation of documents that takes time to do and needs to be validated together with the product. In literature, this challenge is also recognised. In State of Agile Survey (2015) it is mentioned that the cost and time spent validating new and upgraded systems is one of the top three issues that prevents improving the product development processes. However, they do not elaborate on a solution for this challenge aspect.

Another important factor that was mentioned was traceability. Kappe (2013) mentions that the document *"TIR45:2012, Guidance on the use of AGILE practices in the development of medical device software"*, by the AAMI, covers several key aspects including traceability, verification and validation. It also provides examples on agile methodologies that covers the aspect of traceability. State of Agile Survey (2015) mentions that the path forward is collaboration, visibility and traceability. Because of the challenges involved in regulatory documentation, generating the required traceability documents should be an automated process. Companies should look to a purpose-built software solution that incorporates this functionality—preferably one that conforms to their business needs and processes.

Customer expectation

The customer expectation challenge category relates to challenges regarding the demands and expectations of customers on a company and how that conflicts with working agile. One interviewee from each of Company 2 and Company 4 reported challenges within this category.

One challenge mentioned was that when wanting to work agile, customers did not understand the agile way of working since it was not as well described within the regulations they followed. Instead of containing agile process descriptions, most of these regulations are leaned towards waterfall processes. One interviewee explained: *"I would like if actually the requirements came from the the customers, that they understood this agile way of working"* (Interviewee 4).

Another challenge explained in the interviews was that the industry lacked an acceptance for continuous small releases. One interviewee felt that there seemed to be a common understanding amongst customers and industry that releases were large and delivered every sixth month to every third year, which went against their company's wish to deliver more often. The interviewee explained: *"we need to get an acceptance for doing many releases and to have continuous small improvements. (...) we're now up in two releases externally per year, and it's hard to get acceptance for that, simply speaking, and that's not very much"* (Interviewee 4).

Reflection

When working with agile methods, there is a will to be able to release new updates frequently, as Agilemanifesto.org (2015) states in one of its principles: *"Deliver working software frequently, from a couple of weeks to a couple of months, with a preference to the shorter timescale"*. An aspect mentioned in an interview was that customers wanted faster releases but knew they were to expect long release times due to the process of certification. Long release times are common in medical software development, however there is a positive attitude amongst some customers towards more frequent releases, which could indicate that the industry is approaching an agile acceptance.

A mitigation strategy mentioned by agile methodologies, inspired by Agilemanifesto.org, (2015), is customer collaboration and on-site customers which could aid with challenges for customer expectations. However, no literature has been found showing a connection between customer collaboration and customer expectation or the effects from such strategies.

5

Challenges validation

At the end of the study, a questionnaire was sent out to the participating companies asking them to validate the elicited challenges. There were a total of 10 respondents to the questionnaire of which 7 took part in the interviews. The questionnaire respondents were asked how strongly they agreed with each challenge category. From the resulting data from the questionnaire a heat map was created (Figure 5.1) to visually show how frequently the different options of agreement for each challenge category were chosen. A white field indicate no respondents choosing that option and the more answers given for an option, the deeper red the square is coloured.

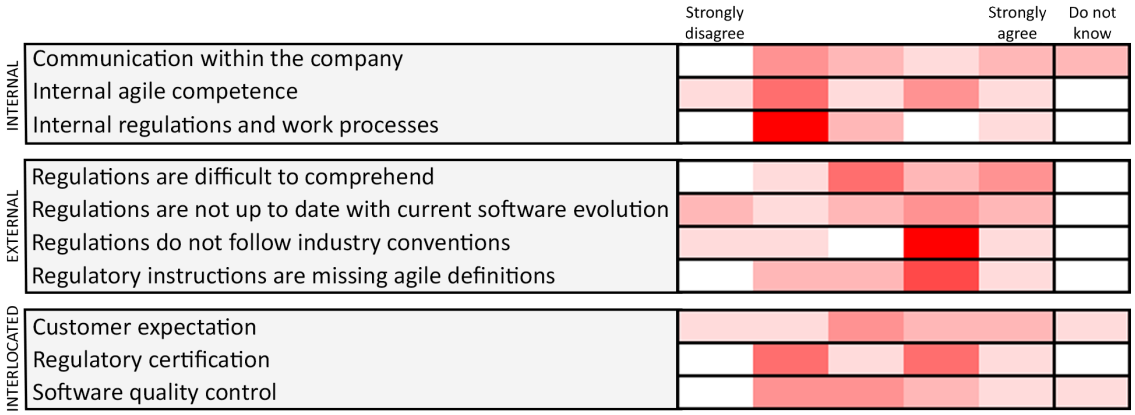

Figure 5.1: Challenges validation result. Data gathered from the questionnaire represented as a heat map. The coloured matrix represents how the respondents have answered the questionnaire. Each row represents the challenge category that was asked about. Each column represents the different options that the respondents could choose, from *"Strongly disagree"* to *"Strongly agree"*, including the choice of "Don't know". The colouring of the cells in the matrix correspond to how many respondents chose that option. A white colour represents no respondent selecting this option. The deeper red the colour is the more respondents answered that option. Each respondent had to choose exactly one option for each challenge category.

There was a great spread of answers for each challenge category ranging from *"Strongly disagree"* to *"Strongly agree"* on most challenges. The difference in answers could possibly be related to the different roles the respondents had within the companies, where the experience of how the challenges were perceived could differ. Looking at the three different challenge areas of which the challenge categories

belonged to, the collected answers leaned towards different ends of the scale. Looking at internal challenges, they leaned more towards strongly disagree in contrast to external challenges which leaned more towards strongly agree. The interlocated challenges were more balanced towards neutral. An interesting aspect seen in the data collected from the questionnaire was that there was more of an agreement towards external challenges than internal challenges.

For each area in the questionnaire, the participants had the opportunity to provide textual feedback and comments for the challenge area overall. Looking at the internal challenges, there were two comments falling within existing categories. *"Primarily we need to work more agile across all aspects of the business and get a coherent understanding of how we should and especially, can work"* which falls within internal regulations and work processes and *"Upper management need to understand agile principles and embrace them"* mentioned in internal agile competence. There was also an interesting comment where a questionnaire participant did not believe that the provided challenges were the biggest ones facing the industry, rather that the industry is not used to working with agile and therefore do not know how to adopt agile methodologies.

For the interlocated challenges, a participant mentioned that from experience, it is not the control processes that are too heavy, rather it is the processes that are outdated and strict. The participant also said: *"I would argue that quality control is even more important in a agile environment, and especially in our field, but that conventions and processes are not yet up to date with agile methods"*. Another participant also mentioned that agile methodologies within healthcare could be easier to adopt and use if there were more cases or examples of companies working successfully with agile methods.

It was also mentioned as a comment for the whole study that there are challenges with work processes together with different customers; *"Further challenges arise in working with integrated systems with multiple customers where the agile and regulatory interpretations are often slightly different"*.

6
Discussion

This chapter provides a discussion on the results reached in this study, the effectiveness of the chosen research method, possible threats to the validity of the study as well as suggested future work. Specifically, the three first sections of this chapter each treats one of the three research questions of this study. The first section, 6.1, will present a general discussion of the results from the first research question and compare the results to found related work. The second section, 6.2, is a discussion of the second research question, if the challenges are consistent for healthcare software companies. The third section, 6.3, presents a discussion on the third research question, how to resolve the challenges. This will take all challenges into account and address them as a whole rather than on an individual level, which is discussed in the reflections under the Challenges chapter. At the end of each of the three sections, 6.1 to 6.3, a summary will be held of the reached answers to the respective research question.

6.1 The agile challenges in regulated healthcare environments

When performing research looking into possible causes and solutions for challenges, there are different solutions that can be arrived at based on the interpretation of the causes. In this matter there is a distinction between this research and other related work. All related work found that brings up causes has chosen to focus on causes being company internal, and has placed the responsibility for solving the challenges on the practitioner. This is well highlighted in the study by McHugh et al. (2013) where they mention in the conclusion: *"The literature review, questionnaire-based survey and AAMI TIR 45:2012 act as evidence that there are no external barriers to adopting agile methods when developing medical device software and that barriers that do exist are primarily in-house barriers within the organisation, which can be overcome."*

This study contrasts related work since not only internal challenges are brought up, but also external and interlocated. Therefore it is difficult to compare the results arrived at to those of related research. However, the general gist of the challenges elicited by both this research and others' seem to correspond very well, although this study has focused on presenting more detailed information about the challenges

than what the papers of related work has done. As such, this study provides an extension to the knowledge of the research field.

Most literature focus on the aspects of adoption and how agile methodologies lack the means needed to work with developing for medical software. The addition brought by this research is to also include a view on challenges that apply on already working agile processes and challenges that could need a dialogue between industry and the regulatory bodies in order to be solved. On a higher level, there does not seem to be much difference in what challenges are reported by related work as being barriers towards the adoption of agile and what challenges this study has found for practitioners already working agile. This is again, however, difficult to compare at a lower level since the amount of details in the challenges' description in related work is too low to compare to the more detailed results of this study.

6.1.1 Answering research question 1

As answer to research question 1, *What challenges are encountered when developing with agile work methods within regulated healthcare environments*, this study elicited a total of 37 challenges, summarised into 10 challenge categories based on similarity. These categories can be seen in Table 4.1 and represent the essential challenges perceived by practitioners in the regulated software healthcare industry. The categories were further divided into three challenge areas based on where the cause for them was perceived to lie.

6.2 Company factors affecting which challenges are perceived

This chapter discusses interesting aspects and differences between companies that could affect the challenges and categories found and can be explained by one or several parameters, such as company size which we found was the most relevant. Company size can loosely be coupled to other factors such as company maturity and experience within the field; complexity of current work processes and its organisation; the range of products developed; and the classification level of the developed medical devices. The relation to these sets of factors makes company size the first natural factor to look at when wanting to see trends in which challenges affects what kind of companies. The content in this discussion is based on what was found during the analysis of the interview data.

Looking at the different company sizes, this study had a range from small start-ups to very large companies with several tens of thousands of employees. From the interviews, there was a conclusion that could be drawn when looking at company size and previously existing work processes. When looking at the small companies, they had a common factor of having relatively new work processes based on agile concepts which was working well for them. Looking at the larger companies, however, they all had previous processes ranging back to when waterfall processes was

the standard. Thus when wanting to adopt agile methods at larger companies, the result ends up becoming a combination of the old work processes together with new ideas of agile methodologies. It is mentioned by Saboo (2014) that in order to adopt an agile methodology, a slow change is needed from the previous work process. This will lead to a combination of waterfall processes and agile methodologies which is also mentioned by Bose and Thakur (2013) who describe that a mixed methodology is a way to solve potential issues. According to the study, companies mostly develop using agile methodologies wrapped within a waterfall process for parts outside of software development such as planning and delivery.

Another interesting aspect that was brought forward in the larger companies had to do partly with internal communication and how the departments and work processes were set up. When interviewing different roles within the same company, there was a difference in experienced challenges. While process management thought it was difficult to know how to interpret the regulations in order for them to be able to construct suitable agile processes for the company, development perceived challenges with management not wanting to adopt agile.

Common challenges to companies in the study

Even though certain challenges seem to be more prevalent when looking at certain company factors, there are two categories which seem to be present in all companies within the study. Firstly, the challenge category "Regulatory certification" is something that is brought up in the interviews by companies of all different company sizes. This is likely explained by certification being an activity all companies have to go through before product release, and as Fitzgerald et al. (2013) mention, the frequent deliveries of agile pose a lot of cost in review and approval activities. As such, frequent releases of agile are less suited in a regulatory domain. The second category faced by companies of several different sizes is the category "Regulations are not up to date with current software evolution". The individual challenges within this category faced by each company differ however, which would indicate that the challenge category as a whole can affect many different kinds of companies. It is, however, difficult to draw any conclusions on whether the details of the posed challenges are equally shared between companies.

This study has included companies operating in Sweden while the study performed by McHugh et al. (2012) included companies operating in Ireland. When comparing the results of these two studies there are little difference in elicited challenges. The main challenges reported by McHugh et al. (2012) were; Lack of Documentation; Traceability Issues; Regulatory Compliance; Lack of Up-Front planning; and Managing Multiple Releases. While the findings in this study are more detailed around the regulatory compliance challenges, several challenges were also found to be related to documentation, traceability, up-front planning (e.g. localisation requiring up-front planning of requirements) and the difficulty of managing multiple (i.e. frequent) releases. This suggests there being little overall difference between companies operating in these two countries.

6.2.1 Answering research question 2

Based on the discussion in this section the second research question of this thesis, *"are the encountered challenges consistent for healthcare software companies"*, can be answered. It is possible to see that there are some challenges that might only appear for certain companies. Large companies have challenges associated with hybrid agile methods and internal communication. There has also been one challenge identified as likely being common to all companies in the industry, the challenge of certification.

6.3 Challenges resolution

The elicited challenges were set into three areas based on which party - practitioners or regulatory bodies - that was regarded to hold the major capability of solving the challenge. This section aims to provide a discussion on possible solutions applicable within each of these areas. This will be done by addressing three topics. Firstly, a discussion will be held on literature resources that have been found providing suggestions for suitable solutions. Secondly, a discussion will be held on the suggested solutions of hybrid agile methods. Lastly, a look will be had into the solutions suggested within the individual reflections of the Challenges chapter to see if there are any overarching solutions suitable for solving the whole area.

Internal challenges

The area of internal challenges contains issues that likely have their cause within company practise, and can as likely be solved by change of this practise. The healthcare software industry has two aspects to address in its practise. The first aspect is being successful with respect to its agile methodology. The second aspect is being compliant in regards to any posed regulations. When looking into solving the first aspect there are many literature sources that address how to successfully adopt or run an agile methodology that could prove useful. This is likely a cause of the great popularity that agile has had within the software industry throughout the last decade. However, when also regarding the second aspect, the one of complying to regulations, the amount of literature available becomes severely reduced. While it might be possible for practitioners to find suitable answers to their challenges within literature pertaining exclusively to agile, practitioners should arguably also validate their practise ideas towards resources covering the combined field of agile and regulatory.

When reviewing the resources explaining how to work agile within a regulated environment, there are a two main sources found that could be relevant to practitioners.

The first is AAMI's TIR:45 (2012) providing guidance within most aspects of practise on how to make an agile methodology comply with healthcare regulations. The second resource is the e-book by Kappe (2013) which refers to the AAMI TIR:45, but also recognises that the TIR:45 document does not in fact treat risk management, and as such Kappe provides an extension for that.

Apart from seeking aid from literature and research in general, the internal challenges seem to align themselves well to be solved by the industry sharing best practises. The healthcare industry seems to still be suffering from a lack of understanding of how to do fully agile work processes, and in this early adoption stage that the industry is in, a wide sharing of success stories could prove helpful. As one respondent to the challenges validation questionnaire wrote: *"It would be good to see more cases/examples of companies working successfully with agile methods."*

External challenges

The area of external challenges is presented in the interviews as caused by the regulatory bodies and the regulations put upon practitioners. Solving these challenges would with that mindset be the responsibility of the regulatory bodies. However, when wanting to suggest possible solutions to these challenges, it becomes clear that very few literature sources speak about how the regulations could change, and very few literature sources provide an angle of critique towards the regulatory bodies. Based on the problem formulation of this research it is therefore difficult to provide concrete, or well backed up suggestions for how to solve the external challenges.

The regulatory side of the industry are trying to provide own solutions to some of the challenges presented, such as the AAMI TIR:45 document (2012) to combat the perceived lack of agile definitions. However, it is difficult to judge, based on the interviews held as part of this research, whether the results of these attempts have been considered by practitioners, and how well they have proven capable of mitigating the targeted challenges. One interviewee specifically mentioned TIR:45, but the company had issues with their own internal regulations being too strict to likely be able to try out its guidance.

With the difficulty of suggesting solutions to the external challenges explained, it is suitable to say that there seems to be a possibility for the regulatory bodies to do three things to help alleviate the external challenges. Firstly, the regulatory bodies can revise their regulations with the aim of seeing how well they match new industry conventions. Secondly, the regulatory bodies can revise their regulations with the aim of seeing how well they are understood by practitioners, and how easy it is to arrive at different interpretations of the regulations. Lastly, the regulatory bodies can revise the support material that is provided practitioners and consider how well this material is helping them apply the regulations. They can also consider how well this material is helping the industry evolve any old practises and conventions still present towards more modern versions where there is better support for agile

methodologies.

Interlocated challenges

The interlocated challenges are challenges perceived in this research as being too complex for the responsibility of their solution to be attributed to any one side of regulatory bodies or practitioners. Likewise with the external challenges it is difficult to find resources suggesting full solutions to the interlocated challenges. There do exist resources that could be used by practitioners to a certain, perhaps small degree alleviate the problem. This would however not solve any challenge fully, and similarly it is unlikely that any act by the regulatory bodies can completely overcome a challenge for the whole industry. These challenges seem to indicate a need for future discussion and cooperation between regulatory and practitioners in order to well understand each other's needs and develop a reasonable solution outside the reach of any individual party.

6.3.1 Agile compared to hybrid waterfall-agile processes

When looking into agile development, there exists a variety of methodologies that can be used and combined in order to make a development process more iterative. There is also an alternative to having a fully agile process by combining iterative methodologies with existing linear methodologies and thus having a more hybrid approach.

The survey State of Medical Device Development (2015) has throughout both the year 2014 and the year 2015 performed a survey regarding agile methodologies within software healthcare companies. In the first survey they have almost 500 participants where the majority are working with Class II or Class III medical devices. In the second survey, they have over 900 participants of which over 60% has been working within the life science industry for 10 years or more. The survey reports that in 2015, with rounded values, 20% had an agile work process, 28% had a hybrid agile work process, 18% had an iterative agile process, 10% had a waterfall process and 24% had other processes. From 2014 to 2015, agile has increased with 3%, hybrid has increased with 12%, iterative waterfall has decreased with 2% and waterfall has decreased with 10%. This reflects itself on the companies that are part of this study where the larger companies all previously had waterfall processes and have recently shifted towards a top level process that is more hybrid while the software development process is more agile.

The interviews mentioned that the regulations were written without agile support, and some parts even written in a waterfall-like manner leading to the work process being interpreted from the regulations and ending up lacking agile support. When wanting to adopt agile methodologies, it is important that it is well understood how

to implement such an approach. One speculation is that in order for companies to apply an agile approach company-wide and for their internal regulations, the external regulations need to fully support agile and by not doing that it is difficult to comprehend how agile methods can be used in the process. The regulations need not only to provide understandable agile solutions but also to do so on a level that developers can understand and share in a compliant way.

Also mentioned was that due to existing work processes not being agile combined with people having experience with working more sequential with processes such as waterfall, it is difficult and time consuming to alter the process towards including more agile methodologies. This is an issue that exists in a lot of companies outside of the healthcare sector but is more prevalent here due to regulations being in play. It is not easy to change a way of working when needing to comply with regulations and making sure to remain validated.

Looking at different work processes, Bose, Lipika and Thakur (2010) introduce traditional software development methods and agile software development methods. They present advantages and disadvantages with traditional waterfall model as well as agile software development methods. They also present having a hybrid model combining the existing waterfall model with agile methods together with its advantages and disadvantages. Their paper has a focus on the methodology Scrum, and provides guidelines for organizations to adopt agile methods and a basis for hybrid methods. Looking at the large companies in our study, a hybrid model is a way to overcome some of the challenges that currently affects agile development within regulated environments.

Boehm and Turner (2005) look into management challenges with integrating agile methodologies in traditional development organizations. They find that there often are conflicts between the agile methods and the old work processes. One example is when merging the new and old processes, it is difficult to know how to do so successfully while keeping agility in the process without discarding any currently defined and refined work systems. There are also issues such as variability; the occurrence of different artifacts created by the two different processes, such as different lifecycles and documentation demands. Boehm and Turner (2005) identify a list of barriers which they provide suggestions for how to resolve. Their conclusion is that combining work processes can be successful but would require a lot of work from the companies and more research is needed within the field.

6.3.2 Resolving all challenges as a whole

The results from the first research question of this thesis brings forth challenges aimed towards different aspects of software development within regulated environments. The results are presented and reflected upon individually. However, as mentioned in reflections for the challenge categories, such as *Regulations are diffi-*

cult to comprehend and *Internal communication*, and also brought forward in the discussion above, there exists connections between challenges that need to be taken into consideration when trying to resolve them.

Trying to correct individual challenges when adopting agile methodologies is difficult due to a lack of taking the whole development process into consideration. McHugh et al. (2013) mention that three medical device software organisations had successfully adopted agile practices within their previous development process. All three of the organisations had however recognized that no single agile methodology could be fully followed when developing medical device software and had instead chosen to integrate appropriate practices with their previous traditional plan driven software development life cycle. In the survey State of Medical Device Development (2014), it is mentioned that in order to overcome challenges presented by regulatory documentation, companies should look into purpose-built solutions that looks at more than only single factors such as documentation or tracing.

6.3.3 Answering research question 3

The answers to research question 3, *"How can the challenges be resolved while still keeping to an agile approach?"* have been given in the discussions held in the reflections of the Challenges chapter, as well as the discussion contained within this parent section. Summarising the solutions suggested for each challenge area, the Internal challenges area contains the following solutions: In order to avoid challenges with communication a company should make sure to communicate across methodologies within the company as well as its departments. It should also use common tools between all methodologies. To more successfully adopt and promote an agile methodology the company should make sure to on board and train middle management in the usage of agile methods. To alleviate challenges connected to company work processes or internal regulations the company should transition slowly when adopting agile. Lastly, the company should also increase the amount of automation done, and again, make sure to communicate between methodologies and departments.

For the external challenge area, there have been few solutions found during this research and only three solutions have been suggested. Firstly, to help with comprehension of regulatory material, a company can acquire help from external sources, such as notified bodies, or set up internal departments handling the interpretation of the regulations. These solutions might however introduce new challenges within *"Internal communication"* or *"Internal agile competence"*. Secondly, to better understand the regulations posed on its customers, a company can ask the customers to run training sessions, where appropriate, for developers to get an increased knowledge of the regulations in the customer's domain. Lastly, when concerned with the challenge that regulatory documents are missing agile definitions, one solution might be to look into the AAMI TIR:45 guidelines (2012), and the addition of risk

management activities by Kappe (2013). For the challenges of regulations not being up to date or not following industry conventions no solutions are suggested.

Similar to the external challenges area, the interlocated area has had few solutions suggested in literature. To combat challenges related to software quality control, suggestions are given in the AAMI TIR:45 guidelines (2012) on how quality control can be done in an agile environment. These suggestions might be applicable to companies and help them overcome these challenges, however this possibility is uncertain. Furthermore, to alleviate the challenge of regulatory certification the only solution found has been to run an hybrid agile methodology. However, this is not regarded as a successful agile solution from the perspective of this thesis, as it can be argued that hybrid methodologies still miss several valued aspects of ordinary agile methods. The challenge of customer expectation had no found solutions that could be backed up by literature or interview data.

6.4 Research methodology

The initial part of the study was focused on finding out what challenges that exist within the context of this research and therefore the choice of research method was to do an exploratory study. This choice of research method appeared to be a good choice for this study and relevant challenges were found.

Given the time span for the research and the context, the initial estimation for the number of interviews to include was to have at least eight in order to get a valid amount of data to be able to draw conclusions. It was unlikely that we would reach research saturation, as defined by Strauss and Corbin (1998), where collecting more data seems counterproductive, so the upper limit of interview participants was simply how many we had time to muster. For collecting the data in a qualitative and open-minded way, interviews were suitable. Several of the challenges found were likely able to be identified based on the open-ended answers from the questions asked. During the study, 9 interviews were held across 5 companies, including several different employee roles and a large range of company sizes from start-ups to very large companies. Looking at the elicited results, this research sample has provided a good range of challenges being able to show the prevalence of perceived challenges within several areas and surrounding several subjects. It would however have been possible to draw stronger conclusions with more potential data if more companies were part of the study.

The questionnaire used for challenge validation intended to validate how relevant the found challenge categories were for companies included in the research. Using a questionnaire for this type of verification worked well and the results provided good feedback as there were answers indicating that the challenge categories indeed were relevant. There were also answers indicating that the challenge categories were less relevant, however this inconsistency is to be expected as it is likely that employees

having different roles and tasks at a company will perceive different challenges as being more or less relevant.

Our method for finding solutions to the elicited challenges was to look into related work or other relevant literature and to look into what solutions might have been provided in the interviews. While the interviews did not focus on finding solutions, but rather on eliciting challenges, they still provided some solutions which proved valuable. However, our chosen main method of finding solutions, by looking into literature, did not work well. Throughout the literature studied, there was little presented material which could work as solutions for the elicited challenges. This could indicate that there is a lack of research done on how to resolve these kind of challenges, and mainly the external and interlocated challenges.

6.5 Threats to validity

The following limitations to this study were identified and categorized based on descriptions of the Validity section in Runeson and Höst (2009). As causal relations are not examined in this research, limitations within internal validity has not been of interest. Aspects of external validity however, might be affected by four factors. Firstly, the sample size of companies and interviewees included in the case study might prove too small to provide strong generalizable conclusions for the whole population of practitioners within the software healthcare industry. The sample chosen for this study have been sufficient to show the prevalence of perceived challenges, and the validation questionnaire done has helped strengthen the elicited results. Nonetheless, it is possible that an increased sample size could have provided additional results in the form of new challenges, or further aspects of currently found challenges.

A second threat to validity is possible selection bias among the sampled practitioners. This can have occurred since the majority of interviewees were all Swedish and as such there is an apparent possibility of Swedish work culture affecting which challenges are perceived. However, based on the qualitative approach of the study, results should be generalizable within a close context to the case, and it is then possible that results hold for practitioners having similar work cultures.

Thirdly, the reliability of the results can be affected by a few factors. Firstly it is possible that communication between interviewer and interviewee during the interviews was misinterpreted and as such, a wrong interpretation of a challenge could have been presented as elicited in this study. Secondly, the domain knowledge of the researchers has greatly increased throughout this study. It is therefore possible that more accurate data could have been gathered in interviews, should they have been performed with the researchers current domain knowledge, where the better understanding of the situation could cause better follow-up questions to be asked. Two methods were chosen to help reduce the impact of these threats to validity. One

method was that each interview was audio recorded. This meant that there was arguably less possibility for the researchers to misinterpret the interview data. The other method was to include the challenges validation questionnaire in the study, which would allow the participants to acknowledge whether they found a challenge to be true, regardless of whether it might have been wrongly interpreted during the interviews.

Lastly, in regards to the validity of this research's challenges validation questionnaire, there is a risk that the answers provided in the questionnaire are faulty. Since the descriptions of the challenge categories, on which the respondents answered, have been abstracted from the more concretely described challenges, there is a risk that the abstract description has lead to misinterpretation. This is applicable in the specific case of answering whether a topic is a challenge in the situation where agile is combined with regulatory demands, as respondents could have misinterpreted and answered based on whether the topic was a challenge in either an agile situation or a regulatory situation (but not the combined situation). To reduce the probability for this misinterpretation, it was expressed in each question that the respondent should answer if they thought the challenges were applicable within an agile-regulatory context.

6.6 Future work

Throughout this thesis, several suggestions for suitable future work have been found. Firstly, it could be interesting to extend this research by looking into a stronger validation of the challenges presented. This can suggestedly be done from two angles. One angle is to extend the validation questionnaire done as part of this thesis to include more companies and to get more answers. Similar interviews as the ones held in this research could also be held, but with the already elicited challenges as a base for questions and with the aim of validating those. The other angle for increasing validation is to analyse the regulatory documents and guidelines to examine how much of a challenge these actually pose on practitioners and what challenges are only perceived as being challenges with the regulatory side. This could help indicate the true causes of a challenge being perceived, and perhaps further guide how it can be resolved.

A second way to extend upon this research could be to perform similar interviews, but to include a different set of interview participants such as regulatory departments within companies or people from the regulatory or notified bodies. This could provide additional views on the challenges presented in this research, and it could also add new challenges as well as provide new suggestions for solutions. It could also be possible to have group interviews or workshops with different roles or different companies to promote more detailed discussions about the challenges which might reveal further information and insight into the challenges' natures.

Lastly, as a final suggestion on how this research can be extended upon, it could be suitable to further look into how solutions can be designed for the external and interlocated challenge areas by speaking with the regulatory and notified bodies. These parties could be queried about what challenges are facing them when constructing regulations and guidelines for working agile in the healthcare environment. This could provide a wider understanding of the causes for the external and interlocated challenges which would help with the finding of solutions.

7
Conclusion

In this thesis we present challenges elicited from interviews with companies within the software healthcare sector. These challenges are abstracted into challenge categories and challenge areas. For each challenge category, we present a discussion regarding the challenge itself and challenge resolutions, both based on interview data and literature. The challenge categories were sent to the companies in a questionnaire in order to validate how well they are perceived by other practitioners in the industry.

Both in found literature and interview data, a conclusion can be drawn that there exist challenges with working agile together with the regulatory demands when developing within healthcare. From the results of the interviews together with the questionnaire, we can conclude that there are indeed perceived challenges, both internally and externally, and that there are also challenges intricately connected to both parties, so called interlocated challenges. In order to solve these challenges, there needs to be changes both on the practitioner side as well as on the regulatory side for the industry to fully support agile methodologies. There are, however, very few solutions proposed for the external and interlocated challenges as they are seldom recognised by related literature.

Based on the findings of this thesis, in order for companies to be able to adopt and work with a fully agile work method in regulated healthcare there are three needs. Firstly, there needs to be more research done in the field, which we propose ways for as future work. Secondly, there is a need for more resources and guidelines created explaining how to work agile in regulated healthcare environments, and lastly there is the need for an improvement of the existing regulatory documents to better emphasize support for the agile way of working.

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A

Interview guide EN

Interview guide v1.0

1. Overview

- What is your name?

We will first shortly summarize the research and then ask some questions regarding your experience.

<Interview guide text>

- Don't forget, can we record?

2. Biography

What is your current role in the company?
Could you shortly describe the product you are working with?

3. Development

How does your work process look like today?
…. and for how long have you had such process?

If agile:

What kind of agile methods are you using?

If not agile:

Are you familiar with agile work methods?

What kind of regulations (or demands) exists in software development specific within healthcare?
Are there more, and less, important regulations? Do you prioritize the regulations?

If agile:

Have you had any challenges with your agile methods regarding these regulations?

- **Followup: Has there been any tries to solve these challenges / looked into?**

If **not** agile:

Have you thought about agile work methods? What has prevented you from using them?
Would you see any issues with changing to an agile work method?

In the future, as a next step, what would be a natural change for your work processes?
If you were to imagine a perfect world 5 years from now, how would you like your processes to look?

"When you consider the regulations you must follow:..."
How do you connect the regulations to your work process?

How do you know you satisfy the regulations?

What kind of tools are you using for the work process?

Regarding your deployment/delivery activities, are there any aspects you focus more on due to the environment of healthcare?

4. Company

What roles have you got experience from and for how long did you have them?
How long have you been working at the company?
How long have you been in the software industry?

How long have you been involved with this project or similar projects?
How long have the company developed this kind of product?
Who is the end user of this product and how is it used?
How large is the company?

5. Additional information

Have you previously had any challenges / (issues) with development and regulations?

- How did you solve these?

B

Interview guide SV

Intervjuguide v1.0

1. Översikt

- Vad heter du?

Vi kommer i kort att sammanfatta studien och sedan köra på intervjun som kommer att röra din erfarenhet inom området.

<Intervjutext>

- GLÖM INTE: Kan vi spela in?

2. Bio

Vad är din nuvarande roll i företaget?
Kan du kort beskriva den produkt du arbetar med?

3. Utveckling

Hur ser er arbetsprocess ut i dagsläget?
… och hur länge har ni haft den processen?
Om agilt:
Vilka agila arbetsmetoder använder ni?
Om **inte** agilt:
Känner du till vad agila arbetsmetoder är?

Vilka sorters regleringar (eller krav) på mjukvaruutveckling finns specifikt inom hälsovård? Finns det mer, eller mindre, viktiga regleringar? Hur prioriterar ni dem?

Om agilt:
Har ni haft några utmaningar med agila metoder gällande regleringar inom hälsovården?
Followup: Har ni haft några tankar/idéer på hur man kan lösa dessa utmaningar?

Om **inte** agilt:
Har ni haft några tankar om agila metoder? Vad har tagit emot att använda dem?
Ser du några nackdelar med att byta till agila arbetsmetoder?

I framtiden, vad skulle vara ett naturligt steg för era processer att förändras?
Om du föreställer dig en prefekt värld, 5 år i framtiden, hur skulle du vilja att era arbetsprocesser såg ut då?

“När man ser till de regleringar ni måste följa…”
Hur kopplar ni regleringarna till er arbetsprocess?
Hur vet ni att ni uppfyller regleringarna?

Vilka sorts verktyg använder ni inom/för arbetsprocessen?

Gällande release/delivery, finns det några aspekter som är förändrade, eller fått mer fokus, på grund av hälsovårdsaspekten eller de rådande regleringarna?

4. Företaget

Vilka tidigare arbetsroller har du erfarenhet av och hur länge hade du dem?
Hur länge har du jobbat på företaget?
Hur länge har du jobbat i mjukvaruindustrin?

Hur länge har du varit involverade i detta projekt eller liknande projekt?
Hur länge har företaget utvecklat denna typ av produkt?
Vem är slutanvändaren av produkten och hur används den?
Hur stort är företaget?

5. Ytterligare information

Har ni haft några tidigare utmaningar relaterade till utveckling med regleringar?

- Hur löste ni dessa utmaningar?

C

Questionnaire

Agile challenges within regulated healthcare environments

Thank you for participating in this survey.

This survey is part of a research trying to identify challenges emerging when adopting or working with agile software methodologies in healthcare environments regulated by for example the FDA or Läkemedelsverket. During the research, challenges have been identified through a set of interviews held at five different companies, your's included. This survey will be used to validate these challenges by letting you answer how applicable you find them to be at your company.

Three challenge areas have been identified with a total of 10 challenges. Should you have any questions regarding this research, survey or otherwise, please feel free to contact us.

This survey will be written in English but you are free to answer in either English or Swedish.

1. Company

The answers to this survey are anonymous. The company name will only be used to count the number of answers per company and connect company size to answers.

2. Did you take part in the interviews for the study?

- [ ] Yes, I took part

3. Work methodologies

What methodologies are being used within your current project?

- ( ) Waterfall-like
- ( ) Mixed waterfall-like with agile methodologies
- ( ) Agile methodologies
- ( ) Other

4. Select device classification

Which classification does the medical device you are working with now have? Where Class I is the lowest and Class III (or IV) is the highest.

[Please choose] ▼

In the following three pages, the areas with challenges will be presented. You are asked to validate how much you agree to the listed statements being challenges for your company. This will be measured with a scale ranging from ‘strongly disagree’ to ‘strongly agree’. There will also be a text field for each challenge where you can provide a potential mitigation strategy if you have an idea. It is not required but much appreciated.

Next

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0% completed

CHALMERS

Internal challenges

The internal challenges area includes challenges which are perceived as being caused by company internal factors. Three challenges were identified in this area during the research.

Please select how much you agree with the following statements while working with- or trying to adopt an agile methodology for your company:

5. Communication within the company

A challenge exists because of problems with company internal communication. One example is that the development and regulatory departments are not sharing knowledge well enough. Another example is vertical communication between managers or manager and developers.

	strongly disagree 0 1 2 3 4 strongly agree	don't know
Communication within the company is a challenge within an agile-regulation context	○ ○ ○ ○ ○	○

6. Internal agile competence

This challenge includes aspects such as a differing understanding whether agile is applicable in a regulated environment, that agile methods has not been accepted fully throughout the company or that the regulatory department within a company does not express support for agile methods within the work processes.

	strongly disagree 0 1 2 3 4 strongly agree	don't know
Internal agile competence is a challenge within an agile-regulation context	○ ○ ○ ○ ○	○

7. Internal work processes and internal regulations

This challenge includes aspects such as not being able to fully adopt agile because internal regulations are missing support for iterative processes. It can also include company internal terminology which is difficult to match to terms used in the rest of industry and regulatory documents.

	strongly disagree 0 1 2 3 4 strongly agree	don't know
Internal work processes or internal regulations are challenges within an agile-regulation context	○ ○ ○ ○ ○	○

Have you got any thoughts on how your company could mitigate these challenges, or other thoughts?

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External challenges

The external challenges area includes challenges which are perceived as being caused by regulatory bodies, such as FDA or the Swedish Läkemedelsverket, or regulatory documents outside of the company. Four challenges were identified in this area during the research.

8. Regulations are difficult to comprehend

This challenge includes understanding of which regulations that apply, correctly interpreting the regulatory documents as well as to find the right balance in interpretation such as documentation.

	strongly disagree 0 1 2 3 4 strongly agree	don't know
Regulations being difficult to comprehend is a challenge within an agile-regulation context	○ ○ ○ ○ ○	○

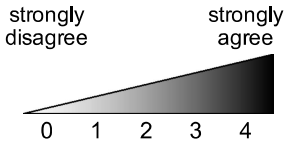
9. Regulations are not up to date with current software evolution

This challenge includes aspects such as physical documentation having to be produced even though the company can handle good traceability etc. through digital documentation systems. The physical documentation also put a demand on features being specified early.

	strongly disagree 0 1 2 3 4 strongly agree	don't know
Regulations not being up to date with current software evolution is a challenge within an agile-regulation context	○ ○ ○ ○ ○	○

10. Regulations do not follow industry conventions

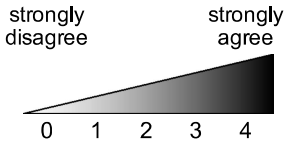
This challenge includes that regulations are not up to date with new conventions regarding certification; changing small details with a product delivery, such as a description on an application market, could lead to new build numbers resulting in the need for re-certification even though nothing essential has changed.



Regulations not following industry conventions is a challenge within an agile-regulation context	○ ○ ○ ○ ○	don't know ○

11. Regulatory instructions are missing agile definitions

This challenge includes regulatory documents describing work processes as waterfall processes and therefore lacking agile definitions as well as difficulty in updating internal instructions due to external ones missing agile definitions.



Regulatory instructions missing agile definitions is a challenge within an agile-regulation context	○ ○ ○ ○ ○	don't know ○

Have you got any thoughts on how your company could mitigate these challenges, or other thoughts?

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Interlocated challenges

The interlocated challenges area includes challenges which are perceived as being connected to both the companies and regulatory aspects and will therefore probably need an adjustment by both in order to be solved.

12. Customer expectations

This challenge includes aspects such as customers not willing to accept continuous or frequent deployment or that customers are used to old waterfall processes and are hesitant towards agile methods being used.

	strongly disagree 0 1 2 3 4 strongly agree	don't know
Customer expectations is a challenge within an agile-regulation context	○ ○ ○ ○ ○	○

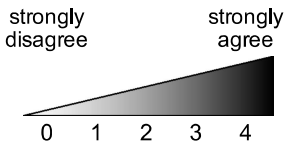
13. Regulatory certification

This challenge includes that even small changes in software can impose re-certification. Also that the certification process is lengthy and can extend product release by months and that frequent release is difficult due to this.

	strongly disagree 0 1 2 3 4 strongly agree	don't know
Regulatory certification is a challenge within an agile-regulation context	○ ○ ○ ○ ○	○

14. Software quality control processes are too heavy

This challenge includes all aspects of software quality control processes, such as verification, validation, quality assurance, traceability, etc. being difficult to perform or requiring much resources. This challenge also covers issues such as user documentation localization having to be validated before release.



Software quality control processes are too heavy is a challenge within an agile-regulation context	○ ○ ○ ○ ○	○

Have you got any thoughts on how your company could mitigate these challenges, or other thoughts?

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15. Is there anything else you would like to share?

16. Enter your email if you want to receive a copy of the report for the finished research

Press next to finish the survey.

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Thank you for completing this questionnaire!

We would like to thank you very much for helping us.

Your answers were transmitted, you may close the browser window or tab now.

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