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Designing Medical Devices for Manufacturability: How to Do It and Why You Should

Practical advice from three industry experts on how to keep manufacturability top of mind in the design process.

By Amanda Pedersen, July 28, 2021

Product design engineers today face so many pressures associated with cost and turn-around time, that manufacturing considerations sometimes end up on the back burner. *MD+DI* recently interviewed three industry experts on how to keep manufacturability top of mind in the design process, particularly when designing a medical device.

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First, let's define the term, 'design for manufacturability'.

Design for manufacturability (DFM) is about designing functional parts that meet manufacturing constraints, said Uday Komaragiri, SIMULIA R&D life sciences industry portfolio director at *Dassault Systèmes.*

"It answers the questions, 'Can my part be manufactured as-designed?' and "What variability does a manufacturing process introduce to my design and how do I address it?' In other words, how close will the 'as-manufactured' part be to the 'as-designed,' and will it meet functional requirements? While this is true for any traditional manufacturing practice, it is even more relevant for additively manufactured parts where the variability introduced by the manufacturing process is still largely unknown and is typically resolved using trial and error approaches," Komaragiri told *MD+DI*.

Design engineers nowadays are increasingly using simulation to help understand this variability and come up with the most optimal design that meets manufacturing constraints right from the get-go, Komaragiri said. He also noted that design for assembly (DFA) is a common partner to DFM, because parts have to be assembled into components or sub-assemblies, and then into the final product.

All of the experts we spoke with on the topic agreed that design for manufacturability is a process that needs to happen at the earliest possible stage of the design process.

"OEMs should engage their outside supplier partners for exposure to their product and the need it's being designed to meet," said Doug Pletcher, vice president at *Intricon*. "There may not be any breakthrough ideas from an outside partner but if there are, the benefits can be significant. Even the most minor tweaks to design can make a major difference in a product's cost per unit."

While it's common practice to focus on cost per unit, Pletcher told *MD+DI* that yield, quality, reliability of the device in use, robustness of the product, and stability during the manufacturing process can all be positively affected when DFM is incorporated into the process.

Some OEMs leverage the DFM expertise of their suppliers more than others, he added, so there is diplomacy involved in making suggestions during the DFM phase, which is important to understand.

"DFM isn't about people telling other people how to do their jobs — it's about additive ideas that come from the collective goal of getting a device to market on time and within budget by eliminating surprises during manufacturing," Pletcher said.

Why is design for manufacturability important in medtech?

A lot of things can go wrong if design engineers don't take manufacturability into consideration. Steve Santoro, executive vice president at *MICRO*, told *MD+DI* that it's important for companies to work closely with their manufacturing partners, especially when it comes to tolerances on medical device features.

"You kind of back yourself into a corner if you make the tolerances so tight there's only a limited number of technologies that you can use to manufacture them," Santoro said.

These considerations are particularly important in highly-regulated industries like medtech.

"Medtech is one of the most highly regulated industries, which makes it difficult to make subsequent changes to a product during development and manufacturing," Pletcher said. "Options and foresight into ways to enhance the manufacturing of the product should be taken into consideration from the beginning. Even the smallest minor changes in the product after it has been

launched can take months to implement given our stringent regulations."

Well-performed DFM can reduce the incidence of malfunctions while keeping device costs to a minimum, Komaragiri said.

"The reduction of variation in manufacturing costs money," he said.

When making disposable drug injection devices, for example, the conflict is one of 'sufficient' quality at minimal cost —because billions of parts are being made. Komaragiri said quality is usually measured by consistency, dimensional accuracy, strength/stiffness and material characteristics.

"For implants, cost efficiency is not an issue because volume is low, but quality has to perfect all of the time," he said. "A malfunction due to manufacturing variation is not acceptable."

In all cases, he said, DFM and DFA better serve product development by being integrated into the design process from the beginning, helping to converge the design more quickly and reducing the potential for manufacturing-based problems late in a program.

Not taking manufacturability into consideration during the design process tends to drive manufacturing costs up quickly. And if a device works but is too expensive to market, that can be just as bad as if the device failed. Santoro said some companies are better at managing this risk than others. For established companies with a lot of experience, it comes naturally, whereas younger companies or companies where there has been a lot of staff turnover don't have the tribal knowledge that can play a vital role in the design and development process. Most contract manufacturers can ultimately get the device to work, he said, but whether or not it will be cost effective is the real question.

Design engineers should also take manufacturability into consideration when selecting materials.

Komaragiri recalls a customer having issues with designers specifying materials for which no toxicity studies had yet been done, and this not becoming evident until after all the design work is complete. Toxicity studies take a long time to conduct and easily extend the program unexpectedly, he said.

Best practices for designing for manufacturability in the medical device industry?

Komaragiri said close collaboration with manufacturing engineers and early use of simulation is key to understanding and avoiding many manufacturing-related design issues.

"Virtual [design of experiments] can help understand the relative importance of various design and manufacturing parameters, and give insights into how the part can be redesigned to meet both the functional requirements and manufacturing constraints," he said. "Finally, it's important for device manufacturers to do this in a design environment that offers full traceability to any manufacturing and simulation data, so design decisions are fully documented for regulatory purposes."

Pletcher said the simplest way to start incorporating design for manufacturability is to ask the manufacturer to cue up possible future design adjustments early in the process. This helps move DFM upstream so it's not an afterthought, Pletcher said. He also recommends tracking a few good ideas, something as simple as an alternative adhesive that can be assessed in parallel during development, when you can know and test the options.

"It is inevitable that a company will come back later, after a device is on the market, to ask a manufacturer to find a way to cut costs," Pletcher said. "If there were alternative ideas identified at the onset, they will be easier to assess and implement as appropriate."

Another good tip from Pletcher is to make sure there is mutual respect among everyone involved in the process.

"A product will get out the door better and faster if all are gathered around the drawing board," he said. "DFM is a pragmatic approach to bringing specialists in their respective areas together to add productive ideas and insight."

Pletcher recommends choosing a supplier that has some understanding of the clinical procedures associated with the new product and knows the end goal of the clinical procedure. For example, he said that even though *Intricon* may make just the electromagnetic micro-coils used in the tip of a surgical navigation product, the organization is familiar with how everything must work together to successfully track through vasculature and airways.

Contract manufacturers also have to be careful not to presume they know more than they do, and to recognize when to take the lead from the customer, Santoro said.

"I think there has to be a balancing act there," he said. "...the more each one knows each other, the more both sides understand what each brings to the table."

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