



# Developing a nimble, cost-sensitive approach to medical device design

Front-loading design work through 'hobbyist' platforms saves time and money

by Norbert Sparrow in PLASTEC New England, Medical

It wasn't always like this, but there's no getting around the fact that cost constraints have become a central concern for medical device OEMs. Gone are the days when incremental improvements in a product could justify a price increase.



Sean Priddy, Business Development Director at Creation Technologies, has some suggestions for medical device manufacturers wrestling with cost constraints and outcomes-based value propositions.

The techniques have proven their worth at his company, an electronics manufacturing services (EMS) provider headquartered near Vancouver, BC, Canada, which does a significant portion of its business with medical device OEMs. Priddy will detail these strategies at the forthcoming BIOMEDevice exhibition and conference, co-located with PLASTEC New England in Boston next month. He shared some of them with PlasticsToday in advance of the event.

Priddy comes from a design background—Creation Technologies is his first stint with an electronics company—and much of his advice informs the device phase of a product's life cycle.

"Design tends to happen in a vacuum," says Priddy. "Design engineers typically don't have good visibility into supply chain pricing or problems that may occur during the manufacturing process. All of the problems get backloaded," he explained to PlasticsToday. "When they do have visibility into the manufacturing process, they make better decisions. That's where our design centers excel," says Priddy.





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Creation Technologies operates two design centers in addition to 10 manufacturing facilities, two rapid prototyping centers and a global materials sourcing group in locations across North America and China.

The company's forté is high-complexity, medium-volume electronics, which makes it an excellent fit for the medical technology industry—indeed, all of the design centers and manufacturing facilities are certified to ISO 13485—but it also serves the EMS firm well in transportation, energy "and other sectors existing within a regulated market," says Priddy. "Having a structured process in place is essential to working with regulated industries, where all the process infrastructure and checks and balances are documented," he explains, but those requirements can slow down time to market.

One remedy, says Priddy, is to front-load as much design work as possible.

#### **Creation Technologies Product Innovation Centers**







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"If you look at electronics over the past decade, and it's certainly true in software development, it's been all about agile design. Incremental development, quick iterations and cycle times . . . you evaluate where you are before you move forward, rather than planning out a year-long project where everything has to be done in sequence" explains Priddy. "You try to learn as much as you can about the requirements up front before you even begin productizing the device."

Priddy will explain the process during his presentation at BIOMEDevice Boston, but it essentially involves leveraging open-source software and "hobbyist" platforms such as Arduino and Raspberry Pi to do quick experiments before you have all your design inputs.

Your team can look at five or six different things at the same time and not be locked into a rigid sequential process.

"Once you've played around on these platforms and decided on your specs, you can feed them into your formal requirements," explains Priddy. That flexibility is gone once your project is under medical device process controls, where every step needs to be documented and signed off on, Priddy adds. "Front load as much as you can into what can be called the research phase before you do the development that feeds inputs into your specifications. Quick experiments can give you good answers," stresses Priddy. "If you're doing that under design controls, it slows everything down."







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Priddy also espouses a decidedly low-tech way to test some design assumptions: Use a nonfunctional physical prototype, a box with cables, for example.

"Walk the user through various scenarios: How would you take it out of the box? How would you plug it in? Turn it on? It's pretty amazing what you can learn from a nonfunctional device," says Priddy, who adds that you may well discover hidden requirements before you even commit to anything technical.

Priddy will discuss these and other strategies for designing engaging and effective medical products in a cost-conscious business environment during the Medtech Design session at BIOMEDevice Boston on April 14.

For more information about attending the event, which comes to the Boston Convention & Exhibition Center on April 13-14, go to the BIOMEDevice website.

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Sean Priddy has 20 years of professional experience developing embedded electronic products for the industrial, aerospace, consumer and medical device markets. Sean uses his technical expertise to help medical device OEMs design and develop high-performing products, and has specific acumen in connected device design for companies looking to leverage the Internet of Everything in their next-generation devices.