Balancing Agility and Discipline in a Medical Device Software Organisation

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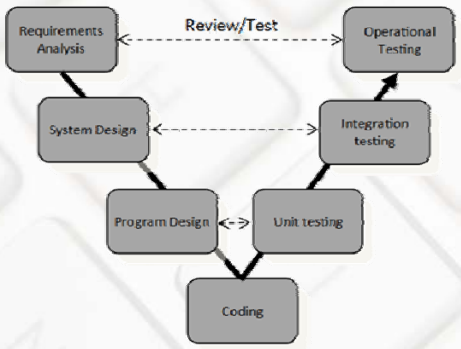
Overview

- Introduction
- V-Model for medical device software development
- Medical Device Software Development
- Agile versus Plan Driven Software Development
- Home-Ground Analysis
- Case Study in BlueBridge Technologies
- Results of Home Ground Analysis
- Conclusion from study

Introduction

- Medical Device Software must be developed in accordance with both a customers requirements and the requirements of regulatory bodies
- Regulatory bodies place some constraints on the methods used to develop medical device software
- Regulatory bodies dictate the necessary deliverables which must be provided when seeking regulatory approval
- Medical Device software is **typically developed in accordance with the V-Model**
- Agile methods are gaining momentum and acceptance in the non-safety critical software development industry
- Agile methods appear to help address some of major problems associated with following a plan driven software development lifecycle
- Medical device software organisation must be structured correctly to reap the benefits of adopting agile methods

V-Model for Medical Device Software Development



- Variation of the Waterfall Model.
- Identifies different stages of testing
- Shows the relationship between different stages of the development process
- This relationship is used to determine if a stage has been completed successfully
- Testing of a product is planned in parallel with the corresponding stage of development
- **Produces necessary deliverables required by regulatory bodies**

Medical Device Software Development

- A perception exists amongst medical device software organisations that international regulations and standards prevent the adoption of agile methods
- No direct barriers exist from regulatory bodies to adopting agile methods
- US FDA General Principals of Software Validation states:
  "this guidance does not recommend any specific life cycle model or any specific technique or method"
- US FDA General Controls 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"
- IEC 62304:2006 Medical device software - Software life cycle processes 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."

Agile -v- Plan Driven B. Boehm and R. Turner

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/organisation 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 requirements evolution
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

Agile and Personnel Levels

Alistair Cockburn , Barry Boehm & Richard 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

Cockburn described these as Levels of skill and understanding required for performing various agile or disciplined functions. Boehm and Turner subdivided Cockburn's Level 1 "Software practitioner looking for a simple procedure to follow" into Level -1, Level 1B and Level 1A

Home-Ground Analysis

- 5 Critical Success Factors
  - Size
    - Size of the organisation
  - Criticality
    - Consequences relating to a failure of the software
  - Dynamism
    - Number of requirements changes introduced in a typical month
  - Personnel
    - Level -1, Level 1b, Level 1a, Level 2 or Level 3
  - Culture
    - How much of the organisation thrives on "Chaos". Chaos refers to how empowered and comfortable staff feel within the organisation

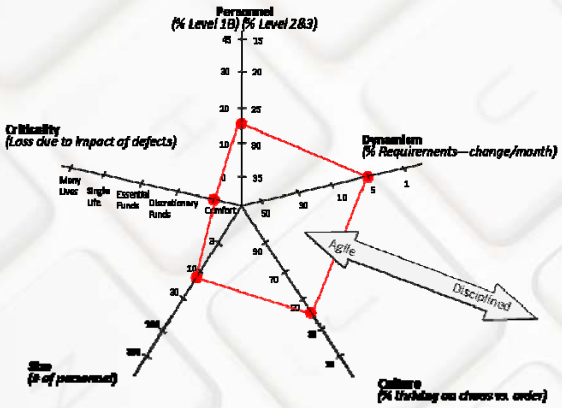
The Case Study

- BlueBridge Technologies is an Irish owned company
- They have a track record in developing embedded systems across a number of sectors including the Automotive and Medical Device domains
- One of their core services is the development of Medical Device Software
- They want to use state of the art software development methods for their medical devices and that involves implementing a hybrid agile and plan driven approach utilising the V model
- They realized that this was a difficult endeavour and they requested assistance from the RSRC to evaluate their company before embarking on this strategy
- To determine their strengths and weaknesses in this context it was decided to perform Home-Ground Analysis which provides a graphical representation of how agile or disciplined an organisation is
- To do this a series of questions were asked of key stakeholders within the organisation and the results were analysed and plotted onto a polar chart

Questions Asked

#	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%

Results Plotted on Polar Chart



- Culture – Suited to Disciplined methods
- Dynamism – Suited to Agile or Disciplined methods
- Personnel – Suited to Agile methods
- Criticality – Suited to Agile methods
- Size – Suited to Agile methods

Conclusions

- To be successful organisations do not have to be suited to agile techniques in all the five critical success areas
- The results of our study showed that Blue Bridge Technologies is primarily suited to adopting agile methods based on positive results from three of the five critical success areas
- Dynamism was rated as close to the periphery which suggests that agile or disciplined methods could be used
- One area which the study identified where BlueBridge Technologies were more suited to disciplined development practices was with regard to Culture
- The organisation was advised to increase the level of empowerment of their personnel to help develop a suitable culture to facilitate the successful implementation of agile methods
- Once this has taken place a tailored set of agile practices suited to the development of medical device software will be presented to BlueBridge Technologies and the RSRC will provide assistance for their implementation

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Questions

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BlueBridge TECHNOLOGIES

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