Barriers to Adopting Agile Practices when Developing Medical Device Software

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Abstract. Agile methodologies such as XP and Scrum are founded upon the four values and twelve principles of agile software development. A software development project is only considered to be truly agile if these values and principles are followed. However, software developed for use in medical devices must be regulatory compliant and this can make the process of following a single agile methodology such as XP difficult to achieve. This paper outlines how we identified the barriers to agile adoption in the medical device software domain through performing a survey. These barriers include: lack of documentation; maintaining traceability; regulatory compliance; lack of up front planning and the process of managing multiple releases. Based on this research recommendations are also made as to how these barriers can be overcome.

Keywords: Safety Critical, Agile, Plan Driven, XP, Scrum, Barriers, Medical

1 Introduction

Software is playing an increasingly important role in healthcare [1]. As the reliance on this software is increasing, regulatory controls are evolving to ensure the safe and reliable performance of medical devices, to prevent harm to patients, clinicians and third parties.

Software is developed in accordance with a customer's requirements. Software used as a medical device or as part of a medical device must also be developed in accordance with the regulatory requirements of the region in which the device is being marketed [2]. The generic software development industry has benefited from adopting agile practices [3]. These practices are procedures defined as being highly effective and efficient [4] such as sprint planning, an open office space, daily meetings and product backlogs from Scrum, these have the added benefit of being more cost effective [5]. However, there is a low rate of agile adoption amongst safety critical software developers [6]. The reasons for this are still being investigated. This paper presents research performed to identify the barriers to adopting agile practices when developing medical device software.

As part of this research, a survey was conducted amongst medical device software development organisations in Ireland. This paper also provides recommendations as to how these barriers may be overcome.

The remainder of this paper is structured as follows; in section 2, we present the challenges faced by medical device software developers. In section 3, we outline the survey conducted and present the results. In section 4, we examine each of the barriers identified in section 3 and recommendations are presented as to how these barriers can be overcome. Finally, in section 5, we present our conclusions and outline how this work will contribute to future research.

2 Challenges to Developing Medical Device Software

Software developed for use as a medical device or as part of a medical device in Europe must conform to the latest amendment to the Medical Device Directive (MDD) 2007/47/EC [7] and the guidance of the associated MED DEV [8] document. Software developed as a medical device or part of a medical device in the US must conform to the FDA 21 CFR Part 820 [9] Quality System Regulations and conformance is recommended to one or more of the following Food and Drug Administration (FDA) guidance documents:

- General Principles of Software Validation (GPSV) [10];
- Medical Device Data Systems Rule [11];
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices [12];
- Draft Guidance for Industry and Food and Drug Administration - Mobile Device Applications [13];
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software use in Medical Devices [14].

Both the US and European regulations dictate what information a medical device software development organisation must produce in order to achieve regulatory conformance. However, these guidelines do not mandate the usage of a specific lifecycle to produce this necessary information. IEC 62304:2006 – Medical Device Software – Software life cycle processes [15] is harmonised with the MDD [16] and is approved for use by the FDA. IEC 62304 also does not mandate the usage of a specific lifecycle.

Research conducted at Cochlear [17] , Abbott Diagnostics [18], Medtronic [19] and a Danish Pharmaceutical Company [20] revealed that medical device software developers are actively seeking an alternative to traditional plan driven methodologies. These case studies revealed that following agile practices can resolve problems associated with plan driven software development.

3 Barriers to Agile Adoption

As part of their on-going research the authors performed a survey of Irish medical device software development organisations. Twenty medical device software development organisations were surveyed with multiple responses being received from each organisation. The survey revealed that 100% of the respondents who are currently marketing medical device software are developing it for use in Europe. In addition, 79% of these are also developing medical device software for use in the US.

The survey identified that 50% of the organisations are developing software in accordance with the V-Model. An important finding was that another 25% of the organisations are developing medical device software in accordance with agile practices. The remaining 25% of organizations are developing software in accordance with other development lifecycles such as the Waterfall, and Iterative & Incremental approaches. Participants were asked as part of this survey, to identify the barriers to adopting agile practices when developing medical device software. The following issues were identified by participants as barriers:

- Lack of Documentation;
- Traceability Issues;
- Regulatory Compliance;
- Lack of Up-Front planning;
- Managing Multiple Releases.

4 Overcoming Identified Barriers

Five barriers to agile adoption have been identified through the survey as outlined in section 3. Each of these barriers was examined and recommendations made as to how these barriers may be overcome.

4.1 Lack of Documentation

The Agile Manifesto [21] has four key values. One of these values is "*Working Software over Comprehensive Documentation*". This value would appear to be a direct contradiction of the regulatory requirements. The FDA regulations require a medical device software development organisation to fully document requirements prior to development [22]. However, Robert Martin, one of the authors of the Agile Manifesto states [21];

"*Produce no document unless it's immediate and significant*".

In terms of achieving regulatory compliance, documentation is significant and as such it would still be produced when following agile practices. Research conducted by Berard [23] examined the misconceptions regarding documentation and agile software development. Agile software developers deliver what is requested by the customer.

Simply put if a customer/regulatory body requires documentation from an agile development team there are no barriers in place to prevent the team from producing this documentation whilst still following agile practices.

4.2 Traceability Issues

In order for medical device software development organisations to achieve regulatory approval they must provide evidence of traceability from the requirements specification to each stage of the development process. The FDA General Principles of Software Validation (GPSV) [10] document mandates that code must be linked to requirements and test cases. Using agile practices, requirements are not fixed before development begins and during development changes to requirements are welcomed. However, once the requirements specifications and changes to the requirements specifications are fully documented, traceability can still be maintained. The FDA General Principles of Software Validation state;

"*Most software development models will be iterative. This is likely to result in several versions of both the software requirement specification and the software design specification. All approved versions should be archived and controlled in accordance with established configuration management procedures*".

This statement acts as evidence that regulatory bodies acknowledge that requirements can and do change and this is acceptable as long as configuration management procedures are adhered to. This results in requirements that can be used to perform traceability.

Lee et al, [24], present a tool known as "*Echo*" which can be used to capture requirements as part of an agile development project. This tool provides a mechanism to maintain traceability between the requirements and each stage of development whilst developing software in accordance with agile practices.

4.3 Regulatory Compliance

Regulatory controls and development standards provide guidance in the development of a safe and reliable medical device. However, the MDD, the FDA and the IEC 62304 standard do not enforce the use of a specific software development lifecycle. IEC 62304 states;

"*(The IEC 62304) standard does not require a particular software development life cycle model*"

As a caveat to the previous statement, IEC 62304 also states;

"*Whichever life cycle is chosen it is necessary to maintain the logical dependencies between process outputs*"

The FDA GPSV states;

> "*(the FDA) does not recommend the use of any specific software life cycle model. Software developers should establish a software life cycle model that is appropriate for their product and organization*"

The Association of the Advancement of Medical Instrumentation (AAMI), are currently in the process of mapping the principles of the Agile Manifesto to IEC 62304 [25]. As part of this research by the AAMI, each of the 12 agile principles is mapped to a specific stage of development in accordance with IEC 62304. The upcoming release of this document will provide evidence that agile practices can be followed without jeopardising the process of achieving regulatory approval.

4.4 Lack of Up-Front Planning

Plan driven software development lifecycles such as the V-Model place a large emphasis on up-front planning. This up-front planning can provide stability and a point of reference for a development project [2]. However, up-front planning can be difficult to perform following agile practices as requirements changes are welcomed and expected in an agile project [21]. Whilst this is the case, before a project begins agile practices use techniques such as user stories. These are a form of up-front planning [26] and can provide the necessary stability to allow a project to begin.

4.5 Managing Multiple Releases

Software projects developed in accordance with agile practices are divided into iterations. Agile teams attempt to have a potentially shippable system at the end of each iteration [27]. Due to the safety critical nature of medical device software, regulatory requirements prohibit medical device software developers from releasing unfinished software into a live patient environment without being fully tested [10].

However, whilst agile teams typically develop a shippable system during each iteration, this is not a requirement of agile practices. Agile teams can combine components developed during iterations and perform the necessary testing once a number of iterations have been completed. The process of managing multiple releases can be further improved through using third party software tools which are currently available such as "*Subversion*" [28].

5 Conclusions and Future Work

Research into the usage of agile practices when developing medical device software is still at an early stage. There have been reported successes of utilising agile practices when developing medical device software however, these successes have been performed in isolation and are yet to be replicated.

As a result of the survey outlined in this paper, a number of barriers to agile adoption in the development of medical device software have been identified. Through examination of the relevant medical device regulatory requirements, international standards and guidance documents it may be concluded that none of the barriers identified are insurmountable. Each of the barriers were analysed in detail and information has been provided as to how these barriers can be addressed. The research outlined in this paper is part of a larger study and these results will be used to assist with further research into the use of agile practices for medical device software development.

Whilst this research identified the perceived barriers to adopting agile practices within medical device companies, further research will identify the critical success factors to using agile practices when developing medical device software. The research outlined in this paper will also contribute to the development of a software development lifecycle for medical device software that will integrate the stability of following a plan driven software development lifecycle with agile practices.

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6 References

1. Abraham, C., E. Nishiharas, and M. Akiyama, *Transforming healthcare with information technology in Japan: A review of policy, people, and progress.* International Journal of Medical Informatics 2011. **80**(2011): p. 157-170.
2. Ge, X., R.F. Paige, and J.A. McDermid, *An Iterative Approach for Development of Safety-Critical Software and Safety Arguments*, in *Agile 2010*. 2010, IEEE: Orlando, Florida. p. 35-43.
3. VersionOne, *State of Agile Survey - The Stage of Agile Development*. 2010.
4. http://agilemindstorm.com/agile-glossary/ Accessed 20/02/2012
5. Turk, D. and R. France, *Assumptions Underlying Agile Software Development Processes* Journal of Database Management, 2004. **16**(4): p. 62-87.
6. Cawley, O., X. Wang, and I. Richardson, *Lean/Agile Software Development Methodologies in Regulated Environments – State of the Art*, in *Proceedings of Lean Enterprise Software and Systems, . .* 2010, Springer Helsinki, Finland. p. 31-36.
7. European Council, *Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007*. 2007.
8. European Commission, *Medical Devices Guidance Document - Qualification and Classification of stand alone software MEDDEV 2.1/6*. 2012.

9. FDA, *Title 21--Food and Drugs Chapter I --Food and Drug Administration Department of Health and Human Services subchapter h--Medical Devices part 820 Quality System Regulation*. 2007, *U.S. Department of Health and Human Services*.
10. FDA, *General Principles of Software Validation: Final Guidance for Industry and FDA Staff*. 2002, *Centre for Devices and Radiological Health*.
11. FDA, *Federal Register **73** (31), 8637 (15 February 2011)*. 2011.
12. FDA, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. 2005, *U.S. Department of Health and Human Services*.
13. FDA, *Draft Guidance for Industry and Food and Drug Administration - Mobile Device Applications*. 2011, *Centre for Devices and Radiological Health*.
14. FDA, *Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software use in Medical Devices*. 1999, *U.S. Department of Health and Human Services*.
15. AAMI, *ANSI/AAMI/IEC 62304, Medical device Software - Software life cycle processes*. 2006.
16. European Council, *Commission communication in the framework of the implementation of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (Publication of titles and references of harmonised standards under the directive)*. 2010.
17. Rottier, P.A. and V. Rodrigues, *Agile Development in a Medical Device Company*, in *Proceedings of the 11th AGILE Conference. AGILE '08*. 2008, Springer: Girona, Spain.
18. Rasmussen, R., T. Hughes, J.R. Jenks, and J. Skach, *Adopting Agile in an FDA Regulated Environment*, in *Agile Conference, 2009. AGILE '09. .* 2009, Springer: Chicago, IL p. 151-155.
19. Spence, J.W., *There has to be a better way! [software development]*, in *Proceedings to Agile Conference, 2005. .* 2005, Springer: Denver. p. 272 - 278.
20. Heeager, L.T. and P.A. Nielsen, *Agile Software Development and its Compatibility with a Document-Driven Approach? A Case Study*, in *20th Australasian Conference on Information Systems Compatibility of Agile and Document-Driven Approaches*. 2009: Melbourne.
21. Martin, R.C., *Agile Software Development - Principles, Patterns and Practices*. 2003: Prentice Hall.
22. Vogel, D., *Agile Methods:Most are not ready for prime time in medical device software design and development*. DesignFax Online, 2006(July 2006).
23. Berard, E.V., *Misconceptions of the Agile Zealots*, in *Software and System Process Improvement Network*. 2003.
24. Lee, C., L. Guadagno, and X. Jia, *An Agile Approach to Capturing Requirements and Traceability*, in *Proceedings of the 2nd International Workshop on Traceability in Emerging Forms of Software Engineering (TEFSE 2003)*. 2003: Canada.
25. AAMI, *Gudiance on the use of agile practices in the development of medical device software TIR-Master_4-00*. 2011, Association for the Advancement of Medical Instrumentation.

26. Paetsch, F., A. Eberlein, and F. Maurer, *Requirements engineering and agile software development*, in *Enabling Technologies: Infrastructure for Collaborative Enterprises, 2003. WET ICE 2003. Proceedings. Twelfth IEEE International Workshops on*. 2003. p. 308-313.
27. Berczu, S., R. Cowham, and B. Appleton, *An Agile Approach to Release Management*. 2008.
28. http://subversion.apache.org/ Accessed 12/01/2012