

RegCF video for Marlo Walpole

To be honest, when I was first approached about SafeRX, my first response was no. I just didn't want any part of bringing another opioid on the market. But after talking to Mike and digging in a little, I soon realized that that's not at all what they're doing here. Mike has come up with such an elegant technology that enables them to take *existing* prescription opioids, which really *do* have a medical need, and make them a little "safer" – that simply reduces the risk that someone is going to combine them with alcohol and potentially OD. When I realized that this simple little change is not going to single handedly solve the opioid crisis but could realistically save thousands of lives a year, I started digging in more and then started looking at it from a Product Development standpoint because that's my background and then that's when I got really excited. I mean, I've been doing medical device and pharmaceutical/biologic Product Development for a LONG time and I'm used to seeing some great ideas but it's hard to find those great ideas that are also easy or great to execute. But SafeRx's technology really checks off those boxes. First, they don't have to go through extensive drug discovery/formulation/method development etc like for most drugs because all they are really doing is combining existing and already approved products into a single dosage form. And then, because they're just combining those already approved drugs, the regulatory process to get *their* product approved is so much less. Instead of a typical process that could take upwards of 9 years, they could get a product approved in less than 3 because the FDA requirements should be more in line with how generic drugs are approved. Also, their products don't require any specialized testing or manufacturing equipment or complicated methods or storage conditions, so the process really lends itself well to contracting work out instead of doing everything in house and not have to spend money on building expensive infrastructure and hiring a ton of people.

When you look at everything all together, it's pretty exciting. We have an opportunity here to make a real difference, to save lives, to give doctors better treatment options, and to do it in a fairly quick and straightforward way. THAT's a homeroom in my book.