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What?

Product development is the process of turning an idea into something that can be launched in a market or in its intended place of use. It involves everything from the actual construction, to preparing for manufacturing and developing packaging. Even services might depend on some custom software that must go through a product development process.

This step may take several years, depending on the intended product and can be expensive, especially in the life science industry. Thus, it is important that you are well prepared before starting the technical development, by having verified and validated your idea's potential from different perspectives (See tools 1.2, 1.4, 2.1, 2.2 and 3.1). Those tasks, even if they are complex and time consuming, are several orders of magnitudes cheaper than the actual development work.

Why?

It's important for several reasons to have a structured product / service development process. First and foremost, it can ensure that you stay on track and build a product / service that will meet the needs that you have identified. If you lose track of that connection, there is a risk that you will not have a product market fit once you launch your product.

Secondly a well-defined process will help you spend your resources wisely.

Finally, products within the health sector are often regulated, such as a medical devices or diagnostic tools. This entails a predefined product development process to get your product certified and thereby able to enter the market.

How?

At this point we introduce the Software Development Life Cycle (SDLC), a step by step process that guides the development of software. It consists of 6-8 major phases, which include planning, analysis, designing, building, testing, deploying and maintenance. We present some of the SDLC methodologies that can be adopted during your product development.

As mentioned, some of the phases indicated have already been covered in the previous sections of this toolkit, or are yet to be covered, therefore our emphasis will be on the **design and building phases** of the SDLC. For each methodology, we introduce the basic concepts which you can expound on using the recommended resources.

Waterfall Methodology

Waterfall development is a linear methodology that has been the dominating development process for many decades. In short it defines a few steps where you deliver an artifact, starting with requirements, ending with a finished product. The methodology has been criticized in the past decades due to its linear approach and the lack of interaction with external stakeholders such as customers or future users.

Agile methodology

Agile development is a term that stems from the software industry. It is widely popular. At its core it means that you delegate the detailed planning on how to build the product/service to the development team who will develop it iteratively (step-by-step) by presenting and testing versions to involved stakeholders continuously, usually every 4-6 weeks. Each release will show small incremental changes from the previous release. Through this methodology the development project stays on track because the team is able to identify and address small issues continuously through the frequent stakeholder feedback, before evolving into significant problems. In the end the developed product will have the desired functionality. Sometimes this is also referred to as iterative development.

Some other frameworks to look up are **Scrum and Kanban**. Scrum helps to structure more complex development projects by breaking them into smaller deliverables, while Kanban visualizes task work flows which helps in optimization of the flow of tasks between different teams.

Lean agile is another approach that focuses on improving the efficiency of the development process by eliminating any wastage in form of resources like time, finances, staff etc.

The DeVops approach is also agile and capitalizes on collaboration between the operations and the development teams throughout the development lifecycle to attain the expected result.

Design-based methodologies

Worth mentioning is also design-based methodologies such as Design Thinking, Biodesign and User Centered Design (UCD). Biodesign is a process of developing systematic MedTech Innovations, while Design Thinking and UCD are methodologies best known for close interactions with the future users and stakeholders during the design and development process. These three are heavily focused on the initial steps of the process, going from a need to a concept or an idea about the solution, followed by testing and developing together with the users.

Resources/Sources:

<https://www.scrum.org/>

<https://en.wikipedia.org/wiki/Kanban>

<https://biodesign.stanford.edu/about-us/process.html>

<https://www.usability.gov/what-and-why/user-centered-design.html>

<https://www.interaction-design.org/literature/article/5-stages-in-the-design-thinking-process>

<https://www.roberthalf.com/blog/salaries-and-skills/6-basic-sdlc-methodologies-which-one-is-best>

<https://www.techtarget.com/searchitoperations/definition/DevOps>

<https://brainhub.eu/library/differences-lean-agile-scrum>

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