PLAYING THE FEDERAL GAME

Patience Required in Agency Activities

By Tom Schuman

EDITOR'S NOTE: Third of a six-part series throughout 2017 with Fishers-based Recovery Force. View the previous articles in the January-February and March-April archives at www.bizvoicemagazine.com

Starting and growing a successful technology business in Indiana might surprise some not familiar with the Hoosier state. But it is becoming a more common mission for many, including the team at Recovery Force.

"We're committed to Indiana. Selfishly, we're natives of Indiana, we're raising our families here, we're committed to being here for the long term," declares president and CEO Matt Wyatt.

Of the four drivers in the Indiana Chamber's *Indiana Vision 2025* economic development plan, Attractive Business Climate is the one where the state has arguably placed the greatest emphasis in the 21st century. Indiana fares well in a number of state-by-state comparisons on tax and regulatory matters. Health care outcomes are another story, but efforts continue in that area.

So while Wyatt says there have been "no barriers at all" to starting and incorporating a company in Indiana, Recovery Force and others must also deal with Washington, D.C. and our federal government. For his organization, that includes the Food and Drug Administration (FDA, for product clearance) and the National Institutes of Health (NIH, for grant funding).

In the first two months of 2017, Recovery Force received good news from both – FDA clearance to market the Class II 510K, RF 1400 Active Compression Wrap and a nearly $250,000 Phase 1 Small Business Innovation Research grant from NIH. The initial wearable back product is to aid, among other uses, in the prevention of deep vein thrombosis, enhancement of blood circulation, diminishing post-operative pain and swelling, and reducing wound healing time.

"With respect to FDA, I had some experience on that regulatory pathway before. So I was able to manage my own expectations in that process," Wyatt affirms. "Once we made our submission, I was pleased with how quickly we received clearance. The FDA was very responsive. There was open dialogue before we formally responded to their questions. That was a good experience for us.

Adhering to the rules

The interaction with the two federal agencies is dramatically different. While the FDA submission was made in September 2016, it was preceded by several years of work on product development and processes. On the grant side, there were lengthy response periods and multiple submissions before the late January approval from the National Heart, Lung and Blood Institute within NIH.

Some of the early forms of company products are displayed above the working area of Recovery Force CEO Matt Wyatt.

"With NIH, I had no frame of reference," he continues. "I will not forget beginning to write the first grant (submission) in the summer of 2014. That was a three-year process I did not anticipate. It's a great award because it validates the patient need for this product. You probably have a better chance of hitting the lottery than getting an NIH award."

Jeff Schwegman, director of engineering for Recovery Force, notes that the FDA process was first released shortly after he graduated from Rose-Hulman Institute of Technology in 1997. While there have been advances in what must be done before submission – "you need to develop it further

and get it closer to ready for manufacturing" – the work to get there is relatively unchanged.

"The medical device development process takes a long time. You do that using design controls. You develop a set of requirements and test to those. You prove the device is safe and effective for what you are trying to do," Schwegman explains. "Once you have done all that work, then you submit. You have to have all your documentation in place.

"We really put our time in up front, focusing on designing and developing a product to meet what we needed it to do. When we submitted, there were questions and a few additional tests we had to run. They didn't change any of our testing. Our review met the schedule. The FDA portion ended up relatively smooth."

Polina Feldman, Ph.D., director of research, came on board at Recovery Force in 2015. It's not uncommon, she relates, for it to take between six months to a year for feedback following a grant submission.

"Each time you submit, a panel provides critical feedback, both good and bad, to make it better to figure out a way to commercialize the product," she shares. Some of that feedback from the first submission was a lack of information on optimizing the product in a clinical setting to test for compliance.

"Because of my past experience writing grants, I could kind of gauge where the weaknesses and the strengths were in the grant." Feldman add. "The other question is that when the grant goes to NIH, it is really up to each agency (within NIH) to make that decision. That is really unpredictable.

"We know who sits on the panel but we don't know what they are motivated by. They may be motivated by the innovation, they may be motivated by the strong team, they may be motivated by how much value it provides the patient. Another part of the equation is the number of applications submitted each year."

Building on success

As indicated in the January-February *BizVoice* story introducing Recovery Force, one of the early NIH examiners called the technology "a marvel in engineering." The first two grant submissions were scored favorably, but did not fall within the funding range.

"It's never easier," Feldman says of the grant process. "But getting the Phase 1 is a signal from the NIH that, "We want to fund, we are on board with the product you are making, we see the value in terms of patient care and we want to give you the opportunity to do what you said you're going to do.' "

Only those receiving Phase 1 grants can apply for Phase 2 awards, up to $1.5 million. Feldman indicates the likelihood of receiving Phase 2 monies increases by 50%, with Wyatt adding that the next round, if received, will be ideal for helping conduct clinical trials.

A separate grant for a diabetic shoe product was submitted in January of this year.

On the FDA side, the work done thus far will also prove helpful for future submissions.

"We're established with the FDA. We're registered, and we're on their radar now," Schwegman offers. "It's the first time this nickel titanium technology of ours has been evaluated to be safe and effective.

"If we want to do another product that is a 510K medical device, we can reference our own device that already has the same technology and theoretically it should go (even) smoother with the FDA. In general, we've got a baseline now set."

Fielding a strong team

While Schwegman and Feldman played lead roles, both are quick to point out the consultants and partners that are essential to most effectively complete the work.

"You really need a quality regulatory consultant who has a lot of experience writing these submissions – knowing how to strategize on the words that you put in there and how the FDA is going to respond," Schwegman contends. "There is a way you write these – it's not typical writing, not even typical technical writing. In our particular case, one or two of the members of that team used to work for the FDA; they used to be on the other end reviewing these."

Brian Stasey and Wyatt prove to be a strong balancing act when combining their ambitious potential with the realities of meeting immediate needs.

Indiana companies assisted in other areas, including a software tool that consolidates necessary documentation into an easy-to-follow dashboard. Indianapolis-based Pearl Pathways contributed in multiple areas, including helping earn Institutional Review Board approval, which is required of any studies involving human subjects.

Feldman stresses that grant consultant Kris Parmalee played a pivotal role in that process. In addition, Recovery Force receives a $50,000 matching grant from the state's Elevate Ventures program.

The two Recovery Force team members are used to the often deliberate pace that is required in their work.

"Grant funding in general … you just to have very patient. It's a slow process," Feldman relates. "I always have the end in mind in terms of collecting data and validating our product. It's important to be very thorough. I always just try to remind everyone we're going to get there."

Schwegman acknowledges that the few who have tried to cheat the system are responsible for the sometimes glut of regulations.

"I've seen a lot of people try to fight it; to be honest, you can't win that one. I preach patience," he concludes. "We are moving fast compared to most medical device companies, especially the big ones. Not as fast as you want to move sometimes but …"

RESOURCE: Recovery Force at www.recoveryforceusa.com