Science.
Applied to Life.™

From Mind to Market

How to transition from concept to commercialization while being mindful of timing constraints.

Medical Materials & Technologies

From Mind to Market

How to transition from concept to commercialization while being mindful of timing constraints.

Introduction

Key questions:

What is the market size?

What competitor products exist?

What are our core strengths?

Can we create something new and/or better?

How long will it take to develop?

What is the window of opportunity?

Do you launch a 'good enough' device early, while investing more time in developing the 'best' solution for the next generation?

What is the opportunity cost compared to other development opportunities?

For every 1,000 experiments 3M Scientist Audrey Sherman attempts, one succeeds. "You know the route to the grocery store," Audrey explains. "You follow it, and you're guaranteed a successful outcome." Audrey's job is to take the road less traveled.

"We go where people haven't gone before."

A similar approach applies when taking a device from mind to market. You might have some ideas, processes and procedures in place – some starting blocks to put plans in motion – but it's important to consider all the possibilities. Looking at what won't or hasn't worked, brings you closer to what will.

Timing is another key variable. "Time" is a broad term, and it's meaning changes depending on where you are in the design phase.

In this eBook, we'll share best practices and timing tips for each phase:

1. Concept
2. Prototype
3. Test
4. Scale and Launch

1. Concept

Brainstorm, ask questions, do research and ensure your design and manufacturing partners can support your goals. Invite product designers, project managers, research scientists, sales, marketing, business development, and technical services to the table. Ask experts who have listened to customer needs and complaints to share insights. Pain points will inform device design.

Go beyond the *what*. Get to the *why*.

If designing a continuous glucose monitoring device for diabetics, the why behind the device might be: “to help diabetics live active, fulfilling lives.” You seek a solution that goes beyond information and data capture. You want a glucose monitor that can withstand sweat, sun, and swimming pools. You want a glucose monitor that’s reliable and resilient. You want a tool that helps diabetics live life to the fullest, no restrictions.

Let’s talk timing

In the concept phase, plan your project and estimate how long each phase will take. Additionally, consider time in the context of device design itself.

Critical care data, for example, is captured immediately, in an instant. Trending data, on the other hand, creates baseline parameters, because it is captured over time. In the case of a diabetic, consistent data capture can be extremely meaningful; it gives a more accurate picture of what triggers spikes or dips in glucose. Together, patients and providers can look for patterns. You’ll also want to select an adhesive solution that remains securely in place for the life of sensor and battery. These are all ways timing must be accounted for in the context of device design.

2. Prototype

Key questions:

Does it work to solve customer needs?

Is my idea feasible for manufacturing as well as for the customer?

What test methods will be used?

What would the customer use for testing?

How does this fit customer specifications?

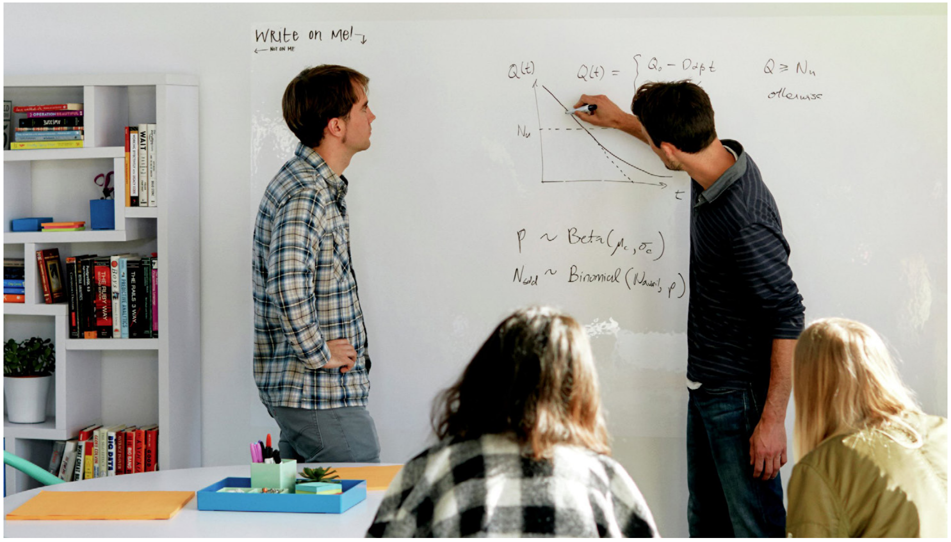
Does it work to solve customer needs?

When you prototype, cast a wide net and keep your options open. As you iterate, your ideas begin to take shape in new and exciting ways. Talk to experts to gain insight and expertise along the way. Remember that novel solutions frequently come with the added burden of developing new procedures to test your device.

Let's talk timing

Now is the time to fail fast and fail forward. Consider rapid prototyping. The faster you can iterate, the faster you can optimize your solution. Another factor to keep in mind is mechanical versus technological prototyping. In the former, you might be iterating sizes and dimensions, in the latter, you might be iterating different sensors. No matter what you're iterating, keep manufacturing in mind. If you find you can't manufacture it, move on to the next concept.

3. Test



Key questions:

What are testing parameters?

What test methods will be used?

What would the customer use for testing?

How does this fit customer specifications?

Does it work to solve customer needs?

Who are the viable material vendors?

What is the biocompatibility of the device?

During development, it's important to consider the way the material is tested. For instance, there is no material you can test an adhesive on that will accurately predict adhesion to skin. Polyethylene panels have similar surface energy, but can't sweat, stretch and move. Testing on polyethylene can't tell you which adhesive will ultimately perform best on skin but can weed out many formulations. In the end, there is no substitute for testing the final design under actual use conditions.

Let's talk timing

In a regulated industry, federal approvals play a crucial role in timing. Devices are categorized based on risk in the United States:

- Class I – low risk (i.e. bandages)
- Class II – moderate risk (i.e. powered wheelchairs)
- Class III – high risk (i.e. implantable pacemakers)

Each medical device has a specific regulation which clearly states the classification and risk level.

The time it takes to gain the proper clearance or approval corresponds to device risk. Class I products only require device and establishment listing, and 510(K), De Novo or PMA submissions. Class II and Class III devices typically requires submissions to the agency. This is a Premarket Notification (also called a 510(k)) for Class II products, and a Premarket Approval (PMA) for Class III products. There is also a De Novo pathway for low to moderate risk medical devices that do not fit into a current medical device regulation.

The review time depends on the type of the submission ranging from 30 to 90 days for a PMN (510(k)), 150 days for a De Novo, and 180 days for a PMA (not including manufacturing response time). Note that this is only the FDA review time and does not include the time it takes for the manufacturer to respond to concerns identified by the FDA. See more on the FDA's website for submission timing.

Best practice is to engage the FDA early through their pre-submission process to ensure alignment on any submission filing. This process typically takes 60 to 70 days, see pre-submission guidance here.

Once on the market the FDA may audit at any time, but audit schedules are typically based on risk, with high-risk devices being audited more frequently than low-risk devices.

4. Scale and Launch

Key questions:

What are the process windows?

Do materials meet specifications?

Have you:

- Filed regulatory documentation
- Demonstrated the ability to manufacture at scale?
- Qualified processes?
- Verified designs?
- Sampled the product with a target audience?
- Considered legal implications?

Scale symbolizes a meaningful transition – where the product moves from the lab to life. It's unrealistic to assume manufacturing will match a lab process, so assume adjustments will need to be made. Changes in processes and procedures could make an otherwise viable design fail.

Nothing scales without challenges. The road from pilot to production is rarely smooth. Be prepared for process tweaks and equipment re-design. Invite manufacturing colleagues to get involved as early as possible, so they can preview what's to come. Mixtures, coatings, and materials that behave well in the gallon-quantities won't always behave well in drum-quantities nor at the speeds found in manufacturing settings. Shear rate differences can make 'easy' coating steps difficult. In the assembly of discrete units, thermal bonding of components requires a minimum dwell time which may not be compatible with the required manufacturing throughput.

When you reach the launch phase, the design must be finalized.

Let's talk timing

Many variables, from delivery to dwell time, will play a part in how materials act and come together. Be prepared to communicate. The sooner you flag issues as they arise, the sooner you can mitigate and solve for them. If problems persist, it's important to pinpoint where the breakdown occurs and why. Adhesives generally behave predictably on their own but frequently introduce unexpected variables when incorporated into multi-layered constructions. Adhesives are not simple, pure materials and some of their components might migrate into adjoining layers, changing the adhesive's performance or the properties of those other layers. Select and test all of your materials for immediate compatibility and long-term stability.

Also consider the varying time frames of the lab and the manufacturing lines. A lab sample that is coated within minutes of mixing may behave differently than a manufacturing batch that may age hours before the last of it is coated. Polymers are active and alive, and you can't control how they change during transit, on the shelf, or during manufacturing, but you can anticipate the changes and mitigate the consequences.

Conclusion

At 3M, we can help take your device from concept to commercialization while keeping key questions and timing in mind. Choosing the right partner can make a world of difference.

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