Validation using Agile in the Life Sciences and Health Care Industry

The Life Science and Health Care Industry (LSHC) has always been in the lime light for its strict regulations. Though these regulations are cumbersome, they are deemed necessary in order to comply with patient safety and product quality. In line with the strict regulations, the traditional Waterfall Method was always used in Software Development in LSHC industry.

In recent years, the aspect of being cost –effective whilst not deviating from the regulatory framework has been repeatedly discussed.

The advent of Agile Methodology has disrupted the traditional development methods with its clear focus on continuous development, agility and over all "lean" concept.

"Agile" was introduced as a means to tackle the limitations in Waterfall and other traditional development methodologies by concentrating on continuous improvement and conducting tests in smaller iterations, all the while not compromising on the development quality of a product.
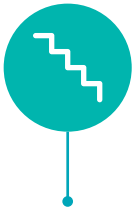
The question then raised by experts was:

"Can agile work in regulated environments where the primary focus is not speed but compliance with a strong focus on product quality and patient safety?"

What is Agile?

Agile is a process by which a team can manage a project by breaking it up into several stages and involving constant collaboration with the customer and continuous improvement and iteration at every stage. The Agile methodology begins with customers describing how the end product will be used and what problem it will solve. This clarifies the customer's expectations to the project team. Once the work begins, teams cycle through a process of planning, executing, and evaluating — which might just change the final deliverable to fit the customer's needs better. Continuous collaboration is key, both among team members and with project stakeholders, to make fully-informed decisions. Adopting the agile validation approach in different verticals such as ERP systems, Digital Health Applications, Software as a Service or even Software as a Medical Device, has proven to work with the end product quality and patient safety not compromised.

Agile vs Waterfall

A quick glance at key differences between Waterfall and Agile indicates why Agile has gained popularity in the recent times.

Waterfall	Agile
The software development process is split into separate phases	Agile methodology separates the project development life cycle into sprints
All stages of project development, such as design, implementation, testing, etc., are finished once, at the same time	Agile follows an iterative development strategy. As a consequence, planning, development, prototyping, and other stages of software development can occur over the entire SDLC more than once
In the Waterfall mode, the "Testing" phase follows the "Build" stage	Agile methodology, testing typically takes place at the same time as programming or at least in the same iteration as programming
Waterfall methodology doesn't involve a great deal of customer involvement	Agile software development focuses on customer satisfaction and therefore includes customer involvement throughout the development phase
Waterfall methodology leans more towards a single structured development process	Agile methodology is flexible and can be tailored to fit individual projects

What are the advantages of Agile?

Additionally, the agile methodology has many benefits including the following:

- It detects issues faster and isolates defects.

- It is very flexible and easily incorporates changes.

- It reduces workload by offering a more streamlined and lean framework.

- It minimises resources hence reducing waste.

- It offers faster turnaround times.

- It reduces the overall time and money spent on a project.

What does FDA says about agile validation?

Life Sciences organisations are continuously concentrating on attempting to develop, update and enhance their processes in order to align their services with the changing trends in technology. The endorsement of regulatory authorities such as the FDA on agile has boosted the use of the Agile Methodology for software developed in the Life Sciences industry.

- FDA does not prescribe waterfall and in fact acknowledges Agile as a Consensus Standard[5; 2].

- Despite the barriers to agile adoption, several LSHC organisations in the industry

recognised the value of agile and have adapted the methodology in accordance with the laws of applicable standards and guidelines used to develop and launch Regulatory Authority's approved products.

- To provide clarity and guidance on the conceptual and practical alignment of Agile – Association of the Advancement of Medical Instrumentation (AAMI) Medical Device Software Committee formed the Agile Software Task Group which produced AAMI TIR45: 2012, Guidance on the use of AGILE practices in the development of medical device software.[5]

- AAMI TIR45 includes a number of main topics, including documentation, evolutionary design, architecture, traceability, verification and validation, management of changes and criteria for "done."

- AAMI TIR45 was acknowledged by the FDA in January 2013. This served to provide clarity and guidance on mapping agile procedures to regulatory demands and to ensure that the Agile approach can be aligned and used to create compliance software for medical devices.

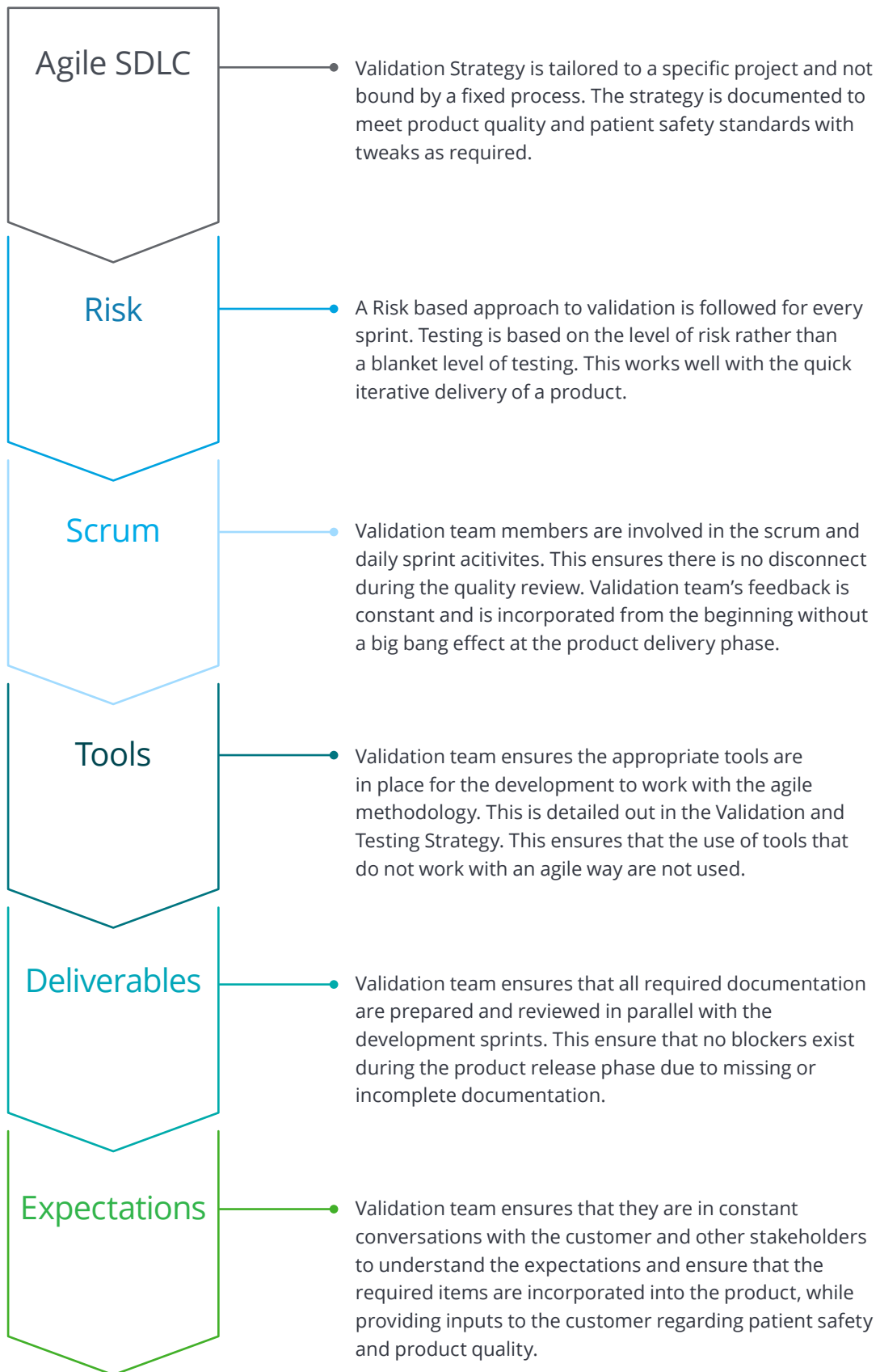## Does CSV (Computerised System Validation) using agile work in the LSHC Industry?

The answer based on our experience is yes, albeit certain pre-requsites (see below) are

necessary in order for agile to seamlessly work in regulated environment.

01. There is clear framework which ensures that consistent and repeatable activities are performed during each life cycle phase.
02. Determine the level of Risk. The level of effort, formality and documentation is commensurate with the level of risk.
03. Customers engaged in developing and/or implementing systems should understand agile principles and consistently use an agile approach.
04. Compliance team input and feedback is provided in real- time during the sprint process and review should be an ongoing activity,
05. Documentation which serves as objective evidence should be determined early on and communicated. Agile doesn't mean no documentation.
06. Use Industry accepted tools that ensure the burden of documentation is minimised. Maximise the use of validated applications/qualified tools and automation.

Additional Success Factors for Agile Implementation in CSV

Based on our experience, the following are key items that can be used as a reference for validation in an agile environment.

Agile SDLC

Validation Strategy is tailored to a specific project and not bound by a fixed process. The strategy is documented to meet product quality and patient safety standards with tweaks as required.

Risk

A Risk based approach to validation is followed for every sprint. Testing is based on the level of risk rather than a blanket level of testing. This works well with the quick iterative delivery of a product.

Scrum

Validation team members are involved in the scrum and daily sprint acitivites. This ensures there is no disconnect during the quality review. Validation team's feedback is constant and is incorporated from the beginning without a big bang effect at the product delivery phase.

Tools

Validation team ensures the appropriate tools are in place for the development to work with the agile methodology. This is detailed out in the Validation and Testing Strategy. This ensures that the use of tools that do not work with an agile way are not used.

Deliverables

Validation team ensures that all required documentation are prepared and reviewed in parallel with the development sprints. This ensure that no blockers exist during the product release phase due to missing or incomplete documentation.

Expectations

Validation team ensures that they are in constant conversations with the customer and other stakeholders to understand the expectations and ensure that the required items are incorporated into the product, while providing inputs to the customer regarding patient safety and product quality.

FAQ

What about implementing Agile in a traditionally Waterfall Based Environment?

This is one of the most commonly raised questions by LSHC organisations who are trying to move to Agile while in the middle of a Waterfall based project.

The primary issue in this situation is not the documentation or the testing, it's the mindset of the team. Agile and its benefits need to be inculcated in to the teams through workshops. A phased changeover, beginning with division of release times into phases instead of a big bang release is a good place to start. A phased changeover is recommended instead of an abrupt one. In short, start with a hybrid Waterfall-Agile working methodology.

For example, start with testing in cycles. Once this has been established, incorporate documentation to be completed into the testing cycles compared to the big bang at the end. Introduce agile-centric tools over the course of the project. When enough confidence in the way of working has been achieved, a complete change over to an end-to-end agile way of working can be established.

Do I have to use specific Tools?

It is challenging to implement agile while using legacy tools or a paper based way of working. Visual representation of the status of the project at all times to the members in the core team is critical for seamless functioning.

Can I use automation in Agile Projects?

The answer is an absolute yes. In fact, Agile works best with automation. This is due to Agile's focus on Continuous Integration/Continuous Development. The catch is that the qualification of any and all automation tools frameworks is mandatory for use in a regulated environment. There are many such tools available in the market currently.

Does agile work while working remotely?

In the current COVID19 crisis, the importance of ability to work remotely has never been more emphasised. To begin with, agile works efficiently with teams spread across the world, in different time zones. The use of tools such as JIRA, Zoom, Teams, and BitBucket enables contemperous working on development activities by all the team members and stakeholders. In our experience as CSV practitioners, the transition to working remote in the current circumstances has been relatively smooth due to the foundation established by the inherent agile way of working, specifically how agile allows flexibility during the delivery of a project. The limitations while working remotely can be addressed by tailoring the activities and deliverables to a new "fit". The answer is therefore yes, agile works even while working remote.

Conclusion

As the FDA, IEC 623304 (Lifecycle Requirements for Medical Device Software) and other regulatory standards do not specifically mention or enforce the use of a specific software development lifecycle in the healthcare industry; Agile can be adopted to deliver CSV activities in a regulated environment, all the while meeting product quality and patient safety requirements. There have been and will always be unknown risks at the initial stage of projects. Agile is the ideal choice to be used for such projects as it will help cater to the unexpected changes in subsequent iterations or sprints.

Life Sciences organisations should incorporate Agile Methodology to refine the quality of the software and continuously improve their processes[2]. As Agile allows to incorporate feedback during the entire process, it provides an opportunity to check the progress at regular intervals with quality embedded throughout. Agile focuses on aligning the final product more accurately with the customer's needs without compromising product quality, patient safety and data integrity.

How Deloitte helps in Agile in Validation?

Deloitte has a trained and experienced CSV (Computerised System Validation) team providing services to Life Sciences and Health Care (LSHC) customers. Deloitte CSV team is trained and experienced in implementing agile methodology in a regulated environment. The CSV team is heavily involved in validating numerous digital health applications, Software as medical Devices, Patient Management tools and Enterprise Resource Planning (ERP) Solutions such as SAP. The team also assist customers in implementing the latest regulations in IT systems such as GDPR (General Data Protection Regulation) and Serialisation.

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