A Developers Perspective: An Analysis of Processes Involved in Software Development of Health Care Industries

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Abstract - Software is now becoming the primary differentiator for medical devices manufacturer. Software development is driven by the risks, stringent quality requirements (such as safety, reliability), regulatory challenges, market pressures and significant complexity. To balance these, medical device industries need effective software development process to satisfy their client's need. This paper identifies the actual barriers associated with software practices during development of medical software. We have focused on some of the processes such as V-model, agile and formal methods which was currently followed in most industries. We analyzed the strengths and weaknesses of the various approaches employed in medical device software development. A closer examination of these processes indicates that there is a potential demand in the area of process improvement in the field of medical device software.

Keywords- Health care devices, V-Model, SDLC in health care industries

I. INTRODUCTION

Highly regulated industries in globe are pharmaceutical, health care or medical, aerospace and automotive. Global Industry Classification Standard (GICS) categorized health care sector into the following domains

- Category 1: Health care equipment
- Category 2: Health care services
- Category 3: Pharmaceuticals
- Category 4: Biotechnology

Medical devices and Medical device software comes under first and second category. As per CEI/IEC 62304:2006, software life cycle standard, "medical device software is defined as" software system that has been designed and developed and embedded into the medical device or used as a standalone medical device in its own right" [1]. Software will get used as a part of a system (i.e) usually acts as a component. (E.g. pacemakers, Infusion pumps, MRI devices)

The complexity and the content of medical device software is increasing day to-day basis. For e.g. Pace makers and Infusion pumps may have more than million lines of code. In these, the safety and reliability are utmost important. For diagnosis and treatment applications, various medical devices are in use. They actually varies in complexity from insulin pumps, digital thermometer, cardiac monitors ,pacemakers, to ultrasound imaging systems, analyzers, Proton beam therapy systems and nuclear medicine imaging system.

II-ISSUES IN MEDICAL DEVICE S/W DEVELOPMENT

Medical devices usually designed and developed to perform a wide variety of functions. Software, residing in those medical devices will interact with the body and perform several tasks such as monitoring blood flow, heart rate etc and it will assist doctors as far as medications is concerned. People have identified the number of barriers when developing medical device software, by means of conducting research through literary review and questionnaire based survey. The process steps by means of which medical device software has been developed creates heightened challenges to the developer community which was primarily associated with User interface, control, data integrity, data consistency and security.

A. Regulatory Concerns

Software usually will get developed according to customer requirements, but safety critical software such as medical device software must be developed in accordance with the requirements of customer and National /International regulatory constraints are as per the local regional requirements (i.e.) market of the software, whether it may be stand-alone or part of a hardware device [2]. For e.g. If a medical device is to be sold in the United States, it must be developed as per Food and drug administration (FDA) quality regulations and its applicable standards. Like FDA, many international regulations are applicable to the medical device

software development. Guidelines provided by regulatory bodies should be strictly adhered during software development in medical device industries. There is a popular assumption, FDA and other regulatory bodies suggest the usage of specific software process. But in reality, they are not partial to any methodology [3-5].

The guidance of various regulatory bodies states that software developers should establish a software process that is suitable for their product development and industry. The S/w life cycle model should be selected in such a way that it covers software from its birth to its retirement.

1. *Importance Of software development process*

Software life cycle model should identify, organize, establish, manage, and control software development activities and provides a framework for monitoring and controlling the s/w development project [6]. Engineers of developing medical device software have to concentrate heavily on the following activities of software lifecycle process.

2. *Manage Risks associated with the device:*

Risk assessment is really important. It is a central activity in medical devices conception. Risk management specific to software has its own guide (IEC/TR 80002-1) and Risk management has its own standard (ISO 14971).If we don't do this, we may not able to sell it.

3. *Choose a development process:*

The development process is a structure for the entire software development. Either Waterfall or Iterative or Extreme or Formal methods or anything else, the developers should adhere the process [7]. It is an (hidden) expectation of reviewers during certification. The documentation is also important during the process. IEC 62304 standards is the central standard for Software medical devices. It has requirements which can be met only with a good development process.

The remaining portion of this paper is organized into the section showing various process employed in medical device organization globally and its individual merits and demerits .we present and analyze the various software development process followed in an organization. We analyzed the strengths and weaknesses of the various approaches and demonstrated how it can be effectively tailored for their product. Many organizations has employed waterfall approach for the software development for medical device, but resulted in a long time – to-market and a large release overhead which were seen as major drawbacks in the quickly changing market.

III-PROCESSES INVOLVED AND IT'S DEMERITS

Several organizations made a transition from waterfall model to iterative model after few months of development. For instance, Philips Medical Systems Healthcare IT, made an initiative to adopt an iterative development approach combined with best practices of IBM's RUP. Often, Developers, end users, and stakeholders may be in different geographical locations. Hence process need to be organized.

A. *V-Model*

Several organization including, an organization named Roche Molecular System, tailored a process, standard V-model [8], which is actually the enhanced version of Waterfall model. The activities described by this model are as follows:

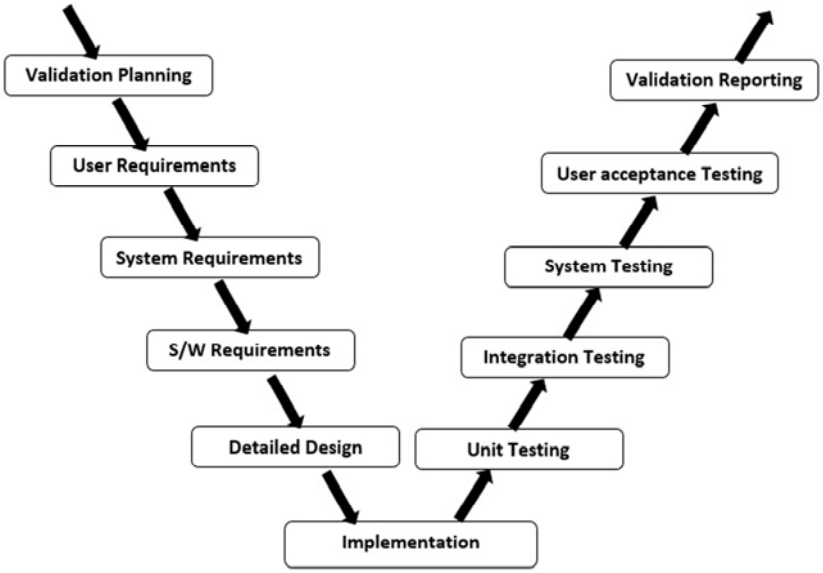

Fig 1. V-Model

In this model, development process starts with gathering customer requirements and then proceed to the creation of detailed design (depicted in the left arm) followed by the actual implementation and then progresses towards the testing (depicted in the right arm).Fig.2 provided the details about the about the deliverables and the way of interaction happen between stakeholders throughout the model.

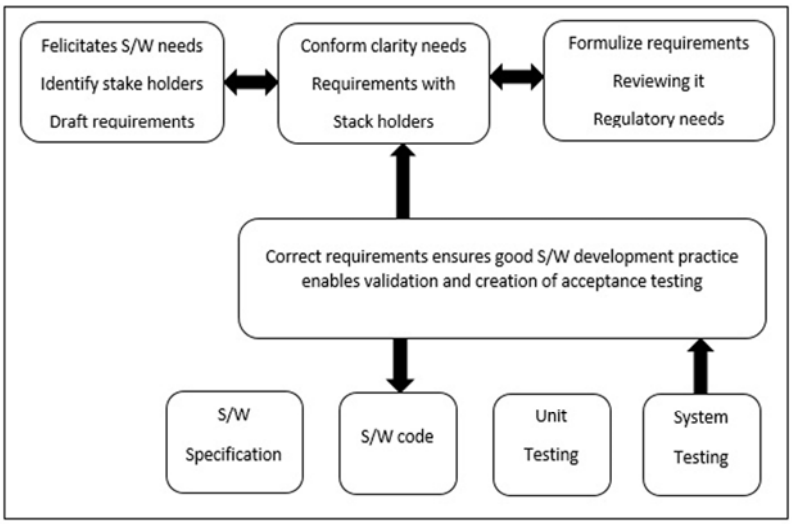

Fig 2. Deliverables

By means of using this V-model as a base and tailoring it, Roche Molecular system developed a basic tool used to support activities in IVD instruments. It comes under "S/w acting as an accessory of a medical device" as described by the FDA regulations. Regulatory control boards, Quality control activities and several functional areas were involved in these kind of project development [9].

B. Challenges

In this environment, the communication risk was very high. In order to avoid potential complexities associated with these models, several mitigation activities were performed such as establishing process in the area of requirements gathering and user acceptance definition. Several measures were also taken by means of conducting weekly meetings, creating prototypes, and interactive discussions. But there was always inherent communication barriers associated with geographically distributed projects and this was evidently seen in these projects. The problems associated with the V-model and the place where it actually occurred is shown in the following table:

TABLE I
Key findings

Characteristics	**Description**
Delays in feedback	Several deliverables had to be reviewed and inspected by various representatives who were in geographically remote locations.
Development Time	Delays will easily creep into the system development process and it generally create impact in the deadlines or milestones.
Communication Tools	Mostly asynchronous tools such as sending messages through email, chat or voice messages .These tools exhibited their limitations. The other communication mechanism requires additional infrastructure and were expensive.
Stakeholder's Involvement	Every stakeholder need to get actively involved in requirement gathering process and continue to be up to final validation. It will be very difficult to achieve.
Change Request	After several months of usage, several change requests was submitted and it is very difficult to incorporate.

C. Agile Practices

Agile methods are being widely used in medical device software development. Agile model is actually a collection of models such as Extreme programming (XP), Scrum, Crystal, Dynamic systems development method (DSDM) ,Agile modeling, Lean software development, and even the Rational unified process(RUP).Out of which, Scrum and Extreme programming is widely used in critical software development such as medical device software. People would like to employ extreme programming combined with plan driven development methodologies.

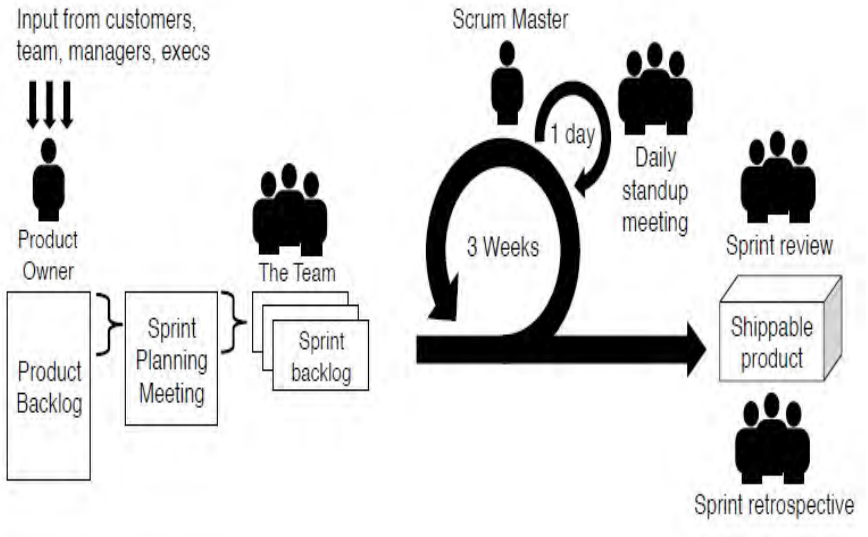

Fig 3. SCRUM

Scrum, the agile model was developed jointly by Sutherland and Schwaber [10] and was evolved into more sophisticated model over the years. Scrum, comprised of iteration of development "SPRINTS" with an initial planning phase and a final closure phase of Sprint review and retrospective. In planning, scope and architectural concerns will get addressed and release management will be included as a closure phase. There is strong evidence on the Scrum that it enables the development team to react and promote changes throughout the project. The activities described by Scrum model are depicted in the following figure:

D. Models for adopting Agile

Stephenson, McDermid and ward [11] tailored agile practices and produced model for the development of regulated systems. This model was originally called as 'Agile Health Model". It provides only the possibility of applying agile practices into safety critical projects. Paige et.al combined agile and safety principles and concentrated on the following ideas: pair programming of software and system Engineers, risk management techniques, tools for generating documents, pipelined iterations [12]. Several case studies proved the presence of risks when applying agile practices into medical device software development.

E. Challenges

Even though the regulatory bodies and medical device software development standards do not dictate the usage of software development life cycle, but they suggested a set of deliverables which device manufacturers must produce. No single agile methodology is suitable for developing medical device software and provides sufficient coverage areas necessary to achieve regulatory conformance [13-15].Software developers can follow agile practices if it produces the necessary deliverables for the medical device development. The potential problems associated with the agile model and its presence is indicated in the following table:

TABLE II
Key findings

Characteristics	Description
Stakeholder Involvement	There will be always a need to interact with every group of stakeholders. It is very difficult to perform since we need to consider external certification regulatory organization. Contact with domain experts and users are very crucial.
Requirement Analysis	Identification of requirements will get performed in product backlog, sprints plan phases of Scrum and while writing user stories in the planning phase of XP.But these activities usually resulted in the ambiguous, incomplete requirements.
Traceability	Agile always inhibits traceability. Powerful toolset needed to perform it.
Safety and Security	Lack of formal planning and risk mitigation occurs in agile methods.
Technology and Architecture	Lack of architecture plan, Lack of crucial implementation decisions**.**
Documentation	Lack of Documentation usually occurs. Agile development concentrates and recommends conversation than producing documents. But regulatory bodies require a certain level of documentation as far as medical device software development is concerned.
Testing	Incomplete test plan usually emerge and there will be low coverage in unit testing and acceptance testing. Extensive testing is important but no opportunity here to perform such testing.
Effectiveness	Compliance with regulation and standards slows down development process and development speed.

F. Formal Methods

Formal methods were defined as "Method of developing software systems using mathematically based languages, techniques and tools. Mathematical concepts were used in creating specification and verification of software systems" [16]. Furthermore, it will be more suitable for systems where high degree of reliability and correctness are mandatory. Medical device software systems need such high degree of reliability and even correctness proof is the desired one in these systems. Various regulatory bodies now started to recognize that formal methods may be appropriate and effective method in building confidence in a design. Formal methods are not followed frequently, because the required level of commitment by the practitioners will be very high and only few will have the awareness about the concepts of the formal method model. Hewlett-Packard ,Waltham and HP,Bristol developed medical equipment –AIB(Analytic Information Base),a real time database for collection of data from medical devices using formal methods [17].

The level of formal methods applied in the specification and design phases of software development. It resulted in outcome such as error free code from formal method specification. Hewlett Packard, McMinnville and HP, Bristol developed another equipment, Defibrillator, a medical instruments control system. They applied formal specification for their development and it resulted in defect free code during test. They actually developed in accordance with FDA regulations [18].

1. Challenges

Even though, there is a strong evidence showing the usage formal methods applied in safety critical software such as avionics software, signaling software ,spacecraft, only few attempts have been made in medical device software development. Formal method does not evolve into common practicing usage by the software Engineering community. The following are commonly recognized reasons for it.

- Discrete Mathematics skills are required to apply formal methods.
- Time consuming.
- Tools are needed, but awkward, buggy tools only available.
- Experts needed
- Expensive

G. Adoption of Processes

Software plays a crucial role in medical device development and medical device regulations. Software makes medical device systems, a complex one. However, complexity makes strict adherence to well defined and documented processes, a mandatory one. It is one of the desired characteristics in the medical device software development. Regulatory bodies such as Food and Drug Administration(FDA)(FDA/CDRH 2005;FDA Regulations 2006,FDA/CDRH 1999)(US requirement)and the European Commission under its medical Device

Directives(MDD)(European Council 1993)(CE marketing requirement) must provide compliance and approved if medical devices are to be marketed. Medical device companies must produce a design history file which describes about the various software components and processes followed on during the development of their products [19] [3-6].

The biggest challenge in medical device development is to develop a medical software product in a cost effective manner as well as meeting FDA and international regulatory regulations. Choosing a good Software Development process and placing a quality system in place are the most important tasks need to be performed by the companies.

IV. CONCLUSION

If Software development process is not properly chosen it may not be possible to meet the customer expectation with the rigor and security required while making a product as well as Extra cost will get incurred and project completion will get delayed. Rejected submission could occur, that will lead to further cost and delays. The choice of selection of a process will play a major role in the medical device software development. Development process seems overwhelming in these industries. There is a need for an effective, flexible, continuously evolving, easily tailorable process in this domain. Researchers have an opportunity to deliver development process that develops reliable and flexible system.

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