MDevSPICE - A Comprehensive Solution for Manufacturers and Assessors of Safety-Critical Medical Device Software

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Abstract. Software development is frequently challenged with quality concerns. One of the primary reasons for such issues is the very nature of the software development process. First, it can be difficult to accurately and completely identify the requirements for a software development product. Also, the implementation on various platforms and the need to integrate with sometimes unforeseeable additional systems adds complexity. For safety critical domains, such as the medical device and healthcare sectors, these hurdles are amplified. Whereas a failure in a desktop application may be resolved through a restart with no harm incurred, a failure in a medical device can have life threatening consequences. Our work in the Regulated Software Research Centre (RSRC) aims to support medical device producers in the production of safer medical device software. In this paper, we describe the MDevSPICE framework and how it addresses the safety concerns faced by medical device producers.

Keywords: Medical Device Software, Software Process Improvement, Medical Device Software Process Assessment and Improvement, MDevSPICE.

1 Introduction

As software is increasingly incorporated into medical devices, so too is there a growing need to address the potential harm that can be caused by faulty software. As recently as 2011, "software failures were behind 24% of all the medical device recalls" FDA [1]. While the medical device domain is controlled by regulations that are designed to promote safety, the regulation is in practice satisfied through the implementation of appropriate process and quality standards. In recent years, a significant number of new or extended medical device software standards and guidance has emerged, with the result that we now have a large body of often disparate information on how best to implement medical device software. This circumstance gives rise to a number of issues. Firstly, with the information originating from different sources, it is expensive and difficult for manufacturers to determine the scope of each source, and more difficult still to accurately determine

A. Mitasiunas et al. (Eds.): SPICE 2014, CCIS 477, pp. 274–278, 2014.

the overlap and distinction between the sources. Secondly, competent authorities are also challenged to stay in tune with the emerging standards and guidelines in a domain that traditionally had a much smaller software footprint. Thirdly, the task of both manufacturers and competent authorities is further complicated by the absence of a consistent, internationally recognized and authoritative framework for assessing the manufacturers to deliver robust and reliable software to the medical device sector.

To address these issues, researchers in the RSRC have developed an internationally recognized framework hand-in-hand with the international standards organisations that consolidates the disparate medical device best practices into a single framework: MDevSPICE (formerly known as MediSPICE). Furthermore, the MDevSPICE framework is leveraged on leading generic software engineering best practice frameworks, and provides for a consistent and repeatable method for evaluating the competency of medical device software developers.

2 Medical Device Regulation and Standards

A medical device can consist wholly of software or have software as a component of the overall device [2]. In order to market a medical device within a given jurisdiction, it is necessary that the device complies with the regulatory demands of that region. The two largest global bodies involved in the development and evolution of medical device regulation are the Food and Drug Administration (FDA) and the European Commission (EC).

In the case of the US, the FDA issues the relevant regulation through a series of formal channels, including the Code of Federal Regulation (CFR) Title 21, Chapter I, Subchapter H, Part 820 [3] (ref. Figure 1). In the EU, the regulation is outlined in a number of sources: Medical Device Directive (MDD) 93/42/EEC [2], Active Implantable Medical Device Directive (AIMDD) 90/385/EEC [4], and *In-vitro* Diagnostic (IVD) Medical Device Directive 98/79/EC [5] – with all of these being amended by MDD 2007/47/EC [6]. Both the US and EU regulations outline varying degrees of safety concerns dependent on the medical device classification, which is broadly similar in both jurisdictions, ranging from Class I devices that are not intended to support or sustain human life, to Class III devices which have a critical role to play in supporting life.

The regulation outlined in the previous paragraphs may be satisfied through the implementation of medical device guidance and standards. ISO 13485:2003 (ISO 13485 from hereon) [7] outlines the requirements for regulatory purposes from a Quality Management System (QMS) perspective. ISO 13485, which is based on ISO 9001 [8], can be used to evaluate an organisation's ability to meet both customer and regulatory requirements. However, ISO 13485 does not offer specific guidance on software development, a role that is filled by IEC 62304:2006 (IEC 62304 from hereon) [9] which outlines the lifecycle processes necessary for the safe design and maintenance of medical device software. Beyond IEC 62340, numerous additional standards and guidance documents exist, such as ISO/IEC 12207:2008 and ISO/IEC 15504-5:2012 (ref. Figure 1) and these have been integrated into the MDevSPICE framework. In Figure 2, we provide an overview of the primary standards and sources of best practice that have been incorporated into the MDevSPICE solution. With all of

the acknowledged best practice and guidance for medical device software development now housed within a single framework, it is possible to assess medical device software development to the most rigourous level. This MDevSPICE framework can be adapted and extended as the underlying standards and guidance evolve, thus ensuring that by adopting the MDevSPICE solution, organisations and assessment bodies can be confident that no key items have been overlooked.

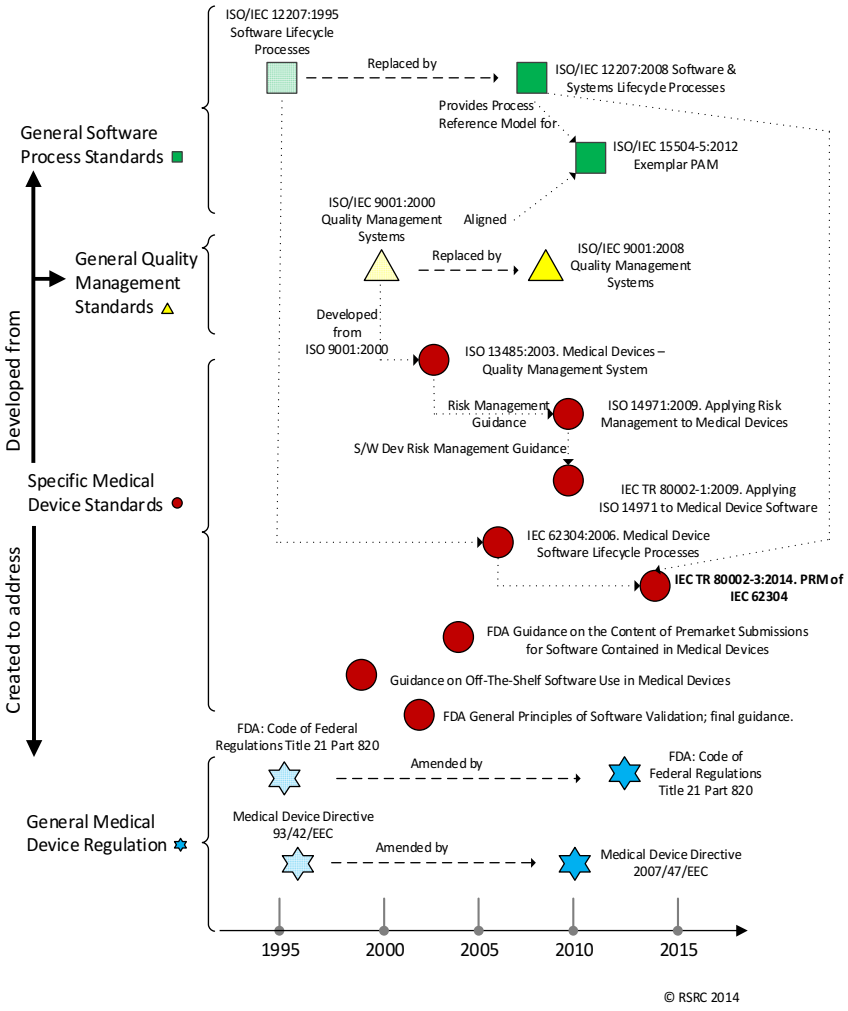

Fig. 1. Medical Device Regulations and Standards

In developing MDevSPICE significant international standards engagement has been required, with IEC TR 80002-3 (Process Reference Model for IEC 62304) now published [10]. IEC TR 80002-3 represents the culmination of many years of dedicated work by the RSRC, creating important new standards within the working

groups of both the ISO and the IEC. Work of this nature also established a solid international agreement on the contributions made by the RSRC. Through working with international standards working groups such as IEC SC62A/ JWG3, IEC SC62A/JWG7 and ISO/IEC JTC1 SC7 WG10, the RSRC has advanced other standards, including IEC 80001-1-7 (Process Assessment Model for IEC 80001-1) and IEC 80001-2-8 (Guidance on standards for establishing Security Capabilities identified in IEC/TR 80001-2-2).

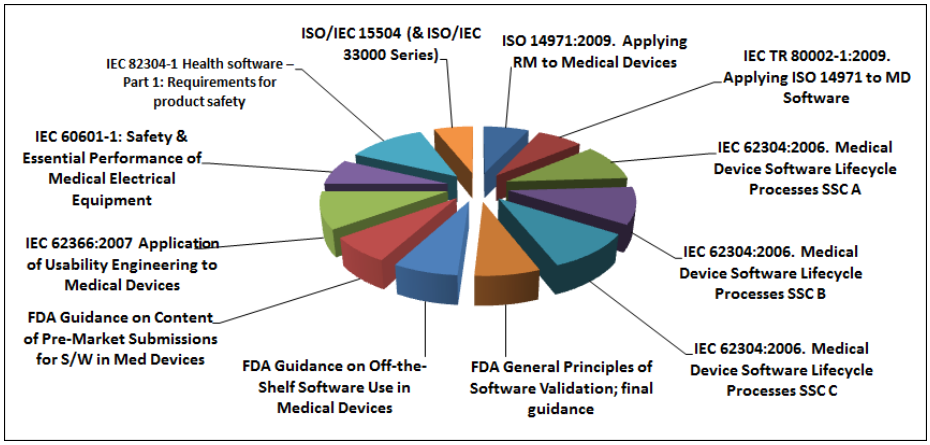

Fig. 2. MDevSPICE Process Assessment.

MDevSPICE itself is scheduled to be brought to the global market in Q4.2014 and it will for the first time concentrate the accumulated medical device best practices from all leading sources, while also supporting the industry and regulators in consistently and accurately evaluating software process implementation. This is good news for regulators, as a robust and thorough framework grounded in international standards will exist for assessing medical device software producers. And it is good news for the producers too, as all the medical device know-how will for the first time be assembled in a single, authoritative framework.

Acknowledgments. This research is supported by Enterprise Ireland and the European Regional Development Fund (ERDF) under the National Strategic Reference Framework (NSRF) 2007-2013, grant number CF/2012/2631, and in part by the Science Foundation Ireland (SFI) Stokes Lectureship Programme, grant number 07/SK/I1299, and the SFI Principal Investigator Programme, grant number 08/IN.1/I2030 (the funding of this project was awarded by Science Foundation Ireland under a co-funding initiative by the Irish Government and European Regional Development Fund).

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