Medical Device Software Process Improvement
A Perspective from a Medical Device Company

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Abstract: When manufacturing medical devices there are many constraints that have to be taken into account such as safety, compliance with regulations and traceability. To do this, well-defined processes are used. With this in mind we examine how process improvement is implemented in a medical device company while managing the resultant change. The case study presented in this paper investigates the use of Kotter's Change Model to support the implementation of process improvement in a medical device company. The results of the case study demonstrate that Kotter's change model was an appropriate model to use. The sense of urgency Kotter stipulates was inherent in the company. The team was aware that change was needed. A flaw in Kotter's approach is that there is no recommendation for a pilot project. Having a pilot project worked well for this company as it helped to eliminate stress and anxiety. A further case study is planned in the company to observe how the process is working after implementation of the full project.

1 INTRODUCTION

In the healthcare industry, medical devices are manufactured to aid patients. To safeguard patient safety and minimize risk such devices are regulated. The regulatory body in the USA is the Food and Drug Administration (FDA) whereas in Europe the regulatory body is the European Commission (EC) using the Medical Devices Directive (MDD) (EU Council 1993), (EU Commission 2007). Regulators can also approve standards such as the International Organization for Standardization (ISO) standards.

Recently the MDD (2012) amended its definition of a medical device to include software. Therefore, software can, in certain cases, be classed as a standalone medical device. In addition, medical device software embedded within a medical device or used in the manufacturing of a device is also subject to regulation.

In our research, we are interested in how MD companies cope with change of processes. Therefore, this paper documents a single case study where the company changed their documentation process from being document-centric to being artefact-centric. It was important for this company to undergo change in a controlled manner, which would not affect their regulatory status. We studied the software development process of a medical device company to see how they developed and implemented the software documentation process.

2 SOFTWARE FOR THE MEDICAL DEVICE INDUSTRY

The medical device industry faces persistent challenges, including competitors, government regulations, and productivity and quality issues. To remain competitive, they must reduce costs, streamline Research and Development, increase accountability, incorporate traceability and accelerate time to market.

Standards and guidelines have been developed to aid in achieving the safest possible product. For example in America the U.S. code of federal regulations title 21 part 820 governs the quality system regulations.

The international standard (ANSI/AAMI/IEC 2006) governs Medical Device (MD) software development life cycle (SDLC) processes. A set of processes, activities, and tasks that are needed within a MD SDLC process are defined by The International Electrotechnical Commission (IEC) 62304 (Cawley et al 2011). However, these authors

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also point out that reading the standards can lead to incorrectly thinking that a waterfall-type software development methodology is the best methodology to use. They suggest that companies should ensure knowledge of Annex B of the IEC 62304 standard. Individual MD companies can decide which methodology to use.

2.1 Literature Review and Related Work

McCaffery et al (2012) point out that with regulatory compliance in mind, MD companies usually use a SDLC such as the V-model. Agreeing with this, Cawley et al (2011) also state that more emphasis is being put on how to improve SDLC processes such as by using a more iterative development methodology (Spence, J.W. 2005; AAMI 2012). Having studied the use of SDLCs in MD companies another issue that arises is that there does not seem to be a method for quantifying just how much process is enough (Cawley et al 2011). To ascertain where too much rigour is being applied and possibly reducing the amount of work required, Cawley et al (2011) recommend carrying out a process review. Companies attempting to improve their products also have to change their development processes to ensure high quality products (Hayes and Richardson 2008). Companies implementing process change can benefit from using a change management model but published models usually relate to organization change as opposed to process changes (Hayes and Richardson 2008).

Introducing change must be a formalised planned process. Even though it is sometimes considered that having a process can be an overhead, change management techniques have shown that when change is planned it is more likely to be successful (Forte 1997). Most planning models assume that changes in organisations are planned changes (Hayes and Richardson 2008). The models stipulate that, for successful change, certain sequential steps need be executed. Kotter's model is one such change management model. The steps described by Kotter (2005) are:

- Establish a Sense of Urgency
- Form a Powerful Guiding Coalition
- Create a Vision
- Communicate the Vision
- Empower Others to Act on the Vision
- Plan for and Create Short-Term Wins
- Consolidate Improvements and Produce Still More Change
- Institutionalise new approaches

Focusing on the implementation of process improvement in a medical device company, this paper investigates the hypothesis that "Eight Steps to Transforming your Organisation" (Kotter 2005) is a suitable framework for such a change.

The literature review revealed there is no model available to provide software development teams' guidance on end-to-end software development that conforms to regulatory requirements. Burton (2008) proposes an alternative process improvement model and he states that even though there are standards and guidelines it not possible to guarantee complete regulatory compliance and existing process improvement models are not broad enough.

2.2 The Company

MedIn (an alias) is a medical device company with branches located in Ireland and abroad. Within the particular plant we investigated, Research and Development is performed along with the manufacturing of commercial MDs. The MDs contain embedded software. When developing a product, MedIn always start with identifying the intended use, as this will establish the device class, which in turn identifies what regulations and standards must be complied with. Their risk analysis process can help determine the class of device.

Currently, each of these product development processes are documented and reviewed at every phase in a document-centric approach. The company decided to move to an artefact-centric approach for managing their product development processes. To facilitate this, MedIn have chosen a software product from a leading software provider. This software provider offers artefact-centric product development solutions.

For MedIn this software provider had the main advantage of:

- Provision for regulatory compliance such as electronic signatures and adherence to FDA standard 21 CFR part 11

In addition, artefact-centric approaches aid:

- Time-to-market
- The software can provide better visibility into the progress of product development, and reduce the work needed to maintain traceability and respond to change.

MedIn are applying software process improvement in a safety critical environment while minimizing risk and adhering to regulations. Figure 1 shows the applicable regulations for MedIn's core product. The primary or core regulations are:

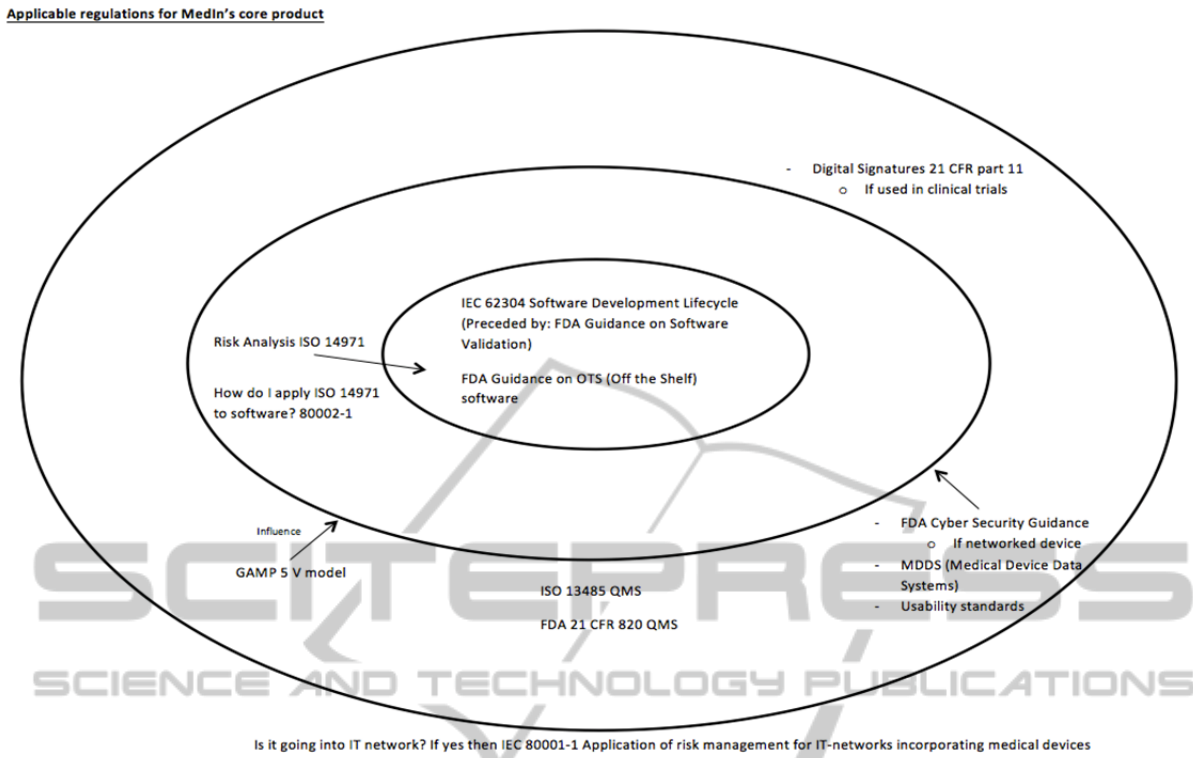

Figure 1: Regulations applicable to MedIn.

- IEC 62304 Software Development Lifecycle
- FDA guidance on Off The Shelf (OTS) software

Next the risk management regulation applicable is ISO 14971. The guidance document on how to apply ISO 14971 is found in 80002-1. Finally the following regulations influence the product, namely:

- GAMP 5 V model
- ISO 13485 Quality Management System (QMS) for use in Europe
- FDA 21 CFR 820 Quality Management System (QMS) for use in USA
- MDDS (Medical Device Data Systems)
- Usability standards
- If a networked device then
  - FDA Cyber Security Guidance
  - IEC 80001-1
- If device used in clinical trials then
  - Digital Signatures 21 CFR part 11

MedIn purchased an artefact-centric software package from a leading software provider. Training on the application of the software was given by the chosen software provider to key personnel identified within MedIn such as the quality team and the software development team. A small sample project was chosen to demonstrate and test the use of this new approach. When complete the plan is to test and use this new approach with a live project.

MedIn plan in the future to further improve their process by moving from the current SDLC process of a V-model to an agile software development process. To implement this they have identified that this might have to be achieved with smaller deliveries, which is in fact smaller V-model deliveries.

3 RESEARCH APPROACH

After completing a literature review of software development within healthcare, we were interested in understanding how process improvement within MD companies is carried out. Therefore our research question was as follows:

> How does a medical device company plan (manage change) and implement process improvements while also adhering to regulations governing its medical device products?

The approach taken was to commence a single case study within a MD company. One of the authors spent three months onsite and became

immersed in one project. This project was set up to support the company in moving from a document-centric approach to more integrated, artefact-centric approach for managing their product development processes. The company viewed this proposed process improvement as a change management issue. They were particularly concerned with how to manage this change effectively while also remaining compliant to the relevant regulations?

In addition to being a participant-observer on the project, the researcher held one-to-one interviews with software development team members. The 7 interviewees were all experienced in product development processes. They included software developers, a quality engineer and regulatory manager. The interviewees' work experience spanned 5 to 20 years.

As recommended by Miles and Huberman (1994) triangulation (applying a combination of research methods) was used to facilitate the validation of information and to remove bias. Artefacts were collected on site such as process and procedure documents, policy documents, presentations, organisational charts, relevant standards and email correspondence. This provided the authors with a rich collection of project data and statistics. Participant observations, interview data, and artefacts were analysed to understand the case study. We reviewed the data within the structure of Kotter's Change model, which allowed us to understand how change had been made within the organization, whilst still maintaining the regulatory requirements, which are so important from its sales' perspective. This facilitated the gaining of a holistic view of the working environment. We analysed the data focusing on Kotter's steps 1 to 6. Steps 7 and 8 are outside the scope of this paper.

4 RESEARCH FINDINGS

4.1 Software Process in MedIn

Regardless of any change to the documentation process, it was important that the SDLC continued to adhere to the relevant regulations. In MedIn, processes are described and documented. These, in turn, are mapped to a relevant standard. Standards have accompanying guidance documents to aid interpretation. Usually medical device software developers develop software with a plan driven sequential SDLC, such as the V-Model (McCaffery et al 2012).

Within MedIn software to be produced can be divided into one of three groups of software process:

- Development
- Maintenance
- Customization

For development in MedIn the V-model is used. For class A devices developed in MedIn the V-model used but Architecture Design, Unit test and Code reviews are optional. MedIn do Verification &Validation (V&V) but it is optional in the regulations.

From our case study analysis, key factors were identified which affect the SDLC process within MedIn, namely safety, regulations, standards and business focus.

To address these factors the following Quality Processes are employed in the company:

- Quality Management
- Risk Management
- Change Management
- Configuration Management
- Software Safety Classification
- Traceability

It is the responsibility of the CTO to manage SDLC processes – User Requirements, Verification and Validation Planning, Specification Design, Traceability, Pre-Production, Internal Validation, Customer Acceptance and Production. In addition, he has responsibility for the implementation of the Quality Processes listed above.

4.1.1 Development Process

The current software development approach within MedIn is the V-model. This is the standard V-model. In the future MedIn plan to use the agile model for software development. To incorporate the agile model for development with medical devices it is envisaged that there would be more frequent releases. The releases will have less functionality. MedIn plan to break the proposed release version into multiple deliverables each containing a sub-set of the overall functionality. The core principle here is that the sub-sets shall be fully documented and tested in their own right – so in theory could be released individually. In practice though, they will not release to customers until they have all functionality for the full release ready. Agile will not remove the need documentation, as this is necessary for regulation compliance. Overall MedIn want to become more iterative and get more feedback.

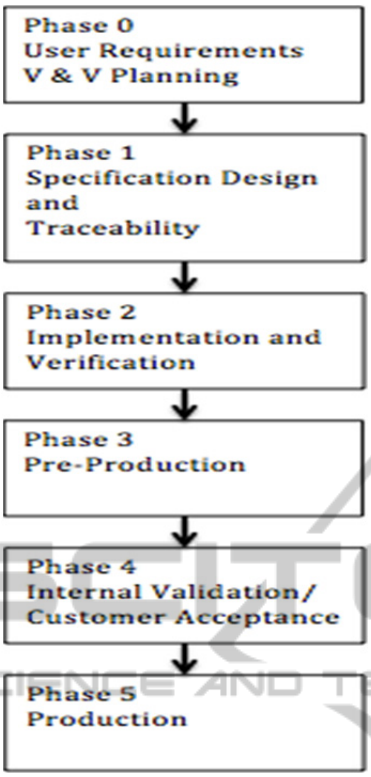

Figure 2: Customization Process within MedIn.

4.1.2 Maintenance Process

The Maintenance process can be either a non-conformance request or a modification implementation. If a modification implementation then it can take the form of a new feature or a change request.

4.1.3 Customization Process

The customization process in MedIn differs from the development process and is done in phases as shown in Figure 2. MedIn find that these phases work more efficiently for the specific needs of a customization task.

4.2 Analysis of Change

Further to understanding the software development process, we analysed the change, which the company was undergoing with relation to its documentation. We discuss our findings in terms of each of Kotter's (2005) steps.

4.2.1 Establish a Sense of Urgency

Having analysed the use of Kotter's model during a software process change project in a development company, Hayes and Richardson (2008) agree that, prior to any change, the need for such a change must be communicated to everyone in the organisation. They further state that management should be behind the change and that the development team must be motivated to realise the change. Lack of urgency is a common reason why many organisations fail when implementing a change (Hayes and Richardson 2008).

MedIn are a medical device company that uses processes to develop their medical devices while also adhering to the relevant regulations governing its medical device products. Prior to implementing the new system, MedIn used a document-centric approach for managing their product development processes. This process was a manual paper based approach where for regulatory compliance all documents had be reviewed and manually signed by the quality control department. The documents were then stored and easily accessible to a regulatory auditor for regulatory compliance. In MedIn as the current process was no longer useful it was taking up too much time for employees, adding unnecessary complexity to projects and clouding visibility on project status. Each document had to be individually signed after each review by the software quality team members. It was then stored in a suitable location so that it was readily accessible for regulators to inspect. This document-centric approach involved members of staff having to process and file each document. This had been recognised by management and employees and was the driving force behind the change that was being undertaken.

Further disadvantages were:

- Using documents to manage the product development process clouded visibility into project status
- Design transfers between teams were complicated by using documents
- Accountability was hindered
- Creating, managing, and reviewing documents were the most time-consuming tasks

Management and employees recognised that this situation could not continue. It was cumbersome and not cost-effective in a competitive market. In summary, the sense of urgency came from throughout the company.

Therefore, MedIn investigated moving away from a document-centric approach to another approach but they were restricted in that any new approach had to be regulatory compliant. One

method that offers regulatory compliance is an artefact-centric approach. An artefact-centric approach relies not on documents but on commercial software to create, track, and trace individual artefacts and work items. The advantages in moving to an artefact-centric approach that MedIn had identified were:

- Time-to-market
- The software can provide better visibility into the progress of product development, and reduce the work needed to maintain traceability and respond to change

4.2.2 Form a Powerful Guiding Coalition

Kotter (2005) recommends gradually involving different members of the organisation in the change to form a project team. In the case of MedIn it began with the Chief Technology Officer (CTO) of the company getting support from other senior management. The CTO reviewed and identifed a suitable software product to facilitate the planned change in process while still adhering to relevant regulatory constraints. Key staff members were also identified and chosen to be trained initially on how this new process could work. Time was allocated for the members to implement a pilot project with the new process. The guiding coalition was driven by the CTO. However, as other key staff members were involved, there was an involvement from staff throughout the company.

4.2.3 Create a Vision

For organisational change, Kotter also recommends that a clear vision and plan for implementing change is needed. To aid the management of regulatory compliance MedIn decided to use a software package to track product development artefacts, verification and validation artefacts, internal validated IT systems, and other activities.

Management within MedIn identified the need to develop an implementation plan which stated the objectives of the change. This was used as the basis to identify the vision of the project. From this, management were enabled to plan the training needs, staff and the scope of the pilot project.

4.2.4 Communicate the Vision

Communication of the vision should come from senior management. Once the implementation and training plans were identified, management had a vehicle by which they could carry out this communication effectively. They were able to discuss implementation with all employees who subsequently undertook the relevant training. Therefore, employees became aware of relevant tasks to be completed in the project and of their roles within the project. Kotter's (2005) Step 4 recommends communication of the vision should come from senior management. This was the case in MedIn, as the project was driven by the CTO.

4.2.5 Empower Others to Act on the Vision

Obstacles, such as organisational structure should be removed. At MedIn the project began with staff training followed by a pilot implementation before a planned rollout the new artefact-centric approach to all projects. The importance of the vision was evident to the team members as the actions that were put in place such as the pilot project demonstrated that, from a Senior Management point of view, this was an important project which needed to be worked on by everyone. The team members were keenly aware that the existing process was very time consuming and burdensome and that the proposed vision was a more time efficient process.

4.2.6 Plan for and Create Short-term Wins

Change should have clear goals and objectives and take place in small steps. Within MedIn, this was done by allocating relevant team members to carry out a pilot project. The pilot project which Kotter does not mention actually worked well for MedIn. It allowed the team members to become acquainted and familiar with how the new process should work.

4.2.7 Kotter's Steps 7 and 8

Kotter's (2005) Step 7 Consolidate Improvements and Produce More Change recommends that management or change advocates should be become more involved in the process thus ensuring continuation of changes. Kotter's (2005) step 8 Institutionalise New Approaches recommends that for success change has to be implemented so that it is now part of the organisation's culture.

Currently these last two steps are out of the scope of this case study as the process change is not yet complete. A further visit is planned to MedIn to observe how the process is working after implementation of the change.

5 DISCUSSION

For this case study Kotter's change model was

appropriate. The sense of urgency Kotter stipulates was inherent in the MedIn project. The team was aware that change was needed. A flaw in Kotter's approach is that there is no recommendation for a pilot project; this actually worked well for MedIn as it helped to eliminate stress and anxiety. There were specific aspects of the model that were overlooked and there were elements that were necessary. For instance Kotter's (2005) step 5 Empower Others to Act on the Vision was nessessary for team members to have awareness of the importance of the vision. The team members were given the time to carry out a pilot project using the new artefact-centric approach.

At the end of the 3-month case study the change implemented thus far was working well and to an organized plan going forward. A further case study is planned to see if this move to this new approach is working as planned.

6 CONCLUSIONS

We studied the SDLC within a MD company. Cawley et al (2011) point out that many MD companies are pre-occupied with complying with regulations and that MD companies are looking at how to manage process improvement while not affecting regulatory compliance (Cawley et al 2011, 2013). This was found to be true in our case study also. There does not seem to be a method for quantifying just how much process is enough. This is a significant challenge facing medical device companies. They further recommend auditing existing processes to review where improvements could be made to maybe, for example, save time. They also note that the challenge for researchers is to develop architectures and methodologies that facilitate advancements while being flexible to how the regulators might respond.

The research presented in this paper documents a single case study in MedIn. We have demonstrated that process improvement when managed through the use of a model will support the implantation of change in an organisation. While Kotter's change model (2005) was a good basis, there were specific aspects of the model that were overlooked and there were elements that were necessary. Therefore a more tailored and specific framework is required. Due to regulation restrictions and business concerns such as time to market, MD companies have to implement change in an organised and planned fashion.

7 FUTURE WORK

A futher case study is planned in the future within MedIn, allowing us to study how process improvement change has been managed in the longer term. We recognise that doing a single case study presents changes which are specific to one company, but analysing these changes allows us to recognise the difficulties faced by and strategies used by MD companies when implementing change. We have a starting point upon which to build our research and to investigate change management within the MD industry.

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