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Balancing Agility and Discipline in a Medical Device Software Organisation

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Abstract. Agile development techniques are becoming increasingly popular in the generic software development industry as they appear to offer solutions to the problems associated with following a plan-driven Software Development Life Cycle (SDLC). However, agile methods may not be suited to all industries or organisations. For agile methods to succeed, an organisation must be structured in a way to accommodate agile methods. Medical device software development organisations are bound by regulatory constraints and as a result face challenges when they try to completely follow an agile methodology, but can reap significant benefits by combining both agile and plan-driven SDLC such as the Waterfall or V-Model. This paper presents an analysis of a medical device software development organisation based in Ireland, which is considering moving to agile software development techniques. This includes the performing of a Home-Ground Analysis to determine how agile or disciplined[1] the organisation currently is. Upon completion of the Home-Ground Analysis recommendations were made to the organisation as to how they could tailor their existing structure to better accommodate agile development techniques. These recommendations include adopting agile practices such as self-organising teams to promote a culture of "chaos" within the organisation.

Keywords: Agile, Medical, V-Model, Home-Ground Analysis

1 Introduction

Software developed for medical devices must be developed in accordance with not only a customer's requirements, but also with any regulatory requirements of the region where the device is being marketed. Such regulations place constraints on the methods used by software development organisations when developing regulatory

[1] We use the term "disciplined" to reflect common usage [e.g.24], but this is not to imply that the agile development approach is undisciplined.

compliant software. These regulations dictate the necessary deliverables which must be produced when developing medical device software as the safety of medical device software is determined through the software processes followed during the development [1]. Such required deliverables support the *traceability* of the process.

Software development organisations producing software for use in non-regulated environments are reaping various benefits of utilising agile software development methods [2]. Adopting agile methods can reduce costs, improve time to market and increase quality [3]. Despite these potential benefits, there is still a low adoption rate amongst medical device software organisations [4]. A survey of medical device software organisations highlighted that regulatory controls appear to act as the single biggest barrier to adopting agile practices when developing medical device software [5]. Due to regulatory requirements it can be challenging to apply agile methods such as Scrum and XP [6]. However, in-fact no barriers exist that prevent employing individual agile practices when developing regulatory compliant software [7] .

This paper examines a medical device software development organisation is preparing to employ agile methods. However, before employing these agile techniques a Home-Ground Analysis [8] was performed to determine their current organisational structure. The Home-Ground Analysis examines five critical success factors for adopting agile methods with an organisation.

The remainder of this paper is structured as follows: Section 2 presents research into medical device software development to place this work in context; Section 3 discusses the significance of balancing agility and discipline; Section 4 outlines the analysis performed within a medical device software organisation; Section 5 presents the conclusions and outlines future work for this research.

2 Medical Device Software Development

Medical device software development organisations have two types of customers: end users and regulatory bodies. The regulatory requirements can appear to be restrictive and prevent the adoption of agile methods. However, closer examination of the regulatory requirements and development standards reveal there are no direct barriers to utilising state of the art development techniques such as agile. In fact, the regulations and standards do not mandate the use of a specific software development lifecycle. The Food and Drug Administration (FDA) General Principles of Software Validation (GPSV) [9] states:

"*this guidance does not recommend any specific life cycle model or any specific technique or method"*

The FDA General Controls [10] also states:

"*Although the waterfall model is a useful tool for introducing design controls, its usefulness in practice is limited […] for more complex devices, a concurrent engineering model is more representative of the design processes in use in the industry"*

Concurrent engineering can be defined as *"simultaneous design of a product and all its related processes in a manufacturing system*" [11]. It should be noted, that in

concurrent engineering, concurrency refers to designing with a view to multiple phases and to simultaneous development of components (not to *phase* concurrency).

To accompany these documents IEC 62304:2006 Medical Device Software – Software Lifecycle Processes [12], which is an internationally recognised standard for the development of medical device software, states:

"it is easiest to describe the processes in this standard in a sequence, implying a "waterfall" or "once through" life cycle model. However, other life cycles can also be used."

These statements demonstrate that regulations and standards do not prescribe the use of a specific software development lifecycle. Rather, existing regulations require that the Software Development Life Cycle (SDLC) produces the necessary deliverables related to achieving regulatory compliance, which facilitates the development of safe software.

2.1 The V-Model for Medical Device Software Development

Medical device software is typically developed in accordance with the V-Model [13]. The V-Model is a variation on a sequential model described by Royce which later became known as the Waterfall Model [14] and it identifies that there are different types of testing such as modular testing and integration testing [15]. The V-Model shows the relationship between the two sides of the development process as shown in Figure 1. This relationship is used to determine whether each stage has been completed successfully. If a problem occurs during the verification or validation of any one stage, then the opposite stage on the "V" must be revisited and if necessary reiterated [16]. Essentially, the testing of a product (right-hand side of the V) is planned in parallel with the corresponding phase of development (left-hand side of the V).

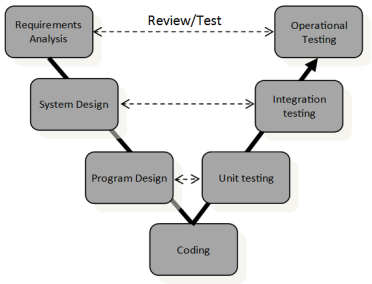

Figure 1 V-Model

The FDA mandates that traceability be an integral part of a development process [17]. While the V-Mode may appear to be a good fit, in practice the V-Model presents the same problems that are associated with utilizing any sequential plan-driven SDLC. For example, as requirements are fixed at an early stage, it can be very challenging to introduce a change in requirements once the project is underway. Also, it can be very difficult to capture all of the requirements at an early stage of a project [18].

Furthermore, any changes introduced once a project is underway can create cost and budget overruns as it requires revisiting earlier stages of the V-Model [19].

As a result of the problems associated with following the V-Model, medical device organisations are looking at the non-regulated software development industry to determine whether lessons learned there can be applied to developing medical device software. As a result, medical device software organisations are examining the possibility of employing agile techniques.

2.2 Using Agile Practices to develop Medical Device Software

As part of our on-going research, a mapping study was performed covering the period between 2002 and 2012 to identify reports of the use of agile methods in medical device software development. This mapping study revealed that there is a relatively low amount of publicly available information detailing the experiences of employing agile practices within medical device software development organisations. However, whilst the information is relatively scarce, a common trend is emerging in the instances where agile has been successfully adopted. In each case the organisations began by attempting to completely adopt an agile method such as Scrum or XP, however they discovered this was not possible and as a resulted tailored their existing plan driven lifecycle to incorporate agile practices [20-22].

Each of the organisations, including, Cochlear [20], Abbott [21] and Medtronic [22] reported significant benefits as a result of incorporating agile practices into their existing SDLC. In October 2012 the Association for the Advancement for Medical Instrumentation (AAMI) produced a guidance document known as AAMI:TIR 45:2012 [23] which maps agile practices to each of the stages of IEC 62304. This document as well as the reported successes from industry strongly suggests that agile practices can be successfully adopted to develop regulatory compliant software.

3 Balancing Agility and Discipline

Some software development organisations seem to be better suited to following agile methods, whereas others seem better suited for plan-driven methods. By determining an organisation's existing structure it can be determined which approach is more suited to the organisation. Table 1 shows circumstances where following agile or plan-driven methods, is most suited. It can be seen from the table that an organisation can be agile in one way but plan-driven in another.

Table 1 Agile and Disciplined Methods Home Ground (Boehm and Turner [24])

Characteristics	**Agile**	**Disciplined / Plan Driven**
Application		
Primary Goals	Rapid value; responding to change	Predictability, stability, high assurance
Size	Smaller teams and projects	Larger teams and projects
Environment	Turbulent; high change; project-focused	Stable; low-change; project/organization focused
Management		
Customer Relations	Dedicated on-site customers; focused on prioritized increments	As-needed customer interactions; focused on contract provisions
Planning & Control	Internalized plans; qualitative control	Documented plans, quantitative control
Communications	Tacit interpersonal knowledge	Explicit documented knowledge
Technical		
Requirements	Prioritized informal stories and test cases; undergoing unforeseeable change	Formalized project, capability, interface, quality, foreseeable evolution requirements
Development	Simple design; short increment; refactoring assumed inexpensive	Extensive design; longer increments; refactoring assumed expensive
Test	Executable test cases define requirements, testing	Documented test plans and procedures
Personnel		
Customers	Dedicated, collocated CRACK* performers	CRACK* performers, not always collocated
Developers	At least 30% full-time Cockburn level 2 and 3 experts; no Level 1B or -1 personnel**	50% Cockburn Level 2 and 3s early; 10% throughout; 30% Level 1B's workable; no Level -1s**
Culture	Comfort and empowerment via many degrees of freedom (thriving on "chaos")	Comfort and empowerment via framework of policies and procedures (thriving on order)
* Collaborative, Representative, Authorized, Committed, Knowledgeable ** These numbers will particularly vary with the complexity of the application		

In Table 1 each of the sections are self-explanatory except for the concept of levels in the Developers section of Personnel. Cockburn categorised personnel based upon a system of levels. He explained the concepts of "Levels" of skill and understanding

required for performing various agile or disciplined functions. Cockburn presented three levels, which were drawn from the three levels of understanding in Aikido (Shu-Ha-Ri) [25]. Shu-Ha-Ri describes the three phases from learning to mastery. Firstly, *becoming proficient* at a task; secondly, when you become proficient at that task you must *make innovations* and finally the actions you perform become natural and no longer are performed following a defined method, i.e., you *become creative* [26].

Boehm and Turner [8] further sub-divided Level 1 into three sub-levels, namely, Level -1, Level 1B and Level 1A, to address some of the distinctions between disciplined and agile methods. Table 2 shows the different levels and the criteria applied to each level.

Table 2 Personnel Levels (Cockburn and Boehm & Turner)

Level	**Criteria**
Level -1	Unable or Unwilling to collaborate or follow shared methods
Level 1B	Hard Working, less experienced, needs structure
Level 1A	Hard Working, less experienced but feels comfortable working in a structured way
Level 2	Functions well in managing small teams in precedent projects
Level 3	Functions well in managing large and small scale teams in unprecedented projects

3.1 Home-Ground Analysis

When examining an organisation's existing structure Boehm and Turner presented five critical decision factors which can be used to determine the relative suitability of agile or disciplined methods in a particular project situation. These five critical success factors are: Size, Criticality, Dynamism, Personnel and Culture.

These five critical decision factors are plotted onto a Polar Graph (or "Radar Chart") (see Figure 2), "Size" and "Criticality" are similar to the factors used by Cockburn [25]. The "Culture" axis is used to plot how much of the organisation thrives on "chaos" and how much thrives on order. "chaos" refers to how empowered and comfortable staff within the organisation feel. If the majority of the organisation thrives on "chaos" then this suggests staff are more suited (and open to) using agile methods. If, on the other hand, they thrive on order then this suggests disciplined methods are more suitable. For the "Dynamism" axis, agile methods can succeed with either a high or low number of changes; however, disciplined methods are more suited for development contexts with relatively few changes. The "Personnel" axis is used to plot the numbers and "Levels" of personnel within the organisation. Disciplined methods can succeed with both high and low skill levels; however, agile methods require a richer mix of higher-level skills [27]. Once an organisation is assessed on each axis, the polar graph can be populated, which provides insights into

whether the organisation is more suitable for agile methods or for disciplined methods.

It is of course possible, if not very likely, that a company is close to the centre in some areas but close to the periphery in others. In such cases, the organisation would benefit from taking elements from both agile and disciplined methods, thereby using a tailored SDLC Also, if a company would rather be more disciplined or agile in a particular section the polar chart can be used to graphically represent the existing structure and recommendations can be made as to how changes can be implemented to achieve the desired structure.

By performing a Home-Ground Analysis a more accurate representation of the organisation can be achieved. An organisation may present itself as rigidly disciplined; however, a Home-Ground Analysis may reveal that it is, in fact, rather agile in specific areas. The Home-Ground Analysis displays an organisation's existing structure which can be used to determine which of the five critical success factors within the organisation need to be modified if the organisation wished to become more agile or disciplined. With regards to the development of medical device software, research has revealed that a combination of both agile and disciplined/plan-driven methods has proven successful [20, 21, 28].

4 Case Study: Agile in Medical Device Software Development

BlueBridge Technologies is a Product and Innovation Service Provider servicing primarily the Life Sciences and Medical Device Industries. One of their core services is regulated software. BlueBridge Technologies has a track record in developing embedded systems across a number of sectors including Automotive, Medical Device and Clean Tech. BlueBridge's roots are based in the development of software for use in the automotive industry. As a result they have vast experience with regulatory constraints and also the safety critical nature of the software which they are developing.

BlueBridge Technologies wishes to develop their software in accordance with state of the art development principles in order to improve time to market, increase efficiency and improve quality for their clients. After performing market research, BlueBridge Technologies concluded that the latest state of the art development techniques involved utilising agile practices in concert/combination with the V-model. However, some of the development team had limited experience in utilising agile techniques. As a consequence, BlueBridge Technologies became involved in the work of the authors in order to implement agile practices successfully as appropriate when developing medical device software. Based upon the findings of the mapping study performed as part of on-going research by the authors, BlueBridge Technologies decided to integrate agile practices with their existing plan driven software development lifecycle. BlueBridge Technologies currently develop software in accordance with the V-Model.

4.1 Home-Ground Analysis

As previously mentioned, the Home-Ground Analysis can provide a clear graphical representation of how agile or disciplined an organisation currently is. As part of the work with BlueBridge Technologies it was decided to perform a Home-Ground Analysis to determine in which areas they are currently disciplined and in which areas they are agile. Once the analysis was complete, specific recommendations were made as to how BlueBridge Technologies can become more agile in areas which are currently disciplined. To perform the Home-Ground Analysis, a series of questions were asked of key stakeholders within the organisation. These questions are shown in table 3 and the results were analysed and a plotted onto the polar chart shown in figure 2.

Table 3 Questions asked as part of Home-Ground Analysis

#	Question	Possible Answers
1.	How many people are employed within your organisation?	0-100
2.	How many of your employees work as part of the development team?	0-100
3.	As a percentage, how much of your development work in a month is spent on accommodating requirements changes?	0% - 100%
4.	Considering each member of your development team, in which of the following categories would you put them?	a. Unable or Unwilling to collaborate or follow shared methods b. Hard Working, less experienced and needs structure c. Hard Working, less experienced but feels comfortable working in a structured way d. Functions well in managing small teams in precedent projects e. Functions well in managing large and small scale teams in unprecedented projects
5.	Should a defect emerge in the software you are developing which of the following could possible occur?	a. Minor – Comfort Only b. Minor loss of funds c. Major loss of funds d. Loss of a single life e. Loss of many lives
6.	What percentage of you organisation is dependent on discipline?	0% - 100%

4.2 Results

Figure 2 shows the results of the Home-Ground Analysis performed on BlueBridge Technologies. It can be seen from the figure that three of the five areas of critical success are located close to the centre (i.e., suitable for agile methods). These areas are the size, criticality of the software being developed and personnel. Agile software development techniques are ideally suited to organisations with small number of personnel or adopting small teams. Performing agile practices such as daily stand up meetings and sprint planning meetings can be difficult to perform with a large number of personnel. To accompany this, while research has shown that agile methods can be used to develop all types of medical device software they are again more suited to the development of software which is less critical [29].

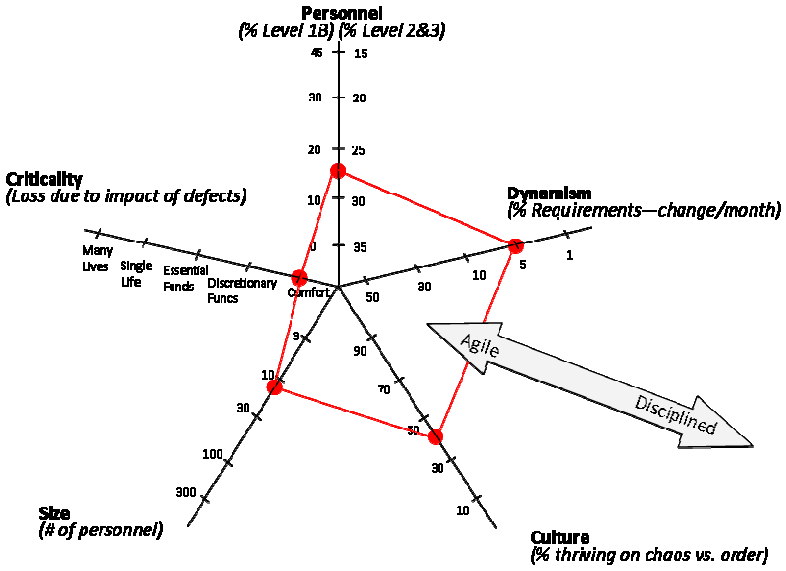

Figure 2 Home-Ground Analysis of BlueBridge Technologies

The result of the analysis shows that the organisation's culture is better suited to disciplined methods as it is located closer to the periphery. Dynamism is located close to the periphery which suggests that agile or disciplined methods can be used.. Agile methods can succeed with either a high or low number of requirements changes per month; however, disciplined methods can have difficulty accommodating changes. This amount of dynamism would work well in either an agile or disciplined methods.

4.3 Discussion

The results of our study show that the organisation is primarily suited to adopting agile methods. An organisation does not have to be suited to agile techniques in each

of the five critical success areas. However, as BlueBridge Technologies wishes to utilise agile practices, two key areas of particular importance in agile development are personnel and culture. In BlueBridge Technologies, culture is currently more suited to disciplined development methods. There is a percentage of the organisation which thrives in "chaos"; however, to be ideally suited to adopting agile methods BlueBridge needs to be located closer to the centre of the polar chart. To improve the level of "chaos", the organisation is advised to increase the level of empowerment of the personnel within the organisation through the use of the agile practice of self-organising teams, by performing planning games and daily stand up meetings. Many of the agile methodologies, such as DSDM and XP, advocate team empowerment.

5 Conclusions and Future Work

Traditionally, medical device software organisations follow a disciplined plan-driven development approach as these approaches produce the necessary deliverables required when seeking regulatory approval. However, there are problems associated with following plan-driven methods such as being inflexible to change. Agile development methods appear to solve the problems associated with following disciplined plan-driven methods. Agile and plan-driven methods are not mutually exclusive. Research has revealed that medical device software organisations can benefit from incorporating agile practices into their plan driven approach. This paper presents research that discusses the use of the Home-Ground Analysis which is used to determine how agile or disciplined an organisation is. Once the level of agility or discipline within an organisation is established, if that organisation wishes to become either more agile or more plan driven, they can clearly see which of the five key critical success areas need to be changed in order to achieve the desired goal.

A medical device software organisation (BlueBridge Technologies), wishes to reap the benefits associated with utilising agile practices. Recommendations have been made as to how they can modify their existing structure to become more suitable for adopting agile development techniques. However, prior to making these recommendations an understanding of how disciplined or agile the organisation currently is, was required. To achieve this, a Home-Ground Analysis was performed. The Home-Ground Analysis revealed that whilst the size of the organisation, the Cockburn Levels of personnel levels and the criticality of the software being developed are suited to employing agile methods, the culture within the organisation is more suited to a disciplined approached. The dynamism of the company would be appropriate for both agile and discipline methods. The Home-Ground Analysis revealed that of the five critical success factors, the organisation is currently suited to agile methods in three of the critical success factors and suited to disciplined methods in one of the critical success factors with the remaining critical success factor currently being suited to either agile or disciplined methods. This current organisational structure could support adopting agile methods.

BlueBridge Technologies is an innovative organisation and there is a percentage of the organisation suited to working in a "chaos" environment; however, for agile methods to be successful BlueBridge Technologies ideally needs to be located closer to the centre of the polar chart. This empowerment can be achieved by employing

techniques such Planning Game, Team Reflections, Co-Located Teams, Daily Stand-Up Meetings and Self Organising teams.

The Home-Ground Analysis performed on BlueBridge Technologies is being used to determine which areas within their organisation need to be modified in order to accommodate agile practices. Once the necessary recommendations i.e. empowering employees, have been implemented a tailored set of agile practices suited to the development of medical device software will be presented to BlueBridge Technologies. By modifying the existing structure to accommodate these agile practices, they will have a greater chance of succeeding and achieving the desired results.

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