

Agile/Scrum Adoption in Regulated Industries



Introduction

According to the 2013 State-of-Scrum Report, Agile/Scrum is being practiced in 33% of highly regulated industries like finance, healthcare, insurance and aerospace. This paper will discuss the business problem, how Agile/Scrum works, commonalities, and the pros and cons to applying Agile/Scrum to a regulated environment.

The Business Problem

In order for companies in highly regulated industries to remain competitive and successful they need to operate in a transparent environment which values collaboration, frequent inspection and quick adaptation to change, leading to self-organising and self-managing highly motivated teams. The Scrum naysayers view the Scrum methodology as having little structure or discipline while promoting people over process, forgoing documentation for working software, valuing collaboration (the spoken word) over contracts (the written word), and promoting being nimble and quick over following a plan for the plan's sake. The Waterfall methodology no longer works in a world of constant change. The ability to decrease time to market is critical. The frequency of regulation changes, the increased focus on testing documentation for auditors, and the constant pressure from clients to deliver faster and more often makes a strong case for adopting Scrum in a regulated environment.

Background

The goal of Scrum is to respond quickly and flexibly to changes in requirements during the project without sacrificing quality, cost control, and especially user requirements. A couple of key results of implementing Agile/Scrum are customer satisfaction and business success. These results are achieved by implementing the Agile Manifesto for Software Development. The Agile Manifesto was created in 2001 in Utah by 17 developers who met to discuss lightweight development methodologies.

rigorous documentation is key and management chaos cannot ensue. It did not happen if it is not documented and time to market remains critical. All statements in the Manifesto are required on both sides of the statement. In a regulated environment, it is very important that due diligence be applied to the right side of the Manifesto. Keying in on collaboration and people allows for a truly self-organised and self-managed, cross-functional team to form.



Agile Scrum Methodology

Role definition and the cadence of Scrum rituals are essential, supported by an SDLC that enforces a rigorous change management process. The primary roles are: product owner (PO), scrum master (SM), business analyst (BA), technical manager (TM) test lead and core project team (CPT) including

Individuals and interaction	OVER	Processes and tools
Working software	OVER	Comprehensive documentation
Customer collaboration	OVER	Contract negotiation
Responding to change	OVER	Following a plan

That is, while there is value on the right, we value the items on the left more.

Since 2001, the Scrum Methodology has been the most widely adopted of the Agile toolset. This paper will focus primarily on Scrum.

When an organisation makes the decision to adopt Scrum, most team members think no documentation, manage as we want and how we want. As we know, in a regulated environment

developers, technical managers/system architects, testers, Scrum master, and business analyst. An ideal team consists of 7-9 people. The quality assurance (QA) role works incrementally in each iteration with the team.

The PO is responsible for the product ROI and release content. The SM manages the release project, creates the release plan with the CPT, helps the CPT to get their work done through disabling barriers, and acts as liaison to the PO and TM. The BA drafts use cases and requirements. The TM works closely with

the PO and SM to ensure all technical issues are resolved and to direct the development team as needed. The test lead creates test strategy. The core team designs, codes, tests, and builds the software increments. The QA role ensures product quality and auditability.

The Scrum rituals are as follows: daily stand up, backlog grooming, iteration planning, showcase and retrospective. In the daily stand up, the team members exchange information while answering three questions; what did I do yesterday, what will I do today, and identify impediments to the work in the current iteration. This is not a status to the Scrum master; it is an update to the team and promotes team collaboration. The burn down chart is displayed in the stand up, focusing the team on the remaining work in the iteration. Emphasis is on remaining work, not completed work.

The backlog grooming is owned by the PO. The backlog, use cases/user stories, change requests and bugs, are reviewed and prioritised by the PO with input from the TM as to technical sequencing. This enables feature sets to be completed, where requirements are known without waiting for all requirements to be known. Quality is ensured by continuous regression testing and integration testing as new feature sets are added.

Iteration planning is a review of the work the team will accept into the iteration. A typical iteration is usually two to four weeks. At this point, the level of design is such that the team velocity is confirmed. Upon completion of iteration planning, the team should be able to create tasks, which will enable them to complete the iteration work in accordance with the team’s Definition of Done, which is an agreement, set up front, between the CPT and the PO.

The showcase demonstrates the completed work to

stakeholders, subject matter experts (SMEs), end users and/or business users. A showcase is performed to take early feedback, to reduce last-minute surprises, and to validate that the product development team is building the right product. This is the benefit of frequently inspecting and adapting. Necessary changes to ensure client satisfaction can occur often and quickly.

Lastly, the retrospective is just that – the team looking inward. It is a time for the team to identify those items that worked well, what needs to be improved, and what needs to stop now. It is performed in a constructive way, with the team focusing on the implementation of the Scrum process and how to make it work better for the team. The reflections are implemented immediately and results are discussed in upcoming retrospectives.

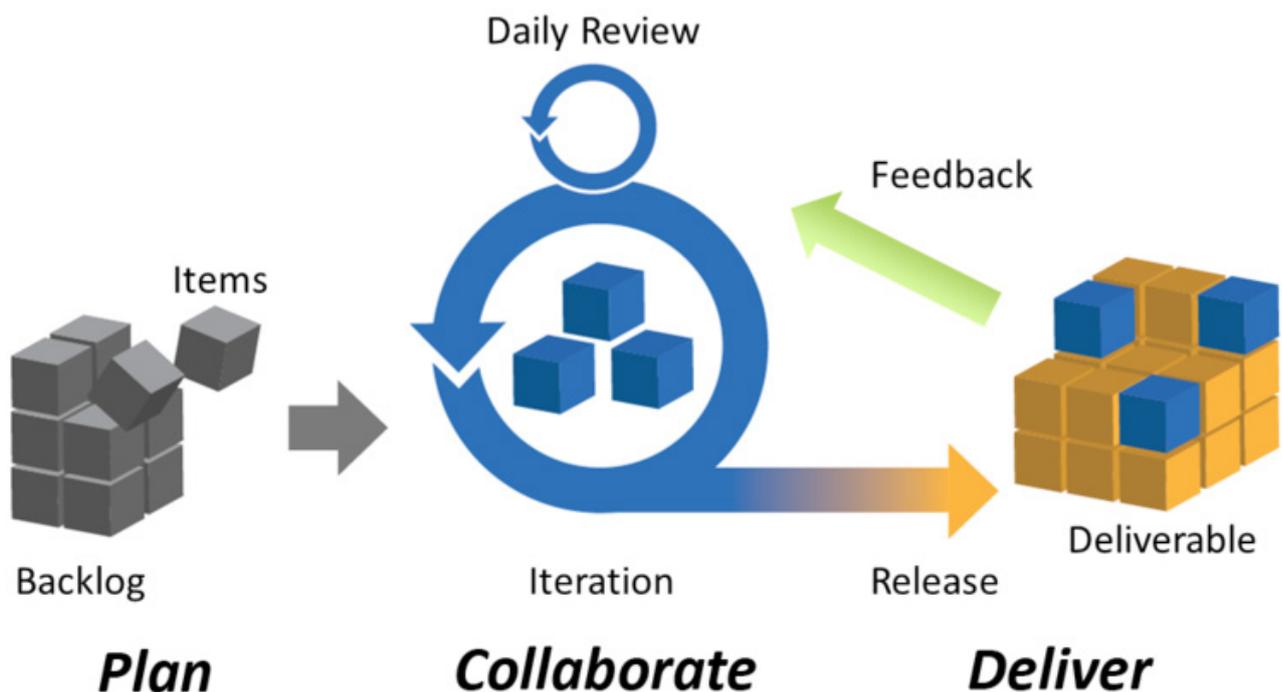
The Pros and Cons to Applying Scrum in a Regulated Environment

Regulatory control consists of two main models: prescriptive and descriptive.

- In the prescriptive model, the regulations define what must be done and, in most cases, how it is to be done.
- In the descriptive model, the regulations define what must be achieved and for the most part leave the how to be determined by the regulated organisation.

Today, regulations are primarily following a descriptive approach. As a result, it is imperative that the regulated organisation document the “how”, that being the processes. The implemented processes need to support and follow the documentation so as to be ready to demonstrate in audits.

In regulated environments, the traceability chain that links requirements, architecture, design, implementation, and testing



Agile Project Management: Iteration

and the control of changes to any of the former, are tough expectations to fulfill. It becomes a daunting task when they evolve and change at the rhythm of every iteration, making it very hard to produce up-to-date documents that make sense when inspected by an auditor. The use of tools that can accommodate these changes and keep the traceability chain consistent becomes invaluable.

When the Agile Manifesto is read by management, the interpretation is no documentation required and no processes in place, leading to chaos. As a result, risk-averse executives and stakeholders, including quality, auditors and clients, are usually highly skeptical of the Scrum methodology, when in fact, Agile is a very disciplined method of delivering software while allowing for nimble adaptation. Scrum is a shift of mindset. A management transformation is necessary during the Agile transformation of an organisation. Changing practices need to come from individuals at the top and middle (implementors) of the organisation. Project control at the management level is no longer valid. Instead, the team is empowered and, as Agile maturity is achieved, the team will evolve to be self-managing and self-organising. This bottom-up approach requires management to support and listen to the team developing a culture of trust, transparency and freedom.

In regulated environments, Scrum highlights those attributes that are paramount.

A more visible audit trail is achieved through a high degree of transparency supporting Title 21 CFR Part 11, part of the Code of Federal Regulations. The documentation discussed and displayed in client audits becomes more clear and self-explanatory. A higher level of traceability is achieved at the project level and test coverage gaps are easily identified. With every iteration, the small chunks of work that have been completed are inspected in a showcase. The remaining work is quantified in the burn down chart offering transparency and visibility to management enabling proactive, not reactive, strategic decision-making.

The Scrum definition of done is another means of expressing transparency. It is an agreement between the CPT and the PO as to when an iteration is completely coded, tested, and ready for delivery. This agreement draws distinct lines declaring it is either done or it is not done.

The process offers flexibility, quick client feedback and the ability to swiftly adapt to change. A robust change management system to manage changes and mitigate risks associated with change is key. The change can be changing regulations or regulation deadlines, or the client changing requirements. This flexibility and adaptability leads to quicker time to market, higher quality (focus on building the right product as identified by the client), and improved stakeholder satisfaction. Higher quality is also achieved by allowing the testers to tailor their test scripts to requirements that have been thoroughly decomposed and vetted by the entire team.

Documentation is a sticking point. The manifesto values working software over comprehensive documentation, leaving room for interpretation. For regulated industries, the audit team will identify how comprehensive the documentation needs to be, and that will be driven by client expectations and regulatory

guidelines and requirements. Documentation for the team and management is created when deemed appropriate and useful.

Conclusion

In this paper we have discussed the Agile component Scrum and the benefits of adopting Scrum, in highly regulated industries where safety is key and executives are highly risk-averse. The visibility attribute inherent to Scrum enhances the safety concerns and is a benefit to any organisation. Scrum is a set of guidelines designed to be formed. These guidelines, in association with the roles and process rituals, can be implemented in a regulated environment, while keeping a strict focus on key drivers of the industry and implemented in ways that provide strong support for compliance with regulations.

The Association for the Advancement of Medical Instrumentation (AAMI) has produced a new Technical Information Report, TIR45, that gives guidance on the use of agile practices in medical device development. This “*Medical device software - Software life cycle processes*” report adds new insights on the agile development process.

- Apply the values of AGILE in a way that **enhances** a robust quality management system.
- Apply the practices of AGILE within the context of an established quality management system.
- Set the correct expectations by defining the SOFTWARE DEVELOPMENT LIFECYCLE MODEL. Demonstrate how an INCREMENTAL/EVOLUTIONARY lifecycle satisfies regulatory requirements.
- Establish robust change management systems to manage changes and mitigate risks associated with change.

References

1. “The State of Scrum: Benchmarks and Guidelines”. ScrumAlliance, released June 2013
2. “Regulated Businesses Can Use Agile.” Donovan Burba, PM Network, January 2015
3. “Manifesto for Agile Software Development.” See document for names of creators.



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