WHITE PAPER

EMBRACING AGILE PRACTICES IN MEDICAL DEVICE SOFTWARE DEVELOPMENT

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Agile as a development methodology has been there for over two decades. It has been prevalent in non-regulated industries such as e-commerce, retail etc., but the medical device industry has been cautious in embracing this methodology. This article explores the ways of implementing an agile methodology for developing medical device software through a defined framework. This framework provides guidance on agile implementation, coupled with information on abiding by stipulated regulations which are critical to meet the objectives of regulatory compliance and patient safety.

Benefits of Agile

In today's highly competitive world, organizations whose products make it to the market early have a high chance to capture the market share. Agile ways of working pave the way to get to market swiftly and thereby provide the device manufacturer with early mover advantages.

Agile emphasizes frequent development and testing cycles. This enables early defect detection and fixing of issues, thereby leading to improved product quality.

End users get to see interim versions of the product at regular intervals and can provide instant feedback and thereby be confident of product usability.

New product development exposes new risk areas which are addressed better by following agile methods. As risks are identified at a feature level, implementation of risk mitigation actions and continuous feedback on the same by end-users help in making the feature and eventually the overall product more robust.

Adoption Challenges

Despite the benefits, there are some challenges in adopting agile by many medical device companies.

There is a natural resistance among medical device software developers to switch from the de facto waterfall methodology to agile. This can also be due to the inherent culture within the organization wherein the senior management itself is not willing to try and adapt to new methodologies. Changing the way an organization operates is always difficult.

There is a belief in the industry that, since medical devices need to be safe, effective, and reliable, the agile methodology does not have sufficient rigor to be used in these critical systems to ensure regulatory compliance.

In case of a medical device with embedded software, medical device developers have a perception that it may not be feasible to use agile methods to develop the software component, as the hardware component cannot be turned around as quickly as the software.

AAMI TIR45

All the above factors reflect lack of proper interpretation of agile. In fact, none of the regulations or standards, mandate any methodology to develop the medical device software. To address these industry concerns, a committee of industry leaders came up with AAMI-TIR45 in the year 2012 which acts as a guide for software-based medical device development.

AAMI TIR45 and Agile Manifesto

Product quality is one of the key tenets of regulation in the LS Industry. Agile methodology also emphasizes building quality into the product. Thus, the vision of regulation and agile converge at this point of building high-quality software. The interpretation of values of Agile Manifesto from AAMI TIR45 perspective is as below.

- **Individuals vs processes and tools**

  The existence of processes and tools cannot ensure success by themselves. The constant emphasis on safety and risk aspects through backlog prioritization, retrospections, and planning practices help in achieving this value of the Agile Manifesto.

- **Functioning software vs elaborate documentation**

  Development teams need to produce documentation which can be valuable for themselves and for regulatory personnel. The documentation is continuously evolving rather than being a one-time update. Continuous integration, deployment, and testing practices are the key to a good quality working software.

- **Rigorous change control system vs planning**

  Apart from good planning practices, establishing a robust change management system is a crucial factor in effectively managing the ability to change quickly to align with the requirement.

- **Collaboration with Client vs Contractual agreement**

  Collaboration with client (especially product owner) on a regular basis is critical to the success of agile projects. Continuous focus on achieving "DONE" criteria is the key.

AAMI TIR45 and IEC 62304 Alignment

IEC 62304 is an international standard on medical device software lifecycle processes, and it is accepted by most global regulatory bodies including the FDA.

The below snapshot (Fig 1) depicts the alignment of AAMI TIR45 with IEC 62304(Till Design Verification).

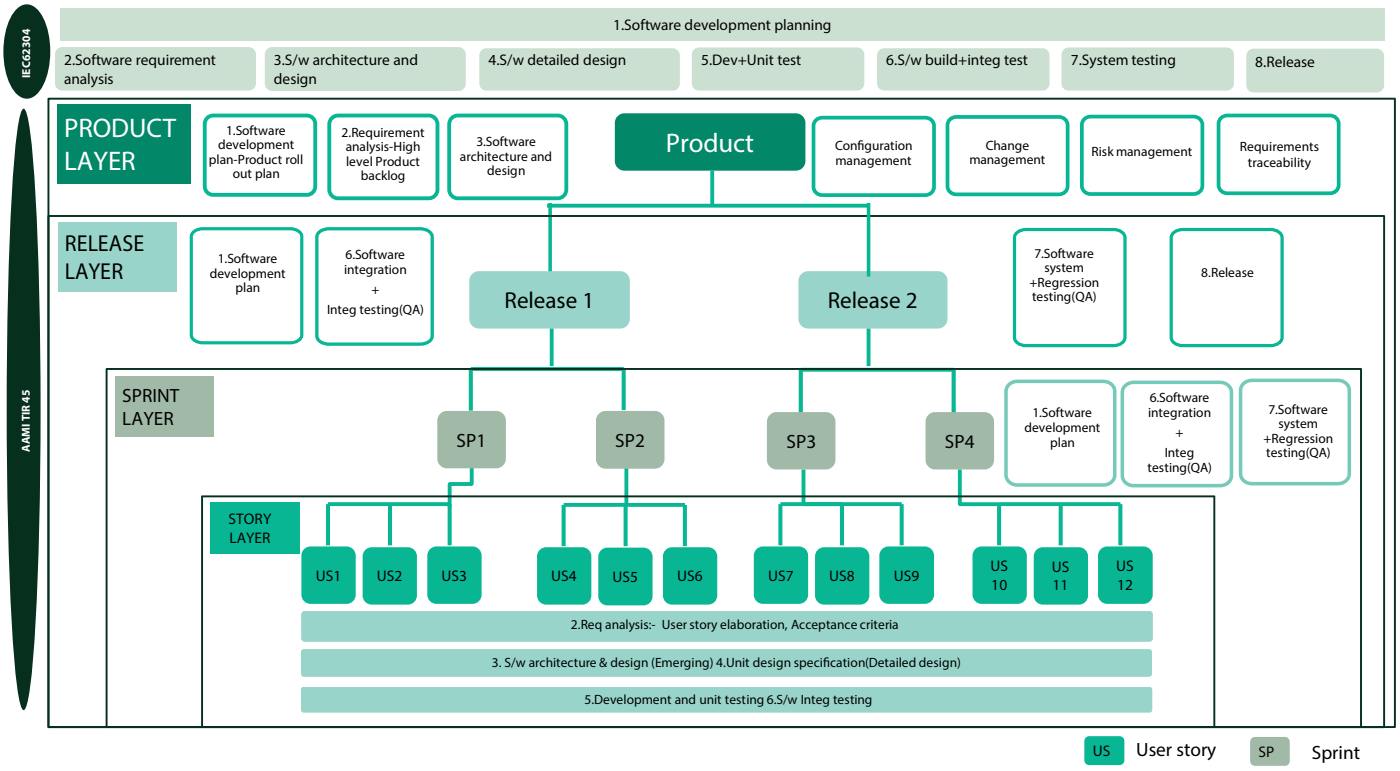

Fig 1. AAMI TIR45 aligned with IEC62304(Till Design Verification)

As per AAMI-TIR45 the design controls are organized across multiple layers as below

- Story layer is for the development of identified requirements
- Sprint layer is a culmination of multiple user stories
- Release layer consists of multiple sprints
- Product/Project layer consists of multiple releases

Processes such as configuration management, change management, risk management etc., deliverables such as risk register, requirement traceability, etc. are continuous in nature and are executed across the product life cycle.

Each sprint has multiple user stories to be developed. Various activities have to be accomplished to consider the user stories as "Ready" to move into the development phase. The phase that deals with the completion of prerequisite activities for the user story development is known as Definition of Ready (DOR) phase.

Once the user stories are ready, they are followed by design & development activities. The phase which confirms the completion of all the defined design & development activities is known as Definition of Done (DOD) phase. Continuous integration, continuous review, and testing practices ensure the required output quality prior to the start of SIT.

The entire sprint would be assessed for ensuring the proper functioning of the software in line with the requirements, which is done in the System Integration Test (SIT) phase. Formal milestone reviews are planned at sprint and release levels, thus satisfying the regulatory requirements.

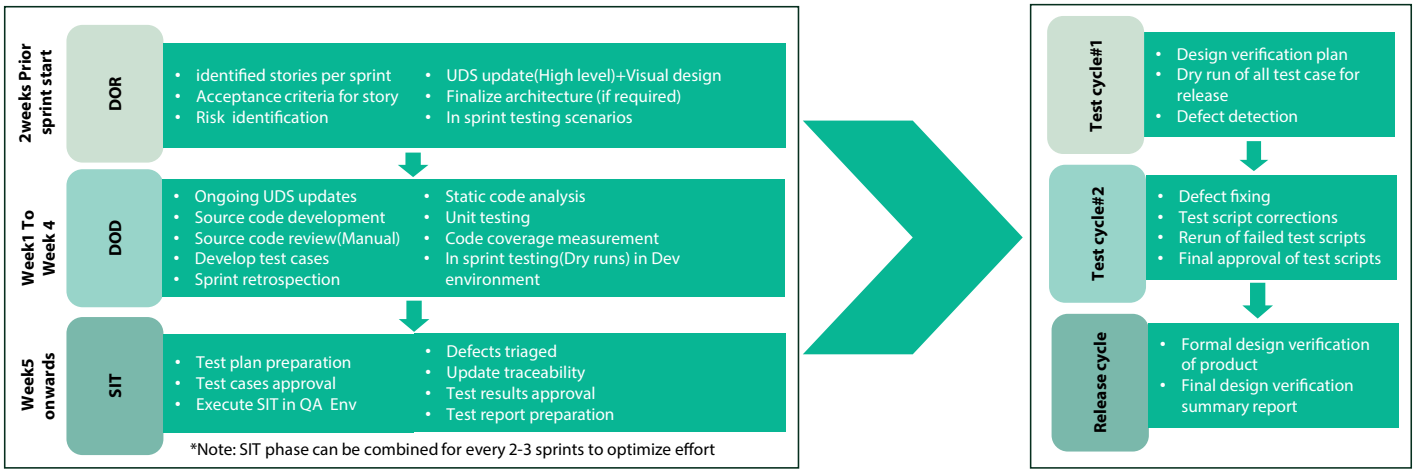

Fig2 Proposed agile framework

Agile Approach for Embedded Software in Medical Device

So far, the framework for leveraging agile methodology for developing a software-only medical device product was discussed. In the following section, a hybrid agile workflow for developing embedded software (e.g., Software-in-a-Medical Device) is presented. The non-software components (mechanical and electrical) are developed following the standard waterfall methodology, while the software component is developed using the agile methodology. At a logical point, all the components are integrated and tested to get feedback on the overall product functionality. Verification/Validation of the entire unit is done together to ensure the implementation of all requirements into the product.

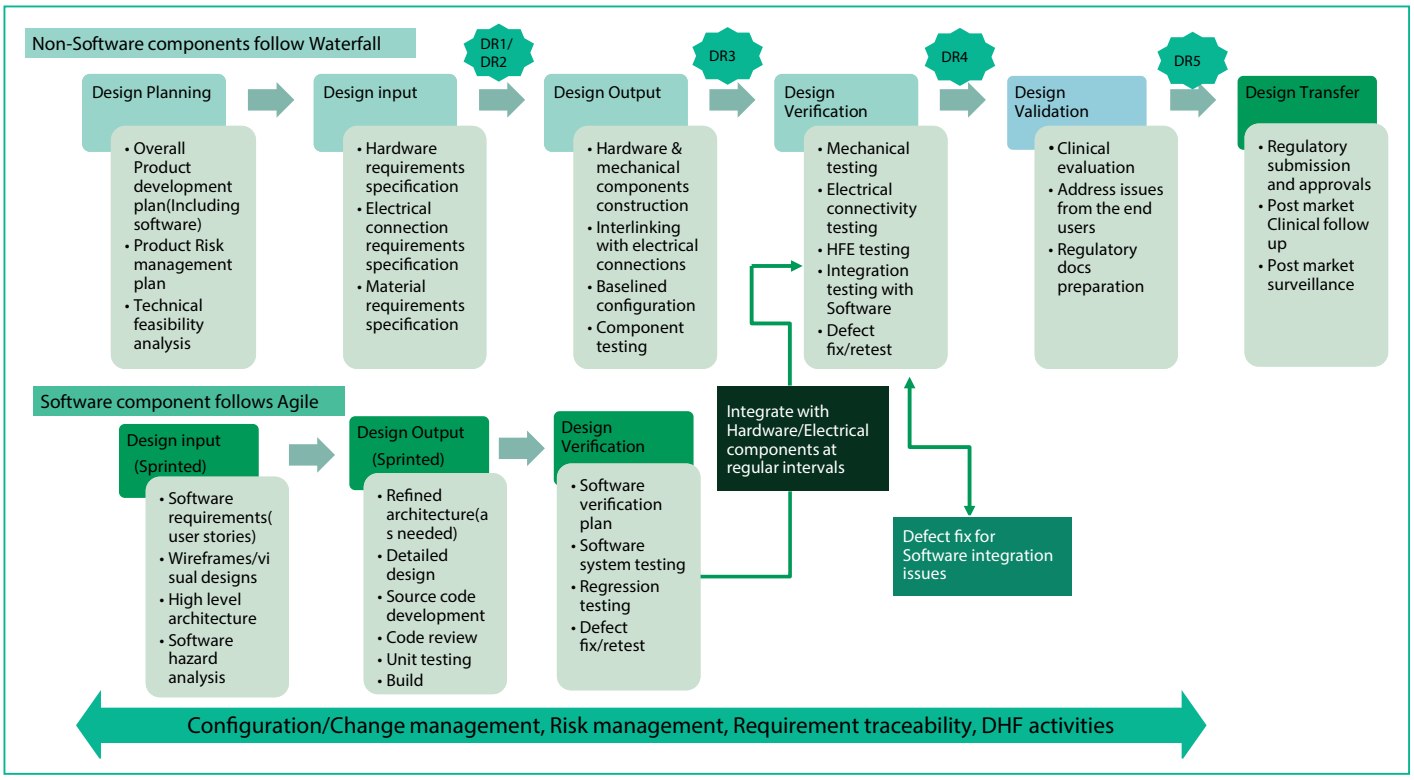

Fig 3. Hybrid agile framework for Software-in-a-Medical Device (embedded software)

Final thoughts

Agile methodology is a key differentiator when it comes to the speed of delivery and improved product quality. Through this article, the framework to use an agile methodology to develop software for a medical device is presented, which should enable faster product development and also meet all the necessary regulatory compliance requirements. It is in the best interest of the medical device industry to adapt agile methodology in software development to reap its benefits and serve the needs of the patient community faster.

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