Med-Adept: A Lightweight Assessment Method for the Irish Medical Device Software Industry

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Abstract

In this paper we describe how a lightweight assessment method was developed to educate Irish software development organisations in relation to becoming medical device software suppliers.

1. Introduction

Research has identified two important sectors for the growth of the Irish economy they are Medical Devices and Information and Communications Technology (ICT). The Medical Device (MD) and diagnostic industry is a cornerstone of the Irish economy. The sector has been identified, by both the Irish Industrial Development Authority and Enterprise Ireland, as a key growth area. Of the world's top 14 MD companies 11 have a base in Ireland; the indigenous base is also evolving rapidly; over 80% of the companies in this sector are involved in significant innovation.

At present the Irish MD industry is focused on manufacturing. The sector is particularly dependent on the continued use of stents in the treatment of cardiovascular disease. Therefore, either the discovery of an effective drug treatment for vascular plague or the general migration of the manufacture of medical devices to low labour cost locations could negatively affect the future growth of the Irish MD sector. The Expert Group of Future Skills Needs (an Irish Government advisory body) [1], has highlighted ICT forms a major part of the MD sector globally, however in Ireland, where a significant ICT sector exists, only a small part of the MD sector involves ICT. The report also highlighted that Ireland does not have a strong presence in the production of electronic based medical devices (which would include substantial software development).

There is therefore an opportunity to reduce the sectors dependence on stent manufacture by supporting the development of a software based MD industry in Ireland. This can be achieved through providing a range of services that will encourage existing indigenous MD companies to consider developing software and encourage multi-national MD companies to consider Ireland as a location for developing software. It will also provide opportunities for Irish software companies to develop software for the MD industry. However, to take up this opportunity they will need to demonstrate that their software development processes are both capable of producing high-quality software and achieving regulatory compliance. Thus, there is a need for a low resource software process assessment to determine the current state of their software development practices.

2. Software for the Medical Device Industry

Due to the safety-critical nature of medical devices, organisations developing MD software are expected to produce high-quality software through the use of defined processes. To tackle these issues, governments have put in place regulatory bodies to define regulatory systems for medical devices and to ensure that only safe medical devices are placed on the market. To aid the control of medical

devices, regulatory bodies have adopted a classification scheme. The device manufacturer is obliged to establish and perform both pre-market and post-market duties as defined in the quality system regulations. The quality system requirements for Europe are defined in the ANSI/AAMI/ISO 13485 standard [2] and the requirements for the U.S.A. are defined in the 21 CFR Part 820 Quality System Regulations [3]. Applicable requirements are typically directly related to the class of the device. The regulatory or approved body, through its audits, checks conformance to the quality system requirements periodically.

In an attempt to address the vagueness of the regulatory requirements, the FDA published separate regulatory guidance documents for required software activities [4,5,6]. In Europe, many organisations rely on the regulatory guidance documents from the FDA due to insufficient guidance provided for the equivalent CE marking process. Additionally, there has been a steady progression in the MD software sector with the release of new and updated standards in an attempt to address the knowledge gap that exists between the high-level regulatory requirements and the low level detail and knowledge required to adequately satisfy those requirements.

Whenever we mention MD guidelines within this paper we refer to the following medical device standards and guidelines: ANSI/AAMI/IEC 62304 [7], FDA [4,5,6,8], European Council Guidelines [9], ISO 14971 [10], EN 60601-1-4 [11], GAMP 5 [12], TIR 32 [13], AAMI/IEC 61508 [14], and IEC 60812 [15].

3. Software Process for Medical Device Software Development

With the development of formal SPI models such as CMMI® [16] and ISO/IEC 15504-5 [17] researchers within regulated environments such as the Space and Automotive industries started to investigate how they could utilise these models to improve the practices within their industry domains. However, they discovered that although the existing models are comprehensive, neither CMMI® nor ISO/IEC 15504-5 addressed all of the regulatory needs and constraints of their specific industries. Researchers therefore sought to adopt the practices within these models while also expanding on them to account for regulatory requirements within their own domains. This resulted in the production of full SPI models tailored specifically for the Space domain [18] and Automobile domain - Automotive SPICE [19].

The authors are in the process of developing Medi SPICE which will be a comprehensive software process assessment model for the medical device industry [20] which is based on the AMMI/IEC 62304 standard, associated MD standards and guidelines (listed at the end of section 2) and ISO/IEC 15504-5. Medi SPICE like ISO/IEC 15504-5 and Automotive SPICE will contain both a Process Reference Model (PRM) and Process Assessment Model (PAM) that provide comprehensive coverage of the FDA and European Council guidelines, and associated standards (e.g. ISO 14971, IEC 60601-1-4,TIR 32 and GAMP) for the complete software development lifecycle. The overall objective of Medi SPICE is to provide a conformity assessment scheme to support first, second or third party assessment results that may be recognised by the regulatory bodies. The Medi SPICE PRM and PAM is being released in phases and once complete, will consist of a defined set of software processes that will contain base practices which when utilised will assist medical device software development organisations to fulfil the regulatory guidelines and standards of the medical device industry.

4. The Med-Adept Method

One of the main goals of the Regulated Software Research Group in Dundalk Institute of Technology is to support the growth of a MD software development industry within Ireland. The authors previously developed the Adept method [21] which was based upon the ISO/IEC 15504-5 and CMMI® models. Consequently, we based the Med-Adept method upon relevant process areas from the CMMI® and ISO/IEC 15504-5 models and included input from AAMI/IEC 62304. This therefore enabled the existing Adept questions to be established as the foundation for the new method and for additional questions to be added to enable coverage of relevant AAMI/IEC 62304 process areas. The Med-Adept method consists of an assessment component for each process that is deemed applicable for software development organisations wishing to become medical device software developers. However, even

though each assessment component adopts a CMMI process area name, it provides coverage of CMMI®, ISO/IEC 15504-5 and AAMI/IEC 62304 practices through containing questions that relate to CMMI®, ISO/IEC 15504-5 and AAMI/IEC 62304

A key decision in the development of the Med-Adept method was to decide what process areas should be included. The process areas included in Med-Adept were chosen because:-

A. They have process area counterparts included within the AAMI/IEC 62304 standard;
B. They were previously included in the Adept method;

We then analysed each of the CMMI® process areas using the factors in Table 1 (see below).

Table 1. Suitability of CMMI® process areas for inclusion in Med-Adept method

CMMI® Process Area	**Satisfies A**	**Satisfies B**
Requirements Management	**Yes**	**Yes**
Project Planning	**Yes**	**Yes**
Project Monitoring & Control	**Yes**	**Yes**
Configuration Management	**Yes**	**Yes**
Measurement & Analysis		Yes
Process & Product QA	**Yes**	**Yes**
Supplier Agreement Management		
Requirements Development	**Yes**	**Yes**
Technical Solution	**Yes**	**Yes**
Verification	**Yes**	**Yes**
Product Integration	**Yes**	**Yes**
Validation	**Yes**	**Yes**
Organisational Process Focus		
Organisational Training		
Organisational Process Definition & IPPD		
Integrated Project Management & IPPD	Yes	
Risk Management	**Yes**	**Yes**
Decision Analysis & Resolution	Yes	
Organisational Process Performance		
Quantitative Project Management		
Organisational Innovation & Deployment		
Causal Analysis & Resolution	Yes	

Table 1, illustrates, that eleven of the twenty-two process areas from the CMMI® model satisfied both factors and should be included in Med-Adept.

4.1 What processes are included in Med-Adept?

In addition to the Med-Adept method enabling assessment against eleven CMMI® process areas it should also assess ISO/IEC 15504-5 and AAMI/IEC 62304 processes that are related to the eleven selected CMMI® process areas. The procedure for selecting the Med-Adept process areas was as follows:-

Step 1. Select one of the eleven CMMI® process areas (previously included in Adept – satisfies B in table 1);

Step 2. Serially scan this process area against the following list of 16 AAMI/IEC 62304 processes and select related ISO/IEC 15504-5 processes:- Risk Management, Configuration Management, Software Requirements Analysis, Software Development Planning, Software Architectural Design, Software Detailed Design, Software Integration, Software Unit Implementation and Verification, Integration Testing, Software System Testing, Quality Assurance, Software Release, Software Maintenance,

Software Problem Resolution, Documentation, Software Safety Classification.
Step 3. Repeat Steps 1 and 2 for each of the eleven CMMI® process areas.

As a result of performing these steps the CMMI® to AAMI/IEC 62304 and ISO/IEC 15504-5 processes (software related) area linkages were determined (see table 2) and the Med-Adept method provides coverage of 11 CMMI® process areas, 12 ISO/IEC 15504-5 and 11 AAMI/IEC 62304 processes.

Table 2. CMMI® to AAMI/IEC 62304 and ISO/IEC 15504-5 process linkages

Med- Adept Processes		
Adept Processes		
Selected CMMI Process Area	**Selected ISO/IEC 15504-5 Process**	**AAMI/EC 62304 Process**
Risk Management	Risk Management	Risk Management
Configuration Management	Configuration Management	Configuration Management
Requirements Management Requirements Development	Requirements Elicitation Software Requirements Analysis	Software Requirements Analysis
Project Planning Project Monitoring & Control	Project Management	Software Development Planning
Technical Solution	Software Design Software Construction	Software Architectural Design Software Detailed Design
Product Integration	Software Integration	Software Integration
Validation Verification	Software Testing Verification Validation	Software Unit Implementation and Verification Integration Testing Software System Testing
Process and Product Quality Assurance	Quality Management System	Quality Assurance
		Software Release Software Maintenance Software Problem Resolution Documentation Software Safety Classification

It can also be observed that Med-Adept does not provide coverage of 5 AAMI/IEC 62304 processes. However, the main purpose of Med-Adept is to provide a low overhead assessment that will educate organisations in relation to generic SPI and in particular medical device software development process. Therefore, it is not intended to provide comprehensive coverage of CMMI, AAMI/IEC 62304 and ISO/IEC 15504-5 processes, but rather a starting point through focusing upon the processes that will provide the most benefit to organisations.

To encourage uptake of the Med-Adept assessment by Irish software organisations we wish to reduce the cost and time associated with the assessment. On-site interviewing is restricted to one day as this proved attractive to companies in relation to performing the Adept assessment [22]. Consequently, an Med-Adept assessment method will be limited to providing coverage of four selected CMMI® and (the related) AAMI/IEC 62304 and ISO/IEC 15504-5 processes as the aim of Medi-Adept is to introduce organisations to medical device software processes in a low overhead manner. Companies wishing to be assessed in more than 4 of these processes will then be able to extend the assessment across additional days.

4.2 The Stages of the Med-Adept Method

The Med-Adept method is divided into eight stages and the assessment team consists of two assessors who conduct the assessment between them.

Stage 1 (*Develop Assessment Schedule and Receive Site Briefing*) involves a preliminary meeting between the assessment team and the software company. The assessment team will discuss the main drivers for the company embarking upon a Med-Adept assessment During **stage 2** (*Conduct Overview Briefing*) the lead assessor provides an overview of the Med-Adept method for members of the organisation who will be involved in subsequent stages. **Stage 3** (*Analyse Key Documents*) provides a brief insight into project documentation. The primary source of data for the Med-Adept method is through a series of process area interviews conducted during stage 4. The main part of the Med-Adept method is **stage 4**. In this stage key staff members from the assessed organisation are interviewed. In an attempt to reduce the overhead of the assessment we restrict the scope of the assessment to 4 process areas (there are a maximum of 4 interviews). Each interview is scheduled to last approximately 1.5 hours. Each interview involves two assessors, and at least one representative from the company is present for each process area interview.

Table 3, illustrates (for example, the processes of risk management and configuration management) that the process interviews within an Med-Adept assessment includes additional questions to provide coverage of relevant AAMI/IEC 62304 and ISO/IEC 15504-5 processes in addition to the CMMI process areas. When developing the interview questions we mainly looked at the base practices and did not perform a detailed investigation into similarities and differences between CMMI®, AAMI/IEC 62304 and ISO/IEC 15504-5. Instead we checked the relevant interview questions from the Adept method to see if they covered their counterpart in AAMI/IEC 62304 and ISO/IEC 15504-5 processes.

Table 3. Breakdown of Med-Adept Questions

AHAA Interviews	**No. of Adept Questions**	**No. of New Questions**	**No. of Med-Adept Questions**
Risk Management	39	23	62
Configuration Management	39	2	41

Within Adept 39 questions were used to provide coverage of the specific goals of the CMMI® and the base practices of ISO/IEC 15504-5 for risk management. Med-Adept is more comprehensive and has 62 scripted questions for risk management (see Table 3). Med-Adept not only contains CMMI and ISO/IEC 15504-5 based questions, but also 23 additional questions that are specifically related to the risk management process of AMMI/IEC 62304 and other associated medical device standards and regulations. The configuration management process has 2 additional questions added to meet the specific requirements of Med-Adept.

On completion of a Med-Adept assessment companies will receive feedback regarding the current state of their practices in relation to CMMI, AAMI/IEC 62304 and ISO/IEC 15504-5 (unless a company specifies that they are only interested in one of the models).

Stage 5 (*Generate Assessment Results and Create the Findings Report*) is a collaborative exercise between the assessors which results in the development of the findings report. The resultant findings report consists of a list of strengths, issues and suggested actions for each of the process areas evaluated. The findings report is developed through reviewing the interview notes for each of the 4 assessed process areas. **Stage 6** (*Deliver the findings report*) involves presenting the findings report to the staff in the assessed organisation who participated in the interviews. **Stage 7** (*Develop a SPI Path with the Company*) involves collaborating with staff from the assessed company to develop a roadmap that will provide guidance to the company in relation to practices that will offer the greatest benefits in terms of the organisation's business goals. Companies wishing to become medical device software developers will be recommended to focus upon establishing working practices that will assist them to adhere to AAMI/IEC 62304 practices and to prepare them for future Medi SPICE assessments. **Stage 8** (*Re-assess the SPI Path and Produce a Final Report*) involves revisiting the assessed company approximately 3 months after the completion of stage 7 and reviewing progress against the SPI path that was developed in stage 7. The outcome of this stage will be an updated SPI path and a final report detailing the progress that has been accomplished along with additional recommendations. This stage is important as it provides feedback and assistance to the assessed company after a period of time. This

stage also assists in compiling research material in terms of SPI experiences.

5. Observations from a Med-Adept assessment

The Med-Adept assessment was performed in an Irish MD organisation MedSoft (a pseudonym). MedSoft were aware of CMMI and ISO/IEC 15504-5, but they had not previously utilized these process improvement models. Before undertaking the assessment they were not familiar with the AAMI/IEC 62304 MD standard. On completion of the assessment the software development manager stated it had been beneficial to MedSoft in a number of ways. These included the provision of high-level training in relation to CMMI and ISO/IEC 15504-5 in the areas of risk management and configuration management. In addition they gained an insight into the MD regulations that are required to achieve compliance for these specific practices. Another important outcome was the assessment provided an introduction to the MD software development standard AAMI/IEC 62304. MedSoft also recognised the benefits of having an external auditor and in this situation receiving guidance in relation to improving their configuration management and risk management processes. Furthermore MedSoft identified the benefits of utilizing the Med-Adept lightweight assessment which did not require preparation on their part and took very little time to perform.

The results from the Med-Adept assessment highlighted that MedSoft's configuration management processes were very strong with regard to control, but they could be improved in terms of management. It also identified there was room for improvement in their risk management development practices. Therefore, if the recommendations in the Med-Adept findings report were implemented they would enable MedSoft to have both strong configuration and risk management practices.

The software development manager and the engineer both agreed that the strengths and weaknesses highlighted in the report were an accurate reflection of the company's risk management and configuration management practices. The management and staff of MedSoft also recognized that the recommendations were realistic and achievable and if implemented they would bring improvements and benefits to their organization. The software development manager stated that initially he intended championing these improvements in the location where the assessment took place. He then went on to state that he would oversee their implementation in other locations so that the overall organization could benefit from the assessment. MedSoft representatives met internally to discuss developing a SPI path after the Med-Adept findings report was presented. The objective of this meeting was to review and prioritise the report's recommendations and to plan how they will be implemented in a new project (which is stage 7 of Med-Adept).

Having discussed the assessment process with the management of MedSoft they outlined the benefits it offered. They also requested that within 6 months their software processes would be re-assessed (which is stage 8 of Med-Adept). With the objective of receiving feedback regarding the progress of their SPI initiative. This will also provide the assessment team with an opportunity to validate and or refine their improvement recommendations. Regarding Med-Adept the only area for improvement they identified was only 2 process areas had been assessed. It was agreed that on the release of the second edition of Med-Adept an additional assessment involving other software process areas will be undertaken.

6. Conclusions and Future Plans

The goal of a Med-Adept assessment is not certification but to provide a lightweight method for indicating to companies: the current state of their software processes; recommendations as to how they might improve; the status of their software processes both in terms of CMMI® and AAMI/IEC 62304 and ISO/IEC 15504-5; and their suitability to become medical device software developers. It is important to educate software development organisations in relation to how they may become medical device software developers and how they should improve their software development processes so that they may compete within this domain. This requires an appropriate approach that facilitates education and engages software development managers in a quality agenda. The application of the Med-Adept method will help raise the level of SPI knowledge within the assessed organisations. Also, the high-level findings report and the detailed SPI path will provide a road map for SPI within each assessed organisation. Furthermore, as the Med-Adept method requires little internal staff time, this should prove attractive to SMEs from a resource viewpoint.

From a research perspective the Med-Adept method: enables the Regulated Software Research Group (RSRG) at Dundalk Institute of Technology to gain an understanding as to whether existing software development practices within Irish companies are more CMMI, AAMI/IEC 62304 or ISO/IEC 15504-5 based. This will assists the RSRG in understanding areas that will present Irish software development companies with difficulties if they are to become medical device software development organisations – therefore this awareness will enable the RSRG to provide guidance within these areas; and will enable the RSRG to gain an understanding in relation to the strengths (profile) that Irish software companies possess particularly in relation to developing software for the medical device industry.

This paper has described the development of the Med-Adept method that provides coverage of 11 CMMI process areas, 12 ISO/IEC 15504-5 and 11 AAMI/IEC 62304 processes. It described a pilot release of the Med-Adept method, providing coverage of 2 processes. It also considered how a Med-Adept assessment was conducted in an Irish medical device software company. The company has since prioritised actions and are currently engaged in adopting a number of the recommendations as part of their software development practices. In the future we plan to extend the number of processes that may be assessed. We will extend the Med-Adept assessment to provide coverage of the remaining nine applicable processes that are displayed in table 1.

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References

[1] Expert Group of Future Skills Needs. 2008. "Future Skills Needs of the Irish Medical Device Sector", http://www.skillsireland.ie/press/reports/pdf/egfsn080205_medical_devices.pdf

[2] ISO: 13485, Medical devices -- Quality management systems -- Requirements for regulatory purposes, http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=36786

[3] 21 CFR Part 820 Quality System Regulations, http://www.gmp1st.com/mdreg.htm

[4] CDRH, General Principles of Software Validation; Final Guidance for Industry and medical device Staff. January 11, 2002

[5] CDRH, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; Guidance for Industry and medical device Staff. May 11, 2005

[6] CDRH, Off-The-Shelf Software Use in Medical Devices; Guidance for Industry, medical device Reviewers and Compliance. Sept 9, 1999

[7] ANSI/AAMI/IEC 62304, Medical device software – Software life cycle processes, Association for the Advancement of Medical Instrumentation, 19-Jul-2006 (replacement for SW68)

[8] FDA's Mission Statement - http://www.fda.gov/opacom/morechoices/mission.html

[9] European Council, 1993. "Council Directive 93/42/EEC Concerning Medical Devices", 14 June 1993.

[10] ANSI/AAMI/ISO 14971, Medical devices – Application of risk management to medical devices, 2nd Edition, 2007

[11] BS EN 60601-1-4: Medical Electrical Equipment, Part 1 - General requirements for safety. (2000)

[12] GAMP 5, 2008. GAMP 5: International Society for Pharmaceutical Engineering (ISPE): A Risk-Based Approach to Compliant GxP Computerized Systemsan-2008. http://www.techstreet.com/cgi-bin/detail?product_id=1559506

[13] AAMI TIR32:2004, Medical device software risk management, 2005

[14] IEC 61508, 2006. IEC 61508 Overview Report, A Summary of the IEC 61508 Standard for Functional Safety of Electrical/Electronic/Programmable Electronic Safety-Related Systems, 2006, http://www.exida.com/articles/iec61508_overview.pdf. Last accessed August 2008.

[15] IEC 60812, Analysis technique for system reliability - Procedure for failure modes and effects analysis (FMEA), 2006.

[16] CMMI Product Team, Capability Maturity Model® Integration for Development, Version 1.2 (2006), http://www.sei.cmu.edu/publications/documents/06.reports/06tr008.html, Technical Report CMU/SEI-2006-TR-008

[17] ISO/IEC 15504-5: 2006 Information Technology – Process Assessment – Part 5: An exemplar Process Assessment Model , JTC 1/SC 7

[18] Cass A., and Volcker C. 2000 , SpiCE for SPACE: A method of Process Assessment for Space Projects, SPICE 2000 Conference Proceedings, http://www.synspace.com

[19] Automotive SIG, The SPICE User Group, Automotive SPICETM Process Reference Model, 2005, available from http://www.automotivespice.com

[20] F. McCaffery, A.Dorling, "Medi SPICE: An Overview", 9th International Conference on Software Process Improvement and Capability Determinations (SPICE 2009), pp. 34-41

[21] F. McCaffery, I. Richardson & G.Coleman, "Adept – A Software Process Appraisal Method for Small to Medium-sized Irish Software Development Organisations", European Software Process Improvement and Innovation Conference 2006, EuroSPI06, October, Finland

[22] Anacleto, A, von Wangenheim. C.G, Salviano. C.F, Savi. R. 2004, "Experiences gained from applying ISO/IEC 15504 to small software companies in Brazil", 4th International SPICE Conference on Process Assessment and Improvement, Lisbon, Portugal, pp.33-37 (April 2004).