Best practices for medical device prototyping

By Todd Owens and Raghu Vadlamudi

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As the physical actualization of an engineer's idea to solve a problem, a prototype serves a critical product development purpose in helping engineers learn how a product will function in actual use before creating and investing in production-ready manufacturing processes. It's important to learn as much as possible about the product through prototyping phases, so design, performance, functionality and materials used for the final product meet desired outcomes. When done well, going through the prototyping process can save manufacturers significant time and resources, and keep products on track for market.

However, the process of design and prototype creation to end product rarely goes seamlessly. Here are common challenges to look out for and how to overcome them to ensure your processes go as smoothly as possible.

Finding the right balance

Challenges within prototyping often center around misaligned expectations and objectives. Timing, talent and available budgets can also be challenging. Manufacturers should execute a few thorough measures before beginning to develop the prototype, including:

- Define the desired outcomes of the device, as well as expectations for each element of the prototype.
- Establish a clear communication plan for stakeholders.
- Draft a written project plan that outlines either a multistage or multiphase approach with desired outcomes, deliverables and budget.
- Create contingency plans to readily adjust timelines, stage-gates and budget if and as necessary, based on learnings during the prototyping process.
- Identify, evaluate and select the appropriate prototype materials in advance.

Plan to work in stages

As noted above, it's important to understand and define the desired outcomes of the device, and to deploy a multistage or multiphase approach. The first stage is often a very short time frame with minimal monetary investment. This may involve simple, printed mockups, an explanation of components and the goal. If that stage has a positive outcome, the next logical stage would be a machined prototype. Again, based on outcomes, the machined prototype could evolve into injection molding of individual parts, for example, which may be the desired manufacturing process for serial production.

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Evaluate product risks

Assessing product and component risks can also help alleviate time and budget constraints. Higher-risk products and components will often receive more focus and require more modifications through prototyping. For example, a product with microfeatures may cause concerns about durability and manufacturability. A prototype strategy to save cost and time could involve reducing the complexity of lower-risk elements of the product design, putting a deeper focus on higher-risk areas.

If manufacturability is of little concern from a risk standpoint, prototype costs and budget concerns can be cut. For instance, building an injection mold to create a product is often more expensive than machining from stock materials, because of the capital investment. If it can be easily manufactured, time and money savings likely occur.

Stay abreast of what's possible

It's important to stay up to date. As technologies advance from hypothetical ideas to innovative, next-generation tools, prototyping improves, costs lower and development accelerates. Case in point, it wasn't that long ago that artificial intelligence (AI) and Big Data changed what's possible by making it possible to quickly model and simulate the performance of components and devices. A more recent major advancement – additive manufacturing, also called 3D printing – is rapidly becoming an extremely important and frequently used tool to streamline the prototyping process. Now, within a matter of hours, engineers can print parametric models of concepts to test and address design features, saving days – sometimes weeks – developing prototypes.

However, it's also crucial to understand the limits of new and forthcoming technologies. For example, 3D technology only recently became capable of reliably producing micro parts and features for prototyping, but remains too cost prohibitive for mass production. Similarly, AI and Big Data also face challenges, particularly regarding the lack of diversity in data, collection inconsistencies and still-forming best practices for evaluating its use in product development.

Exercise patience as standards develop

Beyond their own technical limitations, new technologies also need to be worked into regulatory approval processes, which takes time and due diligence from both manufacturers and regulators. With patient lives at stake, it's in everyone's best interest for medical device manufacturers and regulators to scrutinize new technologies for safety and effectiveness and develop guidelines, before adopting them as new standards and using them broadly to replace already-proven technologies.

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About the authors

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