The Need for a Software Process Improvement Model for the Medical Device Industry

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Abstract – Software is becoming an increasingly important aspect of medical devices and medical device regulation. Software enables highly complex systems to be built. However, complexity is the enemy of safety, therefore strict adherence to well documented processes is important within the domain of medical device software. Medical devices can only be marketed if compliance and approval from the appropriate regulatory bodies (e.g. the Food and Drug Administration (FDA)) is achieved. This paper outlines the development of a software process improvement (SPI) model specifically for the medical device industry. The paper details how medical device regulations may be satisfied by adopting relevant practices from the Capability Maturity Model Integration (CMMI®). Copyright © 2006 Praise Worthy Prize - All rights reserved.

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I. Introduction

Medical device companies base their software development processes on the need to comply with the FDA [1,2,3,4]. Due to the safety-critical nature of medical device software it is important that highly efficient software practices are in place within medical device companies. In fact, integrated into the design process of medical devices, is the requirement of the production and maintenance of a device technical file, incorporating a design history file. Design history illustrates the well documented, defined and controlled processes and outputs, undertaken in the development of medical devices and for our particular consideration with this framework - the software components.

The software framework introduced in this paper will address an opportunity to integrate regulatory issues and process improvement mechanisms in order to achieve greater customer satisfaction, faster time to market and improved software quality.

II. The medical device industry

The risk of patient injury from software defects is a concern due to the manufacture and deployment of increasing numbers of software-embedded medical devices [5],[6],[7]. There have been a number of major medical device product recalls over this past 25 years that were the result of software defects [8]. Change control within medical device software is important as such modifications can occur frequently and may occur at different levels (e.g. design, interface or code), therefore increasing the risk of software failure [8]. It is therefore important that a medical device company has efficient software development processes in place that include change control practices.

According to the Institute of Medicine report ‘To Err is Human’ [9], between 44000 to 98000 people die in hospital from preventative medical errors. The report also says that more people die every year as a result of medical errors than from motor vehicle accidents, breast cancer or AIDS.

Like most industries, the healthcare industry depends on computer technology to perform many of the functions ranging from financial management to patient treatment [10]. The use of software in medical devices has become widespread in the last two decades. Medical devices with software include those that are supplied and used entirely in hospitals and other health facilities, as well as consumer items such as blood pressure monitors. Many medical devices, and their software, operate in real time – monitoring, diagnosing, or controlling a physiological process as it changes.

The complexity and risk profile of medical devices varies widely and range from a consumer digital thermometer for minor diagnosis, and an implanted artificial heart that is critical to preserving a patient’s life, to a therapeutic X-ray machine with a computer user interface, programmable software controlled therapy and anatomical and biophysical modelling in the software, which is operated under a high level of professional staff supervision [11].

Analysis of medical device recalls highlights the diverse nature of medical device software failures. The

¹ CMMI is registered in the U.S. Patent and Trademark Office by Carnegie Mellon University
FDA found that approximately 44% of the quality problems that led to voluntary recalls of medical devices were attributed to errors or deficiencies designed into particular medical devices rather than having been inserted during the manufacturing phase. The study also recognised software quality management practices as a means to prevent failure[12].

In the medical device industry, the software used to control a device takes on an additional role - it must help ensure the safety of the user. There are many challenges to implementing safe software. Software design needs to include deliberate engineering practices and rigorous risk analysis and mitigation needs to be performed whilst at the same time simultaneously addressing potential device failures that may be introduced by the software itself[13].

III. Background and Contribution

The main area of concern for medical device companies in relation to their software development practices is to ensure that the elements required by the Food and Drug Administration (FDA) are in place rather than trying to improve their overall software development practices. GAMP [14] details practices that medical device companies may adopt in order to comply with medical device regulations; however no standards exist within the medical device domain in relation to how such practices could be improved by incorporating practices from formal software engineering SPI models. Previous research has investigated the suitability of using existing software quality assurance standards in order to achieve FDA compliance related to the areas of process management, requirements specification, design control and change control [8]. However, no specific software process improvement model has been developed for the industry.

However, if we investigate other regulated industries such as the automotive and space industries we realise that these domains are not content with satisfying regulatory standards, but have proactively developed SPI models specifically for their domain so that they may continuously improve the development of their information systems to achieve higher levels of safety, greater efficiency, and a faster time to market, whilst seamlessly satisfying regulatory quality requirements. The major SPI models that currently exist, namely ISO/IEC15504 [15] and CMMI® [16], do not address the regulatory requirements of either the medical device, automotive or space industries. Therefore, a new SPI model was developed specifically for the automotive industry; this model was based upon ISO/IEC15504 and is referred to as Automotive Spice [17]. Likewise, a new ISO/IEC15504 based SPI model was developed specifically for the space industry, this model is known as SPIcE for SPACE [18]. Both of these models contain reference and assessment information in relation to how companies may improve their practices within their domain.

IV. SPI Framework Development

Lero (The Irish Software Engineering Research Centre) is currently researching how software processes may be improved within the embedded software industry. As part of this research Lero is aiming to develop a software development framework for the medical device sector that addresses existing regulatory requirements for the control of the design, development, maintenance and support of software. The approach for delivering the software development framework is to establish a model (implemented as illustrated in figure 1) that addresses the relevant regulations, and integrates those constraints within an SPI framework (i.e. Medical Device Software Process Improvement-MeDeSPI).

![Software framework approach](image)

The model will be flexible in that relevant elements of the SPI framework may be adopted as required to provide the most significant benefit to the business. The intention is develop two frameworks, one that is based on ISO:15504 and the other on the CMMI®.

For the purpose of this paper, the SPI framework used will be that of the CMMI® and the regulations used to extend the CMMI® framework will be those of the FDA and the ANSI/AAMI SW68:2001 standard.
which processes should be improved in order to assess results enables companies to prioritise against a target capability profile. Analysis of the capability of selected processes in an organisation and support of software with the following purposes:

- organisations involved in the development, maintenance and support of software with the following purposes:

1. Assess the need for and commitment to the creation of SDMMD and MeDeSPI;
2. Identify which parts of the CMMI® are required to comply with FDA regulation and extend the CMMI® with new goals and practices that are necessary to achieve FDA compliance (i.e. creation of MeDeSPI);
3. Develop process models for meeting the goals of MeDeSPI (i.e. create SDMMD);
4. Test SDMMD with Irish medical device companies.

We have completed stage 1 of this work and are currently performing stage 2 activities. In fact stage 2 has been performed for the risk management [20], requirements management [21], and configuration management process areas [22].

V. Process Assessment

The MeDeSPI framework was initiated by work that one of the authors performed whilst performing research for the Centre for Software Process Technologies at the University of Ulster. This author is now progressing this work with Lero. The initial research work was assisted by the involvement of a steering group with a pilot of 5 medical device companies and a notified standards body (all based in N.Ireland). However, this research has now been extending to include companies throughout Ireland.

The Software Development Method for Medical Devices (SDMMD) will be a defined set of software process models (in effect a methodology) which when utilised will meet the goals of MeDeSPI. SDMMD will cover the complete lifecycle. The project is divided into several stages.

- Understanding the state of a company’s own processes for process improvement;
- Determining the capability of a company’s own processes for a particular contract;
- Determining the capability of another organisation’s processes for a particular contract.

Process assessment is an integral part of software process improvement and provides a way to measure the capability of selected processes in an organisation against a target capability profile. Analysis of the assessment results enables companies to prioritise which processes should be improved in order to increase their effectiveness in achieving their business goals. The assessment results will also indicate the risks involved in undergoing a project using the assessed processes. This enables determination of how effective they are in achieving their goals, and to identify significant causes of poor quality, or overruns in time or cost. These provide the criteria to prioritise process improvements.

The process assessment (MeDeSPI) model is composed of two main components:

- Process areas;
- Capability scale.

Section V.1 lists the process areas that are deemed applicable to the medical device industry. Section V.2 details the capability scale against which each process is measured. The capability scale is based upon CMMI® capability scales. Section V.3 outlines the activities performed in an assessment.

V.1. MeDeSPI Process Areas

SDMMD will provide a software development methodology, which addresses the regulatory guidance criteria, while introducing best practices that can be selected as required. MeDeSPI will provide a means of assessing software engineering capability in eleven areas that have been defined by the FDA [1, 2, 3, 4] as:

1. Level of Concern;
2. Software Description;
3. Device Hazard and Risk Analysis;
4. Software Requirements Specification;
5. Architecture Design;
6. Design Specifications;
7. Requirements Traceability Analysis;
8. Development;
9. Validation;
10. Verification and Testing;
11. Revision Level History.

MeDeSPI is being developed to promote SPI practices into the software development processes of medical device companies. This is an attempt to improve the effectiveness and efficiency of software processes used by medical device companies through investigating the mapping between twelve CMMI® process areas and the eleven FDA areas listed above. The twelve CMMI® process areas that we have deemed appropriate for the medical device industry are as follows:

1. Project Planning;
2. Project Monitoring & Control;
3. Supplier Agreement Management;
4. Risk Management;
5. Requirements Management;
The mappings between the FDA regulatory guidelines and the CMMI® process areas listed above then produce twelve MeDeSPI process areas which retain the CMMI® process area names listed above. Each of the MeDeSPI process areas will then be composed of a number of goals and practices. Goals and practices may be either generic (relating to the entire organisation) or specific (relating to the current process area). MeDeSPI investigates what parts of the CMMI® process areas are required to satisfy FDA regulations, but also investigates the possibility of extending the CMMI® process areas with additional goals and practices that are outside the remit of CMMI®, but are required in order to satisfy FDA regulations (see figure 2).

A-CMMI Practices, not mandatory for FDA.
B-CMMI Practices that are required for FDA.
C-Non-CMMI Practices, mandatory for FDA.

Figure 2. Composition of the MeDeSPI framework.

V.2. MeDeSPI capability levels

The model will help companies to measure their organisational capability and to track progression and achievements in each of the twelve process areas and against process capability levels. The MeDeSPI framework has adopted the following capability levels:

- **Level 0** – A particular process is not performed.
- **Level Med** – Companies must demonstrate that a process area satisfies the goals and performs the practices required to achieve FDA regulatory compliance. This will involve performing some practices which the CMMI® views as generic, although not to the extent of fulfilling any generic goals.

- **Level 1** - Companies must demonstrate that a process area satisfies level Med and the CMMI® capability level 1 goal of performing the CMMI® base practices.
- **Level 2** – Companies must demonstrate that a process area satisfies level 1 and additionally performs CMMI® Advanced Practices, as well as the CMMI® capability level 2 generic goal of Institutionalising a Managed Process.
- **Level 3** - Companies must demonstrate that a process area satisfies level 2 and additionally the CMMI® Generic Goal to Institutionalise a Defined Process (CMMI® Generic Goal 3).
- **Level 4** – Companies must demonstrate that a process area satisfies level 3 and additionally the CMMI® Generic Goal to Institutionalise a Quantitatively Managed Process (CMMI® Generic Goal 4).
- **Level 5** - Companies must demonstrate that a process area satisfies level 4 and additionally the CMMI® Generic Goal to Institutionalise an Optimising Process (CMMI® Generic Goal 5).

V.3. Assessment method activities

To perform a MeDeSPI assessment the following activities will have to be performed:

- Request for process assessment;
- Planning the assessment schedule;
- Briefing the company in relation to the assessment;
- Performing the assessment and collecting information;
- Analysing and validating the information collected;
- Providing a rating for the process area;
- Reporting and inputs to the risk management process.

Each process area included in the assessment will be appraised on the basis of available evidence. The evidence may be gathered using interview, inspecting organisational documents or analysing metrics. The information collected for each process area will be compared against assessment objectives and scope for that process area. Information that supports a particular process rating will be recorded and maintained as
VI. Continuous SPI

SPI is a continuous process that an organisation follows in a cyclic improvement path of performing an assessment, implementing the recommendations from the assessment to achieve improvement, and then starting the cycle again by reassessing to check for improvement. Improvement will be achieved by following this path and adopting specific improvement measures such as the introduction of new or changed practices into established processes and removing inefficient practices. An important step within the SPI cycle is the gathering of information. This information is required to establish the current state and subsequently to confirm the improvements by comparing the initial process assessment results with the re-assessment results gathered after the implementation of the improvements.

VII. Conclusion

Of particular importance to medical device companies is the need to develop medical devices in full compliance with the appropriate regulatory bodies that govern the sale and marketing of medical devices throughout the world. The key business goals of cost effective development and speed to market, are fundamental factors for all companies, but for small new-start companies this is critical. Our studies and assessment of the Irish medical device industry illustrates that the MeDeSPI model has the potential to provide a huge benefit to participating companies as business goals and regulatory compliance may both be achieved [24].

The MeDeSPI model is still undergoing development. We are currently progressing stage 2 of the project. Our approach is to examine all of the appropriate process areas within the CMMI® and ISO/IEC 15504 models that are referred to in the FDA regulations, and investigate the extent to which these frameworks need to be extended to create MeDeSPI. Our vision is to provide a framework that will encourage medical device companies to distance themselves from the concept of developing the software first and then completing the necessary documentation that is required to achieve FDA compliance, to instead pursuing a continuous SPI path that will produce more efficient software development and safer medical devices.

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