A Roadmap to Implement a Quality Management System

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Abstract: In recent years the proportion and complexity of software in medical devices has increased considerably. This has presented an opportunity for software development organisations to expand into the medical device domain. Due to the high level of risk associated with medical devices, strict regulations must be adhered to in order to market such products. One key aspect of these regulations is the necessity to have in place a Quality Management System to help ensure an organisations' ability to consistently meet customer and regulatory requirements. This paper presents a roadmap which can be used to assist organisations, wishing to develop medical device software to implement a Quality Management System.

1 INTRODUCTION

Advancements in technology have allowed medical practitioners to provide a higher level of care to patients and offer a wider range of treatment options. However, when technology is used there is a risk to the patient if that device should fail. To offset these risks organisations must comply with the regulatory requirements of the country where the device is to be sold (Burton et al., 2006).

Software is becoming a more pivotal component of medical devices due to its flexibility and its ability to allow complex changes to be made, without the need for hardware changes (Lee et al., 2006), resulting in increased medical device software complexity (Rakitin, 2006). In addition software can now in its own right also be considered a medical device (Mc Hugh et al., 2011). Therefore software development organisations are subjected to the same regulatory requirements as other medical device organisations.

Software organisations now have an opportunity to expand into the medical domain. These organisations however must develop more stringent processes in order to meet regulatory compliance. A significant difficulty for such organisations is that there is no prescribed method for performing regulatory compliant software development activities (McCaffery et al., 2010). Regulatory bodies instead provide guidance documents outlining what activities should be performed (McCaffery et al., 2010).

To help address this shortfall this paper details a software development process roadmap which can be used to guide organisations through the implementation of a Quality Management System (QMS) which is compliant with the ISO 13485 (ISO, 2003) standard. The roadmap presented here has been developed using the specific practices defined in the Medi SPICE process assessment model, which is designed to assess an organisations ability to develop medical device software.

This paper is structured as follows. Section 2 introduces the Medi SPICE (McCaffery et al., 2010) framework. Section 3 Introduces ISO 13485 and details a roadmap for implementing a QMS, while Section 4 outlines how the roadmap will be validated. Section 5 details some of the limitations of the roadmap and how these will be addressed in the future. Conclusions are provided in Section 6.

2 MEDI SPICE

As regulatory bodies only detail what activities must be performed, medical device organizations 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 (Denger et al., 2007).

Existing generic Software Process Improvement (SPI) models, such as the Capability Maturity Model Integration (CMMI®) (CMMI Product Team, 2006)

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and ISO 15504-5:2012 (ISO/IEC 15504-5:2012, 2012) (SPICE), do not provide sufficient coverage to achieve medical device regulatory compliance (McCaffery and Dorling, 2010). To address this issue a medical device specific SPI framework, titled Medi SPICE, has been developed.

The objective of undertaking a Medi SPICE assessment is to determine the state of a medical device organisation's software processes and practices. This is in relation to the regulatory requirements of the industry and best practice with the goal of identifying areas for undertaking process improvement (McCaffery and Dorling, 2010). 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 (Casey, 2010).

Medi SPICE is based upon the latest version of ISO/IEC 15504-5:2012 and ISO/IEC 12207:2008 (ISO/IEC, 2008). It is being developed in line with the requirements of ISO/IEC 15504-2:2003 (ISO/IEC, 2003) 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.

3 QMS ROADMAP

The *ISO 13485 – Medical devices - Quality management systems – Requirements for regulatory purposes*, is an international standard defining the requirements for the implementation of a QMS to be used for the development of medical devices. The standard not only covers software but also incorporates hardware and related activities such as production and servicing.

The main focus of the QMS is to help insure that high quality processes are implemented and monitored. The standard places a strong emphasis on ensuring the organisation is committed to the quality of their products, through effective process management and a commitment to quality from all levels of the organisation from top management down.

To assist organisations to implement a QMS, a roadmap has been developed. The roadmap is divided into three phases. The first phase is project planning and should occur at the start of a medical device software development project.

The second phase is the system development phase. During this phase the product is built using the system development lifecycle.

The final phase is on-going and irregular activities. The phase contains a number of practices that should be performed during the development of the product however, they do not fall under individual stages of the software development lifecycle. As these do not follow a strict sequence they are not included as numbered steps.

Table 1 outlines the steps included within each phase of the roadmap. The planning phase contains 6 steps, the systems development phase contains 16 steps and the on-going and event driven phase contains 9 steps.

3.1 Project Planning Phase

The first section of the roadmap should be performed prior to the development of the medical device. During this phase the organisation will establish the product scope and the procedures to be used during the development of the medical device.

Step 1: Appoint a Quality Manager. The first step in implementing a QMS is to assign a member of the management team responsibility for overseeing and reporting on the QMS, and promoting the awareness of regulatory and customer requirements throughout the organisation.

Step 2: Define Quality Objectives and Policy. The quality objectives and policy outline the organisations commitment to quality and guide the processes used to ensure product quality. At this stage the organisation's quality manual incorporating the scope of the QMS, and details and justification for any exclusion and/or non-application, is established.

Table 1: Steps in the QMS roadmap.

Planning Phase	Systems Development Phase	On-going and Irregular Activities Phase
Appoint a quality manager	Gather customer requirements	Risk analysis
Define quality objectives	Assign resources	Document management
Establish product scope	Analyse system requirements	Software configuration management
Establish SDLC	Design the system architecture	Quality assurance
High level planning	Software development	Validation and verification
Low level planning	Software requirements analysis	Software review and audit
	Software architectural design	Problem resolution
	Detail the software design	Change request management
	Software construction	Acquisition
	Software integration	
	Software qualification testing	
	Software installation	
	System integration	
	System qualification testing	
	Delivery	
	Customer support	

Step 3: Establish the Product Scope. This step involves the definition of the customer requirements and an internal analysis of the organisations ability to meet these. In addition to this a communications interface should be established to ensure effective communication between the customer and the organisation.

Step 4: Establish the Software Development Lifecycle (SDLC) for the Project. During this step the organisation should define the software development lifecycle that should be used during the development of the product. This should include all processes necessary for the QMS and the sequence and interaction between these processes.

Step 5: High Level Planning. The next step is to define the high level processes necessary for the development of the product. For example, development of a document management strategy.

Step 6: Low-level Planning. While high-level processes define the overall strategy to be employed, the low-level processes are focused on particular areas or provide more detailed instructions to meet the overall strategy.

3.2 System Development Phase

After the planning phase has been completed, the organisation will begin to develop the medical device. These steps follow the order of the software development lifecycle and can be implemented in the presented order.

Step 7: Gather Customer Requirements. The first step of this phase is to determine the customer requirements for the project. As part of this stage, risk analysis should be performed and documented.

Step 8: Assign Resources. When the customer requirements have been defined and understood top management should ensure that adequate resources, in terms of personnel and infrastructure, are in place and documented.

Step 9: Analyse System Requirements. In this step, non-functional requirements, potential risks and performance expectations are identified. The process, and consistency with customer requirements, should be documented and maintained.

Step 10: Design the System Architecture. If external software components are to be used an appropriate acquisition strategy should be in place. The system architecture design should be consistent with the system requirements and the process used should be adequately documented.

Step 11: Software Development. The software implementation process to be used during the project should be documented and maintained. If any deviation from this process is encountered the relevant documentation should be updated.

Step 12: Software Requirements Analysis. The requirements of the software component of a medical device are analysed in the context of the complete system and its operating environment. Traceability and adequate testing should be ensured. Risk control measures should be implemented and any modifications to the system requirements should be documented.

Step 13: Software Architectural Design. As part of the QMS, it is necessary to ensure that the architectural design is consistent with the system and software requirements.

Step 14: Detail the Software Design. A detailed software design document should be produced. This shall be consistent with the system architecture. The

process used should be adequately documented.

Step 15: Software Construction. The software units defined in the software design document should be constructed. Detailed documentation, including traceability, should be maintained as required by the configuration management strategy.

Step 16: Software Integration. The software units should be integrated into the complete software system. The integrated system should be tested independently from the testing of individual components. The results from this testing, as well as the strategy for integration and testing should be documented and maintained.

Step 17: Software Qualification Testing. In this step the integrated software system is tested. User documentation should be updated as necessary. A fundamental component of this stage is to ensure that a regression test strategy is developed and carried out. All processes used and results obtained should be documented and maintained.

Step 18: Software Installation. Documented procedures, including verification and acceptance criteria, should be established as part of the QMS. This documentation should be made available to other agents who have been authorised by the customer to perform installation activities.

Step 19: System Integration. The next step is to integrate the software with the overall system. Each component of the system should be independently verified to ensure that they meet the system requirements. The results of such verification and the process used should be documented. Traceability should be ensured.

Step 20: System Qualification Testing. As part of the system qualification testing phase, a QMS should ensure that the system tests can be traced back to system requirements. The process used should be documented and maintained.

Step 21: Delivery. The QMS requires that the organisation should ensure that delivery conditions, in accordance with the supply agreement, are met.

Step 22: Customer Support. The QMS should ensure that the organisation monitors the operational use and ensure that adequate support is available to the customer. The organisation should also collect and retain customer satisfaction data relating to both the product and the customer service.

3.3 On-going and Irregular Activities Phase

During the development process a number of activities are performed at regular intervals or when specific events occur. The schedule for these activities should be defined during the planning phase; however, the execution of these activities can occur at any time.

Risk Analysis. At all stages of the product development, the organisation should ensure that adequate risk management activities are performed. The level of risk analysis is dependent upon the class of device that is being developed.

Document Management. Throughout the entire development process a consistent document management process should be in place. Each document should be checked before distribution, ensuring they are available where needed.

Software Configuration Management. During the lifetime of the project, configuration items should be maintained and accessible at the point of use. The QMS should ensure that each configuration item is uniquely identified and that a description of each item is maintained.

Quality Assurance. The QMS dictates that regular assessments should be performed in terms of both the processes used during the development of the product and the product itself. Through processes assessment activities the organisation should perform process improvement activities when possible.

The organisation should also periodically assess the achievement of the quality objectives and monitor the performance of the QMS. When a deviation from the quality objective is found, the organisation should strive to take action as quickly as possible to ensure that the quality of the product is not negatively affected.

Part of the assessment and improvement initiatives should be commitment from all relevant departments within the organisation. This will ensure assessment activities will not interfere with the main functions of the organisational units under assessment. The results of the assessment and any process improvement activities that will take place should be communicated to all stakeholders.

Validation and Verification. At regular intervals the organisation should perform validation and verification activities to ensure that the product is correct and meets project requirements and quality standards. The results of these activities should be recorded and any problems identified should be entered into a software problem resolution process. The results of such activities should be communicated to all relevant stakeholders.

Software Review and Audit. At regular intervals the organisation shall prepare and conduct a

software review and audit. If a product is found to be non-conforming then the organisation should take appropriate action either by removing the non-conformities or by authorising its release under concession. If the product is released under concession, the organisation should ensure that it still meets all regulatory requirements. The nature of the non-conformity and the identity of the person(s) authorising the concession should be documented.

Problem Resolution. The organisation should ensure that any problem identified is recorded and the root cause of the problem is diagnosed. The organisation should have procedures in place to alert users of the problem pending a fix or a change. A solution for the problem should then be found and implemented while tracking the status of the issue until it is resolved. If no action is taken as a result of a problem being identified, the organisation should justify and record why no action has been taken. The organisation shall maintain records of all customer complaints.

Change Request Management. A documented procedure should be in place to address change requests. This procedure should ensure that an audit trail is in place enabling traceability. Prior to the implementation the organisation should assess the impact of the change request on both the existing system and other change requests. Additionally the risks associated with the change request should be analysed.

Upon implementation of the change request, the organisation should perform all necessary verification and validation activities. All configuration items should be updated if impacted by the change.

Acquisition. In the event the organisation shall incorporate external software units in the product, the organisation should ensure that an appropriate acquisition process is followed. This process should encompass a process for supplier tendering and selection, acquisition of the product, acceptance criteria and testing and a means for managing changes and resolving issues with the supplier.

4 VALIDATION

Two aspects, order and completeness, of the roadmap presented above will be validated. Order refers to the placement of the practices in each step. It will be necessary to ensure that all practices that are depended upon are in place before an organisation tries to implement any new practices. The completeness of the roadmap refers to its ability to cover the requirements of the ISO 13485 standard.

The order of the implementation steps will be validated using the Medi SPICE dependency graphs (Flood et al., 2012). The practices in each step will be validated to ensure that all dependant practices of each step are performed in the same or preceding steps. If a practice is found to be performed in the same step of the roadmap the organisation will be alerted and instructed to perform this practice before any dependant ones.

In order to validate the completeness of the roadmap a number of qualified ISO 13485 assessors will be asked to review it. A semi-structured interview will then be conducted with the assessor.

5 LIMITATIONS AND FUTURE WORK

The roadmap presented here is based on ISO 13485. In the US the FDA produce a similar regulation, FDA Regulation 21 CFR 820 (FDA, 2007), for organisations wishing to distribute medical devices within the US. Although both documents provide similar guidance additional practices may be required for medical device organisations wishing to operate within the US. However, it should be noted that the FDA are currently implementing a pilot programme to accept a QMS that is compliant with ISO 13485.

The next step of this work will be to perform a similar analysis of the FDA Regulation 21 CFR 820. The relevant best practices will be identified and any additional requirements identified will be incorporated into the existing roadmap to produce a roadmap for organisations wishing to distribute medical devices in Europe and the US.

The roadmap presented above allows an organisation to create a QMS, assuming they have no existing processes in place. In the case of software development organisations wishing to enter the medical device domain, some existing processes may be in place and the roadmap will need to be tailored for these organisations.

In addition to this there are some steps that may not need to be performed, depending on the circumstances of the organisation or product.

To address these issues an assessment method that can be used to determine the organisations existing processes and their specific requirements will be developed.

6 CONCLUSIONS

This paper presents a software process roadmap for the implementation of a QMS for organisations operating within the medical device domain. In order for medical device products to be sold, they must be approved by the relevant regulatory body within the region the device is to be sold, such as the FDA in the US. The regulations set forth by these organisations require that a QMS is in place during the development and distribution of medical devices.

To assist organisations wishing to develop medical devices, this paper details a software process roadmap for implementing a QMS. This roadmap is based on the ISO 13485, an International standard detailing the requirements of a QMS for organisations in the medical device domain, and the base practices defined in the Medi-SPICE PAM.

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