THE VALUE OF AGILE PROJECT MANAGEMENT
IN PHARMA'S RACE TO MARKET

By Julia Palomer, Head of Project Management at UQUIFA Spain
and Amit Manwani, Head of Project Management at SONEAS

Flexibility and agility in the face of uncertainty and complexity have become hallmarks of companies able to survive and thrive in today's pharmaceutical industry.

The increased focus on the unmet needs of smaller, targeted patient populations over the last decade has driven a paradigm shift toward novel drugs that must be produced in faster, more efficient facilities. As a result, drug companies must explore innovative technologies, methodologies, and business models to stay a step ahead of their opponents. Compounding this is the pressure on regulatory authorities to maintain proper oversight while not impeding progress and speed, especially in a post-COVID era where the entire world is waiting for effective treatments. Therefore, as regulatory policies for new drug development tighten and competition grows fierce, manufacturers must identify organizational strategies that can increase their flexibility, so they can keep pace with today's market.

One such approach is agile project management, where the various planning stages of developing a drug substance and/or drug product are executed using a repeated cycle of operations. It focuses on continuous releases and incorporates customer engagement and feedback at every step along the way. Through cross-functional collaboration with integrated project teams, innovative solutions can be explored while simultaneously strengthening productivity, removing non-value-added tasks, and reducing processes' timelines.

PROBLEM SOLVING FOR THE MODERN PHARMACEUTICAL INDUSTRY

Originally created for software development, agile project management is an iterative approach to project management that breaks down large projects into smaller, more manageable tasks. Organizations that rely on this methodology "exhibit central values and behaviors of trust, flexibility, empowerment, openness, and collaboration. In essence, they create a project environment with a mechanism to capture changes and an infrastructure for addressing them, without compromising on scope, quality, or risk." [1] This is vastly different from traditional project management, which uses a "waterfall approach," where each phase is completed in sequential order and follows a rigid time-line that does not consider potential variations in requirements, time, or cost. This leaves little room for adjustments, which is essential in the pharmaceutical industry, as the process for bringing a new drug to market is inherently filled with unpredict- ability. Adopting an agile approach discourages the mindset of continuing to do something simply because it is how it has always been done. It helps eliminate the fear of change, thereby creating an atmosphere where new ideas can be brought up, evaluated, and accepted.

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It helps to eliminate the fear of change, thereby creating an atmosphere where new ideas can be brought up, evaluated, and accepted. However, no modification, no matter how small, will ever be implemented without the consideration of any potential threats to the project timeline, product quality, or patient safety.

While some of the aspects of traditional project management should remain, there must be flexibility within that arrangement, so experts can interact in a more effective way. A long-standing problem in the pharmaceutical industry is working in silos, which is more of a mentality than an organizational structure. The interdisciplinary integration of highly skilled experts that allows each stakeholder to share information and resources is often hindered by a lack of collaboration and communication between departments. Without discussion among each stakeholder in a product's life cycle, there is no way to know the impact of one person's or department's actions on the next until it is already happening, and by then, it may be too late to make a change.

AGILE PROJECT MANAGEMENT WITH US

Using an agile approach, Uquifa breaks down common barriers in drug development and manufacturing by beginning each project with a kick-off meeting that includes project stakeholders to review the plan for how a project will be executed. This involves two stages. The first is a meeting with only the internal experts (Core Team). Then, in the second phase, representatives from the client's team are also included, in order to create a setting that starts the project off on the right foot. The second stage is extremely important. It allows an opportunity for cultural alignment, ensuring both teams are using the same nomenclature and are understanding each other at all levels and in all the disciplines required to successfully execute the project. This means that subject matter experts from different functional areas may have separate kickoff calls once the project officially begins. In some cases, a client may not be able to provide resources for these meetings or may choose to give its CDMO full ownership of the project. Agile project management can still be applied in these situations, with continued feedback and updates provided to the client after the meeting is over.

The group, along with an agenda and a facilitator, continues to meet throughout the life cycle of the project. Ideas and any actions that need to be taken are captured and organized for each project and then shared on a wall (i.e., visual management using a "yellow, paper-like" dashboard) with all project teams as a simplified way of visualizing the workload, prioritizing tasks, and defining responsibilities. Together, the integrated project teams can talk through potential solutions and quickly determine the most effective and efficient way to move to the next phase of a project. This leads to faster decision-making and problem resolution and, ultimately, shorter project timelines and lower costs. As existing and upcoming project needs are identified, our teams can decide what resources and tools they will need to properly support the project. They can also request any additional capital expenditure to accommodate those needs.

This method not only creates learning opportunities for that project, but it also incorporates immediate actions that are applied concurrently to other projects. Moreover, it allows for a continuous evaluation on expansions, whether it is a new technology, a new piece of equipment, a newly created role, etc., which is instrumental to the growth of our company and the improvement of our services.

Traditionally, CDMO services are evaluated primarily on quality, speed, and price, but today, those are just minimum requirements. What makes a true partner is the entire customer service experience, which starts with open communication, responsiveness, and flexibility. Adopting an agile approach allows Uquifa to create processes that are optimized to suit our clients' needs. If changes or adjustments are necessary, there is no red tape to slow innovation and collaboration. Customers have access to our entire team of experts, so we can work together to get things done in real time.

EMBRACING AN AGILE CULTURE

Implementing change can be difficult at any company, but it has been historically challenging to do so at a company developing and manufacturing pharmaceutical products. This is because the pharmaceutical industry is a conservative one since the end customer is the patient. The medicines we make impact people's lives, and this is always present in our minds. Embracing our mission statement 'Chemistry for a better life' has been part of Uquifa's culture since the beginning but embarking on a path toward agile project management has taken us to an enhanced level of transparency in our operations and a collaborative approach that is stronger than ever. These attributes not only benefit our customers, but also (and more importantly), the patients who we ultimately serve.

1. *https://www.outsourcedpharma.com/doc/an-introduction-to-agile-project-management-for-pharmaceutical-outsourcing-0001*