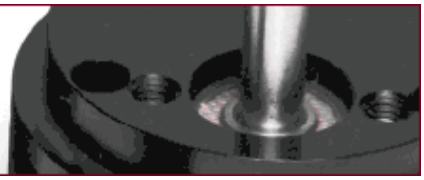

How Enable Injections plans to bring value to pharma with its drug-delivery device

NOVEMBER 27, 2017 BY SARAH FAULKNER — LEAVE A COMMENT

Mike Hooven is no stranger to the medical device industry – he has spent the last 30 years launching companies and developing technologies for a variety of clinical applications. So when he ventured into drug delivery, he knew that he needed to find out what people in the pharmaceutical industry needed.

A number of executives tipped him off that the industry was in search of a way to deliver high volume biologic drugs in an at-home setting, Hooven told **Drug Delivery Business News**. Using that knowledge, he launched Enable Injections in February of 2010.

The Ohio-based company has developed an on-body injector designed to deliver biologics in volumes ranging from 5 mL all the way up to 50 mL. As the rest of the drug-delivery world is beginning to recognize the need for such a device, Enable is busy establishing partnerships with pharma companies.

Hooven, Enable's chief executive, has tried to make his company as attractive as possible for potential partners by knowing how to speak their language.

"The biggest challenge is really integrating the two cultures of medical devices and pharmaceutical companies," he said. "So instead of just hiring device people and then trying to manage the interface between a device company and a pharma company, I hired a combination of device people and pharma people so that now we have pharma people in the company that can provide that interaction because pharma and devices really speak different languages. There's no question about it. You need to have that experience and that background in your company."

The team at Enable Injections set out to develop a device that does two things, according to Hooven – allow a pharmaceutical company to use their existing drug container and give patients the most positive administration experience possible.

"You're not going to make it something the patient looks forward to but you want to make it as pleasant an experience as you possibly can," he explained.

Hooven said that almost all of the companies that Enable deals with have expressed concerns over the risks involved in changing a drug's container. One executive told Hooven that changing the container closure in any way "is 10 times the total risk involved in developing an entirely new device."

Allowing partners to use their existing container was an intentional design choice, according to Hooven. A more surprising choice was creating a device that patients have to load.

Many in the drug-delivery arena tout their pre-loaded devices as simpler for patients. But Hooven said that, in reality, a pre-loaded device can create a host of issues for people at home.

"The first step that nobody talks about with the pre-loaded device is if the drug is refrigerated, the device has to be stored in the refrigerator," he explained.

A two-month supply of a therapy that is dosed once a week will likely take up a lot of room in a person's refrigerator, Hooven pointed out. User studies have also found that people are self-conscious about friends or family members coming over and seeing their medications in the fridge.

Enable's chief executive added that when drugs and devices are stored together in the fridge, people need to wait for the product to warm before dosing themselves.

"The more volume you have of a drug, the longer that's gonna take to warm. So if you think about the total administration time, you really have to start the clock when you as a patient say, 'I want to take my injection now.' So, there's 45 minutes and then, how do you let it warm? You have to put it out. Most people will put it out on the counter and then what we hear is, 'Well, I have kids. They could get ahold of it,'" Hooven said..

In contrast, people who use Enable's device can simply take the vial of medication out of the fridge, insert it into the device and begin administration as soon as the drug transfers.

"It's a simple, passive warming. It's just the warming that occurs when you have a relatively small volume of refrigerated drug passing through a relatively large volume of room temperature transfer device and room temperature injector," he said. "So it's really simple and the patient can use the device immediately."

Hooven also noted that pre-loaded devices have to be big enough to fit a container closure that is capable of being filled on a pharmaceutical filling line. This can force the device-maker to create a product that is bigger, less discrete than desired by users.

"When you look at all of this and you weigh all of this against the patient simply doing one extra step, which is inserting the vial into the system, they overwhelmingly prefer the patient-loaded system," Hooven said.

As Enable Injections has pitched its technology to potential partners, the company has tried to position its device as a product that can add value in the pharmaceutical industry.

Hooven often hears from companies that are spending time and money reformulating drugs to be delivered subcutaneously via syringe in 10 mL quantities. To those companies, Hooven points out that Enable's technology can potentially lift the constraints placed on formulation teams and take some of the risks out of the drug development process.

"I can say, 'Just keep it at 10 mL, deliver it in this device and users will actually prefer it over a syringe," he said. "More and more, drug companies are beginning to understand how devices can add value to their business."