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Abstract. Three surveys conducted over a 6 year period revealed that medical device software organisations have difficulties in the area of requirements management, namely accommodating changes in requirements. Medical device software is traditionally developed in accordance with a plan driven software development lifecycle (SDLC). These SDLCs are rigid and inflexible to changes once the requirements management stage has been completed. Agile methods are gaining momentum in non-regulated industries but as of yet, the adoption of these methods in regulated industries such as the medical device software domain remains low. This study presents an implementation of agile methods within a medical device software development organisation based in Ireland. This implementation involved integrating agile practices with a traditional plan driven SDLC. Upon completing this implementation within a medical device software development project, the organisation identified cost savings and a reduction in the rework required when introducing a change in requirements.

Keywords: Agile, SDLC, Medical, AV-Model, Hybrid, IEC 62304

1 Introduction

Three surveys, in 2007 [1], 2010 [2] and 2012 by the Regulated Software Research Centre at Dundalk Institute of Technology revealed that medical device software development organisations face challenges in managing requirements during development. Medical device software is typically developed in accordance with a plan driven Software Development Life Cycle (SDLC), such as the V-Model [3]. The V-Model appears to be the "best fit" with regulatory requirements as it produces the necessary deliverables required when seeking regulatory approval. However, use of the V-Model or any other SDLC is not mandated by international medical device software regulations or development standards [4]. Based upon this, an examination was performed of the software practices and methods in non-regulated domains to determine if lessons learned in these domains could be applied to the medical device software development industry.

This examination revealed that the adoption of agile practices within these non-regulated domains is increasing. A large scale survey of the software development industry revealed that 80% of respondents reported that they are following an agile approach [5]. These industries reported adopting agile methods for various reasons, one of which being the ability of agile practices to accommodate changes in requirements at any point in a development project.

Based upon this, the study focused on the medical device software development industry. An extensive mapping study was conducted to determine if agile practices have been used in regulated software domains and if so, how have they been adopted and to what success [6]. This mapping study revealed a very low adoption rate of agile practices within the medical device software development industry however, in instances where they have been adopted they have proved successful. For example, Rasmussen, Hughes, Jenks and Skach [7] reported that adopting agile practices in Abbott Diagnostics improved the process of requirements management during a medical device software development project. Further to this, where agile practices have been adopted successfully in the medical device software development industry, they have been integrated with a plan driven SDLC as no single agile method is sufficiently comprehensive in producing regulatory deliverables.

As a result of this research, a decision was taken to produce a hybrid SDLC incorporating agile practices with a plan driven SDLC in order to overcome the challenge of accommodating changes in requirements at any stage during development. This hybrid SDLC known as the AV-Model, was then implemented within a medical device software development organisation to validate its efficacy in practice.

The remainder of this paper is structured as follows; Section 2 presents the development of the AV-Model, Section 3 discuss the organisation and project in which the AV-Model was implemented, Section 4 presents the results produced as a result of the implementation of the AV-Model and Section 5 presents the conclusions of this research.

2 AV-Model Development

The process of developing the AV-Model was broken into clear distinct phases:

1. Selection of foundation plan driven SDLC;
2. Preparing for inclusion of agile practices into plan driven SDLC;
3. Identification of applicable agile practices.

2.1 Selection of Foundation Plan Driven SDLC

When selecting the foundation of the hybrid SDLC, a number of plan driven SDLCs were examined. From performing a literature review we discovered that the V-Model is the most appropriate model on which to base the hybrid SDLC. The reasons for choosing the V-Model are:

- Medical device software organizations typically follow the V-Model. Consequently, they are already familiar with the structure and phases of the V-Model and would be more willing to adopt a hybrid model based upon a SDLC with which they are familiar [8].
- Medical device software organizations may have received regulatory approval to follow the V-Model when developing medical device software. If these organizations move to a completely different SDLC, they may need to re-apply for regulatory approval for the new SDLC. This may be a barrier as organizations could be reluctant to undergo the process of achieving regulatory approval again [9].
- Whilst none of the regulatory requirements or development standards mandate the use of the V-Model, it appears to be the best fit with regulatory requirements as it guides organizations through the process of producing the necessary deliverables required to achieve regulatory conformance [10].

2.2 Preparing for Inclusion of Agile Practices into Plan Driven SDLC

Each of the sequential plan driven SDLCs suffer the problem of being rigid and inflexible to change. All of the agile methodologies advocate iterative software development. Iterative techniques offer the ability to accommodate changes more easily than a plan driven approach [11]. However, to incorporate iterative techniques, the process of "Risk Identification" needs to be added to the model. Risk Identification involves analysing the project, dividing it into iterations and identifying the iterations which pose the most risk to the project and then creating a backlog as a result. The iterations identified as posing the most risk are then performed as early as possible in the project. Once risk identification is added, each of the stages of the V-Model is assessed to determine which of them could be performed iteratively. Consequently, all of the stages of the development lifecycle are divided into two categories: those that can be performed iteratively and stages that can only be performed in a single pass. For example, the Food and Drug Administration (FDA) requires medical device manufacturers to submit high level requirements prior to beginning development [12]. Therefore, this can only be done once. Also, the process of achieving regulatory approval can only be sought once a device is completed and the acceptance tests have all passed. Therefore, this can only be completed once. However, other stages such as including "Software Architecture Design" and "Unit Implementation" can be performed iteratively.

2.3 Identification of Applicable Agile Practices

As with selecting a foundation SDLC, a mechanism was required for the identification of suitable agile practices for inclusion into the hybrid SDLC. The primary objective of the hybrid SDLC is to assist medical device software organisations in the area of requirements management. As a result, an examination of the various agile methods revealed that the Scrum method is one of the only methods to provide complete

guidance in all areas of development including requirements management. This finding was supported by the research conducted by Paetsch, et al. [13].

Based upon this, a decision was taken to establish which of the Scrum software development practices could be included into the hybrid SDLC. To discover which practices could be included, an examination of medical device software development regulations was performed to determine if any of the Scrum practices were contradictory with regulatory requirements. This examination revealed that none of the Scrum practices contradict regulatory requirements. To further reinforce the decision to adopt Scrum practices, the findings of the mapping study revealed that where agile practices have been adopted when developing medical device software, they have typically been Scrum practices [14-18].

The identification of suitable agile practices was not limited to the identification of a single agile method for integration with the V-Model. A review of empirically based research produced a list of agile practices from various agile methods which could successfully be adopted when developing medical device software. This review also included the extraction of practices from AAMI TIR45:2012 [19]. While these practices have not been adopted on a specific medical device software project, the authors of AAMI TIR45:2012 have extensive experience in both medical device software regulations and development. This places them as authorities as to which practices can be followed.

While the majority of the practices identified or followed when developing medical device software are typically Scrum practices, a number of other practices have been recognised such as Test Driven Development, Done is Done, Pair Programming and Self Organising Teams. As a result, a number of these practices were also included into the hybrid SDLC. It is expected that practices included from different agile methods will be complimentary [20].

Figure 1 shows the AV-Model which integrates agile practices with the V-Model. While the AV-Model may resemble the traditional V-Model, the approach taken is very different. The V-Model advocates fully completing a single stage before progressing to the next stage whereas with the AV-Model a number of stages are revisited during each iteration.

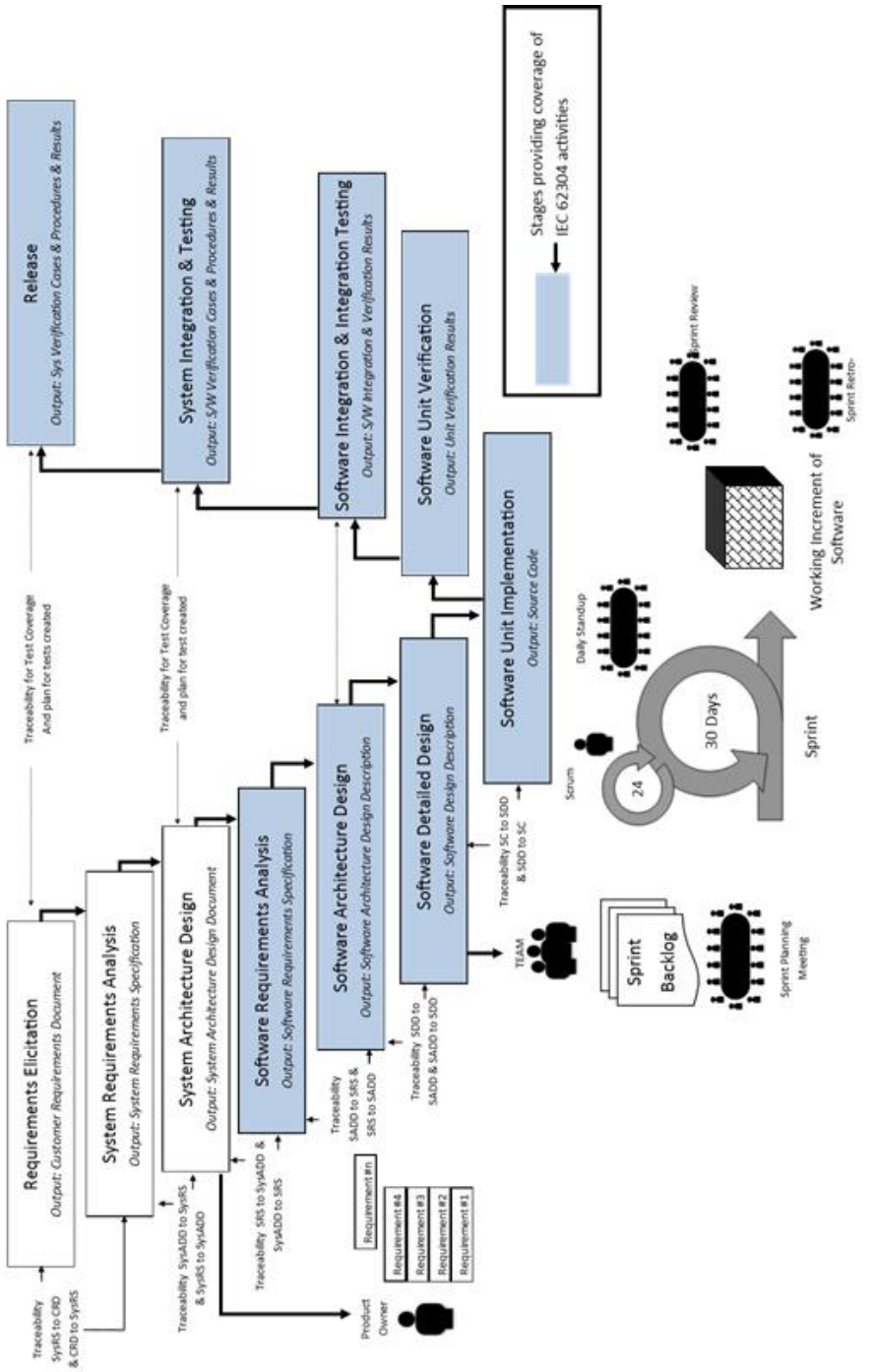

Figure 1 AV-Model for Medical Device Software Development

2.4 Iterative Approach taken by AV-Model

A key component of the AV-Model is iterative software development. This iterative development facilitates changes in requirements at any point in the development life cycle, as no single stage of development is completed until the final requirement is passed through it. Figure 2 shows how a "Proposed System" is divided into a number of "Requirements", which are further sub divided into "Software Items" in accordance with the AV-Model. Once complete, these software items are combined to satisfy the requirement and then the requirements are joined to produce the finished system.

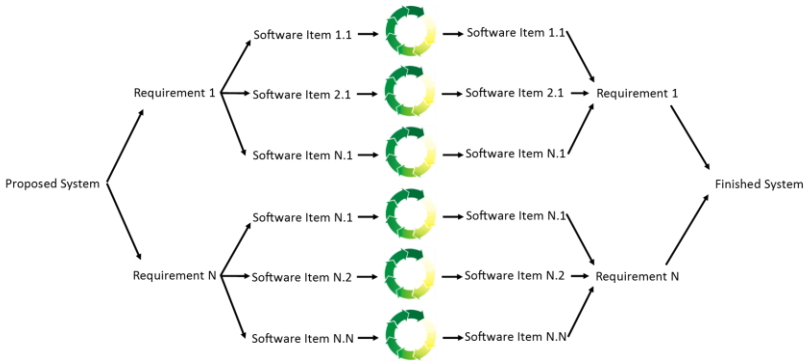

Figure 2 Iterative Approach of AV-Model

Figure 2 would appear to suggest that Requirement 1 is to be developed concurrently with Requirement 2. However, this is not a requirement of the AV-Model. In smaller teams, it may not be possible to be developing a number of Requirements simultaneously. In smaller teams, when developing software in accordance with the AV-Model, once a software item is developed, it is frozen until another software item is finished and ready to be integrated. The same is true of the requirements of the system. Larger teams may be able to develop multiple software items and requirements concurrently. Either form of development is supported by the AV-Model. Figure 3, shows the relationship and activities to be performed at each stage of a development project when following the AV-Model.

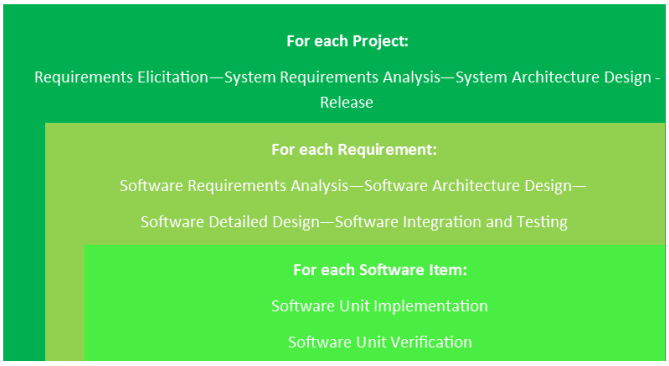

Figure 3 Activities to be performed during AV-Model Implementation

3 Implementation and Validation

A key component of the development of the AV-Model was validation. This validation came in the form of implementation of the AV-Model within a medical device software organisation. This implementation was performed through the use of Action Research (AR). In AR, the researcher works closely with a group of people to establish an improvement path for a given situation. In AR, the researcher does not perform traditional research, instead the researcher acts as facilitator [21].

3.1 Organisation Profile

BlueBridge Technologies (BBT) offer a complete electronics and software development service including design, specification and procurement of the electronics and electro-mechanical systems. They are very strong in analogue and digital hardware and software design. They are highly experienced in design for scalable volume – from low to high volume manufacture. BBT has expertise in circuit design, from architecture, embedded firmware through to schematic capture and PCB layout design and test. BBT are experts in implementing a variety of communications protocols, as well as configuring device drivers. Their broad multidisciplinary team are well placed to develop sensors, both their deployment interfacing and integration and also test and evaluate performance.

3.2 AV-Model Implementation

BBT were awarded the contract to develop a "field use" diagnostics device for the detection and quantitation of antibodies using an enzyme linked immunoassay approach. The technology consists of an electrochemical biochip incorporated into a fluidics device which is covered by a deformable membrane. Upon depression of the membrane at specific loci, sample together with on-chip reagents are transported to a screen printed carbon electrode. A specific reaction then occurs producing an electrochemical signal (current) which is proportional to the concentration of analyte in the sample.

The hand held "reader" component of this technology operates as a standalone unit capable of receiving and interfacing with the credit card size biochip. The product is designed for use by non-technically minded people and therefore the ergonomic considerations are important and a very light Human Machine Interface (HMI) will be critical to the products acceptability and error-free use in the field.

As mentioned, the implementation of the AV-Model was performed through the use of AR. This involved completing 4 activities: *Diagnosing, Planning, Taking Action and Evaluating.* At the diagnosing stage research was performed within the organisation to establish which challenges they wished to resolve through the adoption of the AV-Model. BBT identified that the experience difficulties accommodating changes in requirements when following the V-Model. Once this was established, planning was performed. This planning involved performing training within the organisation. This involved two days of onsite training with the entire organisation.

Once the organisation felt they had acquired the necessary skills, the AV-Model was implemented. During the implementation period the authors performed the role of consultants to the organisation. This involved partaking in the weekly Sprint Review and Retrospective meetings and also being available to answer any queries which arose during when implementation. Finally, at the diagnosing stage an evaluation was performed to establish if adopting the AV-Model, assisted the organisation in overcoming the challenges identified at the diagnosing stage. This evaluation was performed through the use of a Home Ground Analysis (HGA). Two HGA's were performed within the organisation, one prior to implementing the AV-Model [22] and one following implementation. The findings of the initial HGA served as a benchmark which were later used to establish the efficacy of the AV-Model implementation. The initial HGA also served the purpose of establishing whether or not BBT were suited to adopting agile methods. Should the initial HGA have revealed the organisation was rooted in a plan driven approach it may have been beyond the scope of this research to implement the AV-Model. Fortunately, the initial HGA revealed that BBT was equally suited to adopting either a plan driven or agile approach.

3.3 Findings

Figure 4 shows a radar chart plotting the results of the HGA conducted before and after implementing the AV-Model. Since the organisation has implemented the AV-Model, they have succeeded in becoming more agile. Through the process of learning how to adopt the AV-Model, a number of personnel became more familiar and comfortable with agile software development practices. During the implementation of the AV-Model there was a total of 6 requirement changes to be completed. This resulted in 33% of the final project consisting of requirements changes. Prior to implementing the AV-Model, the organisation was very reluctant to introduce any changes once development had begun as they experienced significant impacts on time and budget. Finally, following the development principles of the AV-Model, the percentage of the organisation which thrives on chaos increased significantly.

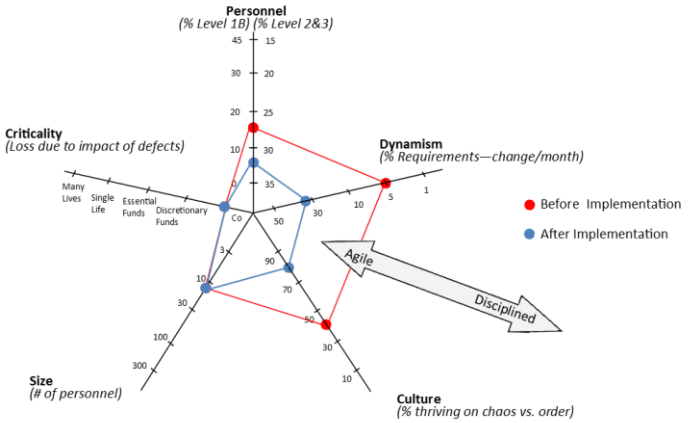

Figure 4 Home Ground Analysis before and after implementation of the AV-Model

To accompany the HGA, key stakeholders within BBT were interviewed once the project was completed. The objective of this interview was to establish if the findings of the stakeholders reflected the statistical data gathered in the HGA. Those involved in the interview were the Marketing Director, the Product Owner and a Software Developer. The interview took a focus group approach where the group was asked a number of questions and those that felt they had relevant input responded.

Q1. Did you perform the same amount of up-front planning when following the AV-Model as you would have when following the V-Model?
Historically, when following the V-Model we would have added an incubation period prior to beginning development. We had this incubation to allow the customer time to fully consider all potential changes in requirements as we know it can be very difficult to introduce a change in requirements when following the V-Model. When following the AV-Model we did not include this incubation period as the AV-Model was advertised as being able to accommodate changes at any point during development.

Q2. Without this incubation period did you miss any potential requirements changes?
The participants confirmed that they did miss three of the changes in requirements i.e. Configure Debugging, Configure Project in IDE and Battery Level Detection. The other three requirements changes i.e. Set/Verify Clocks, Low Power Mode and Flip LCD direction were more subtle changes which would have only been identified once development had begun, regardless of SDLC being followed. However, they did acknowledge that even though they had missed the changes, they found them easy to integrate when following the AV-Model.

Q3. If these changes had been introduced when following the V-Model what the implications would be, with regards to time, rework and cost?
Firstly, the participants noted that while there was 6 requirements changes when following the AV-Model, there would only have been 3 requirements changes when following the V-Model as the other 3 would have been identified during the incubation period which historically precedes implementing the V-Model. Based upon this, the participants confirmed that if they had been following the V-Model and that the changes were identified at week 5 of a 14 week project, they would have been identified at either the “Software Detailed Design” stage or during the “Implementation” stage. As a result, the System Requirements Specification and Software Requirements Analysis documents would be completed. Consequently, to implement the changes identified, all of the preceding stages would need to be revisited and the work completed at each stage updated accordingly. They further explained that this rework would have taken 2 weeks to complete. When considering the implementation of the AV-Model, six requirements changes were introduced. Despite this, the project schedule was not impacted negatively, as the team originally

overestimated the amount of time it would take to address each requirement. Should these 6 requirements changes not have been identified and introduced, the project would have finished approximately 1 week earlier than expected. Therefore, the time spent on introducing the requirements changes as part of this project, when following the AV-Model, was halved compared to following the V-Model. These times solely relate to the development time and do not include the incubation period which would have been included when following the V-Model.

With regards to the cost implications of introducing these changes when following the V-Model, the participants acknowledged that it is hard to quantify however they estimate 15% of the budget would be spent on the necessary rework. As discussed, had there been no changes in requirements, the project would have taken 1 less week to complete with an estimated cost of 7% of the budget being spent on accommodating these changes in requirements.

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Q4. Did your testing process change when following the AV-Model when compared to that of the V-Model?
They confirmed that their testing process had changed, as they had to do more testing as each software item and software requirement had to be tested when it was integrated to ensure compatibility with the other software items and requirements completed previously. However, they did note that even though their testing process changed, there was no time implications as the process of continuous integration ensure all of the integration testing was performed. This continuous integration would not have been performed when following the V-Model as the software system would be developed as a single entity. As a result, they predicted that the time spent testing when following the AV-Model would be very similar to the testing that would have been performed if following the V-Model i.e. testing during continuous integration would take the same amount of time as single phase testing.

Q5. Did following the AV-Model produce the necessary deliverables required as part of IEC 62304?
The participants noted that they were not contractually obliged to followed IEC 62304 on this project however, they did expect at some point the customer would seek regulatory approval for the device in the future, therefore BBT ensured that they produced the requirements as part of IEC 62304. The participants identified that they expected this device to be deemed a Class I device, this meaning they did not need to fully follow IEC 62304. Despite not needing to produce all of the requirements as part of IEC 62304, the AV-Model did provide guidance to meet the requirements which they needed as part of this project

Q6. Was there any business value obtained from implementing the AV-Model?
Historically, when following the V-Model, BBT did not want to see the customer after

development began, as this would typically lead to changes in requirements. They also noted that it can be very hard to impress on the customer the impact these changes can have on budget and time. However, with following the AV-Model, they can now advertise to customers that they can accommodate changes at any point in a software development project at a reduced cost when compared to following the V-Model, feeling this would give them a business advantage over competitors.

4 Conclusions

The AV-Model was developed in response to the recognition that medical device software development organisations are experiencing difficulties when accommodating changes in requirements once the requirements management stage is completed. The AV-Model incorporates agile practices with a traditional plan driven SDLC as a combination of both approaches reaps the benefits associated with adopting agile practices while producing the necessary regulatory deliverables. Once developed, the AV-Model was implemented through AR within a medical device software development organisation to validate its efficacy and to determine if it meets its primary objective i.e. assist medical device software organisations in handling changes in requirements when compared to following a traditional plan driven SDLC. The organisation in which the AV-Model was implemented reported reductions in cost and rework in accommodating changes in requirements when developing medical device software in accordance with the AV-Model, when compared to if they had of been following the traditional V-Model on the same project. In spite of these results, further adoption and analysis of the AV-Model would be useful in determining it's overall effectiveness at assisting medical device software organisations in overcoming the challenges associated with accommodating changes in requirements.

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