

Med-Trace

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Abstract.

Traceability is central to medical device software development and essential for regulatory approval. To achieve compliance an effective traceability process needs to be in place. This is difficult to achieve due to the lack of specific guidance which the medical device regulations and standards provides. This has resulted in many medical device companies employing inefficient software traceability processes. In this paper we briefly outline the development and implementation of Med-Trace a lightweight software traceability process assessment and improvement method for the medical device industry.

Keywords: Medical Device Software Traceability, Software Process Improvement, SPI, Lightweight Assessment Method, SPICE, CMMI®.

1. Introduction

The important role that software plays in medical devices continues to increase. This has taken place in conjunction with the demand for increased medical device functionality. As a result of both of these factors the complexity of medical device software and its development has also increased [1]. This has necessitated the requirement for effective traceability and risk management processes and tools to be put in place to facilitate the development of medical device software.

Medical device companies must ensure that they comply with medical device regulations as governed by the region in which they wish to market their device. If a device is to be marketed in Europe the medical device should be developed using processes that comply with the European Council's Medical Device Directive (MDD) (1993/42/EEC) [2] and amendment MDD (2007/47/EC) [3]. When a medical device is to be marketed in the United States (US) the medical device should be developed using processes that comply with the Food and Drug Administration (FDA)

guidelines. In both locations the medical device companies must be able to produce sufficient evidence to support their product's compliance.

In addition to achieve compliance national regulatory requirements also recommend conformance to a number of international standards which include: IEC 62304:2006 [4], ISO 14971:2007 [5], ISO 13485:2003 [6] and IEC 62366:2007 [7]. Given the need to address the requirements of national regulations and international standards software medical device companies are focused on compliance. While this is essential to market their products it has resulted in a lack of emphasis on process improvement and the achievements of its associated benefits [8].

2 Software Traceability

Software traceability refers to the ability to describe and follow the life of a requirement in both a forward and backward direction. This includes from its origins, specification, development, subsequent deployment and use and through periods of on-going refinement and iteration in any of these phases. The deployment of an effective traceability process is essential to facilitate the development of high quality software systems [9]. Therefore software traceability is key and central to medical device software development and essential for regulatory compliance.

In order to comply with the regulatory requirements of the medical device industry it is necessary to have clear linkages and traceability from requirements - including risks and hazards - through the different stages of the software development and maintenance lifecycles. The regulatory bodies request that medical device software development organizations clearly demonstrate how they follow a software development lifecycle without mandating a particular lifecycle. This is further compounded by the requirement to adhere to numerous standards without guidance on how they should be implemented. Given the lack of guidance and importance that traceability plays in medical device software development it was recognized that this was an important area which needed to be addressed. The authors decided to tackle this important issue by developing a lightweight assessment method called Med-Trace, specifically to assist companies to adhere to the traceability aspects of the medical device software standards and regulations and also to improve their process.

3 Med-Trace and Observations from Two Assessments

Based on the results from an extensive literature review, the relevant areas of the CMMI® [10], ISO/IEC 15504-5:2006 [11] and previous experience of developing lightweight process assessment methods Med-Trace has been developed. Med-Trace is a lightweight assessment method that provides a means of assessing the capability of an organization in relation to medical device software traceability. It

enables software development organizations to gain an understanding of the fundamental traceability best practices based on the software engineering traceability literature, software process models, and the relevant medical device regulations and standards. Med-Trace may be used to diagnose an organization's strengths and weaknesses in relation to their medical device software development traceability practices. The goal of a Med-Trace assessment is not certification, but to assist medical device organizations to improve their software development traceability process.

The Med-Trace assessment method contains eight specific stages. The assessment team normally consists of two assessors who share responsibility for conducting the assessment. Stage 1, a preliminary meeting between the assessment team and the company wishing to undergo a Med-Trace assessment takes place. During stage 2, the lead assessor provides an overview of the Med-Trace assessment to members of the organization. At stage 3 a review is undertaken of project documentation. Staff from the organization with responsibility for traceability are interviewed at stage 4. At stage 5 the assessors jointly develop the findings report. Stage 6 involves presenting the findings report. Stage 7 is the collaborative development of a pathway towards achieving highly effective and regulatory compliant traceability practices. Having participated in the development of this pathway the organization are responsible for its implementation. Stage 8 involves revisiting and reassessing the company approximately 3 months after the completion of stage 7 and reviewing progress against the recommended improvement path, a final report is also produced.

Two Med-Trace assessments have taken place. The first was in an Irish medical device organization, Medical Electronic (a pseudonym). Medical Electronic develop electronic based medical devices that are marketed in the US and Europe. The company recognized the importance traceability plays in medical device software development and they sought a lightweight assessment method to obtain guidance as to how they could improve their traceability process. The second assessment took place in North Medical UK (a pseudonym). The company develop electronic-based medical devices that require compliance with both the FDA and the MDD. North Medical UK also sought a resource-light assessment method to obtain guidance as to how they could improve their software development traceability process.

As a result of both assessments it was clear the organizations recognized the importance traceability plays in medical device software development. This was reflected in the fact that in each, a member of the management team was responsible for its implementation. The lack of detailed guidance on how to implement traceability was highlighted by the management of Medical Electronic and North Medical UK. While these organizations both employed a process for traceability, in each case these needed to be improved and formalized. The requirement for relevant training and the ability to record and leverage best practice

with regard to traceability emerged. The serious limitations of utilizing manual tools such as MS Office to manage traceability was also recognized and needed to be addressed by both organizations.

The findings from the assessments identified important areas where improvements were required and these were confirmed in consultation with the management and staff of both organizations. The adoption of the development pathway provided realistic goals and the collaborative process provided motivation for their achievement. Both organizations are implementing their respective development pathways and have agreed to be reassessed as part of stage 8 of the Med-Trace assessment method.

4 Conclusions

In this paper we have presented Med-Trace a resource light process assessment method for the medical device software industry that can pinpoint specific areas for improvement with regard to traceability. We will continue to refine Med-Trace based on the experience gained in undertaking future assessments, interaction with medical device software organizations and discussions with medical device regulatory bodies. It is envisaged that further research will be undertaken for the development of similar lightweight software process assessment methods in the future.

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