Where do Medical Devices Come From? Interview with Dr. Art Erdman, Director of the Medical Devices Center

Hello, everyone. It's Scott Nelson, and welcome to Medsider, home of the free medical device MBA and you know, we often hear about medical device approvals, how they're performing in clinical trials, etc., but where are these devices actually born? How does a medical device actually go from an idea to an approval? One answer is the Medical Devices Center at the University of Minnesota, and in this interview with Dr. Art Erdman, he's going to tell us how the unique Medical Devices Center is breeding the next wave of medical device inventors and stakeholders. Here are a few things that we learned:

- We're going to cover the Medical Devices Center, where it was born, how it came to be.
- We're also going to learn about why medical device professionals actually want to participate in this fellow's program at the Medical Devices Center.
- We're going to learn more about the funding sources and the business model for the Medical Devices Center, and
- Dr. Erdman is also going to tell us why the Medical Devices Center will help in an effort to face a serious threat to the medical device space.

Now, here's your program.

Scott Nelson: Welcome to the call, Dr. Erdman. Appreciate your coming on.

Art Erdman: I appreciate being here. So, Medical Devices better come from the docs and other medical professionals that have the need. A number of us have looked at the literature and made guesses on what was needed, and developed solutions that later on we find out that we missed something terribly important. So, the creation ought to come from what they call the voice of the customer, and the customers are the nurses or the doctors that are doing healthcare. So, the origin starts there and goes through a process of trying to really understand those needs and converting those to solutions and doing repetitive prototyping and showing to the stakeholders and testing and so forth before you get to one that you try to send to FDA for approval.

Scott Nelson: Got you. That voice of the customer that you mentioned, do you see most medical devices beginning or commencing at that same place or not?

Art Erdman: Yeah, I think the need has to start there, and of course it's a lot of work to do. You have to understand what's on the market, why it's not meeting the need, and there are a variety of deeper analyses like looking at the patent landscape and reimbursement and how many of these are needed and so forth if you're going to actually build a business around it or hopefully license it to someone that is already in that area and has a sales force.

Scott Nelson: Okay. So, that provides a little bit of a segue, and so let's go and dig into the Medical Devices Center and the unique program that you lead there at the University of Minnesota. Can you give us a brief overview of the program?

Art Erdman: Sure. We've been open just over three years and the University of Minnesota has actually invested in the Center also and beyond the physical space, which is very special. We run an annual design of medical devices conference every April in Minneapolis, which is the largest we think in the world of its type over three days and about 1,000 people. We also run a mid-career fellows program. We have eight this year that they come in and spend 24/7 doing medical device development. The center is special, as I said. We have about 4000 square feet and it's on one floor where we're able to do mechanical prototypes, electronic prototypes, connect to software and sensors, and we bring in animal or human tissue or organs and we are able to do prototyping and lots of brainstorming and lots of testing and so forth, and we're right across the street from the medical school so any other facilities we need are close by.

Scott Nelson: Very good. I want to come back towards the end of our conversation and ask you more about that medical devices conference that you mentioned as well as the medical devices boot camp, but can you explain a little bit more about the Fellows program?

Art Erdman: Sure. That's a program where we're in our fourth year, and so the first year we're going up to eight individuals. Last year we had two MDs and two PhDs, and never knew each other, came in, and after a year they had 27 invention disclosures in maybe four or five different areas.

Scott Nelson: Wow.

Art Erdman: People either quit their jobs and come or take a leave of absence, and it's a very exciting program. We put them through what we call a boot camp, which they're doing right now, I just got done doing a lecture for them this morning, where we get maybe 100 people to come in and give an hour of lecture or so on various clinical needs, emerging technologies in science and engineering, regulatory reimbursement, patents, licensing. We probably have six or seven patent discussions so far and so forth. So, they really get downloaded with a lot of information.

From there they go to a clinical immersion program, which is about six weeks, where they go to get magic badges and can go on to about, I don't know, 30 or 40 surgery suites around the Twin Cities and watch surgeries and go on ambulance ride-alongs and collect unmet needs. From there, they start inventing and going through a very systematic process. So, it's very exciting, it's a unique program and one that's focused on solving real problems and creating new solutions and filing patents along the way as well.

Scott Nelson: Okay. So, that boot camp that I referenced earlier, I'm going to forget about it if I don't ask now, but that boot camp is part of these fellows program, then?

Art Erdman: Yes, and so we're doing that right now and it's a place where you just open up the brain and pour all this information in, and it's a very, very high-level training program that prepares them, introduces them to the key stakeholders in the Twin Cities area here in Minnesota and elsewhere. People that they can go back to and get mentored if they wind up needing that expertise and information that brings everybody to the same level playing field because everyone brings in different skills base and interests.

Scott Nelson: Very good. Okay. So, these students, you mentioned that it's almost like a mid-career program. Are they mechanical engineers, are they PhDs, and where are they typically working now in the industry?

Art Erdman: Yes, so a lot of questions. So, it's early mid-career people. We've had individuals quit cold turkey Medtronic or Boston Scientific and come here, and getting a lot less pay, but it's a career choice to come in and do a very specialized program where the objective is to train the next innovation leaders in the medtech industry. Others are maybe closer to their PhDs, and one MD we have this year actually was a practicing surgeon in Western Wisconsin for about seven years and felt that he wanted to try something different. So, that's a great skill to come to us with.

So, everybody brings in a different set of skills, and we'll be doing the program again next year. We'll be advertising starting in January and probably making a decision in the April/May timeframe. So, for those of your listeners that would like to be part of this and have a passion for innovation, I suggest that you look up our program at the Medical Devices Center. Our webpage is www.mdc.umn.edu.

Scott Nelson: Okay.

Art Erdman: From there, you can go to the Fellows program or the conference. This year we have a couple of master's graduates as well that actually have done a lot in the industry and felt like they wanted to really formalize their knowledge in this way.

Scott Nelson: Very good. Okay. Why don't you go ahead and repeat that website address just for those in the audience that didn't quite catch that and the guy who's doing the transcription for this interview? Give that website again?

Art Erdman: Sure. www.mdc for Medical Devices Center dot umn for University of Minnesota dot edu for education.

Scott Nelson: Okay. Very good. I wanted to have one follow-up question in regards to the folks that are coming into this Fellows program. You mentioned typically it's kind of more of a mid-career program. What are they hoping to gain out of it? I'm sure there's a myriad of different reasons, but are there a couple of ones that stand out?

Art Erdman: Yeah, I think they want to just accelerate their career and to come to a place that is highly visible and highly successful in taking skilled people and giving them yet another skill set that is a 24/7 program on all phases of the medical device generation process. It's very special. So, we have some people that are in adjacent industries and want to focus more on the medical device side. So. that's one motivation. The MDs that have been with us, and we've had a couple every year. I think they have this entrepreneurial passion within them that they may or may never go back to surgery. They may want to go in the industry or form their own companies, and we have seen startup companies come out of our program so far, and I'm guessing next year there'll be one or two more.

Scott Nelson: Okay. Very good. Very good. That helps. Let's go back. You said this program has been in place for, was it three or four years?

Art Erdman: It's our fourth year now.

Scott Nelson: Fourth-year, okay. Can you take us back? How did this idea form? How did the Medical Devices Center and the Fellows program come to be?

Art Erdman: The Medical Devices Center came about because the University of Minnesota is one of the top universities in the country and we have a strong department that does basic science, particularly in tissue engineering and other areas. We have strong clinical research going on as well. We can do animal trials and human trials here. The piece that was missing and was pressed by myself and others was a formal center that was on the front end that is taking the needs and turning them into prototypes and solutions to healthcare that would then feed the rest of the system, and so the university invested actually $5 million of its own money into starting up the Medical Devices Center.

Scott Nelson: Okay.

Art Erdman: We were going for about a year, we knew of the Stanford Biodesign program, which had been going I think, at that point about five or six years, and started investigating with Dr. Paul Yock's help the possibility of doing that here at the University of Minnesota.

Scott Nelson: Okay.

Art Erdman: In fact, he spent more than half a day with us early on, giving us here's what worked, and here's what didn't work at Stanford. We learned from that, and with his blessings, we moved ahead. We're not a private university and we're in a very different situation so there were some tweaks made for us to run our program here and it's worked really well.

Scott Nelson: Okay. So, that's unique. I'm sure that helped you. Did you mention, it was Dr. Paul Yock, you said, that you worked with in trying to build the program there at the University of Minnesota?

Art Erdman: Yes.

Scott Nelson: I'm sure that was a huge help in trying to emulate what went right and what went wrong, you know, so you could kind of get off on the right footing. So that's cool. So, was your idea for the Medical Devices Center, was it initially accepted, or was there some effort in trying to win over some colleagues on this process?

Art Erdman: Well, we're all salesmen or sales ladies, and my vision for the physical space was not uniformly embraced. Some of my colleagues said, well, don't we have the machine shops on campus, and don't we have this across here and there? But I think the vision of having them all in one space is really powerful.

Scott Nelson: Sure.

Art Erdman: All we had to do was walk down the hall, and we've had so many phenomenal donations by industry or products, laparoscopic and other instruments. We have bins of these devices that have been donated by local hospitals and by people like Boston Scientific and other industries. These things are available. You can go in and see how they work and take them apart and use parts for new devices. You can save yourself three weeks or three months by just taking apart parts of it and just working on the new functionality that you want to add. So, it's been a wonderfully accepted program. We've had probably 250 tours in three years. Industry comes by and everybody says the same thing, "Oh, I wish I had this when I was at school," and to me, that's the mark of, well, we must have done something right.

Scott Nelson: Right. Right. That's cool. You're almost fostering kind of a startup kind of idea creation environment thereby having all the parts kind of in one place. So that's kind of what it sounds like just listening to hear you describe it. So that's very cool. You mentioned industry interest, Dr. Erdman. Are you currently receiving funding from industry or is it more just charitable donations to the program? Can you explain that in a little bit more detail?

Art Erdman: Yeah, we have some very nice partners. Boston Scientific and St. Jude Medical has given us 50,000 a year each year, and that's just absolutely wonderful. The conference is highly supported by the industry, and we use some of that money to help fund the Center as well. The in-kind donations are pretty phenomenal as well, so I don't have to spend my money that way. Frankly, we hope that eventually that one of the inventions that come out of the program will hit it big, and based on the royalties coming back, we'll be self-funding. But in the meantime, it's very important for the industry to continue to support the program. My dean gets pretty nervous from time to time because that's an expensive training program. He's right. It's the most expensive training program on campus, but on the other hand, I think he and others see the future benefit. It's a really innovative place, and as you said, it's like a startup company or four or five startup companies going.

Scott Nelson: Yup. Yup, and listening to you describe it, that's exactly what it sounds like, and you're fostering that culture there. In terms of the funding, I think maybe I read this in some of the research I was doing, but you hope to be a self-funded kind of operation. What does that look like? What's the end goal? Does a big company like a St. Jude or a Boston Scientific or a Medtronic, do they buy the technology from you from one of these ideas? Can you explain that?

Art Erdman: Sure. That's a really good question. So, our model is twofold. One is the licensing option and we work very closely with our technology transfer commercialization office, and they're wonderful to work with and help us market the ideas coming out of the program. The other model is a startup, and I mentioned that we have two startups that have come out of the program already. Our goal is to get these things out and in one case we actually gave away the technology to a small company because we knew we were on to other things and wouldn't have the energy and resources to pursue it further, so we really wanted to take advantage of all the hard work that the fellows put into the program and get something out there.

Scott Nelson: Okay. Very good. I know we're kind of running short on time, so I wanted to ask you one more question before I ask you for some ending advice, and I want to make sure I touch on that Medical Devices Conference as well. I read a quote in a piece from you, and let me pull it out here. This is your quote. It says you've had at least six visits from Japan to the Medical Devices Center and they're not here to shake our hands, they're here to learn from what we're doing and take those lessons away and try to beat us. You may have remembered the quote, but I think it pertains to other countries basically catching up to the US in terms of our medical device technology. Do you think that's an issue that we're really going to have to face in the coming years? I presume you think the Medical Devices Center is a program that can kind of help with that aspect.

Art Erdman: Yes. This is a serious threat. I went on a state delegation a year and a half ago to the southern area of Japan where they're very serious about getting much more active in the medical device area. Of course, there are some big companies around and so far that is very active, but they would love to emulate what we have in the Twin Cities, Life Science Alley and they're very good engineers and very good scientists.

I think the advantage that we have and may not have for too long is understanding how to be innovative in doing a design process, and we have in the Twin Cities all the pieces. We have the top players of the huge companies, we have small companies, and then we have the support industry, which is so important, which they don't have in Japan. So, that would be the rapid prototyping people, that would be the smaller design firms, that would be the packaging people, that would be the, well, you can go on and on. All those things are here. That's our advantage in the US, the innovation, and the venture capital, and so forth, and we need to keep that. That's why we have this program of trying to generate more and more the entrepreneurs that have the full training to keep ahead and to be a player.

Scott Nelson: Right.

Art Erdman: We don't want to lose that industry like we've lost so many of the industries to other countries.

Scott Nelson: Sure. Sure. That's a great point. We could have a whole separate interview just on that topic alone but for the sake of time, let me move real quick to the Medical Devices Conference. You mentioned that that's held once a year. Can you real briefly kind of give us an overview of what that conference looks like for those that are listening to this that may be interested in attending?

Art Erdman: Sure. So, we run this between the second and third week in April every year, so it's like the 10th through 12th coming up. We just had our 10th anniversary. It's over three days, about 41 sessions. We have a small exhibit with it where companies are very intimate. We cover all phases of medical devices, so we have regulatory sessions, we have company startup sessions, we have emerging technologies like MEMS and Nano, and so forth. We have clinical sessions, we have live surgery sessions, and we always bring in keynotes. For example, we have Jeff Shuren, who is FDA head of devices and radiological health, so we always have some high-level keynotes

as well. So, it's a great place to come and sit next to people and your competitors and talk about our mutual topics, which you don't get to do very often. It's across all the disciplines, so we have industry and we have orthopedics and biology and cardiovascular. So, it's an across-all-disciplines type of conference.

Scott Nelson: Very good. Very good. I think there's a link to that conference, if I remember correctly, all on your website. On the Medical Devices Center website, there's a link to that Medical Devices Conference. So, very good. Lastly, do you have a couple of pieces of advice, you have a long and very impressive résumé kind of in the medical device space. Any thoughts or any little tidbits of advice that you could give for would-be ambitious medical device doers that are listening to the interview?

Art Erdman: Follow your passion. Do your homework. Try to hook up with people that have been in the space where you need some help. I'm a proponent for teamwork, and sometimes entrepreneurs think they can do everything themselves. I haven't seen that work. There are not too many Steve Jobs' out there. Put teams together, run with the ball, don't give up.

Scott Nelson: Yup. Very good. Very good. Well, I know you've got to get running, but real quick, that website for the Medical Devices Center, could you read that off one more time?

Art Erdman: That's www.mdc.umn.edu.

Scott Nelson: Alright. Very good. Very good. Well, thanks, Dr. Erdman, for coming on the program. Really appreciate it, and for those of you listening, make sure you check out the website for the Medical Devices Center. You can learn a little bit more about the program things that we weren't able to cover. So, thanks again, Dr. Erdman. I really appreciate you coming on the show.

Art Erdman: My pleasure.

Scott Nelson: Alright. Thanks, everyone for listening. Take care.