Conference papers

School of Computer Science

2012-05-23

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Recommended Citation

Mc Hugh, M.: Integrating Agile Practices with Plan-Driven Medical Device Software Development. 13th International Conference on Agile Software Development: XP 2012 Doctoral Symposium 2012, June 2012, Vienna, Austria.

Integrating Agile Practices with Plan-Driven Medical Device Software Development

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1 Background

The popularity of Agile software development is growing rapidly with an increasing number of projects being developed following Agile methodologies such as Scrum and XP [1]. Research has revealed that following Agile practices when developing software can have a significantly positive impact in reducing development time, reducing cost and increasing overall quality [2-4]. Whilst Agile practices can have a positive impact on a development project there are incompatibilities between Agile methodologies and the plan driven approaches followed when developing safety critical software [5, 6]. However, it has been recognised that "*formal techniques may be used in an agile way*" [5]. Case studies have been performed in organisations developing safety critical software which validate this statement [7-9]. This Ph.D. is focusing on the area of medical device software development and integrating Agile software development principles into traditional plan driven lifecycles for use in developing medical device software.

2 Research

The objective of this Ph.D. is to investigate integrating Agile practices with plan driven software development lifecycle models for medical device software development. This research will focus on identifying the most suitable or appropriate Agile practices which can be followed when developing medical device software.

2.1 Research Questions

The following research questions have been developed:
- What are the issues with developing medical device software?
- What are the issues with developing medical device software using a traditional software development lifecycle?
- Which Agile practices are suited to developing medical device software?
- How does the existing medical device software development lifecycle need to be tailored to incorporate suitable Agile practices?

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3 Research Methods

This research is being undertaken by adopting the following approach. A literature review was performed. The literature review began broadly by examining the main software development lifecycles being followed in all software development domains. The literature review then focused on software development in safety critical industries and then concentrated on software development in the medical device domain. Once this part of the literature review was completed Agile methodologies where examined. Once this examination was completed the focus moved onto the adoption of Agile practices when developing safety critical software.

Upon completion of the literature review the research questions were identified and formed. At this point, a survey was conducted amongst medical device manufacturers based in Ireland. The objectives of this survey were three fold. Firstly, to learn which software development lifecycle methodologies are being followed, secondly to learn if medical device manufacturers would be open to employing Agile practices when developing medical device software and finally what are the perceived problems associated with using Agile practices when developing medical device software.

To further assist in developing the hypotheses, semi-structured interviews will be conducted with members of the medical device software development industry. The goal of these interviews will be to gain insight into the development of medical device software and to learn what problems these organisations are experiencing whilst following plan driven lifecycles. Once the semi structured interviews have been completed and the results analysed and combined with the results of the literature review and survey, hypotheses will be formed. The results of the literature review, survey and interviews will also be used to identify which Agile practices can be used in the development of medical device software.

At this stage the research method will change to a deductive approach. To test the hypotheses, a number of case studies will be performed. As part of these case studies, recommendations will be made to the organisations as to how problems with their existing lifecycle can be resolved by employing Agile practices. Once these recommendations have been implemented, the results will be analysed. Finally, upon completion of the case studies and testing of the hypotheses the process of verifying the findings will begin. These results will be verified through developing a framework which combines Agile practices with a plan driven lifecycle. This framework will be validated by industry experts.

4 Research to Date

To date the literature review and survey have been completed. The results of the literature review where used to develop the research questions. In conjunction with the literature review, an in depth analysis of the international medical device regulatory environment was performed. This analysis was used to establish how changes to the international regulatory environment affect medical device software development organisations.
The survey was conducted amongst twenty medical device software development organisations in Ireland. This survey revealed which lifecycles medical device

software developers are following. The results also revealed that medical device software developers are open to using Agile practices if it resolved problems with their current lifecycle and finally the results of the survey revealed the barriers to adopting Agile practices within these organisations.

5 Future work

Future work as part of this Ph.D. includes formulating questions to be asked as part of the semi structured interviews, conduct the interviews, develop hypotheses and test the hypotheses through case studies. Finally the framework will be developed and validated by experts.

6 References

1. Conboy, K. and Fitzgerald, B., (2010) "Method and developer characteristics for effective agile method tailoring: A study of XP expert opinion," *ACM Trans. Softw. Eng. Methodol,* vol. 20, pp. 1-30,
2. VersionOne, (2010) "State of Agile Survey - The Stage of Agile Development."
3. Johnson, M., (2003) "Agile methodologies: Survey results.," *Victoria, Australia: Shine Technologies.*
4. Ambler, S., (2008), *Agile Adoption Rate Survey Results: February 2008.* http://www.ambysoft.com/surveys/agileFebruary2008.html#Downloads.
5. Turk, D*., et al.*, (2002) "Limitations of Agile Software Processes," presented at the *Third International Conference on Extreme Programming and flexible processes in Software Engineering (XP2002).*
6. Boehm, B. and Turner, R., (2003) *Balancing Agility and Discipline: A Guide for the Perplexed*: Addison-Wesley.
7. Rottier, P. A. and Rodrigues, V., (2008) "Agile Development in a Medical Device Company," presented at the *Agile, 2008. AGILE '08. Conference.*
8. Rasmussen, R*., et al.*, (2009) "Adopting Agile in an FDA Regulated Environment," presented at the *Agile Conference, 2009. AGILE '09.* , Chicago, IL
9. Heeager, L. T. and Nielsen, P. A., (2009) "Agile Software Development and its Compatibility with a Document-Driven Approach? A Case Study," presented at the *20th Australasian Conference on Information Systems Compatibility of Agile and Document-Driven Approaches*, Melbourne.