Agile: Open Innovation to Revolutionize Pharmaceutical Strategy

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Abstract: Pharmaceutical and software development programs have major similarity. They are highly multifaceted, rely on multidisciplinary functions and usually take longer development cycle with big budget portfolios. In addition, they are often judged based on the quality factors such as reliability, safety, value, capability efficiency and compliance [5]. Both software and drug development teams aims to produce compliant, efficacious, safe, effective, and commercially viable products, they take very different approaches to development, with pharma using the “waterfall” approach, and software, agile approaches [11]. This paper reviews current approaches in software development, and asks whether they might prove useful in drug development.

1. Introduction

Agile and big data analytics opportunity is especially compelling in complex business environments experiencing an explosion in the types and volumes of available data. In the health-care and pharmaceutical industries, data growth is generated from several sources, including the R&D process itself, retailers, patients, and caregivers. Effectively utilizing these data will help pharmaceutical companies better identify new potential drug candidates and develop them into effective, approved and reimbursed medicines more quickly [11].

2. What is Agile?

Highsmith defines “agility” as the ability to balance flexibility and stability [6]. In the software industry, “Agile Development” is an umbrella term for a set of methodologies. According to Larman, methods of agile development apply time-boxed iterative and evolutionary development, adaptive planning, evolutionary delivery, and other values and practices to encourage rapid and flexible response to change in process [10, 1].

The pharmaceutical industry uses the Waterfall development approach, one of the most common and known sequential design process methodologies. It was originally designed for engineering and structure construction industries; gets its name from the way its phases flow downward like a waterfall. The best project types to utilize this methodology are the ones where the requirements are static and clearly stated. Also its up-front requirements and settled timeline and budget lend itself to a robust management structure [14].

In a waterfall product development approach, project managers traditionally identify a number of steps to accomplish a project, which typically must be completed sequentially and depending on type of project could include: Proposal, Discovery, Requirements, Design, Build, Implementation, Verification, Completion, and Maintenance.

The Waterfall method relies on the unrealistic assumption of collecting all requirements during the first phase [8]. In this situation, communication with the stakeholders is signed-off into “Requirements” phase. Once this stage is completed, the process runs “downhill” as in waterfall [7]. This approach may cause detailed and extensive product specifications based on unrealistic assumptions because of a lack of practical experience. Thus, it can deliver a false sense of precision. It also brings the risk of creating very detailed but out-of-date documentation [9].

3. Agile Software Product Development Cycle

Software Product Development Cycle (SDLC) is rooted in principles of “human interaction” management. It differs from Waterfall method of pre-planned process. In an agile development approach project manager defines the project as a series of small tasks and completes them in a responsive and adaptive manner. This approach does not require the impractical assumption of “knowing all requirements” [2]. Out of the potential methodologies such as Extreme Programming, Crystal, Dynamic Systems Development Method, Lean Development, and Feature-Driven Development, “Scrum” is one of the main agile software development methodologies [13].
4. Agile IT Strategy in Pharmaceutical R&D

Strategy - the “art of war” - is primarily about deploying resources into the right area: fast-moving cavalry to take on local challenges in a flexible and responsive way, while slower-moving forces take strategic objectives over long periods. For IT in drug discovery, a strategic objective is typically to improve creativity and the ability to predict adverse events, which necessitates sharing information between projects and sites [4]. But this will only happen if R&D leaders demand that projects go beyond their own immediate operational needs when recording and organizing their results.

Attempts to define a multi-year, global IT program are typically frustrated by constant change - in research methods, in IT technology standards, and in company structure. Agile development helps to compensate for this. It allows rapid delivery of business benefits by allowing information users and creators to collaborate and find the best means to reach a defined and shared business objective [4]. Rapid prototyping and iterative development methods such as Dynamic systems development method (DSDM) and Scrum can clarify key requirements quickly, identifying risks in time to overcome them.

5. Scrum

It's a special way for teams to work together and develop a product, as it occurs in small pieces [3]. in other words, it is a building up process, where a piece is built on the previous pieces, and each time a small piece is completed. It encourages creativity and gives space to teams to be able to respond to feedbacks and change. Scrum can also be thought of as a simple framework for effective teamwork in complex projects which provides a small set of rules aimed to create just enough structure for teams to be able to focus [18].

The aim of Scrum is to be able to respond fast and have flexibility in the development process without sacrificing quality, cost control, motivation or customer needs. In preference to orientation upon high-level and extensive planning and heavily documentation, it emphasizes the need for customer interaction during incremental and focused development cycles [16].

The basic principle of Scrum is to divide the development process into pieces or development cycles. In Scrum terminology, these cycles are named as “sprints,” which have pre-defined tasks to address pre-selected goals of the project. A “Daily Scrum” only lasts 15 minutes and it is used to compare current results with tasks and its associated difficulties or problems. At the end of each sprint, the results are presented which should at that point be potentially deliverable [9].

Each sprint is a time box of a month or less, no more than 30 days, in which the sprint team manages itself-during which a “Done”, usable and potentially releasable product increment is created. A new sprint starts immediately after the end of the previous sprint [15] and each sprint involves parts such as sprint planning, daily Scrums, the development work, the sprint review and the Sprint Retrospective [17]. During the sprint, it is important not to make any changes to endanger the sprint goal. Additionally, quality goals do not decrease however, scope may be clarified and renegotiated between the Product owner and development team as more is learned.

![Figure 1: Overview of Agile process](image-url)

Having such a flexible structure creates a big advantage during projects where customers change their minds about what they want and need (often called requirements churn). In drug development, customers could include marketing and sales teams, supply chain and manufacturing groups, legal, regulatory agencies, contract manufactures and packagers, physicians and patients and many others. In traditional methods, these changes cannot be easily addressed and adaptation cannot be easily managed.

6. Concerns with Agile in the Pharmaceutical Industry

Therapeutic regulations currently follow a descriptive approach. Therefore, regulations in general terms define what must be accomplished and largely leave the question of how to achieve it to pharmaceutical companies. Consequently, regulators expect companies to establish their own documented development programs and show that their formulations and processes are capable of providing safe, efficacious, and effective products [4].
In utilizing Agile, there are two major concerns for the pharmaceutical industry: the fact that Agile tends to “value individuals and interactions over processes and tools” and the agile value of “working software over comprehensive documentation” [4]. However, following the agile or hybrid principle of gathering skilled people and providing them with the means to work just makes a robust process even stronger [11]. It ensures project teams continuously ask themselves if any improvements are needed. This is what regulators explicitly ask pharmaceutical companies to do [12].

In addition, both agile and regulated principles serve the same purpose, if we equate working pharmaceutical product with safe and effective product. In the pharmaceutical industry, documentation is not an end in itself. It is merely a means of showing that the product is going to fulfil its intended use in a safe and effective manner, because it has been developed via a robust process [4].

7. Conclusion

Agile methods strive to achieve results and quality with the help of simple process and less bureaucracy. Such hybrid models, where agile and traditional methods are combined, must be integrated into the Quality Management System when used in a regulated industry to add special sprints for covering formal documentation requirements. To sum up, agile methodology is showing itself a promising way of working and moving beyond software development projects and soon will find its place in various departments of pharmaceuticals and biotech industry.

8. References