



Medical Device Development Best Practices

Q&A with Stratos Product Development

Can you speed your product development process while managing costs effectively?

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In the competitive landscape of medical devices and the advantages to being first to the market, many are tempted to move into product development at a rapid pace. Moving into product development quickly is full of risks, particularly in the medical technology space where development is heavily regulated and process driven. Make sure these components are in place to reduce risk and ensure the smoothest path possible.

1) Spend time early to fully development the product requirements.

It may seem counter-intuitive, but spending time before you begin to develop requirements will save money and get your product to market quicker. Incomplete requirements can have a major impact on scope and should be given significant attention early on. When teams jump into product development prematurely without adequately defined requirements, the result could be something that doesn't meet the goals and you will have to spend time, perhaps, doesn't function well, that can't be used as it was intended or that doesn't have the necessary technical capabilities.

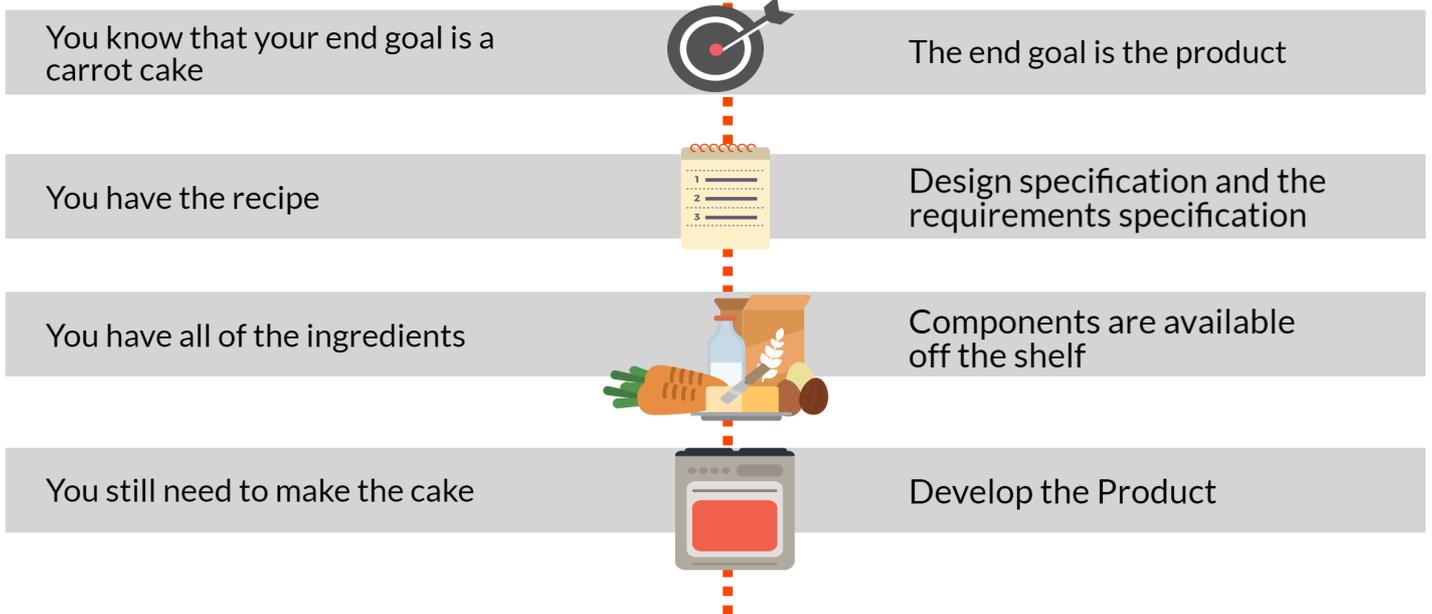
Depending on when these issues are identified the scope creep could be sizeable. Take the time to make sure your requirements are thoroughly documented upfront.

2) Don't start product development until the technology is sufficiently mature.

A common, and often costly, mistake is moving a technology out of research and into development before it is ready. Having a technology working on the bench is not the same as proving it can be commercialized while still maintaining adequate performance. Take the time up front to turn a proof-of-technology breadboard into a proof-of-commercialization breadboard. Use this breadboard to analyze critical performance areas.

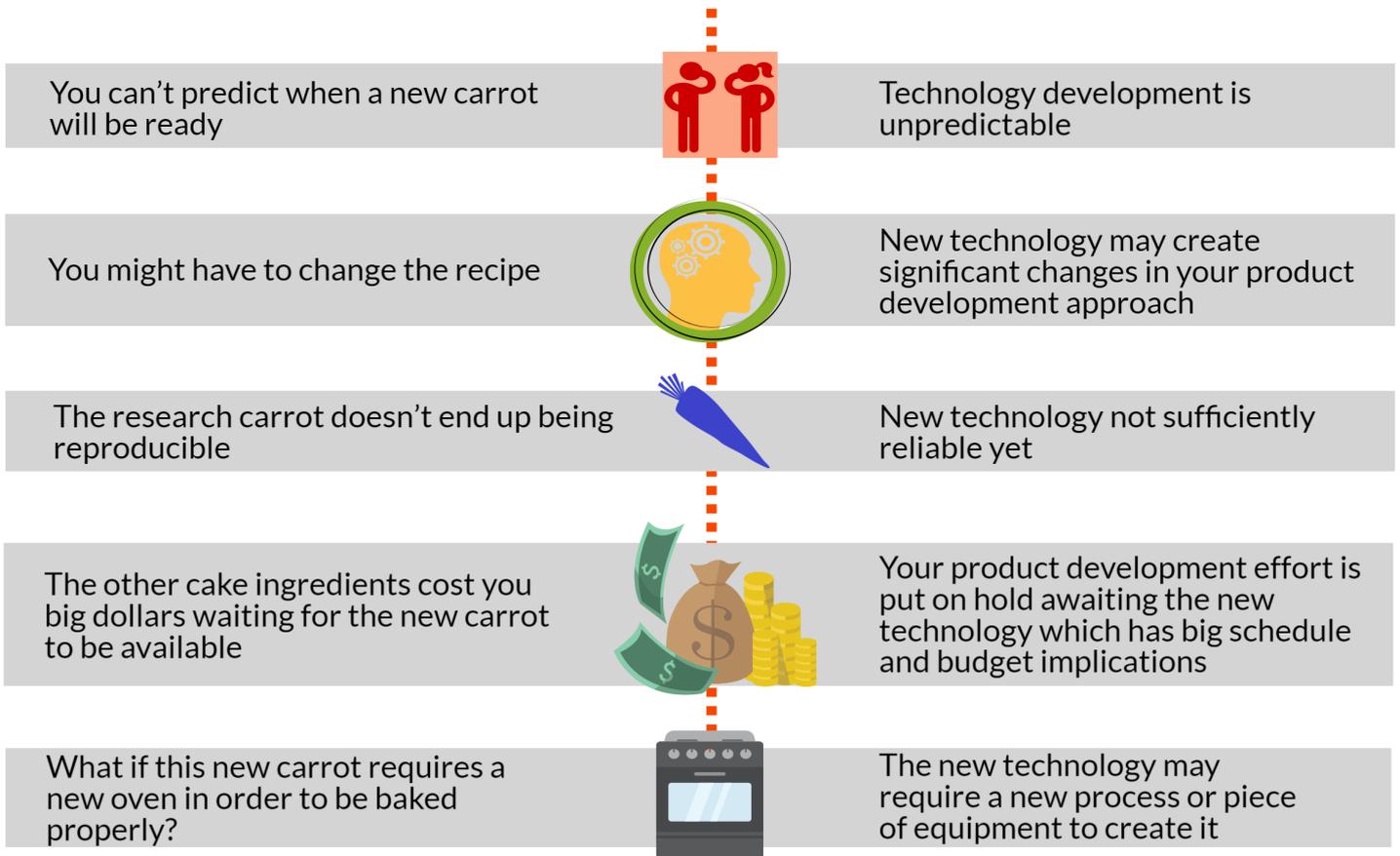
Here's one simple way to think about it.

Product development is like making a carrot cake:



Technology development is like engineering a better carrot for a SUPERIER cake.

There are significant risks that come along with starting product development before the technology is ready:



You can try to do technology development and product development simultaneously, but make sure you are aware of the risks you're taking. And have a backup plan just in case your technology development doesn't go according to plan.

3) Use a systems approach with dedicated leadership.

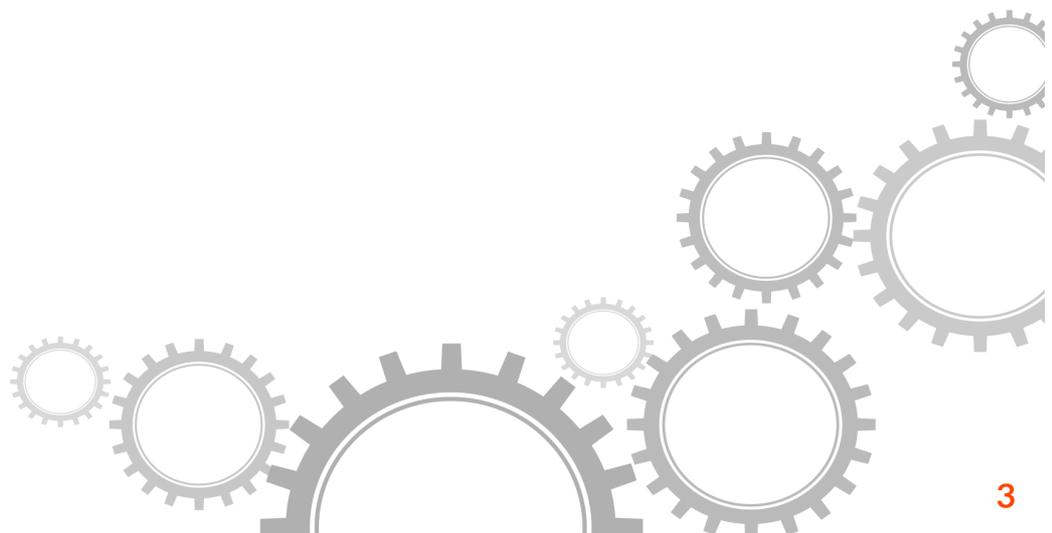
Teams make hundreds of decisions throughout product development. The full, extended team makes some decisions; more are made by the core team, and most by individuals. Every day individual contributors are making decisions. Most are little decisions that seemingly don't affect other team members. For a product development effort it is more often the case that decisions do affect others. Product development is often treated as very task-based, where silos of disciplines work independently of each other. By encouraging consistent communication across disciplines and applying systems thinking, a systems approach to product development is created. A systems approach will arm the team with the information it needs to make good daily decisions. Some of these will be critical decisions, and the system-level perspective will end up saving the project from unexpected delays.



A great way to make sure this happens is by assigning a product manager.



Organizations that practice strategic project management have discovered the importance of having dedicated project managers. When the going gets tough on a project, the team needs all hands on deck. Each team member is required to focus their attention on the critical path. However, a project manager that also has another role on the team will need to peak their performance in both areas simultaneously. This is almost impossible to accomplish and typically results in the project management duties getting thrown aside. However, this is when the PM is needed most – to help guide the team through the critical time in the project, ensuring everyone is working toward the common goal, facilitating communication with stakeholders, troubleshooting, and prioritizing workflow. The PM is the lighthouse guiding the ship through the storm, without which the ship may crash into the rocks. Don't let your teams be vulnerable – practice strategic project management with dedicated project managers.



What are the biggest mistakes medical device developers make when generating a design history file? What complications arise from a lack of proper documentation?

This is a complex topic and there's no simple answer. Always keep in mind that the design history file is intended to be a record of decisions that were made throughout the design process and evidence that the design intent was achieved. If your design history file includes too little information, you will have to go back and redo work which costs time and money. If you include too much you've also wasted effort and you leave yourself open to increased scrutiny by the regulatory organizations. Putting too much information into a design history file can also make retrieval of information more challenging and increase the complexity of managing the information.

Every email or piece of correspondence does not need to be included. If it does answer a question or include concrete conclusions, leave it out. Start the design history file after you have your project requirements clearly documented and your technology is sufficiently mature. Once design has started, the history file will be essential to show intent and track changes and the reason for them.

How can developers make product launches more predictable?

Product development schedules are typically very aggressive, often requiring teams to move quickly. An ongoing review of the risks and mitigations throughout the project will be important. Through this iterative design process, new risks can be identified, assessed and mitigated.

Technology Risk Assessment

The first step in managing development risk is a thorough analysis and assessment of the risks in each of the projects that comprise your product development portfolio. The assessment must first identify exactly what the risks are and where the risks reside in the overall program development path. Examples of these risks may include algorithm development, new material requirements, manufacturing process development, sensing systems, thermal requirements and assay stability.

Once identified, technology risks should be analyzed to determine the current maturity of the technology, its robustness level, current mitigation activities and known back-up approaches. Understanding these parameters will provide the firm with a realistic window on launch predictability for each of its product development programs.

Fast Risk Reduction

Improving launch predictability can be accomplished by undertaking tightly-targeted risk reduction sub-projects in parallel with the overall development program or as gating tasks within the program itself. Rapid development of models, bread boards, prototypes, simulations and performance test regimens along with expert applied research can substantially change the risk profile for a particular development program. These focused risk-reduction activities can be clearly defined and lend themselves well to outsourcing.



What regulatory considerations should be factored in to the development of a medical device in the U.S?



If you are unsure how the FDA will classify your device or which regulatory path will be most appropriate for your product, you may waste a lot of time heading in the wrong direction. Each class of medical device has its own regulatory requirements and there are various possible paths – 510(k), PMA, NDA and others. You can lose precious time and money by assuming incorrectly.

It is possible to err in two ways here: selecting a path that is not stringent enough to gain FDA approval or one that is overly rigid for your product's actual classification. The latter could lead to the collection of unnecessary clinical data or a process with unwarranted design control requirements. There could also be a predicate device or existing clinical data that you weren't aware of that could simplify the path significantly. If there is any ambiguity it is worth the investment to enlist the help of a regulatory consultant to ensure you are on the path to success.

What are the benefits of using development outsourcing?

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Product innovation within a well-established product design company can be challenging. Corporate politics, burdensome development processes, and competing priorities can suppress engineering creativity and limit the acceptance of new ideas. Corporations that are more successful at innovation tend to be smaller companies where bureaucracy and competing priorities don't create road-blocks to creativity and invention. One option for corporations that are struggling to gain a leading edge in product design and engineering is to outsource innovation to a product development consulting firm.

Strategic Benefits of Outsourcing Innovation

Key benefits include:

-  Access to specialized talent: No single company has all the brightest and imaginative people in the world. Outsourcing brings broad knowledge for innovative brainstorming and fresh, new, out of the box ideas. Outsourced consultants infuse artistry and creativity into the innovation process. Further, you get the benefit of expertise in specialized, targeted technical areas, without having that expertise in-house. Examples include moving from Windows-based software products to mobile apps and moving from an established standard medical product to a wearable medical device.
-  Technical risk management: Outsourcing allows exploration of a number of technologies quickly, well beyond what is possible using just internal resources, and leads to faster time-to-market once a direction is chosen. It also allows deeper exploration of a technology's benefits and potential viability before committing money for increased headcount and equipment.
-  Additional manpower: Healthy companies are under pressure to continually find talent to grow the business and increase the number of products and projects under development. Hiring and keeping top internal talent is an incredibly time-intensive and costly process. Outsourcing provides dedicated, focused resources when a company has a shortage of their own resources.
-  Speed: Less interference by internal bureaucracy and politics and faster startup time means quicker time to market. Outsourced consultants are efficient and are not dragged into current product line, sustaining engineering or other internal company distractions. The outsourced team is focused on one task – impressing you with their concepts.

To be successful:

- ☀️ Make sure there are sufficient internal resources to kick-off and support the consultants. The internal team will jointly develop the vision, collaborate and interact with the outside consultants. The emphasis should be on collaboration, working as one team with shared goals, objectives, and measurements of success. Initial face-to-face meetings are the best way to build the relationship and share the knowledge and expectations between internal and external team members.
- ☀️ Find the balance for internal involvement. Share what is wanted, not how to do it. Too much involvement could undermine the benefits of having the consultants' expertise, resources and creativity. On the other side, throwing it over the wall to an external team won't work either - the level of internal team direction and influence has to be just right, which is usually achieved with initial face-to-face meetings and then being available to answer questions as they come up throughout the project.
- ☀️ Protect existing and new intellectual property (IP). Service agreement contracts, agreed to by both parties, can provide some level of protection of any existing IP that is shared with the consultants as well as agreement of ownership and protection of IP created during the engagement. Often a company will choose to outsource innovation only to a consultancy within the same country, where there is a better understanding of IP protection, consultant contracts, and legal systems. This topic is complex and definitely deserves due diligence when entering into an outsourcing agreement.
- ☀️ Have a technology and project transfer plan in place. If the outsourcing is intended to be temporary, make sure the internal team is in a position to pick up the design/execution when the consultants contribution is complete. Invest in the internal team's ability to learn and grow their knowledge of the new technologies and products created during the engagement. Communicate transfer plans to the internal team so they will not feel threatened by the outsourcing efforts and will be adequately prepared to support the ongoing efforts. If the concepts are complete, but your internal team is not, consider letting the consultancy move to architecture or detailed design on your favorites - buying time to get your team ready to take it and run.



Outsourcing product development doesn't mean losing control of the project. It can actually be the catalyst for new and exciting advances for a company's product offering. Don't underestimate the benefit of adding hard to find technical expertise, increased capacity, and dedicated resources to your next effort.

The logo for Stratos, featuring the word "STRATOS" in a bold, sans-serif font. The letter "O" is highlighted in orange, while the other letters are in grey. The logo is enclosed in a white rectangular box with a thick orange border. A thin orange vertical line extends from the top of the box to the top of the page.

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Stratos' experience spans Drug Delivery, Point-of-Care Diagnostics, Consumer Electronics, Digital Health, Catheter Systems, Wearable Devices, Patient Monitoring, Bioprocess Manufacturing and Global Health. Our clients trust us to solve their toughest product development challenges with a constant eye towards commercialization.

www.stratos.com

Additional Resources:

-  [Five Mistakes That Can Derail Your Medical Device Development Effort](#)
-  [The Evolution of Consumer Wearables](#)
-  [Three Primary Causes of Scope Creep](#)

Hear first hand insights and strategies to overcome the challenges in product development, quality management, speed to commercialization, and regulatory harmonization by joining Stratos at:

[The American Medical Device Summit 2016](#)

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