



The Innovators

Conversations

on the Cutting Edge

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Interview with Michael Hess Vice President of Innovation Excellence Medtronic, Inc.



As VP of Innovation Excellence Mike leads the Medtronic R&D council which is primarily focused on R&D productivity. Mike also leads activities focused on improving the culture of innovation and collaboration at Medtronic, and serves as the primary sponsor of internal technical employee organizations. Mike is a Medtronic Technical Fellow, a member of the Bakken Society, and has about 25 issued patents.

Mike has been at Medtronic for 19 years with positions in biomedical engineering, product development, clinical trial management, program management and marketing. He has a BS in Biomedical Engineering from Case Western Reserve University, and a MS in Software Engineering from the University of St. Thomas. Mike can be reached at mike.hess@medtronic.com

Interview conducted by Doug Berger, INNOVATE doug@innovate1st.com

Doug: Let's start by talking about the business challenges that are best suited to an innovation oriented approach at Medtronic.

Mike: If you look at the history of the medical device industry and many healthcare industries, you'll find that product innovation was the starting point and the impetus for the development of different therapeutic areas. It's been the foundation of the markets that exist right now in healthcare. Some of the greatest disruptions to an existing healthcare product line, service, or therapy have been in their delivery or technology, making it much easier, less expensive, or resulting in dramatically improved results.

The way in which we service and sell our products in markets outside the United States is a topic of great discussion. We don't have the healthcare infrastructure in many developing markets as you have in Western Europe, Canada, and the U.S. We need different business models to get products and services to those customers and patients. So there is an opportunity to look at our healthcare delivery model, not just replicate what's worked well.

There's a technology trend to device connectivity. We have the opportunity to connect information from patients and clinicians through mobile communications, for example from pacemakers, neuro-stimulators or products with sensors, like insulin pumps. Medtronic doesn't have a core

competency in telecommunications, and probably never will. So suddenly there's a partnership model in developing these systems, which was not the way we did things in the past. For example, we began partnering years ago to bring data from certain classes of devices over phone lines to clinicians. We definitely want to get better and use that model even more broadly, which will require medical device companies to lean on and leverage technologies outside of our space. The old fashioned way of building it all ourselves with custom proprietary systems is no longer really feasible.

Doug: You've given us a nice segue into the strategic importance of the make or buy decision, and how Medtronic is now approaching that whole area.

Mike: Medtronic, like other large companies, has a history of acquisitions and a lot of our diverse product lines come through that source. Increasingly the decision to make, acquire or buy is spreading deeper in the organization, and it's happening at the project level or in some cases, the component level.

One example is in our Diabetes business. We are currently working on a "patch pump," a new kind of insulin pump which includes a disposable component. This is a different business model for insulin delivery. We are not using a daily injection or our traditional durable pump. Based on our technology and our leadership in insulin delivery, we felt that we could build a better patch pump than pumps that were on the market at the time, rather than attempting to acquire that technology. It was a deliberate attempt to look at the market, look at the competitors, look at our own technology, and determine that we had an opportunity here to get into the marketplace with an organically developed solution.

In contrast, we recently made several acquisitions in the areas of atrial fibrillation and transcatheter heart valves. We felt that outside companies had technology and intellectual know-how which was of great value to us in the short and long term. We determined it would be better to enter those markets by combining these leading technologies with what Medtronic does well - the development of markets and the scaling up of a really good idea and a promising technology, to a full size market opportunity.

Every time now, whether it's the businesses we're getting into or projects in our existing businesses, we're expecting the teams to look at both what we could do internally in terms of developing components or materials, and with whom we may want to partner.

One of our new opportunities is to work with companies whose technology would not have been appropriate for our uses in the past. For example, the very low power requirements of implantable systems, which years ago were very unusual and specialized, are now similar to the needs of consumer electronics and mobile communications. Along with this comes a challenge that these companies have not dealt with before: the regulations and requirements that exist in the medical products industry. We're now looking to partners for technologies, which 10 or even five years ago, we could not have sourced.

Doug: One of your organization innovations has been to create an internal marketplace for solving technology problems.

Mike: Medtronic has tremendous technical depth and breadth. We probably have the most diverse product line in medical technology, and we also have a decentralized R&D organization. The engineers work very closely with the market group and with physicians. It's a great advantage to them to be so closely aligned to their markets. But this means they don't have as much opportunity or necessity to interact with engineers working in other product lines as they might at companies with large, centralized labs. We've begun to put into place online internal collaboration and problem solving tools to connect engineers and scientists in one part of the company to others. We are trying to get at the latent knowledge within the organization and connect expertise that otherwise would not link up. We're encouraged at the initial uptake and the enthusiasm for the idea. It's a different way of working. We're starting to aggressively promote the idea of reaching across the organization, looking for opportunities to help someone else, and reaching out with your own challenges and ideas to see who can provide solutions or ideas.

Doug: Who would have predicted that in the areas of open source software or a Wikipedia, people would contribute so much of their time and expertise to things that had no direct economic benefit to the individuals involved?

Mike: Wikipedia may be one of the purest examples of this collaboration culture at play, where everyone is fully democratically participating and engaging in the sharing of ideas with no expectation of personal payback. We have much more modest ambitions for this effort but the concept is still valid. We think that there is a tremendous horsepower in the organization into which we can tap and unleash. If people take a little time to learn things that Medtronic is dealing with in other businesses, they may find that they have expertise or knowledge to contribute or from which to benefit. Our opportunity is to get these people connected, aware and sharing. I think we'll see a lot of benefit from it in terms of projects that start with a much better foundation of knowledge, or a network of people that can help solve problems more quickly.

The other benchmark to consider here is a company like Cisco, which has a culture that includes very active employee blogging, both internally and externally. Their open sharing of knowledge, ideas, and problems, is very impressive. I would like to see how that evolves at Medtronic, and where those kinds of information networks really take the place of structured meetings and endless emails and memos, only to get lost in a file cabinet somewhere.

Doug: Medtronic is very decentralized. Through portfolio management, are you trying to look at a more optimal way of deploying resources across the entire company, as opposed to portfolio management within each operating unit?

Mike: We have begun putting a more consistent view on the projects that we want to fund. That's most true in our ventures area. We're taking a long list of opportunities in the Medtronic sweet spot and giving them some common criteria. It is most difficult to look at a list of opportunities when the criteria are all discordant. Someone may talk a great deal about technical risks on a project, but not address some market reimbursement issues. Others may talk in great detail about the business model and not get clinical results. Others may address different financial measures over timeframes, or other ways of validating projects, and there are quite a few. So even standardizing

that has helped us in our process of picking where we choose to put our venture investments.

Ultimately the majority of portfolio management is still happening within the businesses. I have spent almost 19 years in our cardiac rhythm business and have a pretty good understanding of the market and what my customers need. I would be very surprised if someone sitting in a corporate office could have that same level of insight into that market, let alone all the diverse markets in which we play.

Consistent valuation criteria provide visibility into the relative returns of our R&D dollars at Medtronic. How much are we getting from these projects over time? Are the businesses and projects that have high returns consistently prioritized, or do they defend an existing market position? Do we have any track record here over time, from which we can learn and make better decisions on the next round of projects in terms of what we choose to fund?

Doug: You're pointing to orthodoxies in the medical device industry that you've begun to challenge.

Mike: I think that is true in some respects. We want to step back and look at some of the conventional techniques that have been used, and ask why approaches from different industries can't have a role to play here. For example, there's some environmental legislation that is systematically closing the door to certain materials. One of those will result in removal of lead from solder. Lead-free solder does not have some of the same properties as does solder with lead. So to learn more, we might look to the defense industry or other industries who have already been dealing with this in their mission critical areas.

When you start to see the magnitude of the efforts required to solve some of these problems, it becomes very attractive to look and see who else is already taking steps in this direction and what of their work can we apply to what we're interested in doing.

Doug: I've talked with a number of people in pharmaceutical R&D who appreciate the strong pressures to disrupt some of the fundamentals of drug research and development. Are there comparable pressures that the medical device community is starting to feel?

Mike: There has been a fairly consistent process for how medical devices have been developed. Most new ideas in medical technology come from a physician in clinical practice. They are usually building a solution in response to some past discovery or clinical problems. Their idea becomes the foundation of a product or an improvement to an existing product, or possibly a whole new therapy. The physician starts working with an engineer on a good idea, and either partners early with a large company, or they secure early financing, move into some pre-clinical or clinical research, and then later look for an exit through an acquisition by a larger company. That model has been around for awhile. Like pharma, there are certain barriers to entry, such as regulatory requirements and clinical trials for pre-market approval and their associated cost, which for some products can run to several hundred million dollars.

Doug: What do you see as the next generation of challenge areas?

Mike: The idea of medical devices being redefined from autonomous to connected is consistent with our earlier discussions. We have information coming out of our devices now, flowing through communication systems into data centers and on to secure websites, being warehoused and analyzed. We have the opportunity to do a lot of very interesting things with the technology as well as the information, and take advantage of what we otherwise wouldn't have in our products to ultimately treat patients more effectively.

The FDA had a workshop on social media and implications for medical device and pharmaceutical companies. There's a lot of gray zone and new ground. We'd love to be able to source ideas from customers and patients about how we can improve their products. Have you visited mystarbucksidea.com? Great system, very innovative. However for our business these suggestions by customers or others may exceed the current approved use of the devices. We need to guard against off label promotion of devices that suggest a use which is not included in currently approved labeling. This idea of sourcing ideas from public forums is really intriguing. There's an obligation, however, to make sure that in the process it doesn't misrepresent the design purpose, function or claims of the products to any participants. As an industry, we need to work through this topic with the FDA, and that effort is already underway.

Doug: Are there any other trends that are going to have a more significant role to play in the whole medical device industry?

Mike: There is the evolution toward restorative therapies. Today, most medical devices are palliative in that they are compensating for some kind of physiologic problem occurring late in the disease progression – like a pacemaker, or artificial joint. The shift towards more restorative therapies that would reverse the disease progression and rehabilitate the organ or the body process will be something in which medical device companies will have a big role to play. We would be redefining what the devices are actually trying to accomplish. The end result could be a portfolio of products or services that are very different than we see today.

Doug: What would you like to touch on in conclusion?

Mike: It is worth mentioning the new considerations as the medical device industry becomes more global. We now see more regional medical device companies offering specialized products. We also want to improve how we can reach outside the walls of the traditional large companies and look for good ideas from other sources, such as these global startups and physicians from other countries where the healthcare markets are still evolving. We will see more and more global inputs into the R&D process. We've always had ideas from around the world but they've tended to flow back into the more traditional R&D groups. We'll see more proliferation of the R&D horsepower around the world to get closer to those sources of the ideas.

In closing, I'd say that medical device is probably one of the most innovative industries that has come along in a very long time. The progress on treating disease for improved quality of life and life expectancy is amazing. Now we are starting to see innovation in how we innovate. As we embrace even more diverse techniques, I have great expectations and great hopes for the

advancements that we'll make in healthcare delivery over the next decade, going beyond what's worked well for us over the past five or six decades.

