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Is Kanban the better Agile Approach in a Highly-Regulated Environment?

Most of the manufacturers in the medical device industry have already implemented – or are about to implement - Scrum or other agile methodologies such as Scaled Agile Framework (SAFe). Even though SAFe introduces elements of Kanban on certain levels, a pure Kanban approach – with even more support for flow control and quality - could be the smarter choice in highly-regulated environments. ❯

Why Agile/Lean?

Using agile methods to develop products or perform operational tasks is gaining popularity, and the trend towards digitalization and workflow automation is driving the adoption of lean and agile practices.

Based on the current market environment, companies can choose between a variety of different lean/agile methods for developing non-tangible goods and providing services. All of these approaches have the same general principles:
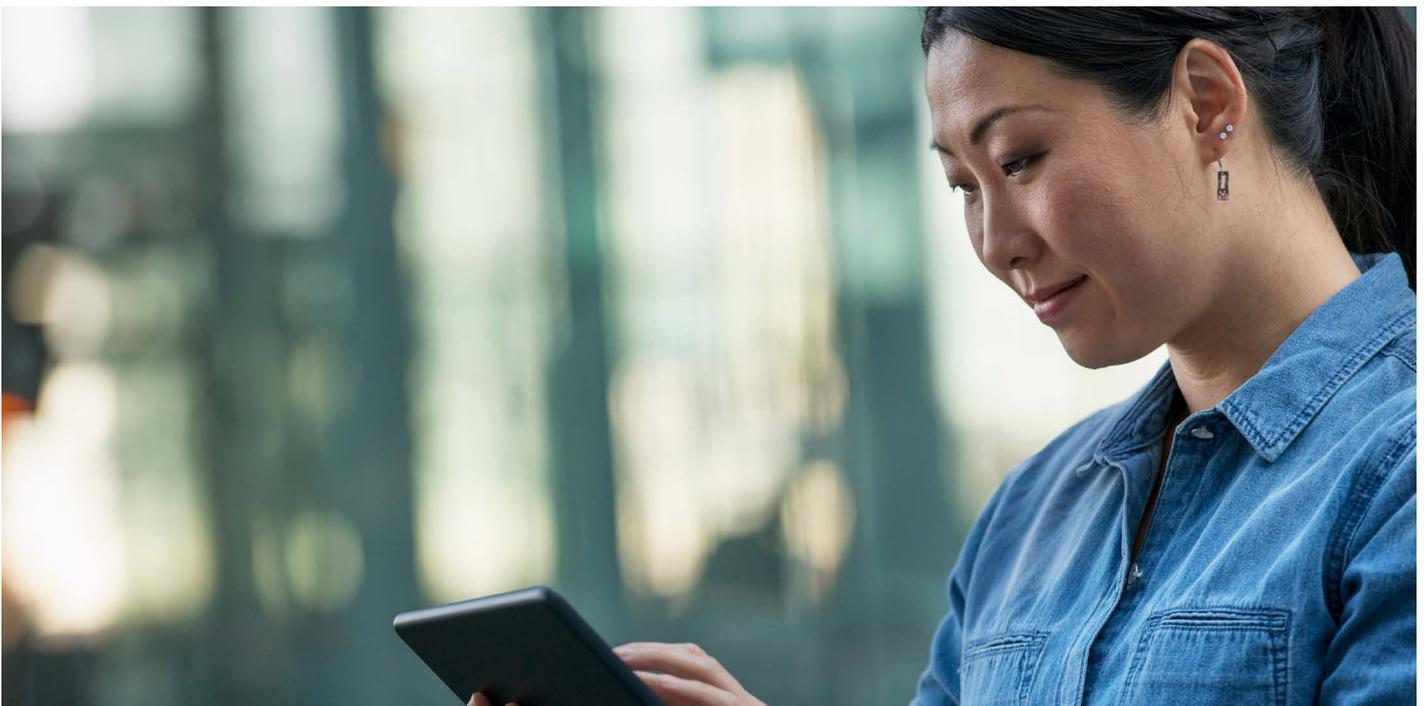
• Empirical methods with formalized feedback loops

• Pull principle and WIP control

• Continuous process improvement

Scrum or Kanban?

Even with their similarities, there is one key difference between Scrum and Kanban that you need to understand before you decide which approach to choose.

• Scrum focuses on iterative product development. This opens up a wide space for agile teams to work in a self-determined, smart, and innovative way, while also requiring a big investment from the team to receive and process feedback on the product. In response to changing customer demand and uncertainty on the market, the teams use Scrum to determine where to go next with the product and how to add the most value to the product in the next sprint.

• Kanban focuses more on monitoring and improving workflows that the team is using. They invest a lot of effort in visualizing and educating the team on the flow and measuring performance and quality. While a sprint in Scrum opens a timebox for each developer to manage to the best of his/her knowledge, a Kanban flow often provides more granularity and allows for more dedicated guidance, responsibility and quality control within a single step.

• For those familiar with the Cynefin-framework, you could say that Scrum has a lot of elements to help manage complex environments. Kanban offers elements and metrics that allow for better flow and quality control in complicated environments, which makes it also perfectly suited for this level of complexity and environments where dedicated flows of activities are required. However, this is certainly a very "black and white view", since both frameworks have a much broader scope than for just one quadrant.

Regulatory Requirements

In highly-regulated environments, companies have to strike the right balance between managing uncertainty and regulatory compliance. The focus in these environments is often on enforcing mandatory process steps and quality, with the methodology defined upfront and documented in formal procedures and work instructions. Medical device engineering is a good example of this, but the same is true for activities like clinical trial/data management or pharmacovigilance. You might think that Kanban was better suited for such environments than a Scrum-based (time-boxed) approach.

Scrum is, however, quite easy to implement in a highly-regulated environment adapting standard elements available within the method to make room for regulatory needs. For medical device engineering, this might include:

- a comprehensive Definition of Done (e.g., to enforce regulatory tasks such as updated risk management files)

- a second Definition of Done for the release (e.g., to enforce a completion deadline for the IFU, the summative evaluation, etc.)

- an additional Definition of Ready (DoR) (e.g., to ensure high-level requirements are updated/created for all user stories loaded into the sprint)

- some quality activities shifted to tasks or acceptance criteria

- formative evaluation added to the product review or system demo

- etc.

Still, one need to add elements coming directly from regulations to find solutions for formal requirements, patient risk file, etc.

On the other hand, it is also worthwhile to understand the advantages the Kanban approach to help you make an educated decision about which application is a smarter choice for your project or operational task.

Implementation Approach

While Scrum and other scaled methods come with a large set of pre-defined activities and roles, the Kanban approach builds on your existing procedures, which it attempts to slowly and very systematically improve. Kanban starts off with your existing roles, as it respects the value of the legacy system. That means that changes to the role models or the staff's formal qualification/training are less frequent and – if necessary – less stressful. This is a significant advantage, especially in highly-regulated environments that have extremely stable roles and procedures and tend to resist ad-hoc changes.

Explicit Visualization of Process Steps

With Kanban, there is a strong focus on understanding the process and documenting the mandatory steps. This allows the core team to cooperate formally with experts (e.g., cyber experts, risk managers, RA managers, etc.) and ensures that no steps are skipped, all responsibilities are clear and that each member of staff has the requisite minimum qualification to perform a quality-critical step (in addition to a record of the user who performed each step on the Kanban board). Kanban also supports the standardization of detailed workflows much better than Scrum.

Explicit (Quality) Policies

The Kanban system enables teams to define (quality) policies for each step, which clearly show the items in a policy that are important for regulatory oversight and need QA attention. Policies like these are extremely valuable when it comes to documenting the quality criteria and achieving a common understanding (e.g., of the meaning of a signature). As with Scrum, these policies (e.g., a Definition of Ready/Done in Scrum) are hardened over time after the team discusses them during sprint retrospectives.

There are some good reasons for using Kanban instead of Scrum, though some of the elements on both platforms are very similar: Kanban also recommends holding Kanban Meetings (basically the same as a Daily in Scrum), Replenishment Meetings (similar to Sprint Planning in Scrum) and Service Delivery Reviews (aka the Scrum Sprint Retrospectives).

We should note that there are also some disadvantages associated with the use of Kanban in projects such as these. Kanban assumes that some activities will be repetitive, and if there is no standardized workflow or the work items (elements traveling through the Kanban system) vary widely in size, you will have to adapt the Kanban system to manage this. Kanban does, however, have predefined solutions for this, so it is still worth clarifying if Kanban is the better choice for your agile approach.

Deloitte has an extensive knowledge base in consulting, implementing and operating agile process frameworks in highly-regulated industries. We would be happy to discuss the options with you and work together to determine what makes sense for your business and regulatory environment.

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