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Welcome to the healthcare podcast brought to you by market scale. I'm your host, Landon Jones. Having a eureka moment and coming up with a brand new idea is only the first step in a lengthy and sometimes tedious process when it comes to medical device development. Here to talk to us about the process of medical technology development and commercialization is David Hibbard, Director of programs for sunrise labs. How are you today, David?

Dave Hibbard 0:36

I'm doing great.

How are you doing today?

Landon Jones 0:38

I'm doing pretty well. Thanks for joining us.

Dave Hibbard 0:40

Oh, thanks for having me on.

Landon Jones 0:41

I guess my first question for you has a bit to do with the state of the industry. So in the last couple of years, we've seen some consolidation within medical development. And I was wondering, what do you think that means to the healthcare industry? And what does it mean for you at sunrise labs,

Dave Hibbard 0:57

in past you see a lot of companies that would go out and really acquire technology, so they're looking for companies that, you know, were smaller, small acquisition, but there's a specific technology that a company was looking to market or really expand the market presence that they have. So I think in the last four or five years, you've seen a bigger consolidation of, of medical companies in general, it certainly makes for a dynamic industry for a company like sunrise. So sunrise does product services development for both large and small companies, you know, across the US, and even some international companies as well. So you know, it certainly makes it a challenge to be able to keep up the dynamics of the industry. I think, in some cases, you see, some of the larger medical device companies, either downsizing some of their engineering group. And of course, you know, for sunrise, it actually helps for us to be able to make a relationship with those types of companies and offer them design services in a specific area that maybe they don't have in house anymore. I think there was also can be a lot of transition costs and transition, maybe loss of knowledge that occurs when you have mergers, if you have people that don't want to go from one company to another for whatever reason. And that's again, an area where, you know, sunrise can jump in and help some of these companies transition through the development gaps that they may have.

Landon Jones 2:24

Now, I also know that you have some pretty cool projects that you've been working on out at sunrise labs, things like wearable devices, that monitor patients response to medication and robotics, even for surgery. Can you tell me about some of those projects that you're most proud of, and kind of what that process looks like to develop new tech?

Dave Hibbard 2:43

Yeah, so in the last couple of years, those are probably two areas where we've seen a lot of interest and a lot of growth. Certainly, for a services company, we do proposals, and we don't win every one of them. But certainly we we go out, we try and often make a best offer we can to help our partners develop products. And we've seen many companies asking about connected devices. So generally, what we're seeing is that people are looking for a way to really do a couple things, they want to help patient with compliance. In terms of how they take their medication, they also want to provide additional information back to the health care provider. So that health care provider can make the best

therapy they can for a particular patient. So you can imagine in like insulin delivery or something like that, where if the user has a continuous glucose monitor, and an insulin pump that they want to be able to see that data in an app, they want to be able to control how well the insulin is delivered, and what the actual dose of insulin is that they're getting. And then the healthcare provider wants to see over the long term, you know, given for a given insulin dose and a given insulin regimen, how are they able to control their glucose levels across the course of a day? They send feedback, and then are they really, really taking the medication when they're supposed to be taking a vacation. So we've worked on other devices where we're giving the user feedback on the quality of a dose of medication that they've taken, and then really kind of providing them with monthly summaries of when they took the dose and how well they took the dose. And again, it's really trying to provide feedback to really help train the user to be able to take that medication more efficiently and presumably come out with better outcomes.

Landon Jones 4:32

So another thing that you do at sunrise labs, from my understanding is medical device commercialization. So getting new ideas into the market, which in most cases can be a pretty expensive investment. Can you tell me a bit more about that process and how sunrise can speed it along?

Dave Hibbard 4:51

Yeah, so there's been some estimates that have come out in the last couple of years. See multiple sources for this where the estimate to do a A Novel device, a high risk novel device can be as much as 94 million to bring a device to market is certainly that's a large figure and intimidating, I think for a new company to come up with that sort of funding, even to bring a low to moderate risk device market through the 510 k process. So the 510 k process is a equivalency process. So you're looking at applying for FDA FDA approval based on previous submissions, usually from another company, but it could be within your own, even those estimates have been as high as \$31, to bring a device to market. So there's lots of reasons why those costs are what they are usually kind of breaks down into three or four different areas that you're going to end up spending money as a startup company one, certainly you're gonna have marketing and launch costs. So once you have that product developed, you're going to end up going to trade shows doing advertising, you're certainly gonna have to build up inventory, you're going to have to go out and do your initial installations and support the initial installations to really get key opinion leaders to buy into the product that you developed. So that's marketing costs, a lot of times can be as much as the development costs, you also, because you are working in the medical device world, you're going to have to face regulatory costs. So regulatory costs can vary from device to device, but there's always a minimum threshold that you're going to have to cross. So you're going to have to have designed controls that are compliant with the FDA requirements. Those include things like risk analysis, compliance to medical device standards, getting the actual regulatory approval itself. And then one of the third big parts of the cost, release and medical devices, the development itself, right. So you have to be able to go through feasibility steps to make sure that your technology is going to work, the way you think it's going to work and be effective for the patient, you have the design costs, and those design costs usually come with multiple iterations, you have to do testing to verify that the device meets what the customer needs. And you have to do validation as well, to make sure that the device can be used the way it's expected to be used. So as far as what can we do to try to make those costs lower and more predictable? You know, one of the things that you want to do is you want to prevent rework. Certainly, one of the areas that sunrise preaches as a company is to do a Technology Readiness Review, before we jump into the actual development of the device, where we need to go through multiple prototype iterations, we're going to want to sit down with the customer and make sure that that device is where the customer thinks it is. The customer may come to us, and they think they have a technology that's ready for development. And we may sit down with them and be like, Okay, well, have you thought about this failure mode or thought about the risk this risk? Or have you thought about the product being used this way, and we really want to make sure that the technology itself isn't lost and ready to be built into a product. One of the other upfront conversations we want to have with the customer is that knowing

what your constraints are. So is your main constraint, time, budget, you know, are you trying to get ready for a particular launch at a particular show? Is there a certain amount of funding that the company has, you know, what is the main driver of when the product needs to be released, and when what sort of fun that you can apply to it. And the big conversation there really is around what is the minimum viable product. So, you know, a lot of times everyone, everyone comes to us and they want, they want the iPad, they want the full Apple device that's crisp and polished, and every feature is complete on the first initial launch. And really, you know, what we try and steer people to is invest the money that you need to invest to make the product that is going to get you into the market, and then continue to refine it over time. You can't go into the market with a device that isn't crisp and clean. But you certainly can go into the market with a device that's over featured where your main features really get kind of lost and muddled. With when you launch the device and everyone says okay, well, there's another product, but what's special about it, you need to really develop the right product. So in order to do this, the company and this could be before they engage a partner or it could be several partners that engaged throughout the process. They need to really do some market research to know what is the field I'm jumping into. You know, I've seen recently some customers come to us with what you might call a me too product right there. They're just trying to get their name out into a field in a crowded space that is, frankly probably going to be hard to really make much of a statement in unless they get acquired by a bigger company. And you know that that can be a challenge. You know, it's to really make sure that you have a good differentiator, right. Sometimes you come in with your differentiator is a new algorithm or new technology. You know, sometimes you come in with it's economics are ease of use, but you need to make sure that you know what your competition is doing. We also early on like to put models or design concepts in front of the customer, and both the customer of sunrise labs, but also the end user. And this has become, in the last probably 10 years a much bigger deal with the FDA as well as making sure that you have a robust Human Factors process that leads to development of devices that are easily used and safely used by the end user. And a lot of that research initially comes out of issues that were seen, probably 10 to 15 years ago, when

the particular example that I always think of is infusion pumps. So in the early to mid 90s, there was certainly a lot of cost saving measures that was going on in hospitals. And one of the ways that hospitals were trying to save cost without affecting patient outcomes was to send patients home to give medicines via infusion pumps or other devices. And what they found was that a lot of people, the lay people, non medical people didn't know how to use a particular device and ended up causing themselves injury, because they weren't using those devices, right. And because of those instances, the FDA really adopted a strong stance to make sure that the whatever device a manufacturer is developing, it needs to be usable and safe to be able to be used in a particular market, particular customer, whoever the end user is. So you need to be very careful about defining who the end user is, what user groups you have, and then making sure that the device actually meets their needs.

Landon Jones 11:43

How long does this process usually take.

Dave Hibbard 11:45

So that varies quite a bit, you can do so there's a area of the human factors called gender research. Agenda research, may be a very quick process, it may be a very lengthy process, it really depends on how much is known in the industry about your particular product. And how much is really left to discover. So if you are going into, you know, use example of an or going into Nomar and you know, you're, say, adding interoperative imaging and you know, like a floor scope or something like that, that fits pretty well into the LR, then maybe there's not that genitive, that much tentative research to do. But if you're bringing like a interoperative mR into the or you have to worry about magnetic components being pulled into the EMR, distortion the images to the metal objects in the field, then there, there may be quite a bit of trying to figure out exactly what the nurses workflow is that surgeons workflow is to try and make sure that the equipment that needs to be removed when you actually want to take an image is removed from the field, and that the procedure can be done safely, including

sterility issues and other issues. So you may spend quite a bit of time going through observing Lars interviewing people that are in the medical profession, whether it's a circulating nurse or scrubbed in nurse or a surgeon etc, just to try and make sure that the product that you're designing fits into their needs. You know, in a lot of cases, you could come out with a great technology that isn't really very usable. And one gets picked up and used across the world. And one doesn't. You know, I think a good example of that might be like an iPod versus I think Microsoft originally had the zoom or Zune or something it was called Originally, I think it actually came out first. But no one knows that name. And phone is probably ever used one, you know everything upgrade to Apple and iPod. So there certainly are big differences you can make there. And then one of the other processes that I wanted to talk about that we've adopted in the last couple of years at sunrise is using agile development methodologies to develop software. And also we've been using at the hardware side as well. So the Agile process originally was mostly focused on software. They have a, what they call the Agile Manifesto, which is a sort of set of guidance principles that they use in Agile to make sure that you have product that meets the customer needs. So when agile originally came out, it was very much focused on making sure the end product meets the customer needs. So you, what you do is you have small bursts of development. And at the end of that burst of development, you deliver some new feature to the customer, let the customer give you feedback on that. See if you want to make changes and then you re iterate and do that over and over again. So you keep doing these quick bursts of development with a bunch of feedback. So in the medical industry, a lot of people look at that agile processes being incongruent with the FDA recommended process, which is generally seen as more of a waterfall approach. So in the waterfall approach, you're writing a set of requirements, then you're writing a set of design documents, then you go through The whole development cycle, then you test it, then you release it. If something goes wrong in the middle, then you kind of go all the way back to the beginning, back to the requirements and definition stage and then repeat the Agile process. In the medical world, I think I in most other manufacturers have sort of divided divided into phases, one phase being a requirements and definition phase, but still doing that in small bursts and making sure that the requirements you're generating have high value. They're not either too light or too heavy, and making sure there's good value to the requirements that you're that you're writing, then you get into adult development phase. And again, you're going to do the same thing, you're going to do a couple of weeks of software, and then you're going to deliver that software back to a marketing group or end user and say, Okay, well, how about this does this look like what you're thinking or what you need, and then you take that feedback, incorporated into the next First, the next sprint of work. And just keep repeating that throughout the whole entire process. The other thing that this Agile process really allows is you to do in the beginning subsystem testing, but eventually integration and system level testing as you go out through the development process. So again, when you look back at sort of the FDA waterfall model, a lot of times, you would develop software for some long period of time, it could be several months or even several years. And then you transfer that to a testing group. And the testing group would be like, well, this is wrong, that's wrong, etc. In the Agile as you create each one of these sprints, you can take that and give it to both the marketing group, but you can also give it to a test. So you can get immediate feedback to make sure that your requirements that you defined early on are getting that

Landon Jones 16:34

so the Agile process is completely separate from the FDA process.

Dave Hibbard 16:38

So I would not say they're separate. Now, I would say that they are they're really living in parallel. I think, I think early on, when agile came out, it was used for a lot of commercial devices. And not much in the medical device world at all. But recently, in the last couple of years, the FDA actually released guidance document on using agile to develop medical devices. And I think from that a lot of development companies have really started to incorporate some of the ideas of Agile into their development process. It doesn't need to be modified slightly. But I think it does, at the end, use a much more predictable path to getting through the development process. It finds issues early. You know, one of the manifestos I think in general development is, you know, test early and often, right. So

you want to find what your failures are as early as you can development, because the later you find issues in development, the more expensive they are fixed. So you always want to try and find those as quick as you can. And using the Agile process allows you to get quick customer feedback and also test feedback on how your product is coming along.

Landon Jones 17:45

My last question for you, David, is what's the most exciting thing about your job at sunrise labs,

Dave Hibbard 17:51

one of the things that I really like about working at sunrise Labs is just the breadth of products that we get to work on. We have customers come in with lots of different ideas, lots of different industries, you know, I've spent about half of my career working in for development for direct sales, mostly in image guided surgery, surgery and radiation oncology. And then I've spent about half of my career working in as more services industry and, you know, working in the service industry, I get to see, you know, like I mentioned earlier, I get to see robotics, I get to see connected devices, I get to do projects that may take a couple of months and projects that take several years. So it's really i think that that breadth and the just the whole litany of customers that I get to meet throughout the daily process that makes it exciting. That does

Landon Jones 18:35

sound very exciting. Thank you so much for coming on the show.

Dave Hibbard 18:38

Oh, thanks for having me on.

Landon Jones 18:40

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