More Usable, by Design

Fewer bells and whistles, greater functionality are seen as keys for medical device designers toiling in an age of austerity.

Jim Stommen • *Contributing Writer*

Once upon a time, any discussion of what's new in medical device design would be dominated by the latest "whiz-bang" technology, with more than a few bells and whistles thrown in for good measure.

Not today. Welcome to 2012 and the world of austerity, where doing more with less gets the royal treatment and cost-control and functionality reign as king and queen.

When *Medical Product Outsourcing* set out to learn what product developers are seeing in their respective marketplaces, our search brought a surprisingly high level of unanimity of opinion, with the word "usability" often being one of the first words out of the mouths of almost every person who was part of the discussion.

Marc Dubreuil, director of business development at Farm, a longtime product development firm headquartered in Hollis, N.H., cited the emphasis on usability of devices, saying he "wouldn't necessarily call it new, but the focus is much greater than ever before."

What is new, he said, is that instead of technology being pushed into the market, "a lot of large medical OEMs are starting to figure out that it's easier to find out what users want and need and then supply that need as opposed to just pushing technology. That being said, new technology gives them added differentiation, added value, things like that. But usability is by far the biggest focus in design today."

Kenneth Fine, president and co-founder of product development firm Proven Process Medical Devices in Mansfield, Mass., echoed Dubreuil's focus on usability. Among several things that he sees as being new and trending, he said there is "more thrust on usability than I have seen in the past, and that to me is occurring for several reasons. One is that it is in the eyes of the regulators more than it has been in the past. Second, a lot of devices are migrating to the home healthcare market and people are getting more used to devices that are very usable, so now healthcare devices have to be that way."

Aidan Petrie, co-founder and chief innovation officer at Ximedica, a Providence, R.I.-based product development firm, said, "What we are seeing right now essentially is the shift to digital health—products with some sort of digital component, wireless component; mobile products that are less about surgery and more about monitoring and diagnostics. There is also the data side of devices, so the tech frontier is being pushed at the moment."

Arthur Erdman, Ph.D., director of the Medical Devices Center at the University of Minnesota in Minneapolis, has been the chair of 11 Design of Medical Devices Conferences that are sponsored by the university each April. The event is among the largest in the world for medical device design, this year drawing 1,140 attendees during four days. To the question of what's new in medical device design, Erdman said there is "less of this [new medical device design] happening at the big companies, and if the device tax stays, it's going to continue to be less and less. So where is it going to happen?"

Usability, Usability, Usability

Fine said that in addition to the usability push, "the big thing in the design world is that now with RoHS (Restriction of Hazardous Substances Directive in the European Union) 2.0 requirements being in place and medical devices no longer being exempt, we're seeing a lot of activity for design and redesign related to making sure that companies can meet those requirements. And certainly with what's going on in the political environment, cost containment and devices needing to show their effectiveness, we're seeing a lot of pressures on what the designs have to do and the amount of time it

takes to design them. We're seeing that impact device design."

And, he said, from a European Union regulatory point of view, design considerations are being linked more with risk management.

"With the way the FDA (U.S. Food and Drug Administration) also is moving in that direction, we're seeing a lot more focus on that in the design process," Fine added.

He said the process of meeting of safety requirements, always an important consideration, is much more important than it has been in the past.

"Now that ISO 14971 (requirements for a risk management system for medical devices) has been around long enough and has worldwide acceptance and the new ISO 60601 (standards for medical electrical equipment) adopted, with a very risk management process centric, the way the FDA is looking at it really is forcing everybody to look at these processes earlier in the design cycles, right at the beginning when requirements are being defined and technology feasibilities are being established. It used to be something that was done later on."

He agreed with *Medical Product Outsourcing*'s observation that ISO standards are being more universally accepted, including by the FDA, albeit on a long-delayed basis.

"Our industry is not too dissimilar from other industries, except that we're 20 to 30 years behind everyone else," Fine said. "As with IT and telecom, when you globalize—and American companies are now very much serving global markets—it's very inefficient for governments, societies and companies to have so many disparate requirements. As governments are going broke everywhere and everybody is trying to be more efficient in how they do things, doing things multiple times just doesn't make sense anymore, so harmonizing best practices around the world is really an efficient thing to do for everybody."

Fine said that of "hot button" issues facing those involved with device design, "cost is always one, plus time to market—all the usual culprits. And, as I said before, usability is a big one. Our customers, especially the larger customers, are focusing a lot more on that area than they have in the past. Apple has trained the world and changed expectations about what to expect from technology. Our customers are really stepping up how they deal with usability and human-and-machine interfaces and things like that."

Fine said virtual prototyping has become a larger part of the process, noting that "the better the models are that challenge a device or a product to the real world, then the better that product will be designed. So if we have libraries of good models—it's almost like the standardization of ISO standards—then it is easier for regulatory bodies as well as industry to know that their product meets the needs."

He said the challenge is going to be the interface between the new concept and the virtual model, to make sure that there is compatibility.

As for design considerations playing a relatively more important role in some therapeutic areas than in others, he said there are a few important factors to consider.

"It relates to the complexity of the technology necessary for a therapy, and also for the criticality of the application," he said. "And the other one is the breadth of the experience base of the users. So when you consider home health, for example, you have users that have less experience with medical devices. They have a much wider background from an educational and cultural standpoint … so the design has to take that into consideration."

Usability as 'Good Practice'

Dubreuil said the usability question "is really just good practice, especially now that the FDA has said, 'Look, we recognize this is good practice; it's the right thing to do and, therefore, everyone will be required to do it in device development.' There are some really good reasons for it, which is why Farm has done it for more than 40 years and it's why we have an in-house research and usability team, but it all dovetails together."

He said when a new client approaches his firm, his team wants to know if the idea has been vetted beyond just the inventor or the group that came up with the idea.

"It's one thing to have a potential solution," he explained, "but what needs to be determined is if this solution is something that physicians would be interested in, and can they actually use the device without needing extensive training and experience. Adoption is key. Last but not least, are they willing to pay for that type of device?"

The process of going from idea to developed product can vary greatly, he said, adding that every project has a slightly different path. Some OEM clients need clarity and new ideas because they're too close to a technology or product.

"They can't see the forest through the trees," he said. "They tell us, 'Give us another 10 ideas that we can look at to determine if there's IP (intellectual property) in that space,' or they want help creating IP around some new ideas and then they'll take the idea forward and produce prototypes. And then there are other cases where we're working with start-up companies where we are all under design controls and the process becomes really formal."

He sees virtual prototyping and other assessment/simulation practices as tools whose use is growing in the design field.

"We do quite a bit of this type of analysis; we think it's a critical component," he said. "We make decisions early in the project about whether there's a need or a fit for analysis, so all of these things are taken into consideration. Virtual prototyping is a tool for us to be able to zero in and refine the design—thinnest wall, maximum strength, shortest cycle times for injection molding, things like that. But ultimately you have to be able to test the part physically to be sure that it meets specifications."

Dubreuil identified "two big opportunities" where design considerations are concerned. The first is in more traditional device markets.

"Orthopedics is [an example of] one of those where we have been machining metal for years," he said. "That market is one that is looking for where technology can give us differentiation—electromechanical technology, sensor technology, anything that is

new and different and unique, and it typically revolves around electronics. You see things like patient-specific knees, for example, that use CT scans and integrated data to get products."

The other opportunity is how to optimize second-generation for the future.

"I say 'optimized,' because we have to be able to determine what features are in products today that aren't used or that don't have enough value and take them out, because we're all going to get squeezed for lower and lower product costs," he explained.

Reflecting the Shift to Digital Health

Ximedica's Petrie said his company is doing quite a bit of work with drug delivery.

"As the patents on drugs run out, companies are looking for different ways to deliver those drugs, so the shift in the design is toward better ways of delivering a particular drug," he said. "A number of the products we are working on are effectively drug-delivery devices."

As for what his company is hearing from its customers in terms of design requirements, he said, "We have seen a number of programs that were perfectly good and interesting, but if they couldn't demonstrate meaningful improvement in efficacy, they essentially got shelved. The bar has been significantly raised for new products. This puts the focus on device development in a different place—programs are front-end loaded to make sure that there is a customer, that there is a reimbursement case, that there is a business case and that all in it is a relevant clinical story. All of this needs to be in order long before firing up the engineers."

Petrie outlined two important topics for companies to consider.

"One is the FDA enforcing the usability guidelines very heavily and very clearly, which has essentially thrown a lot of device companies onto their heels in that they don't have an integrated usability methodology as they develop a product," he said. "We have been doing quite a bit of remediation work on devices that were designed perfectly well, but they simply hadn't filled in the proper components to demonstrate that they had been through the usability process."

The other issue is the speed of technology development meeting the speed of the FDA approval process.

"We have these very fast-moving, nimble companies running into the FDA and not quite understanding why or how they have to behave in order to move their product through," he said. "The FDA, to give them their due, is taking steps to accommodate that, but at the same time, obviously have to adhere to their charter. So there's quite a bit of tension there."

As for trends in design, he said there is a shift from "pure mechanical design to mechanics plus electronics plus hardware plus software. We're seeing more products across all therapeutic areas that have a mechanical component in addition to hardware and software components."

More Flexibility, Lower Costs

On the question of "what's new," Bob Evans, business development manager at KMC Systems, a contract designer and manufacturer based in Merrimack, N.H., said, his company's *in-vitro* diagnostic instrument design customers are looking for smaller, more flexible feature sets, faster throughput and lower development and instrument costs.

"Basically, they want more for less cost, without compromising the quality or the reliability of the instrument," he said.

And reliability is more important these days.

"We're seeing instrument platform design requirements focusing more on reliability that now include methodologies to remote in, to monitor run times and cycle life on components that may require maintenance or field service. So addressing the installed instrument maintenance and field service costs during the design phase is an important performance parameter for our customers."

From a product development life cycle standpoint, Evans emphasized, a robust specification and planning phase is critical and must occur before design even begins.

"The more recent awareness by our customers of coupling good usability requirements from user research with a robust specification and planning phase is a major step toward producing designs that will not only comply with the FDA guidelines, but meet the user needs," he noted.

Evans said that having detailed discussions up front is extremely important.

"Early on in a program, it's all about understanding risk, of either a new technology or its implementation, the instrument packaging and especially the customer interface," he said, touting the benefit of using simulation early in the product life cycle.

"The total product life cycle usually starts with an idea followed by research, which then goes through a business case analysis, which is all typically done internally at the OEM," Evans explained. "After the business case analysis is when [OEMs] would seek the assistance of a company to help them develop and manufacture and provide field service. We have found that with our simulation tools, we can add value earlier in the process when we straddle the business case phase and the early specification/concept phase. We're pretty excited about the fact that this early simulation technique is yielding such great benefits."

Simpler Projects Growing in Frequency

Ed Browka, director of design for Research Triangle Park, N.C.-based Gilero Biomedical, a design and product development firm specializing in single-use devices made primarily of plastic and silicone, said simple is making a resurgence.

"One thing I'm seeing is that we're doing a lot of simpler projects—Class I and II devices. A doctor may come to us and say, 'I need a new device for such-and-such a procedure, can you help me develop this device?'" he said. "Sometimes the device we develop is as simple as a handle with a syringe built into the handle—really a simple thing. We're getting a lot more of those

types of projects—a small company coming to us, or a doctor. Even some of the larger companies are kind of looking for these. One of the projects I recently worked on was taking a respiratory product into a new market. The new market was neonates, so it was a matter of taking a product that fit adults and make it fit very small infants. It's not like it was a brand-new technology, but it still [required] going through the process, including all the regulatory and validation requirements."

Browka said that a sizable part of the design business involves companies deciding to look at ways to refresh existing products or simply at being able to bring about cost savings by reengineering or rethinking the product.

"Sometimes it's reconfiguring an existing product line, or they'll acquire a technology by buying out a smaller company so they'll own a new package of products and would like to simplify the combined product line," he said.

The discussions that are part of planning a product are important, but, as Browka put it, "we also jump to reality very quickly—that's an important step in going from concept to reality."

From a design perspective, one area that seems ripe for growth is home-use products.

"We did a catheter project for paraplegics and quadraplegics where they could self-introduce their catheter," Browka said. "It's a pretty big deal, and there was an integration of design and engineering."

More Built-In Controls

Pat Jones, engineering team leader at Penn United Technologies Inc., a Cabot, Pa.-based company whose Penn United Medical unit provides manufacturing solutions for medical customers, said that the medical group is seeing more controls and electronics incorporated into the devices.

"Before, the doctor or the surgeon would have to activate certain functions, now they're incorporating things like that into the design," Jones said.

In terms of design requirements, Jones said tolerances continue to get tighter, and that's been fairly consistent—though often "difficult to meet" some of the tolerances.

He said that "it's part of our responsibility to help educate our customers' design staffs on what the capabilities of our processes are," Jones said. "We have actually sent engineers to our customers, and we've had customers come into our training center and spend three days learning about how the process works. The manufacturing process needs to be part of the design process, and sometimes our expertise can help identify manufacturing processes that can save on part and assembly costs."

Simulation is a much bigger part of the process.

"Now you can run through multiple iterations of your design prior to having to prototype it," he said. "You're getting so much more knowledge about the part itself and incorporating it with the design."

Visualization Model as a New Approach

University of Minnesota's Erdman said despite market challenges, bright spots of opportunity remain.

"I think that home care has been and will continue to be very important—world-class monitoring systems, sensors and data systems to communicate vital signs and disease conditions, 'Obamacare' or not, that's the future. Underneath that umbrella are all these gadgets and nano-devices, sensors, actuators and labs on a chip—all this that people have been able to develop in other ways, funded through work on space research, defense, aviation, games and other funding mechanisms all over the world and now finding their way into medicine."

He added that a lot of that cutting-edge development is happening at UofM.

"I'm just so excited every day to see these new technologies. It seems to me like we're on this accelerated curve, despite the recession," he said.

Erdman noted that he and colleague Dr. Daniel Keefe have been working for almost three years with FDA on new approaches to designing medical devices using virtual environments, adding that "there's no doubt in my mind that the future will bring very different ways of engineers dealing with data and design, and it's not just for the medical device industry. The supercomputer of a dozen years ago is what we have in our iPad today, almost, so this is a huge change for the people in an analytical, computational environment."

As for how that might fit in the future, he said the regulatory process needs to be changed from total reliance on animal and human trials to minimal reliance on such methods.

"The only way we can really get there is to have reasonably good models of how our devices interface with human tissue and blood," he said.

Erdman said the agency has been very responsive on the question of visualization, with a considerable number of FDAers being exposed to what he and Keefe are developing. The entire first-day theme of the university's design conference this year was on virtual prototyping.

"There is a buy-in on using analytical modeling as part of the regulatory process," he said, "But it goes beyond that. It goes into a collaboration. We are talking about having a public/private partnership focused on developing the infrastructure where there is a totally open system, which is the only way both FDA and companies can work together." ❖

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