

## Build It, Break It and Fix It

Kim Ukura, Associate Editor, PD&D



*"My experience is that engineers go into the medical field because they want to really make a positive difference to improve patient care, just like physicians," says Rich Mueller, chief technology officer for TransEnterix.*

The general surgery market hasn't seen many market-disruptive technologies recently, and Rich Mueller wants to change that.

Mueller, an expert in product development in the minimally invasive surgery market, was recently named chief technology officer at TransEnterix, the company responsible for the SPIDER Surgical system.

In this Electronic Fireside Chat, Mueller discusses how he entered the medical device industry, his philosophies when it comes to new product development, and his concerns for the medical device industry in the coming years.

### **Product Design & Development: What is your background, and how did you get into the medical device industry?**

**Rich Mueller, chief technology officer at TranEnterix:** I attended Case Western Reserve University in Cleveland, OH. I blew my knee out playing basketball and I had to have ACL reconstructive surgery during my winter break.

I got a little askew with my schooling, so I went and did a co-op where you take a semester and summer off to work, then return to school for a semester. I found my

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way to a company called AcroMed, which was purchased by DePuy and is now a Johnson & Johnson company, DePuy Spine. I worked there on and off for about three years while still attending the university.

I was just studying mechanical engineering and I didn't know quite what focus I wanted to get into, but once I started working at AcroMed I decided to take a biomechanics focus. I got to stand side-by-side with the medical students and learn. That started putting things into focus for me.

When you start thinking about orthopedics, spine, and general surgery, a lot of it is just transferring technologies that are known in other industries and evolving them into procedures and techniques. Spine surgery was a little bit like human carpentry in the early stages.

### **PD&D: What unique skills do you think you bring to TransEnterix as chief technology officer?**



**RM:** If you look at what I did when I was at NuVasive, I created a lot of the new technology and new product platforms. When I started there it was small, a start-up – not quite as small as TransEnterix is – but it was on the same scale compared to where it is today. When I got to NuVasive we had maybe 10 or 12 products. When I exited we were a \$500 million company with 70 or 80 formal products on the market.

I think I bring the ability to take an idea and evolve it into a new, market-making procedure, as well as build a very specific product- and procedure-focused portfolio. I also bring the ability to identify and evolve the market and create not only evolutionary products and procedures, but revolutionary products and procedures.

It's exciting when you bring market-disruptive technologies, especially in a market like general surgery that hasn't had tremendous innovation in quite awhile.

### **PD&D: What are some of your philosophies when it comes to developing new products?**

**RM:** I have two. One is that focus and clarity are key to execution. There's a saying: clarity drives confidence, and confidence drives commitment. People will work hard, but if you're not focused and that vision isn't there, you can just work and work and work and it may not be for the right answer. That clarity, by driving confidence inside and outside the organization, will ultimately give you commitment.

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The second thing for me is that I encourage engineers and technical personnel to design it, build it, break it, and fix it much faster than anybody else can ever think of designing it. If you stay ahead of the innovation curve, your competition is only working on your last effort. As long as you're working on the next effort, you're still outpacing them.

### **PD&D: Is it hard to get engineers to buy into the idea of working fast and out innovating themselves?**

**RM:** As long as you give them the right focus, it is something everyone can embrace. When you're in an FDA regulated environment, you're going to have to do tests and break your device. It's just a given, a known. The faster you can get to that breaking point, the quicker you can get to learning. All you're doing is expediting the process.

### **PD&D: When thinking about the current state of the medical device industry, what keeps you up at night?**

**RM:** One thing that keeps me up at night is the reimbursement decisions made by insurance companies and hospitals. When it comes to new technologies and innovative procedures and devices, typically the consideration is only on the bottom line without the complete consideration of the patient benefits or social cost associated with the longer-term recuperation.

Innovation does cost a little bit more, but if you can get a patient out of the hospital and back to work sooner, there's an overall benefit to the patient and society. What does it mean to have someone back to work and not laid up at home?

As newer technologies become a little more expensive, I'm worried that technology could be squashed based on some hospital administrator or insurance company's decision about what is right for the patient. That decision really needs to be done by the care provider who can provide the holistic value statement.

Second, there are some significant changes underway at the FDA and I think there is a little bit of concern as to what that means from a regulatory and approval standpoint. Innovation requires not only the reimbursement and the pay, but also the regulatory approvals at a quick pace.

If that doesn't happen, innovation will take the path of least resistance, which it is right now. Venture capital, incubators, start-ups - they will find its way overseas. Europe is probably 5 to 10 years ahead of us because their regulatory systems are a little more user-friendly.

### **PD&D: There's been a lot of debate about what impact the medical device tax in the health care bill will have on innovation. What are your thoughts on that debate?**

**RM:** It's been dubbed the "innovation tax," and it's a tax that's going to hit the bottom line of companies and stifle development. Those are direct investment

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dollars that hit research and development, marketing, and sales training. It's going to be a percentage of dollars peeled away from innovation.

I didn't make up the term "innovation tax" - that came holistically from the U.S. market saying this is going to stifle innovation. I am concerned about that. The way to get around it is to send innovation overseas where they're not going to get that type of tax.

### **PD&D: Where do you see the medical device industry going in the next 5 to 10 years?**

**RM:** I think patients are going to continue to seek out the latest information before making health-care decisions. They'll seek out the least-invasive surgical care possible from surgeons, and then find surgeons that will provide it. Consumer driven demand will fuel innovation, and it will also encourage surgeons to adopt newer and better technologies.

That's why TransEnterix excites me, that's why market disruptive technologies excite me, and that's why I believe we need to stay ahead of the innovation curve.

### **PD&D: Is there any advice you'd like to offer to young engineers in the medical device field?**

**RM:** I think it's important to not become complacent. Take some risks. Challenge everything within your organization and, more importantly, challenge yourself.

My experience is that engineers go into the medical field because they want to really make a positive difference to improve patient care, just like physicians. I encourage engineers to keep patients at the forefront of their thoughts and actions. I think we can't become complacent. We really need to push and fight and drive for the things that we believe in.

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