THE BIGGEST MISTAKES COMPANIES MAKE COMMERCIALISING DRUG DELIVERY – AND WHAT TO DO ABOUT THEM

Successfully scaling-up a product to industrial production is challenging, but is even more challenging if design fundamentals are not incorporated into the development process. In this article, Beth Blackburn, Director of Systems Engineering, Ximedica, details the pitfalls and potential solutions in setting down requirements early in device development to ensure a product's successful commercialisation.

Early-stage companies have many dragons to battle, particularly in drug delivery. They are fundraising, filing IP, finding suppliers and creating a physical product for the first time. Additionally, they are developing both pharmaceuticals and medical devices, and therefore are navigating the treacherous regulatory and reimbursement pathways for both.

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With so many difficult tasks to complete, companies often skimp on developing solid requirements for their drug delivery devices. Requirements tie together the user needs and the system design in a quantifiable and traceable manner, otherwise referred to as design inputs. Many activities associated with developing clear requirements are out of the scope of the actual technology or invention, and many are expensive. That combination makes it is easy to ignore some of the fundamental principles in device development. However, ignoring them can cost companies more than they often imagine.

WHY DO COMPANIES SKIMP ON GOOD REQUIREMENTS?

There are good reasons companies might drop the ball on developing requirements for drug delivery devices. A lot of early-stage companies think, "We've created a product, we've created some stir, we've gotten funding, we have something that's pretty clear. Let's just go."

That concept that "if we build it, they will come" can lead companies down an unsuccessful commercial path. Furthermore, just because the product is clear to the early-stage company doesn't mean it doesn't require documentation. Requirements development can take time. Moreover, the skills associated with developing clear requirements for drug delivery devices are often unfamiliar to an inventor or a CEO of an early stage company.

Requirements development is the most overlooked aspect of product development, even among companies that have been around a while, maybe even having some products on the market. It is tempting to think that if a company builds several instruments out of the same parts, in the same way, they are in the clear. However, it is important to take time to understand the design, variability in how one change can impact the rest of the design, and how individual components might affect the whole instrument's performance downstream.

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CEOs and CTOs of start-ups are often under immense pressure from their boards and investors to get to market quickly. In particularly unfortunate circumstances, start-ups can be put under pressure to put prototypes into

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clinical trials, an idea that might sound smart to an investor who's in a hurry for a return on investment (ROI), but that doesn't account for the fact that they won't be able to change the design later without showing equivalence. Then, if the requirements aren't clearly documented, they'll have to repeat the trials, which is a huge expense.

These user-experiences are particularly crucial for drug delivery devices, which have a higher than average portion of user-experience as part of their commercial success. Well-defined requirements lead to the lowest-risk and highest ROI at launch, supported by good design and development. Principles such as human factors, ergonomics, user interface and regulatory standards all feed into a healthy requirements definition.

WHAT'S INVOLVED IN DEVELOPING REQUIREMENTS?

Requirements must be developed by compliance with standards, such as safety standards, US FDA guidance documents and more. These tasks are often referred to as the voice of the customer (VoC), user needs and usability. These activities ensure consistency and repeatability of the device and design to avoid potential problems in development, manufacture or post-commercialisation. There are major risks to skipping these steps and rushing to market, litigation and post-market failure being two of the worst scenarios. With a clear view to accepted standards, putting user feedback and user input into a design is critical in early development.

But talking to a potential patient or customer may not be the most intuitive process. In most cases, a company needs to explore the entire ecosystem, because a customer might not be immediately identifiable. For example, a company might be developing a product intended for a nurse, only to find out that if the attending physician doesn't check a specific box on paperwork, the device will never be in the nurse's hand. Understanding who will be interacting with a therapy, as well as when and how, should inform how requirements are developed.

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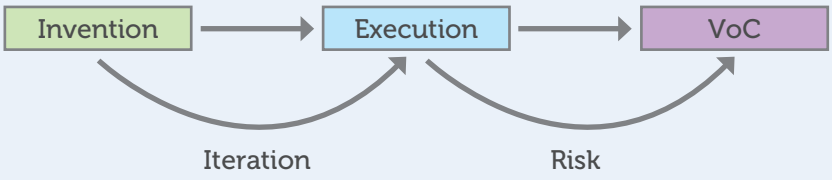
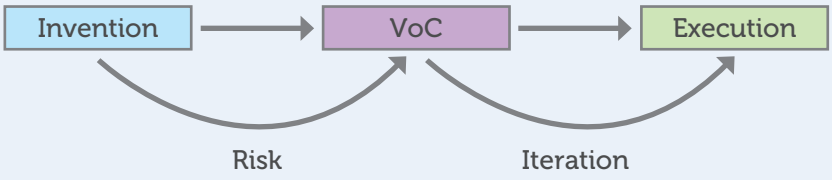
Likewise, requirements must be developed early. Waiting until later in the process, for example, in design validation at the very end of development, means risking the entire development cycle, as well as the development costs. Validating and getting user input early helps mitigate some of those potential risks, as is shown in Box 1.

BOX 1: APPROACHES TO PRODUCT DEVELOPMENT

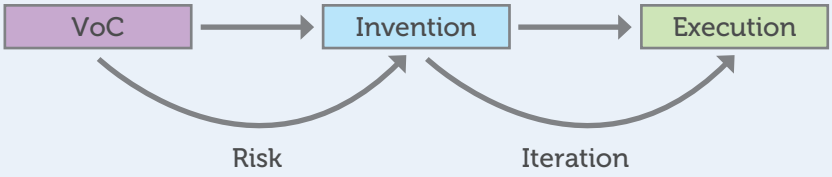
1. Early years:



2. Until recently this was the approach:



3. **Best practice**: this way you can do the least risky thing first and fail fast if necessary...



In addition, the requirements need to transfer over in every stage of development. User needs turn into design specifications, and those translate to the outputs that are verified and validated. It is important that every team member understands the underlying drive of each specification, so that they don't get lost, misinterpreted or garbled as it travels through design phases.

PAIN-MINIMISING OPTIONS FOR DEVELOPING REQUIREMENTS

Early-stage companies, and companies working to put a new product on the market, are navigating new territory. They are short of time, short on cash and are often looking for ways to skip steps. When it comes to setting solid requirements, the most effective way is to talk to every customer and ecosystem member possible. Understanding those needs and making efforts to fundamentally incorporate them into design specs will give start-ups the product development process they need.

A clear understanding of how to set requirements for a smooth regulatory path is also important. For example, "The device should dose accurately" might be an intuitive requirement to a nurse but is not sufficient to help a start-up get through regulatory hurdles. How does one measure accuracy? Is it ± 5%? In practice, the answer depends upon the product, therefore adding the specificity to what your user population expects creates a demonstrable difference. For example, "The flowmeter should meter the product accurately to ± 0.5%" is measurable and will help the company avoid repeating design cycles or ending up in field failures. You can create the specificity through literature reviews and/or competitive product analysis.

But that doesn't mean these companies are on their own. Design and development firms can play an enormously helpful role in developing functional design requirements that can help companies get to market quickly and smoothly, while managing investor expectations.

ABOUT THE COMPANY

Ximedica is a full-service product development firm that is ISO 13485 certified and FDA registered. For 30 years, Ximedica has provided a unique growth platform enabling organisations to successfully deploy medical technology products into the market. Its headquarters are in Providence (RI, US) with offices in Hong Kong, Minneapolis, San Francisco, and Silicon Valley (CA, US). In November of 2014, SV Life Sciences, a Boston-based private equity firm, acquired a majority stake in Ximedica, enabling the company to execute its growth strategy.

ABOUT THE AUTHOR

Beth Blackburn is Director of Systems Engineering at Ximedica, where she leads a broad team of engineers who ensure proper translation of user, caregiver and a variety of additional stakeholders' needs into clearly defined, verifiable design inputs. She has a BS in mechanical engineering from Worcester Polytechnic Institute (Worcester, MA, US) and an MBA from Bryant University (Smithfield, RI, US).