DEVICETALKS | BOSTON

Steering Clear of Common Medtech Failures That Jeopardize Funding and FDA Clearances

WHITE PAPER

Presenters:

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Overview

Medtech companies face significant challenges as they navigate the complex journey from innovation to commercialization. These challenges are often exacerbated with medtech startups, and a substantial number fail due to critical pitfalls in the engineering, testing, and manufacturing stages.

But companies can take steps to avoid jeopardizing funding opportunities. Understanding the most common product development pitfalls, from insufficient design or flawed verification testing strategies to costly Design for Manufacturing oversights, including regulatory delays, helps optimize investment to lower technical risk and reach key financial milestones.

PSN Labs has worked with startups and medtech giants and witnessed firsthand the challenges associated with bringing a product to market. PSN Labs works closely with companies of all sizes to overcome key obstacles in the product development lifecycle, applying in-house expertise toward early-stage planning, robust testing protocols, and scalable manufacturing processes that mitigate risks and ensure the successful launch of medtech innovations.

Context

The presenters discussed common pitfalls in medtech device development and shared effective ways to lower risk in the product lifecycle.

Key Takeaways

Medtech companies can avoid common pitfalls in device development by buying down technical risk.

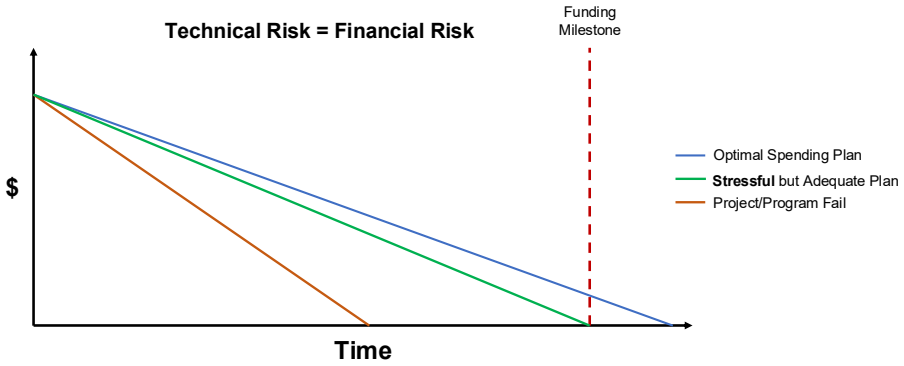
Of the multitude of ideas in the medical device space, few make it to market. Concepts often fall victim to common pitfalls along the path to commercialization, whether being developed as a primary product by a startup or through a project within a large medical device OEM or manufacturer.

Four key funding milestones are associated with common engineering pitfalls—which can result in significant consequences:

Funding Milestone	Engineering Pitfalls	Costly Consequences
Completion of Design Verification Testing (DVT) and validation	New observed failures in DVT. Failure to complete Engineering Confidence Testing (ECT) testing.	Restarting DVT.
Clinical trial	Improper prototypes. Device failures. Failure to understand user needs.	Repeating clinical studies. Reduced confidence.
Biocompatibility testing	Improper Biocompatibility Evaluation Plan (BEP). Not compliant with regulatory guidance.	Repeating biocompatibility testing. Reduced confidents.
Design transfer	Quality objectives not clearly defined. Manufacturing process not derisked.	New molds, tooling, and manufacturing process.

> "Startups have failed because they had to repeat biocompatibility completely . . . because they set up their testing wrong to begin with. That's not just months—it's potentially a year or more, and hundreds of thousands of dollars."
>
> —Matt Heidecker, PSN Labs

Figure 1: Finance utilization dictates startup survival



Avoiding the common pitfalls and achieving key funding milestones along the product development path determines a project's—or an entire company's—survival. Because technical risk and financial risk are so closely tied, optimizing finances to buy down technical risk in the **device design, device testing**, and **device manufacturing** processes increases the likelihood of reaching the next funding milestone.

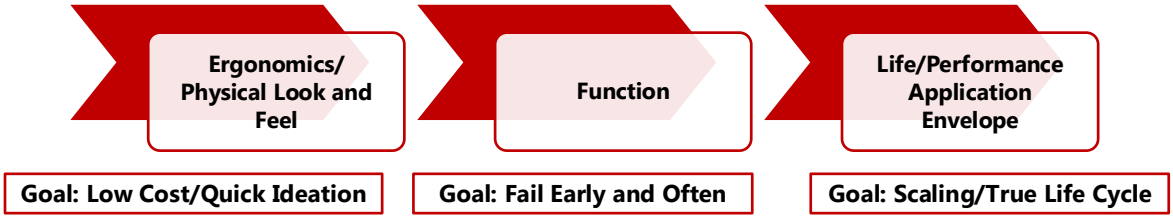
Understanding key technical risks can help identify areas of optimal investment.

Derisking product development depends on recognizing internal limitations and strategically seeking expertise where needed. In each of the device design, testing, and manufacturing processes, understanding the specific pitfalls and associated solutions can help identify gaps in expertise that can be outsourced to buy down technical risk.

Device Design

Pitfall	Why it matters	Solution
Improper user need definition Not accurately capturing *who* is actually using the device, as well as *how* all users (e.g., patients, practitioners, preparers, etc.) will be using it.	Clear, thorough user requirements define the use environment, user group, and how the device is used in practice.	Seek clinical and marketing feedback early and often.
Late risk management Devaluing risk-based thinking and/or applying risk management techniques only at the end of a project.	Risk management tools help identify areas where investment is needed, increasing safety and efficacy to increase the chance of reaching the next milestone.	Identify high-risk areas early on and focus investment on buying down safety and efficacy risk, and even commercial or manufacturing risk. Complete basic risk assessments early (Risk Registry, Preliminary BEP, or early failure mode & effects analyses).
Not respecting design bounds Not seeking to understand limitations of the physics around the device before prototyping.	Uninformed prototyping can be expensive and lead to wasted iterations.	Identify robust testing plans for engineering confidence tests that inform the next iteration of prototypes. Utilize computational modeling and simulation (CM&S) to develop a physics-based digital twin of your device. Grow from directional modeling to representative modeling.
Prototyping the wrong device and/or prototyping the incorrect concept	The correct prototype can more accurately capture a device's intent and associated risks.	Never prototype just to prototype: *Prototyping does not equal progress.* Identify what needs to be learned from the prototype to iteratively progress up the technical readiness scale.

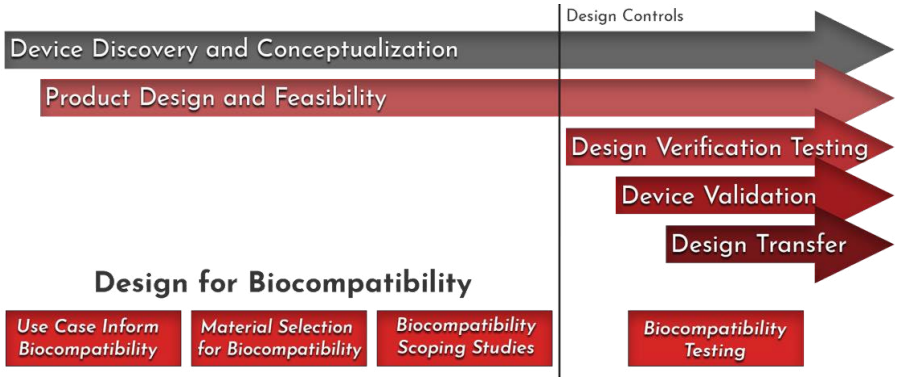
Figure 2: Different prototyping concepts have different goals



Device Testing

Pitfall	Why it matters	Solution
Not understanding materials	Material properties change when the device is used, impacting performance.	Understand what is important to the device upfront and build out a complete list of properties required.
Poor verification planning Skipping ECT to go straight to DVT or DVT that does not sufficiently address requirements.	Pre-investment is much less expensive than finding a failure during DVT and having to retest.	Prioritize learnings from early ECT and usability studies. Complete a pre-DVT—and never go into DVT without knowing the device will pass.
Biocompatibility by ChatGPT Attempting to predict biological response and develop biocompatibility tests using Internet tools such as Google search or AI engines.	Biocompatibility is fundamental to biological safety—there is no shortcut to testing.	Rely upon competent resources attached to reputable organizations with a proven record of achieving clearances. As with other potential pitfalls, identify and address biocompatibility concerns early in the cycle.

Figure 3: Designing for biocompatibility helps avoid waste



Device Manufacturing

Pitfall	Why it matters	Solution
Design not ready Not reviewing the product design for Design for Manufacturing and Design for Assembly issues and inefficiencies. Not seeking supplier or manufacturing support. Not reviewing material behavior after processing.	Designs need to be robust and scalable for commercial manufacturing.	Mechanical engineers are not development/materials engineers. Consult the manufacturing team on early prototype builds and incorporate feedback to design *prior* to when it is needed, as changes can impact other areas.
Misalignment on vendor readiness Expecting to scale directly from 3D-printed prototypes to 10,000 components annually.	As with device designs, manufacturing processes designed for 100 prototypes are likely not capable of handling 10,000 prototypes.	Develop plans early and work closely with every vendor to ensure the design and manufacturing process is capable of inspection, assembly, cleaning, sterilization, etc., at scale.
Lack of design transfer plan Assuming scale-up happens right away, with little lost in design intent and quality.	Ambiguity leads to process control issues and/or back-end device expectation issues.	Drawings and process requirements should be complete and demonstrate manufacturing requirements. Establishing communication with new suppliers sooner rather than later supports a quicker design transfer when ready.

Key considerations and best practices in medtech product development.

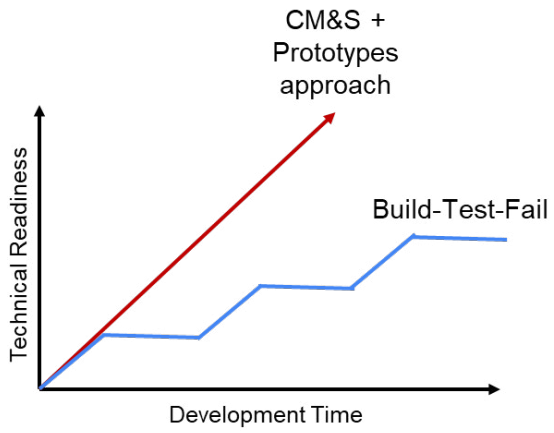
Keep in mind that upfront pricing is not always the true cost. Technical decisions made at the beginning of development, such as materials selection and design concept, are typically the most expensive. Investing resources during the early stages of the product lifecycle in uncovering key requirements and identifying the highest-risk items optimizes investments to decrease strategic technical risk.

Best practices for increasing the chance of reaching commercial availability include:

- Identify and invest early in key risks to the device.
- Utilize virtual prototyping to increase early prototype learnings.
- Design for scale from the start.
- Partner with experts—identify those who have been there, done that.

> "Product development is messy. It is not a straight line . . . with no hiccups. . . The key is to try to understand when those are going to come up and how to avoid them."
>
> —Mark Burchnall, PSN Labs

Figure 4: Iterative virtual prototyping decreases technical risk



Additional Information

To learn more visit psnlabs.com

Biographies

Mark Burchnall
Engineering Director, PSN Labs

Mark Burchnall is a product development consultant with over a decade of experience in the Medical Device and Pharmaceutical sectors. As the Director of Engineering at PSN Labs, Mark leads the engineering department, offering invaluable support to clients in new product development, test method development, functional prototyping, contract manufacturing, and on-market remediation. His team specializes in designing devices that incorporate various design principles, including manufacturing, assembly, sustainability, biocompatibility, reprocessing, and reliability. Mark's background encompasses the development of innovative healthcare solutions in areas such as drug delivery, surgical robotics, pharmaceutical packaging, and catheters. His expertise ensures patient safety and regulatory compliance throughout the design process. Mark holds a Bachelor of Science in Mechanical Engineering from Purdue University and a Master of Science in Mechanical Engineering from the University of Cincinnati.

Matt Heidecker, PhD
VP/Principal Scientist, PSN Labs

Matt Heidecker is the Vice President and Principal Scientist at PSN Labs. Matt's background includes a BS in Plastics Engineering Technology from Penn State-Erie, and a PhD in Materials Science and Engineering from Penn State University. He has spent the last 18 years working in a variety of industries across the world, with the past 8-years at PSN Labs. PSN Labs focus on wholistic product development, testing, and manufacturing that provides a harmonized approach which leads to successful biocompatibility outcomes for medical devices as the focus is on appropriate material selection, design, and manufacturing principles.