

Approaching Agile in Medical Device Development

Unlock the Power of Agile in Regulated Environments

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Summary

Medical device development can benefit much from agile methods. However, attention must be placed on specific issues of the MedTech domain: Regulatory compliance and combined hardware/software systems. Both aspects are not customary in areas where agile methods have originated, and agile techniques might not always be optimally prepared to deal with them.

This white paper lays out a path that organizations in medical device development may follow in order to benefit from the power of Agile:

- Identify your own suitable approach of adopting and evolving Agile. Be prepared for a continuous journey and a steady flow of new advances and improvements.
- Acquire the ability of hybrid development, combining Agile and other traditional approaches. Hybrid development builds the most reliable bridge into new areas of Agile and lets you exert optimal control over risks of change.
- Realize the enormous potential that Agile provides for further improving product quality and for satisfying regulatory compliance. Agile quality management systems differ from traditional ones. However, they offer a very convincing new approach of "quality built-in" into the development organization.

Benefits of Agile that are frequently reported include: Better ability to manage changing priorities, shorter time to market, increased team productivity, and higher software quality. These are highly relevant for MedTech, too.

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The Power of Agile

Agile development is definitely the most modern approach for developing software and software-based systems, with many reported benefits. However, the adoption of Agile varies considerably across business domains.

The state of Agile in medical device development

In medical device development, we can observe the following characteristics related to Agile adoption:

- The importance of software is growing, raising challenges for established development organizations
- Agile development methods are not yet very widespread, many organizations are evaluating them and trying first steps
- Combined hardware/software development is perceived as an obstacle to Agile, which originates from pure software environments
- Achieving and maintaining regulatory compliance is seen as another challenge, raising further questions about the applicability of Agile methods

Key Takeaway

Agile can be highly effective. But it does not work by itself.

Optimal application of Agile requires ongoing attention.

Benefits and power of Agile

Agile appears attractive regardless of its challenges. In a recent study [1], organizations have reported the following benefits from adopting agile methods:

- Ability to manage changing priorities (70%)
- Business/IT alignment (65%)
- Delivery speed / time to market (60%)
- Increased team productivity (58%)
- Project risk reduction (51%)
- Software quality (46%)
- Engineering discipline (44%)

How to unlock the power of Agile?

The potential benefits of Agile are clearly important for medical device development, too. – How can MedTech organizations most successfully adopt agile methods? And in particular, how can they satisfy regulatory constraints in the context of Agile?

The remainder of this white paper recommends a step-wise and well-controlled introduction of agile methods. It allows for co-existence and integration of agile and non-agile practices (i.e., hybrid development). And it promotes a new agile approach to quality and QMS.

Additional Information

Find more information on benefits of Agile in medical device development in the accompanying white paper:

Andreas Birk, “Agile success stories in healthcare: Build on experiences and lessons learned,” SWPM, Jun. 2021.

Access the white paper and related webinar recordings at <https://intland.com/unlocking-the-power-of-agile-in-medical-device-development/>

Transition to Agile

Agile is a journey. It starts when you are considering to try or to adopt it. Unlike other development or project management approaches, there is no single best way of implementing Agile and no normative reference. This gives you the freedom to shape your own approach, and to make it best meet your needs for regulatory compliance.

Follow the basic principles of Agile

The drivers of Agile are self-managed teams that are aligned by an overall vision and the joint objective to provide optimal value to customers. Fundamental to this Agile approach is a quality mindset that permeates the development organization.

Principles from the Agile Manifesto [2] demonstrate that true Agile has quality and continuous improvement built-in:

- "Our highest priority is to satisfy the customer through [...] valuable software"
- "Agile processes promote sustainable development"
- "Continuous attention to technical excellence and good design [...]"
- "At regular intervals, the team reflects on how to become more effective, then tunes and adjusts its behavior accordingly"

Key Takeaway

You need to find your own route to Agile to meet the specific needs of your organization.

Fortunately, we are guided by a wide range of methods and experiences.

Regulatory compliance has not been a concern of early agile methods. However, Agile's quality mindset provides the foundation for satisfying regulatory constraints whenever they are required.

Choose from a wide spectrum of agile methods

The most widely used agile method is Scrum. It consists of a few essential ingredients defined in the Scrum Guide [3]. Teams applying Scrum start out with these essential practices and evolve their own ways of working from there.

Other Agile methods follow the same philosophy: Teams and organizations shall continuously tune and optimize their own approach. Therefore, agile methods include tools for continuous improvement like retrospectives, organizational learning, and systems thinking.

Teams should always feel encouraged to introduce promising elements from other methods into their processes and experiment with them. This offers a wide spectrum of solutions for dealing with regulatory requirements.

Box 1 lists prominent agile methods with brief characterizations of their focus areas and strengths.

Scrum (scrumguides.org)

Team-level, project-based development of products in a series of increments

Kanban (kanban.university)

Team-level, workflow coordination and optimization, for development, services, and operations

LeSS - Large-Scale Scrum (less.works)

Multi-team to organization-wide scaling of Scrum, bottom-up philosophy

SAFe® - Scaled Agile Framework® (scaledagileframework.com)

From multi-team/program to large organization-wide product development; with concepts for important topics like compliance, hardware development, and product management

Box 1. Agile methods, with web links and short characterizations.

Decide how you want to implement Agile

Each agile method comes with at least one recommended approach for implementing it. Very illustrative are two principles of adopting LeSS [4]:

- Deep and narrow over broad and shallow
- Top-down and bottom-up; both must go hand in hand

In my experience, and in accordance with these principles from LeSS: Most organizations can benefit best from starting small, and from spreading incrementally at a relatively fast pace.

For additional advice, there is much experience available. Actively search for it, experiment with it, and use coaching where helpful.

Summary: How should you conduct your transition to agile?

- Select a suitable core method on team level, usually Scrum or Kanban
- Add practices from other frameworks as needed, e.g. from LeSS or SAFe®
- Start simple and extend step by step
- Use available experience and coaching

Hybrid Development

Hybrid development is the application of agile methods in interaction with plan-based approaches, which are also known as: traditional, classical, non-agile, or Waterfall.

In medical device development, agile teams need the capability of hybrid development. Then they can use established means for satisfying regulatory compliance, even if agile solutions are not readily available.

Why hybrid development is important to MedTech

There are four reasons why hybrid development is important to MedTech:

- Product development is so complex that usually not all participants can be gathered effectively under the Agile paradigm
- Especially hardware development can be subject to restrictions that limit the applicability of software development's agile methods
- Regulatory compliance imposes constraints for which suitable agile practices might not be readily available
- During a gradual transition towards Agile, co-existence of Agile and plan-based cannot be avoided and must be managed actively

Key Takeaway

Hybrid development can offer more advantages than Agile alone.

This is particularly true for complex domains like MedTech.

Patterns of hybrid development

Typical patterns of hybrid development are (see Figure 1):

- Obtain input from non-agile sources during agile planning
- Use and maintain non-agile work products within the agile workflow
- Deliver output from the agile workflow to non-agile entities
- Interact and coordinate with parallel non-agile workstreams

Agile teams capable of hybrid development have acquired suitable practices that enable them to master all these constellations.

Agile practices that foster hybrid development capability

Some agile practices and related traditional development techniques are particularly important for achieving hybrid development capability:

- Agile release trains including cross-functional teams
- Tracing between work items
- Product definition
- Product vision and product goal
- Solution intent and/or product requirements specification

Agile release trains are organizational structures that gather all teams and stakeholders needed to develop a set of related product solutions. As an agile practice that has originally been defined in SAFe® [5] they can be used in MedTech to orchestrate the interaction between the traditional compliance manager role and agile cross-functional teams.

Product definition, vision, and goal create a clear overall understanding of a product's objectives and purpose. They ensure that all participants of a hybrid organization are aligned well with each other.

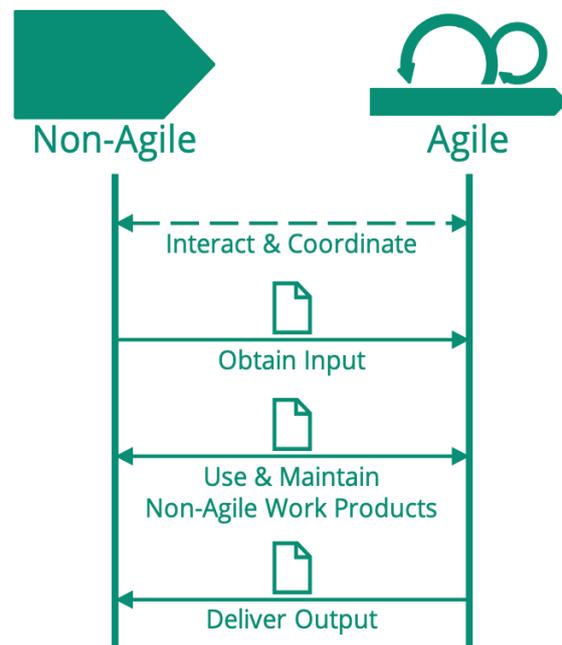


Figure 1. Patterns of interaction between agile and non-agile entities in hybrid development.

Summary: Why and how should you master hybrid development?

- Hybrid development capabilities enable effective collaboration within a large and heterogeneous organization
- Hybrid development capabilities ease integration and adaption of practices from non-agile sources into agile workflows
- Hybrid development capabilities facilitate agile transition while retaining existing cornerstones of regulatory compliance

Agile QMS

A Quality Management System (QMS) is the core instrument through which medical device development achieves and maintains regulatory compliance. QMS have traditionally formed around plan-based management approaches. However, there is no reason why a QMS could not be implemented in an agile manner.

This section demonstrates that Agile can indeed provide better integration of quality matters into development than do traditional plan-based QMS (see Figure 2). It presents three agile practices that help teams to maintain a strong focus on quality and regulatory compliance:

- Definition of Done
- Agile Testing
- Built-In Quality & Compliance

The following subsections explain these practices in some more detail. An additional subsection places them into context with other concepts important to medical device development.

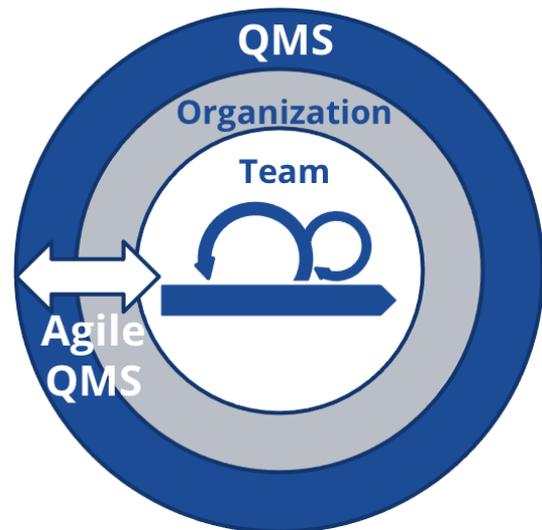


Figure 2. Agile QMS aims at integrating quality matters firmly into the development organization and its teams by using suitable agile practices.

Definition of Done

Definition of Done (DoD) is a collection of quality criteria, which each piece of work (typically a User Story) and each product increment must fulfill in order to be regarded as completed. It is an agile practice that became common through the Scrum method [3].

Agile teams are responsible for defining their Definitions of Done. They also must establish the infrastructure—like specific types of tests and test automation—for effectively applying the DoD. Typically, this leads to a quality attitude and toolset that are deeply rooted in the development team and its development approach.

Agile Testing

Agile development has created a wealth of novel techniques and strategies for testing software and systems [6]. They contribute significantly to the quality advances that can be observed in agile product organizations.

Some of the most important agile testing approaches are:

- Test-First approach
- Test automation
- Test-Driven Development

Test-First approach

Test-First includes a principle as well as a tactic: The principle of Test-First places team-wide priority on test formulation. Collectively considering test criteria and test cases for new functionality creates a deeper understanding of the functionality and its quality characteristics.

The tactic of Test-First relates to the practice that teams should first create an automated set of tests for each user story before they start implementation.

From a QMS and compliance perspective, Test-First fosters an organization-wide quality mindset, and explicit and auditable documentation of quality criteria. It strongly supports risk control and mitigation.

Key Takeaway

Agile brings new perspectives to Quality Management Systems.

It links quality more strongly with development and emphasizes the contributions of quality to the business value of the products.

Test automation

Test automation comprises the various efforts of agile teams to increase their effectiveness of testing and quality assurance. It has led to a wealth of new software development approaches and tooling. They all help to raise quality to a new level.

Examples of agile test automation include:

- Automated unit testing of code modules
- Shift Left and Shift Right movements to integrate testing deeper in all other upstream and downstream phases of the development lifecycle
- Continuous testing practices that run every product change against a huge and ever-growing set of automated tests

The many effects of test automation are not at all limited to functional testing. It has also pushed forward testing and quality assurance for aspects central to regulatory compliance such as usability testing, load and performance testing, and security testing.

Test-Driven Development

Test-Driven Development (TDD) is a style of programming, in which tests must be written prior to each code change in order to indicate whether the code change has been successful or not.

TDD is a very disciplined procedure that demands several detailed techniques. It uses a tool infrastructure called Unit Testing that provides an easy way of automated testing. Developers proceed iteratively in minimal steps of repeated test definition, initial failed test, and implementation until tests pass.

After successful completion and delivery of the code change, the associated unit tests are supplied to the team's or the organization's overall test repository. From there they will be available for all future automated tests to ensure their associated functionality is working.

Built-In Quality & Compliance

Built-In Quality and Compliance are two concepts from the Scaled Agile Framework® (SAFe®) [5][7], the most elaborated approach for agile development currently available. They can provide a blueprint for agile QMS regardless of the agile approach an organization applies.

Built-In Quality

Built-In Quality in SAFe® addresses quality-related principles and practices for agile development teams. They include:

- Definition of Done
- Development flow and continuous delivery pipeline
- Architecture and design quality
- Code quality, system quality, and release quality

SAFe® also relates its Built-In Quality practices to combined hardware/software systems. This underscores the importance of these practices for the development of medical devices.

Compliance

The Compliance practice of SAFe® outlines vital components of agile Quality Management Systems:

- Build the solution and compliance incrementally
- Organize for value and compliance
- Build quality and compliance in
- Continuously verify and validate
- Release validated solutions on demand

Differences to traditional QMS

The SAFe® approach can be contrasted with traditional QMS particularly in the following respects:

- Instead of compliance checks in later phases of development, agile QMS addresses compliance incrementally very early, starting with the initial product increment
- Agile QMS uses Plan/Do/Check/Act (PDCA) cycles for steering product quality towards an optimally compliant solution
- Verification and validation activities in agile QMS are integrated deeply into each development iteration, using practices like Backlog Constraints, agile testing, and Iteration Review.

Other Relevant Practices of Agile QMS

The above practices are important but not sufficient to building an audit-proof agile QMS. Additional practices are needed, in particular:

- Requirements defining regulatory compliance stipulations should be expressed using solution intent or product requirements specification
- Traceability links requirements relevant to compliance with the documentation of tests and other verification and validation activities

Key Takeaway

Agile addresses quality very early in the development lifecycle, and it can bring about a deep-rooted quality mindset.

The agile method of Behavior-Driven Development [8] can root quality even deeper into the development teams. The next section introduces this method briefly.

Behavior-Driven Development

Behavior-Driven Development (BDD) [8] is a comprehensive method that links agile requirements in the form of User Stories with testing and test automation. It is an example of Shift Left testing, where testing is rooted earlier (i.e., more "to the left" or upstream) in the development workflow.

BDD comes with a variety of techniques and tools that serve to sharpen the team's understanding of requirements. It improves control over requirements implementation across the entire development lifecycle.

These practices include the Five Whys technique that clarifies intended business outcome, as well as templates and notations like Given-When-Then and Gherkin that define details of user stories in the form of acceptance tests.

Additional Information Sources

Find more information on agile development practices in an accompanying white paper:

Andreas Birk, "Agile best practice for medical device development: Manage compliance with Agile QMS," SWPM, Apr. 2021.

Practices for introducing Agile in MedTech are described in another white paper:

Andreas Birk, "Agile success stories in healthcare: Build on experiences and lessons learned," SWPM, Jun. 2021.

Access the white papers and related webinar recordings at <https://intland.com/unlocking-the-power-of-agile-in-medical-device-development/>

Summary: How you can set up an agile QMS

- Instrument development with quality-related agile practices that ensure quality will be built into product increments from the outset
- Explicitly define compliance requirements and document their implementation using practices like DoD and tracing
- Blend Agile with existing QMS- and compliance-related practices using the capability of hybrid development

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Agile in Product Organizations

Successful product development is not only a matter of good development practices and effective quality management. It is also the result of many disciplines that must collaborate well with each other.

Product management is responsible for orchestrating the interplay of these disciplines, so that they can create leading products that provide customer value.

Agile practices for product management

There are many agile practices useful to product management. However, some originate from single-team or startup environments. It might be necessary to adapt them carefully to larger product organizations.

Overall, a few issues have shown to be particularly important for product organizations like those operating in medical device development:

- Maintain clear a product strategy, product definition, and product vision in order to optimally align the development organization
- Develop and continuously improve technical and organizational capabilities of product planning and deployment, e.g., product roadmaps, release plans, and automated integration and deployment
- Achieve clear role definitions, especially between business-side product management and development-side agile product owners
- Balance the needs of product specification and documentation with Agile's preference for conversation and communication
- Continuously strive to improve organization-wide collaboration, through a suitable combination of traditional stakeholder management with agile practices like Cross-Functional Teams, Agile Release Train, Customer Centricity, and Personas

Key Takeaway

Product management is responsible for achieving product success.

Therefore it must effectively orchestrate organization-wide agile collaboration.

Agile Release Train integrates compliance management

Agile Release Train (ART) is a concept central to the Scaled Agile Framework® (SAFe®) [5]. It is defined as "a long-lived team of Agile teams, which, along with other stakeholders, incrementally develops, delivers, and where applicable operates, one or more solutions in a value stream."

ART provides a useful framework for including independent quality assurance and compliance management into the overall product management so that they can effectively collaborate with all other parts of the development organization.

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Conclusion

When you are looking for reliable ways to improve effectiveness and efficiency in your medical device development efforts, Agile is worth considering:

- There are reliable paths for adopting and improving agile
- Hybrid development enables you to optimally make use of existing assets while simultaneously unlocking the power of Agile
- The wealth of agile practices like Test-First and Agile QMS approaches give you many promising starting points for rooting quality and compliance deep into your development organization

If you are already applying Agile, you can expect a continuous flow of new discoveries and suggestions of additional agile practices. Each of them might bring you further capabilities and improvements, ranging from enhanced team collaboration to new levels of automation and quality control.

References

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