MPR
PRODUCT DEVELOPMENT

THE
10 COMMANDMENTS
OF
PRODUCT DEVELOPMENT

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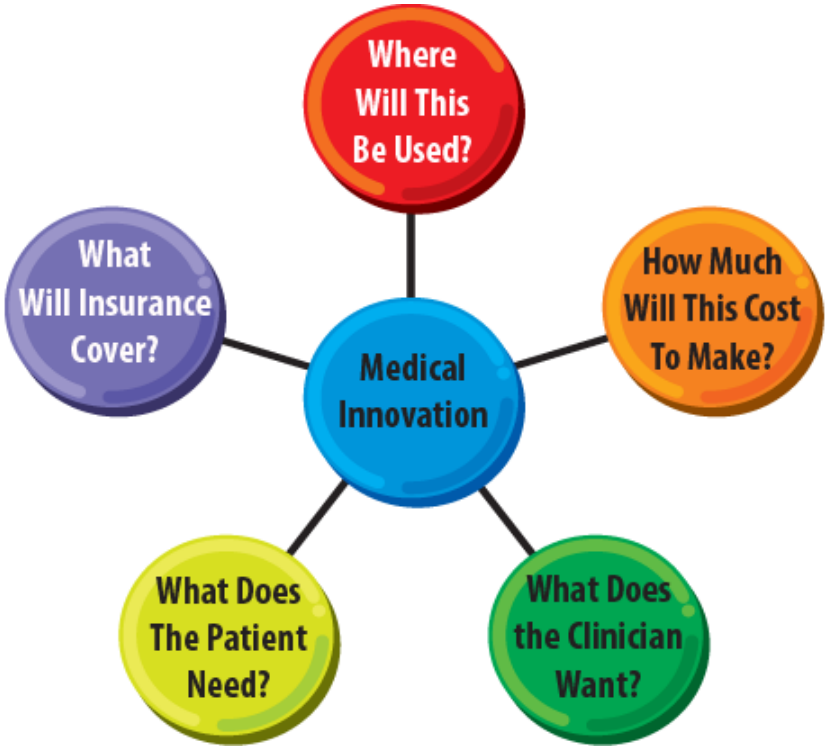
Product design and development is a journey with unexpected twists and turns. People often ask, “how can I make my design process more predictable?” In our 25 years of experience designing medical devices, we’ve found that you can’t always predict all the twists, but there are things that can be done to increase the certainty in a successful outcome.

Here is our “top 10” list of important considerations.



Rule 1:
Know The Stakeholders

Understand all the stakeholders and their needs. Today, more than ever, we have to consider a very broad range of stakeholders– the clinician, patient, regulator, payer, device manufacturer, and more. If we’re talking home health care it gets even more complicated with needs imposed by the diverse range of environments and users – home care nurses, family members, and device distributors. It’s important to understand the constraints and limitations of each user demographic and to map out all of the associated use cases.

Rule 2:
Product Requirements Are Driven by Clinical Needs

Understand the clinical and user needs (which are often more qualitative than quantitative) and then translate each of these to quantitative product requirements. Make sure that requirements specify “what” the product must do, not “how” it must be done. Sticking to the “what” keeps the design space more open for innovation. Separating clinical/user needs from engineering requirements helps with planning for design verification and validation.

Rule 3:
Don't Forgo the "System" Architecture

Develop a high level architecture for the overall system/product. What are the major pieces of the puzzle and how will they go together? Identify at least one way, and preferably several alternative ways, to solve the problem at a “system” level (by brainstorming, own experience, others’ experience, similar products). Create block diagrams for different concepts. This lets you evaluate pros and cons, risks and benefits of alternative design solutions at a high level, before you lock in a specific approach.

Rule 4:
Know the Risks and Work the Hard Ones First

At its core, product development is all about managing risks. These could be technical risks for first-of-a-kind products or organizational risks where you’re treading in unfamiliar territory (i.e., risks associated with a lack of certain technical expertise). Focus on the high risk elements of the design first, and always have contingency plans for the risky items. Stage gate reviews should focus on whether risks have been adequately reduced.

For example, at the product feasibility stage, testing with an alpha prototype should demonstrate that critical technical solutions are workable. Going in to the beta prototype stage, it’s best to have reduced risk to only integration and interface issues.

Rule 5:
Don't Ignore The Laws of Physics

They’re called “laws” for a reason and it's critical to understand how they apply to the product you’re designing. Develop a science-based “feel” for the problems you have to solve by simplifying and analyzing the effects of key parameters. Do product characterization testing to understand how performance is affected by these parameters. Understand why performance is more strongly affected by certain parameters and not others. You should be able to write down the theory of operation based on physical principles.

Rule 6:
Design with Empathy

Ultimately products will be used by people. And people have widely different capabilities and limitations based on their education, backgrounds, working environments, stress level, medical condition, etc.

Understand who your product's users will be and design the product with a view from their shoes. The sooner you can get physical prototypes into prospective users' hands the better, as you often discover unexpected results in the ways people react to things. We find its best to plan for several iterations of user studies.

Rule 7:
Do a "Vertical Slice"

Do what my colleague Craig Mauch calls a "vertical slice." Prioritize the design implementation and then analyze, design, build, and test the most important parts of the system first and let those results define constraints for the less important parts. This is a risk mitigation approach that goes along with rule #4.

Rule 8:
Plan for Things to Go Wrong

Think about what can go wrong. Design the product to cope (i.e., be fault tolerant) when things aren't perfect. For example, think about dimensional tolerances, loose fasteners or connectors, power failure, use errors. Use risk analysis tools like failure modes and effects analysis (FMEA) to manage this process.

Also, when you plan for testing, don't just test to make sure everything works right under perfect conditions. It's just as important to test to see what can go wrong. This challenge testing can include testing at off-normal conditions, at environmental extremes, with inputs of out-of-range data, or with power interruptions. Robustly designed products should be able to cope when conditions aren't perfect.

Rule 9:
Test Early and Test Often

As shown in the picture above, design and development is a process. Be sure to test what you can as soon as you can. Test and debug as much of each design element as possible before integrating with the others. And if you find yourself iterating on the design to fix problems, don't try to change more than one thing at a time.

Testing's no big deal right? The FDA might disagree, click here for more info

Rule 10:
Murphy's Law Always Applies

Finally, Murphy's law always applies and more than ever in the product design process. Be sure to plan for extra time and budget to get things built and tested, nothing is as easy as it looks, and everything takes longer than you think it should.

Questions? Ask The Author

About MPR

we excel when others say "it can't be done"

we have experts in design, development and testing under one roof

our costs are scope-driven so the basis is clear

we don't just design the device, we design the product ecosystem

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