Ways to Doom Medical Device Startup Cheat Sheet

by [deleted] via cheatography.com/2754/cs/16493/

Introduction

A product development veteran of St. Jude Medical and Boston Scientific, Nelson has pretty much seen it all when it comes to the ways a medical device startup can doom itself to failure.
Here is his top seven list when it comes to reasons for medtech startup failure.

Source: https://www.medicaldesignandoutsourcing.com/7-ways-you-can-destroy-your-medical-device-startup/

1. Not managing your budget strategy

Failure to plan financially for what is expected often sets up medical device startups for failure, according to Nelson. “They don’t know how to use their money wisely.”
Before the Great Recession, there were still medtech startups that would invest in space and the best office equipment. But with funding still difficult to come by, that doesn’t happen much.
“Most startups are staying virtual and small,” Nelson said. “They don’t want to build up a lab with a lot of people. Their investors aren’t interested in that. Their investors are interested in solving problems, getting the device to market and selling the company.”

2. Spending money on the wrong priorities

“Companies that have people who’ve never been involved in medical devices before spend money in not necessarily the right order,” Nelson said.
The goal should be to “fail fast” — reducing the risky areas first.
“When we’re working with an early stage startup here and they want to do an entire budget, we say, ‘Let’s take it easy and start with building a prototype,’” Nelson said.
Create a basic prototype, and you can then conduct animal studies, and possibly cadaver studies, to find out how much promise the technology truly has — as well as the most serious failings that need to be addressed as soon as possible.
“Until you do animal studies, you don’t have proof of concept,” Nelson said. “You’ve got to understand what the risks are and address them quickly. It’s like a landmine field. It can be anywhere.”
The catch is having enough money to do the studies and arrive at the proof of concept. That’s why Nelson thinks spending priorities are so important.

3. Not having a regulatory strategy early on

4. Lack of expertise

Humility is a valuable trait for an entrepreneur to have, Nelson said. “It’s more common than not to have obstacles,” Nelson said. “People doing it the first time don’t know what the obstacles are and don’t have the funds to pay someone who is experienced. So they go through it themselves. And that’s where it’s easy to get tripped up.”
Finding a consultant or organization that has that experience, such as Nelson’s Evergreen Medical Technologies, is important.

5. Small market size

“When I was teaching at Carlson, one of the common obstacles was that it was a great idea, but there were so few people who would benefit. So the financing just wasn’t worth it,” Nelson said.
Doing your homework on market size is important.
There are ways, however, to get a device approved through FDA as a compassionate use device for a small market, and then eventually develop the device for another market that is much larger, Nelson said. It’s important, though, to have a good finance person who can help you get through what could be a long journey.

6. No reimbursement strategy

“If you don’t have a reimbursement code, that can be very costly and take more time than you want. … The worst thing is to have a product ready for market and find out you don’t have a reimbursement code,” Nelson said.
It’s important to work on a reimbursement strategy early and to work with groups such as medical associations that can help you achieve reimbursement

7. Failure to lock down IP

Medical device startups need a patent attorney lined up right away. “I think that’s one of the first things a person has to do is have their patent application in the patent office so that they can talk to people,” Nelson said.
No IP protection, and there’s no guarantee that investors or established legacy companies that you’re talking with won’t simply start working on your ideas themselves.

Medical device startups need to quickly understand what the regulatory requirements are so that they can plan for it, according to Nelson. “I’ve seen that hold up companies, and in one case, it killed a company.”
People starting medtech companies can fool themselves into thinking that they understand FDA regulations. “People try to say they have a 510(k). Sometimes they’re right. Sometimes they’re wrong.”
Have a regulatory consultant involved at the beginning, even if they just start out helping a bit here and there, providing input on strategy and planning.

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