A Methodology for Software Process Improvement Roadmaps for Regulated Domains – Example with ISO 62366

Derek Flood, Fergal Mc Caffery, Valentine Casey, Gilbert Regan

Dundalk Institute of Technology,

{Derek.flood, fergal.mccaffery, val.casey, gilbert.regan} @dkit.ie

Abstract. Software process improvement initiatives offer many benefits in terms of productivity, cost savings and quality. As part of these initiatives organisations undergo an assessment and then embark on a software process improvement program to improve their existing processes to meet a desired target. These programs can be improved by the use of process improvement roadmaps that are tailored to the organisation and are usually non-transferrable. Within regulated domains, such as the medical device industry, adherence to international standards must be achieved before products can be placed on the market. This work proposes the use of software process improvement roadmaps to assist organisations achieve compliance with medical device standards. These proposed roadmaps will be generic in nature to meet the requirements of the standard, but will be subsequently tailored to meet the specific requirements of an individual organisation. In this paper we introduce the concept of the software process improvement roadmaps for the implementation of standards and detail a methodology for developing these roadmaps.

Keywords: Software Process Improvement, Software Process Improvement Roadmaps, Medical Device software, IEC 62366

1 Introduction

As long ago as the early to mid-nineties the benefits of software process assessment and improvement and its impact on product quality have been identified and documented in the literature [1,2,3,4]. Research in this area has continued [5] and is best summarised by Paulish and Ebert [6] as: "*with increasing process maturity – which is an investment in process improvement – there is a tangible business impact in terms of reduced cost of quality and less delays. With such data being available from different organisations it is fair to state that – if done well – process improvement has a strong business impact with sustainable ROI (Return On Investment)*". In these circumstances it is not surprising that many organisations undertake Software Process

Improvement (SPI) initiatives to improve their processes thereby increasing the quality of their product and the efficiency of its development.

In highly regulated domains, such as the medical device industry, organisations must demonstrate the quality and safety of their products before they can be placed on the market. Regulatory bodies, such as the Food and Drug Administration (FDA) in the United States (US), regulate these organisations by auditing their development processes. To assist medical device organisations ensure the quality of their products and achieve approval to market their devices, regulatory bodies provide regulations, guidance documents and standards which outline what is required to be compliant.

Adherence to these standards can be difficult for organisations entering the medical device domain due to the lack of specific guidance on their implementation. Regulations, standards and guidance documents outline what needs to be done in order to achieve compliance, but they do not specify how this is to be achieved. Instead the regulations, standards and guidance documents allow organisations to decide on the best method for implementation.

In this work we propose to address this issue through a series of software process improvement roadmaps. These will provide guidance to organisations for adopting specific medical device standards, such as IEC 62304:2006 [7], ISO 13485:2003 [8], ISO 14971:2007 [9], and IEC 62366:2008 [10]. The proposed roadmaps do not assume that any existing processes are in place, allowing for a complete implementation of the standard for organisations with no existing processes.

For organisations that have already some processes in the place, the roadmap can assist them in implementing the remaining requirements of the standard. Through an initial assessment it will be possible to determine what aspects of the standard are already in place and then provide a detailed roadmap on those aspects of the standard that need to be implemented and how these should be applied within the organisation.

The remainder of this paper is structured as follows: Section 2 outlines the role of software within the medical device industry and the importance of standards within this domain. Section 3 then introduces the software process improvement roadmap structure while Section 4 details the methodology used for developing such a roadmap. Section 5 illustrates the methodology through the development of a roadmap for IEC 62366 compliance before the paper is concluded in Section 6.

2 Related Work

2.1 Software Process Improvement Initiatives

There are many reasons why organisations may choose to undertake SPI initiatives. Studies have shown that SPI can offer a high return on investment in the form of productivity gains, reduced time to market and fewer defects reported by customers [1, 2, 3, 4, 5, 6, 11].

In addition to the benefits outlined above, there are many examples of specific successes achieved by organisations undertaking SPI initiatives. Through peer reviews of software requirements to detect defects prior to coding, one organisation was able to reduce the time spent on rework during the coding phase. In another organisation,

improved configuration management practices allowed staff to replicate many errors encountered in the field, reducing the time and expense required to resolve problems [11].

The Software Engineering Institute has set out a roadmap for the undertaking of a software process improvement initiative [12]. This report identifies three main phases in which the software process improvement initiative should progress through. The first phase is to initiate the process improvement initiative which involves learning about SPI, committing initial resources and building a process infrastructure.

The next phase is to baseline the current state of the organisations software processes. This is achieved through the undertaking of a software process improvement assessment, such as ISO/IEC 15504-5:2012 [13] (SPICE) or Capability Maturity Model® Integration (CMMI®) [14]. During an assessment the organisations current processes are assessed and measured, and any weakness or shortcomings are identified. Both ISO/IEC 15504-5 and CMMI® contain capability levels which can allow an organisation to quantify the current state of their processes. These levels also facilitate the setting of targets which the organisation can reach through its process improvement initiative.

The final phase of the software process improvement initiative is to implement or deploy the software process improvements. This stage involves the identification of suitable methods for improving the software processes by addressing the weakness and shortcomings identified during the assessment and then implementing them within the organisation.

Software process improvement is not an overnight activity. It takes long-term commitment from all employees of the organisation, especially senior management, who must provide adequate resources for the implementation of the software process improvement [15]. In describing a usability maturity model developed by Nielsen, the Healthcare Information and Management Systems Society (HIMSS) usability task force noted that it can take decades to reach full maturity [16].

2.2 Software Process Improvement Within the Medical Device Domain

As regulatory bodies only outline the regulatory requirements which must be complied with and not how they can be effectively achieved, medical device organisations have been compliance centric in their approach to software development. As a result, there has been very limited adoption of software process improvement within the medical device domain [17].

In addition existing generic SPI models, such as the CMMI® [14] and ISO 15504-5:2012 [13] (SPICE), do not provide sufficient coverage to achieve medical device regulatory compliance [18]. To address this issue a medical device specific SPI framework, titled Medi SPICE, is being developed [29].

The objective of undertaking a Medi SPICE assessment is to determine the state of a medical device organisation's software processes and practices, in relation to industry regulatory requirements and best practice with the goal of identifying areas for undertaking process improvement [18]. It can also be used as part of the supplier

selection process when an organisation wishes to outsource or offshore part or all of their medical device software development to a third party or remote division [19].

Medi SPICE is based on ISO/IEC 15504-5:2012 [13], IEC 62304:2006 [7] and ISO/IEC 12207:2008 [20]. It is being developed in line with the requirements of ISO/IEC 15504-2:2003 [21] and contains a Process Reference Model (PRM) and Process Assessment Model (PAM). It also incorporates the requirements of the relevant medical device regulations, standards, technical reports and guidance documents.

The Medi SPICE PRM consists of 44 processes and 15 subprocesses which are fundamental to the development of regulatory compliant medical device software. Each process has a clearly defined purpose and outcomes that must be accomplished to achieve that purpose.

Medi SPICE also contains a PAM which is related to the PRM and forms the basis for collecting evidence that may be used to provide a rating of process capability. This is achieved by the provision of a two-dimensional view of process capability. In one dimension, it describes a set of process specific practices that allow the achievement of the process outcomes and purpose, defined in the PRM; this is termed the process dimension. In the second dimension, the PAM describes capabilities that relate to the process capability levels and process attributes. This is termed the capability dimension [22].

2.3 Medical Device Regulations, Standards and Guidance Documents

In order to market a medical device within the European Union (EU), the medical device organisation must demonstrate that they are compliant with the regulations set forth by the EU to receive the CE Mark. Similarly, to market medical devices within the US the organisation must demonstrate compliance with the FDA regulations [23]. In order to help organisations achieve compliance with these regulations the EU and FDA have published guidance documents and also recommend compliance with harmonised or approved consensus standards. Medical device organisations may not follow these guidelines and standards and still achieve approval to market their device; however they must provide strong justification for not doing so.

One of the most fundamental requirements of a medical device organisation to achieve regulatory compliance is the implementation of a Quality Management System (QMS). A QMS ensures that the processes used during the development and production of a medical device are defined and monitored to ensure high quality products are developed. The requirements of a quality management system for medical devices have been outlined in ISO 13485:2003 [8]. This standard is harmonised in the EU with the Medical Device Directive (MDD) [24] and has recently been accepted by the FDA as adequate fulfilment of the requirements of a QMS.

As part of the QMS, organisations must perform risk management activities. To improve the quality of the medical devices and receive regulatory approval, the organisation should identify all possible risk and take appropriate action to help mitigate them. ISO 14971:2007 [9] describes the requirements of a risk management process for medical device development. This standard identifies 6 key stages; Risk Analysis, Risk Evaluation, Risk Control, Evaluation of overall residual risk acceptability, Risk Management Report, and Production and Post-Production information.

IEC 62304:2006 – Medical device software – Software life cycle processes [7], provides specific guidance on the processes to be performed for the development of medical device software. This is an EU harmonised standard and is recognised by the FDA as an approved consensus standard. It is therefore used to develop medical device software for both the European and US markets as well as many other countries.

In 2007 the European Council amended the MDD [24], which governs the approval and marketing of medical devices in the European Union (EU). This amendment came into effect in March of 2010. As part of this amendment the EU recognized the importance of software and revised the directive to include the provision that software can now, in its own right, be classified as a medical device. As a result software can now be subjected to the same regulations and standards as other medical devices [25].

This means that some organisations that develop medical related software may now be developing medical devices and as such must adapt their processes to meet the requirements of the medical device standards outlined above.

3 SPI Roadmaps Towards Standards Compliance

3.1 Roadmap Structure

To assist medical device software development organisations achieve compliance with the required standards, we propose the development of a set of software process improvement roadmaps. For the purposes of this work we define a roadmap as: *A series of milestones, comprised of goals, that will guide an organisation, through the use of specific activities, towards compliance with regulatory standards.*

The roadmap is divided into two levels. The first level defines the goals, grouped into milestones that the organisation should achieve throughout the SPI initiative. The first level of the roadmap is presented at a high level and does not contain any detail relating to how the goals should be achieved. This is done for two reasons. Firstly, by presenting the roadmap as a series of goals traceability to the relevant standard can be easily achieved. Secondly, the high-level roadmap can form a basis for communication across the industry as the same high-level roadmap can be applied to all organisations.

The second level roadmap contains specific guidance for organisations on how to achieve the goals outlined in the high level roadmap. The activities preformed, to meet the goals of the high level roadmap, can vary from organisation to organisation due to their nature, different abilities and resources. Each roadmap is comprised of multiple activities that can achieve each goal so that the most suitable activity can be presented to an organisation wanting to implement the roadmap.

3.2 Roadmap Implementation

The first stage in using the proposed roadmaps is to assess the organisations existing processes and to determine which goals they already meet. This can be done in a number of ways, including the use of existing process assessment models, such as Medi SPICE or assessment models developed from the standards through the transformation method presented in [26].

The next stage is to identify which goals the organisation needs to achieve in order to meet the requirements of the relevant standard. Due to the traceability provided by the roadmap development methodology, it is easy for an organisation to see which aspects of the standard are not being met.

Once the goals to be implemented have been identified, the next step will be to identify the relevant activities that will satisfy these goals. The identification of the correct activities will be based not only on the goals to be achieved, but also on the organisation itself. Factors, such as the organisation's size, the class of medical device being developed, and the distribution of the software development team or teams, can all impact the way in which an organisation will implement the standard.

Once the appropriate activities have been identified for the organisation, they will begin to implement these activities. The roadmap defines specific milestones in a progressive order that will guide this implementation.

4 Roadmap Development Methodology

The following methodology is proposed to provide a systematic approach to roadmap construction. This systematic approach will allow for other researchers to construct roadmaps for other regulated domains, such as the automotive domain or the aerospace domain. The following approach is similar to the transformation method presented in [26] for the construction of ISO/IEC 15504 compliant process assessment and process reference models.

There are a range of research methods that can be used with the following methodology. These techniques are used to validate the roadmap and to assist in the identification of a wide range of activities. By incorporating a wide range of activities, the generated roadmaps can provide a more suitable guidance to implementing organisations.

The methodology used for the development of the roadmaps is as follows:

1. **Identify requirements of the standard:** The first step in the process of developing the roadmap is to identify all of the required activities of the standard. This step is similar to the first step in the transformation process presented in [26].
2. **Logically group all requirements.** The next step is to group the requirements. Requirements can be grouped based on the stage of the software development lifecycle at which they will occur. Some activities are performed throughout the lifecycle, independent of specific phases. In those cases these activities should be grouped together and placed at or before the first stage at which they are performed in the software development lifecycle.
3. **Separate grouped activities in line with ISO/IEC 15504 capability levels.** Once the requirements have been grouped, these groups should be separated based on the capability level at which the requirements should be performed. These groups form the milestones of the roadmap
4. **Order the milestones based on the capability level and logical groups.** All level 1 milestones should be implemented first in the order in which they

will occur in the development process, followed by all Level 2 activities, and subsequently by all Level 3 activities until all of the milestones are in order.

5. **Validate generated roadmap.** The generated roadmap should be validated with industry experts. These experts could be individuals working in industry implementing the standards, assessors regulating organisations using the standards or academics with the appropriate expertise. Members of the standards committee could also assist with the validation.

   There are a number of methods that could be used to validate the roadmap. One approach could be to interview the experts after presenting the roadmap to them and providing sufficient time for them to review the material. Another approach could be a workshop in which the roadmap is presented to the experts and then a panel discussion is used to identify and rectify issues that may be present. A Delphi study could also be used.

   A Delphi study involves multiple iterations and review by experts. In this case the experts are first asked to complete a questionnaire about the roadmap. Once the responses have been analysed, the roadmap is then revised and resubmitted to the experts for a subsequent review. This is repeated until a roadmap is agreed upon.

   The validation should aim to ensure that:

   - The goals are correctly grouped;
   - The milestones are in the correct order for implementation; and
   - The roadmap incorporates all aspects of the standard.

6. **Identify activities that can meet the identified goals**. The next step in the generation of the roadmap is to identify appropriate activities that can be used to fulfil the requirements of each goal in the roadmap. This can be done through a systematic literature review and/or case studies with organisations already implementing the standard.
7. **Validate activities in host organisation**. The final stage of the roadmap development methodology is to validate the roadmap within a host organisation. This will involve the generation of a roadmap for the host organisation and then undertaking a software process improvement initiative to implement the roadmap.

To date this work has developed high-level roadmaps for each of the standards; ISO 14971, ISO 13485 and IEC 62366. The following section will show how the above methodology has been applied during the development of a software process improvement roadmap for compliance with the IEC 62366 standard, which details the application of usability engineering to medical devices.

5 Roadmap to ISO 62366 Compliance

In four US hospitals more than 300 patients were over radiated by powerful CT scanners used to detect strokes and which had obtained FDA approval,. One hospital, which detected the errors after 18 months when patients started losing their hair, found that the overdose was displayed on-screen however the technicians administering the scans did not notice it [27].

Similarly during an analysis of infusion pumps recalled by the FDA between 2005 and 2009, user interface errors were identified as one of the most common cause of the recalls [28]. It was found that on some devices the screen failed to make clear the units of measurement (pounds vs. kilograms) when entering patient data for calculating the dosage, leading to incorrect dosages being applied.

One way to reduce the likelihood of these errors occurring is through the use of usability engineering techniques. This is addressed by the international standard *IEC 62366:2007 – Medical Devices – Application of usability engineering to Medical Devices* which should be utilised during the implementation of a usability engineering process. This standard specifies "*a process for a manufacturer to analyse, specify, design, verify and validate usability, as it relates to safety of a medical device*" [10]

The standard places a strong focus on the identification and elimination of risks associated with the use of the medical device. As part of the usability engineering process, the standard highlights the importance of the identification of Hazards and Hazardous situations, a critical component of the risk management process. The standard (in Section 5.7 Note 2) also recommends an iterative development cycle, specifying the need to perform usability validation throughout the design and development of the medical device.

As part of the usability engineering process, IEC 62366 specifies the need to perform usability verification, ensuring the user interface meets the requirements of the usability specification, and usability validation, ensuring that the primary operating functions can be accomplished through the user interface.

The standard not only requires usability to be incorporated into the medical device, it specifies that usability engineering should also be applied to the development of the user manual and other supporting documentation as well as to the training of users in the use of the medical device and all material necessary to support this training.

Due to the importance of usability within the medical device domain, and the risks associated with the misuse of medical devices, this work has developed a software process improvement roadmap for the implementation of the IEC 62366 standard. This roadmap has been developed and is currently being validated by industry experts.

The first stage of the methodology is to identify the requirements of the standard. When this was performed on the IEC 62366 standard, 44 requirements were identified. These requirements were used as the basis for defining the goals of the roadmap. The following are example requirements taken from the standard.

- *Identify the frequently used functions that involve user interaction*
- *Identify the characteristics that relate to safety and focus on usability*
- *Design and implement the User Interface as described in the usability specification*

When all of the goals were identified, they were then grouped. During this stage, the goals were arranged into 9 groups, which represented the main components of the standard: verification, validation, training, documentation, implementation, the usability process, risk management, task orientated activities, and usability specification. Each group contained between 2 and 7 goals.

Once this was complete, the goals in each group were reviewed and associated with a capability level as defined in ISO/IEC 15504-2. It was found that 37 of the goals would be achieved at level 1 of the ISO/IEC 15504 capability level rating, while the remaining goals (7 goals) would occur at level 2. Based on this the groups were redefined, resulting in the identification of 10 milestones.

The final stage of the high-level roadmap generation is the ordering of the milestones. This was done based on the initial groupings and the capability levels defined in the previous step. The milestones containing level 1 goals were arranged in the order they would be performed in a typical software development iteration. Subsequently all milestones containing level 2 goals were arranged in the same order following all level 1 milestones. The resulting roadmap for IEC 62366 is as follows:

Step Number	Milestone Title	# of Goals
1	Task	5
2	Usability Specification	5
3	Risk Management	7
4	Implementation	2
5	Documentation	6
6	Training	4
7	Verification	4
8	Validation	4
9	Validation Management	3
10	Process	4

The next step in this work will be to validate the above roadmap using industry experts. In order to do this a Delphi research method has been chosen. The Delphi research method allows for multiple reviews of the roadmap until the experts agree on a correct order of implementation for the roadmap. To perform the study experts will be asked to fill in an online questionnaire asking them questions relating to the order of the milestones, the appropriateness of each goal in each milestone and the completeness of the roadmap to meet all requirements of the standard.

6 Conclusions

Entering regulated domains, such as the medical device industry, is a difficult task due to the high level of regulations that must be adhered to. Regulations, standards and guidance documents outline what the organisation must do in order to achieve regulatory compliance; however these documents do not specify how the organisation

should achieve it. This places additional stress and can be seen as a barrier for organisations wishing to enter the medical device domain.

To address this issue, in the context of medical device software development, this paper presents a methodology for the development of software process improvement roadmaps for the implementation of medical device standards. The roadmaps presented are divided into two levels. The high-level roadmap outlines the main goals to be met to achieve regulatory compliance while the low level roadmap provides specific guidance on how to implement the processes necessary to meet these goals.

The presented methodology allows researchers to generate such roadmaps directly from standards and guidance documents released by regulatory bodies. Although the approach requires substantial effort the resulting roadmap will benefit a large number of organisations and provide a foundation on which to build a comprehensive knowledgebase on software processes for regulatory compliance.

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