propharma

Agile Use in Non-Software Project

Pharmaceutical/Devices leaders are dealing with an unprecedented set of challenges and projects to that must all be addressed as effectively and efficiently as possible. As such, these leaders must utilize the tools (e.g., Project Management, Lean Six Sigma/Process Optimization, Organizational Change Mgmt.) in their toolkits to achieve success; however, are they all fully optimizing the use of these tools to achieve the value and outcomes they are pursuing?

Probably not .

For example, Agile methodology is a frequently underused secret weapon for the Pharmaceutical/ Devices leader who wants to see an increase in positive project outcomes. It is disproportionately used in IT implementation projects, but rarely used elsewhere. We will unlock the secrets of how highly effective project managers utilize agile in their toolkits to achieve project success for non-IT implementation projects.

What is Agile?

Agile is a methodology that was initially deeloped to facilitate software project implementation. The ability to break up the development into phases and gain customer approval was notable. The continuous collaboration component of the agile methodology enables delivery of a complete final deliverable to the customer. It has been found that those same principles for delivering a final and complete software product can be effectively utilized to provide non-software products with the same levels of completeness.

propharma

This methodology was developed specifically for software development. The short iterations, or sprints, were designed to find and address software bugs, issues, and problems before the programming had gotten too far down the road. Agile is evolving into the go-to method for projects outside of the software realm and moving more specifically into Pharmaceutical and Medical Device project management.

The agile methodology began development in 2000 and was formally introduced in 2001 with four guiding principles.

1. Individuals and interactions
2. Working software
3. Customer collaboration
4. Responding to change

However, over the years those four guiding principles have evolved into 12 guiding principles. Even though the number of guiding principles has grown, they can all still be applied to non-software projects.

1. Satisfy customers through early and continuous delivery.
2. Welcome changing requirements even late in the project.
3. Deliver value frequently.
4. Break the silos of your project to create awareness and collaboration
5. Build projects around motivated individuals.
6. The most effective way of communication is face-to-face.
7. Working software is the primary measure of progress.
8. Maintain a sustainable working pace.
9. Continuous excellence enhances agility.
10. Simplicity is essential.
11. Self-organizing teams generate the most value.
12. Regularly reflect and adjust your way of work to boost effectiveness.

Why does it work for non-software projects?

The attributes of the Agile methodology are equally beneficial in non-software projects. In non-software projects, agile project management can help teams to adapt to changing requirements, manage risks, and deliver value to stakeholders. Even non-software project stakeholders, owners, and sponsors want to be satisfied with their final product.

Examples of projects

- Mass documentation updates i.e., manufacturing batch records due to process changes
- Mass labeling updates i.e., label updates of all product labels due to required compliance changes.
- Product designs
- Development of construction and infrastructure projects
- Resolving a complex process issue

Limitations of Using Agile

Agile is amazing project management method. However every method has its limitations. This methodology is no different. Agile has a few limitations as well. The first limitation is that it is unsuitable for maintenance projects as those projects do not require much documentation. The Agile methodology is heavy in execution. Since Agile was developed for software development, those software developers are focused on one main thing: coding. During the coding process, there is very little to no documentation taking place. In maintenance projects, that is the exact opposite. During maintenance projects, everything must be documented and traceable for future review, which is the opposite of software coding and development.

The following limitation is related directions to one of the Agile principles which is user interaction and involvement. One of the most essential features of the Agile methodology is the focus on user involvement. Due to the heavy on user involvement, the success of the project heavily depends on communication and cooperation of the customer. The project's success depends on the customer's communication and collaboration.

The final limitation that I explore is the team. Agile will not work with large teams. The most effective team size is between 3 to 9 team members. Less than 3, there aren't enough to execute the work, however, for more than 9, there will be too many to work properly, correctly, and efficiently.

What Can Make Implementing Agile Difficult?

- Poor resource planning
- Limited documentation
- Fragmented output
- No finite end
- Projects with no fixed timeline or scope
- Difficult measurement

Case Study Scenario

The Agile methodology was utilized in a Pharmaceutical Serialization program. Serialization was mandated in November 2017 thus requiring updates to equipment, processes, and documentation.

For this case study, the agile methodology will be examined in the documentation update project to satisfy the FDA (Food and Drug Administration) requirement of all products needing to be serialized for them to be distributed. The short iterations enabled the project team to make improvement strides as the project progressed.

The evaluations and acceptance between iterations of batch records and products made it easier to identify problems and address them with 10 - 20 product codes, which was the number of product codes in the sprint, as opposed to 500 product codes which was the total in the entire project.

Complete Case Study available upon request.

Conclusion

In conclusion, the Agile methodology is no longer only for software projects. The agile method is rapidly evolving and of utilized in other projects and applications. The right project manager can efficiently and effectively use Agile methodology in the Pharmaceutical/Medical Device industry.

improve the health and safety of patients

From early concept development through each clinical phase, product launch, and commercialization, we partner with pharmaceutical, biotechnology, and medical device clients to tackle complex challenges. We help to ensure regulatory goals are met, business objectives are achieved, and patient health and safety is improved.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle

🖥 www.ProPharmaGroup.com
✉ Info@ProPharmaGroup.com

propharma