Tyler Kern: 00:03
Welcome to the Sunrise podcast, powered by Sunrise Labs. Hello, and welcome to Making Bright Ideas Work, a podcast from Sunrise Labs. I'm your host today, Tyler Kern. Thank you so much for joining us for this episode of the show. Today, we're diving in and talking about quality assurance teams and building a foundation of trust within a team and with clients. And we have two subject matter experts joining the podcast today. We are excited to have them along with us. We have Spencer Zawasky. He's the Principal Quality Engineer and Test Manager at Sunrise Labs. Spencer, thank you so much for joining us today.

Spencer Zawasky: 00:36
Thanks, Tyler. It's good to be here.

Tyler Kern: 00:37
Absolutely. Absolutely. Happy to have you along. And also we have Trisha Bouthot. She is the Director of Quality and Test at Sunrise Labs. Trisha, thank you so much for being here.

Trisha Bouthot: 00:46
Thank you, Tyler.

Tyler Kern: 00:47
Absolutely. Well, I'm excited to have this conversation with each of you today. So Spencer, let's just start off here. Can you detail for us what a quality engineer does and what your role is in medical device development process?

Spencer Zawasky: 00:59
Sure. So quality's a big field to talk about. But specifically in terms of medical devices, and at Sunrise, it means two specific things. So the first part starts as quality, but it's most often referred to as verification and validation and that it has to do with making sure that the product does what we say it's going to do and that the product actually meets the needs of the ultimate users, the patients, the doctors, the operators.

And the other area is often called quality assurance. And that has to do with making sure that we follow the processes, basically the rules that we say we're going to follow, making sure that we follow our own rules. And so that when we make a medical device, we can make it in a reproducible and consistent fashion. And so, yeah.

So what is an engineer with, let's say a V&V engineer do at Sunrise? So our customers range quite a bit in terms of the size and scale of their operations. But I think a fairly typical example of this type of product we would work on would be, let's say a Bluetooth thermometer. So there's an existing thermometer and we're adding Bluetooth to it, what does a quality engineer do in that circumstance? Well, the development process starts, there's a concept phase, and once people have decided that, "Oh yeah, okay, this is a real product. We need to make this into a real medical device and we're going to sell it" and blah, blah, blah, blah, blah, the development activity starts with generating requirements. In essence, creating a contract with stipulations in that contract as to the exact things a product is supposed to do, those requirements define the product. And it's a V&V engineer's job to make sure that they understand very clearly what those are and ultimately to make sure that the product performs according to those requirements. And further, that those requirements are the correct requirements that they represent.

In fact, what we want the medical device to do, and that it results in a safe and effective medical product, which doesn't answer the question. Sorry. I'll keep talking. It doesn't answer the question, well what does a V&V engineer do? So first thing, I have to read the requirements. So I, in fact, would participate in the writing of those requirements and in all of the follow-on design activities that have to

do with design and development, the architecture, breaking it into different modules, and making sure that different pieces are implemented. And through that whole process, I have to keep my eyes on the prize. I have to keep reminding myself, okay, how does this relate to those requirements? How does this relate to how the patient is going to use this device? How am I going to prove, ultimately, at the end of development, that this device actually does the things that we said it was going to do.

Most often, that's testing. I have to come up with some kind of a test that I can perform in a controlled way that I can execute in a controlled way and then I can record so that when we go to the FDA and say, "We would like to be able to sell this device, and here's why we think this device both meets its requirements and is safe and effective. Here's a pile of evidence that you can review, and upon reviewing it, you will agree with us that we should be able to sell this medical device."

And so I'm doing that testing. I'm writing that testing, I'm interacting with the design team, making sure that these are the right kinds of tests to be performing, that they haven't made it super hard for me to do those tests or maybe there's a different way that I should be doing the testing. And then ultimately, documenting what those tests are, getting all of that approved, and then executing those tests, as I said, in a very controlled fashion so that I can carefully record all of that activity so that other people can look at what was done and say, "Oh yeah, not only is this a safe and effective medical device, but you've demonstrated, which is evident, that this is a safe and effective medical device."

Tyler Kern: 05:28
So Spencer, one of the things you mentioned there was process. Why is process such an important thing for you, especially as it relates to quality assurance and what you're doing with medical devices?

Spencer Zawasky: 05:40
If you're a company of one, and what you're doing is creating a medical device and you invent it all by yourself and then you make it all by yourself, and then you sell and support it all by yourself, there's not a whole lot of need for process because the entire life cycle, the entire design, the entire definition of the product is in your head. And that's great, but almost no one can do that. And so, when you have to share these duties with other people, you could tell how to do it without writing anything down. But I think you'll agree that the way to solve these problems is to actually document what needs to be done so that it can be done by various individuals, various times, and a very reproducible, very consistent manner. And that's what the process offers us, is a way to remove the personalities from the success of the development endeavor, right?

We've created a repeatable activity that other people can look at, can comment on, can improve, or criticize, a reproducible activity that anyone in theory or at least a trained individual can come in and say, "I understand how you did that. I understand how to do that. I will now join your company and do this." And won't be that, "Oh, we added another engineer and they did it a completely different way. Oh, which medical device did you get? Who built it?" That shouldn't matter. The processes should be the process and we should all be following the process and creating a consistent and a quality medical device. That's what a quality device means, is that it is consistently manufactured. It's consistent in its implementation. The code in a software, a medical device, the code is written by multiple different people, but they've written it in a consistent and uniform fashion. The process ensures that that can happen.

Tyler Kern: 07:49
Absolutely, absolutely. So Trisha, as we talk about a quality assurance team, what are the principles that a good quality assurance team should be built on, and what are some of those principles that you would say are extremely important for a good quality assurance team

Trisha Bouthot: 08:07
Listening and communicating, active listening being key, communicating effectively, knowing who your

audience is, leading them, and understanding their options and potential solutions to some of their problems. Sharing knowledge is a big one. We, as an organization, share a lot of knowledge. We have many lunch and learns and technical sharing sessions. And as a quality department, we meet multiple times a week and share in our experiences. There's so much power in knowledge transfer and sharing both good and bad lessons learned. It really helps our team to be efficient.

Tyler Kern: 08:54
So where does trust fall into the conversation when we talk about quality assurance teams and how they're able to work together and what that looks like for a company? Talk to me about trust and what it looks like for a company to have trust all throughout the organization, so then quality assurance is able to operate with that as one of its principles. Break that down for me.

Trisha Bouthot: 09:17
Sure. Trusting in your team and allowing them to really dig in and own their tasks, without micromanagement, fosters innovation. It's really exciting to see the things that your team can do when you trust them with things. I mentioned earlier about knowledge sharing, and it's really related to trust, empowering people, allowing them to own their tasks and own their responsibilities really puts forth a better product than they would if it's, say me directing them to do something my way. I feel like it's my job to guide them, remove obstacles for them so that they can be much more productive. This is way more effective than directing and telling them what to do.

Spencer Zawasky: 10:06
If I can amplify that a little bit and expand it maybe. The medical device business is a business about trust. I think that the whole purpose of having a regulated industry is so that people can purchase a medical device or be prescribed a medical device, or end up in a hospital where they're using medical devices without having to worry about like, "Well, wait a minute, where did that come from? How do you know it works?"

The fact that the FDA stands between just a random company deciding, "Oh, we're going to make a heart pump and then putting it on the market." There's a level of trust that comes out of the regulated system that we work in. And that trust is, in some respects, enforced by a quality assurance team. We're the ones that have to honor that trust in a way that I don't think is quite as prominent to the developers in an organization. The developers are trying to implement. They're trying to make the idea real, but at the end of the day, what they have to do also is make a product that people can trust. And how do you honor that? That's what quality assurance provides, is a way to prove that you can trust this device to make you better, to heal you, to help you take your medicine on time, or to help you breathe or whatever it is. It's a critical, it's an essential part of what quality assurance is.

Trisha Bouthot: 11:48
Part of our job is twofold. One, internally to make the organization understand that there are rules, as Spencer's talked about, that we need to follow. And it's our job to help the development teams follow that path and help get them to a product that they can then deliver to a client. And on the client-side of things, knowing that we are going to be able to get them there, to help get them what they need for their submission, that have done our due diligence, that we have provided them with a product that they can take forward into the market. I think trust is a big part of that.

Spencer Zawasky: 11:48
I agree.

Tyler Kern: 12:41
So you spoke about trust, Spencer, and the importance, especially in medical device development. How does working in an environment that has trust throughout it, how does that affect your role and your job? And what does that look like specifically for you?

Spencer Zawasky: 12:57
I think it's probably useful to try to imagine what it's like where there isn't trust. How does an organization like quality assurance function and is in an environment where there is no trust, or where quality assurance is not a trusted organization? So if you're operating in a situation where you cannot rely on other people to do their jobs, then you can't focus on your own job. You constantly have to be looking over your shoulder and trying to figure out how can I work on this if no one is going to help me or if I can't get honest feedback, or if someone is always trying to put me in harm's way or blame me for not meeting a deadline. So that's what we call a negative definition.

But a more positive description of what happens when you're operating in a trusting environment and where quality depends on operating in a trusting environment is for quality to function, we are inherently the loyal opposition. It's our job to tell people when they're doing stuff wrong or when they've gotten distracted by some feature and they've left out some other feature, or when the product is not meeting the needs of the patient, or an extreme circumstance where someone could actually be hurt by the product. We have to be the people who stand up and push against the overwhelming desire to move forward and deliver a product and say, "Whoa, you need to listen to me. You need to trust me when I tell you, you cannot continue in this direction. This has to be fixed, or this is wrong, or this needs to be addressed in some way."

Trisha Bouthot: 14:48
In the environment that we work in, where we're a services organization, people really rely on us to understand what it is to navigate through the development process. Building trust within our team and in our project teams is critical. We often find ourselves in situations, we're faced with a number of obstacles and criteria that we need to meet, whether it's on the regulatory side of things, on the budget side of things, on the schedule side of things.

And getting the project team to listen to the quality organization and the things that we have to offer the project teams can really help get the project to that end line much, much faster, because there are many ways to solve a problem, understand what the project is facing and coming up and working together to provide an optimal solution that helps meet the needs all around, that helps minimize a budget impact let's say, or a schedule impact, help producing a product that will make it through whatever compliance 510(k) or PNAS PMA submission that a client will need to do in order to get the product out on the market. It's our goal always to give the client the best possible solution to their problem, their product and get that product out on the market as fast as possible.

Spencer Zawasky: 16:40
The idea that a quality organization is a luxury or is an add-on, or even in some negative circumstances, is slowing a project down or increasing the cost of a project, often, that thinking is very short-sighted. The whole purpose of a high functioning quality organization is to make sure that you get to succeed on the first try, as opposed to trying and failing and trying and failing and trying and failing. The point is to anticipate where you may fail or where a product might not meet the requirements, where the product might not meet the needs of the end-users. It's a lot less expensive to get it right on the first try. Even if you have to work a little harder or take a little bit more time on your first try to make it count, that's what quality brings to the table.

And in the moment, it doesn't always seem like that's true. In the moment, it seems like the quality organization is moving the finish line further away. But more often than not, the quality organization is making clear to you a hurdle that you haven't seen yet and is trying to get you to address it while there's still time and money to address it. Because a lot of these medical devices, a lot of these small companies that we work with, they never get to market, or if they get to market, their product fails and they disappear, or they get subsumed in a different, bought out by a bigger company or just disappear altogether. It's hard to do this. And if you make mistakes early on that you don't correct, they will destroy you in the long run.

Trisha Bouthot: 18:33
It's so important for an organization to share their thoughts and ideas and opinions. It's crucial because the different disciplines come at a problem from many different directions and understanding the various concerns and being able to share those without the fear of being wrong or making a mistake. I think that that's understanding what all the constraints are, what everybody's concerns are, I think it just helps produce a better product all around, understanding everybody's input to a problem. And I think that working in an organization that promotes different thoughts, wants people's ideas. We come up with some fantastic solutions for whether it's a process improvement internal or in the way that we would solve our problems and get the product developed. Yeah, I definitely think that it plays a huge role in the organization as a whole.

Spencer Zawasky: 19:44
Yeah. And when you're working in an environment where there's a great deal of respect, and there's a great deal of trust, your opinion counts for something. People will listen to you. People want to hear what you have to say, even when it might come out and potentially negative or critical way. The fact of the matter is if you have a relationship, and if you have a respectful relationship, people are not going to assume that you're just being a jerk, that there's some merit to whatever you're saying, and that they're going to look for the merit in what you're saying, even if maybe you're having a bad day, and you're not saying it in the most constructive and conducive way.

Tyler Kern: 20:26
So Trisha, in a sense, is trust the thing that keeps a good quality assurance team from maybe operating or being perceived as the development police, the people that are there just to tell you when you're doing something wrong? Is trust really that ingredient that helps the quality assurance team from being viewed as a negative entity, but rather a positive one that keeps people on the right track, following the right processes and the things that we've discussed?

Trisha Bouthot: 20:54
I believe so. I think often the quality team is seen as the quote cop, right? The police. I like to think of us more as like a crossing guard. It's our job to help you get from point A to point B swiftly, safely. Sometimes we run into obstacles, but our engineers are equipped with skills to help navigate around those obstacles. And much of what we do on the development side for medical products, it's critical that we comply with standards and guidances, but there's so many ways to solve problems, and our team is open to listening and understanding all aspects of the problems, of the projects and to help come up with the best solution and the best process for the development of that product.

Spencer Zawasky: 21:45
Yeah. Sunrise is a fairly small company and on a regular basis, we deal with various different clients who have very different needs. It's a rather unique challenge for a quality assurance group to work in an environment like that. Because I think when you're a single purpose company and you're making a single product, you can nail it down. You can write it all down and you can have a process that you just follow with no ambiguity and no problems.

You just, "It says right here, step one, step two, step three." But we don't really have that luxury. We are adjusting on the fly to different client needs, to different clients, to different situations. And yet, the entire time, we're still trying to make sure that we are complying with the standards, with the regulations, that we're meeting the client's expectations, that we're communicative through that whole process about why you cannot do whatever that is or why it's really better to do it this way, or well, if the client wants it that way, then we should at least do it along this path, instead of along that path, because we do not have that luxury of perfecting the process for our single product. We are a services organization and it's our job to find the custom solution for each client.

Trisha Bouthot: 23:20
We've even had some big players, big medical device manufacturers that come to us for development and while they have their own very good quality management system, it often stifles the organization from getting something done quickly, especially if it's more on the experimental side. So we find that in many cases, we have clients who want to come to us because we can be a bit more agile. They trust that we can get it done. They know that we know what we're doing. We've done it day in and day out on a variety of different products from class two in-vitro diagnostics to class three critical care. We can scale up and down and provide what we think is a good solution for getting the product completed for our clients.

Tyler Kern: 24:24
Spencer, are there examples that you have seen out, maybe even external to the medical device world, where you have seen maybe a lack of quality assurance and as a result, the product failed or something along those lines? Have you seen examples of that, where you look and you say, "That's a quality assurance issue," and you as an engineer can see the signs of that?

Spencer Zawasky: 24:48
All the time. That's one of the sort of, I'll call it an occupational hazard, but you get used to looking at things a certain way at work. And when you go home, you can't turn it off. It becomes part of just how you look at the world. And I do a lot of software testing at Sunrise and in my career. And so it seems like I'm always testing software. I've found bugs in the software of my car and I can reproduce them, and I have been sorely tempted to call up the manufacturer and tell them that this is the bug that they need to fix. But really, I have to turn it off. I have to draw the line there.

It's interesting, in some sense, the question that you're asking about lacks the necessary QA. It's a hard judgment to make how much is too much. I'll say it again, Sunrise being a small company and being a services organization, we can customize our solutions to the clients and to the situations. Each different situation demands a different consideration for how much is enough. One of the things the larger companies have tried to do is they've tried to make us one size fits all solution. And in a lot of cases, that means way more process or way more testing than might actually be wise or cost-effective, honestly. So we have the leeway to be able to say, "Okay, none of that testing is going to actually be important. Let's do some other testing," or "None of this activity is likely to show any benefit to the ability of the product and meet its requirements or to the safety of the product." We can just not do it, or we can apply that energy somewhere else. But in terms of can, I give you an example of lapse.

Tyler Kern: 26:59
Would you say that everything going on with maybe the Boeing 737 MAX or something like that would be a quality assurance?

Spencer Zawasky: 27:07
Boeing's whole situation right now is kind of a nightmare. When you skimp on the quality assurance. It's the opposite side of the coin there in terms of what's the necessary quality assurance. The question becomes, "Okay, well, if this is too much, and this is too little, then what is just enough?" That line is not an obvious one. And if an administration comes in and says, "We're going to spend 50% less money on QA, or we're going to spend 10% less money on QA, or we're going to spend 90% less money on QA," that doesn't immediately translate into 50% more bugs or 90% more bugs or problems. It's a randomized process. It increases the likeliness that something bad is going to happen after the product ships, but it's not a guarantee that something bad will happen after the product ships.

And so, the Boeing example with the 737 MAX and their complicated system and their autopilot and their desire to continue to meet their sales goals and continue to meet their shipping schedules, this is the sort of thing that you see in a microcosm sort of all the time, necessarily the quality activity

happens later than the design and development activities happen. And if a schedule starts to slip, the temptation is to start squeezing the quality team to make sure that they do their work faster somehow, or that they do it in less time or that they add more people. And how much is enough, is a question that you always have to answer on every project individually. Even the big companies have to make those decisions. And sometimes you have to say, "Okay, we are okay not doing some kind of testing or some other kind of testing."

We had a client come in who had decided that their relatively inexpensive medical device was going to use this relatively inexpensive battery, probably because they already had a production deal for other reasons, and had this battery in high quantities. And so what they then came up with was a series of rather demanding constraints around the shelf life of the product. And early on, we could tell that this battery was probably not a good choice for the shelf life of the product, the nickel–metal hydride batteries that you often deal with. In general, lithium-ion batteries are great, but you maybe don't want to wear them on your body all the time, because when they do catch fire, and sometimes they do, they are very energetic and it can be very uncomfortable to have a lithium battery catch fire on your person.

The older technology in nickel-metal hydride is far less uncomfortable when it fails in proximity to your body. But there's reasons why everyone loves lithium-ion batteries is because they have great energy density and you can charge them and recharge them over and over again. And they don't have memory and there's all sorts of wonderful reasons why lithium batteries are great. But they chose nickel–metal hydride and nickel-metal hydride doesn't do as well on the shelf. And so we designed some very elaborate tests, elaborate tests with a large amount of batteries because we really wanted to be very, very sure that at a production scale, that when they shipped thousands or tens of thousands of these products, that they would all meet the bare minimum requirements that they set for them and that they could last on the shelf under different environmental conditions. There's always going to be some loss, but it'd be an acceptable loss of products with the battery that they chose.

And so we developed these elaborate tests and we ended up baking the batteries in an oven to simulate both the amount of time that they would spend on a shelf somewhere and to simulate being in a warmer climate for a longer period of time. And then we had a range to these arrays of little battery testing circuits and plugged them all in, and then we had an automated system that would turn them on and off and charge. And at the end of the day, it, it did not pass.

That product ended up not making it to market. In fact, I suspect that it was largely due to the fact that they chose this battery well ahead of time, and for reasons that were not the performance of the battery, they chose it for operational reasons, not for technical reasons. And it meant that the product couldn't be couldn't be sold. It wasn't going to meet the requirements. And we spent a lot of time and energy basically proving it wasn't going to meet the requirements, but that's better that we did that than they made the product, they manufactured the product, they shipped it around the world and then it sat on shelves and then didn't work. So as expensive as it was to do all of that quality assurance, it was cheaper than failing.

Tyler Kern: 32:31
Absolutely. So as we begin to wrap up our conversation here today, and we've covered a lot of ground as it relates to quality. And so Trisha, I want to give you the opportunity first, and then Spencer we'll come to you. But I want to give you the opportunity to give us maybe a summation of the importance of quality assurance and the role that trust plays throughout an organization, especially as it relates to quality assurance. So Trisha, let me turn it over to you. Just give us a summation of some of the things we've discussed today and hit on the importance of quality assurance.

Trisha Bouthot: 33:01
I think one of the major themes that we were trying to get across is that in low trust environments, you tend to see hindered innovation, leadership, hindered growth, everything taking so much longer, it's

more inefficient, it's less exciting. And I think that you have less knowledge sharing, right? We talked a bit about knowledge sharing earlier on in our discussions. And it's so critical in what we do learning other experiences, how we can always do better. Part of what we do in quality assurance is continuous improvement, how we can be better, how we can be more efficient, how we can be faster, how we can put out a quality product consistently, time over time, in a high trust environment. We empower our people to come up with the best solutions, to be innovative, encourage that. It keeps people excited, wanting to always do a good job, put out a quality product, always do better. All around it, it ends up saving the company time and money.

Spencer Zawasky: 34:23
I can definitely get on board with that. I think Sunrise is a great place to work. I think we have a very trust-based and respectful environment inside quality and across the company. I think Trisha is right when she says that or implies that an authoritarian organization, where you're supposed to do what you're told, is not an organization where you're going to find problems before they happen. People will not want to speak up to say, "Oh, this isn't going to work, or this might hurt someone." They're going to keep their heads down and they're going to try to get through the day. And that's not how you make a quality product. It's not how you make a safe and effective medical device.

We're a small company too, which means that we're agile enough to be able to jump from a process-heavy situation where a big company might have lots of rules that you have to follow, to a small three-person startup where they don't understand what quality is and what they need is the bare minimum because their app has to get to market in six months or something, or the window, the investors will start shutting them down. There's a lot of different demands on us and we're here to try to solve that problem. And it's a difficult job to do under ordinary circumstances. If you don't feel like people trust you, or if you don't feel like you can trust the people you're working with, then it becomes orders of magnitude more difficult. Your clients will pick up on that and they won't trust you, and they'll be second-guessing you, and that just makes the whole job harder. Yeah, trust is a bedrock principle to quality assurance and to making safe and effective medical devices.

Trisha Bouthot: 36:17
I encourage the engineers, whether they are fresh out of school or been with the group for years, to speak up. They're the subject matter experts. The program managers and the engineers are depending on the quality organization to know the process, how to get those devices out, and to make sure that those devices are inherently safe by design. It's highly encouraged for the quality engineers to speak up, provide their opinions, and not feel stifled that they should feel empowered to share their thoughts. Junior engineers often a fresh set of eyes to a problem. And it's really important because the team is really relying on what our team knows in order to help solve those problems and get that device out.

Tyler Kern: 37:19
Absolutely. Absolutely. Well, thank you guys so much for your insight today, Spencer Zawasky and Trisha Bouthot, for talking a little bit more about the importance of quality and assurance, how this works within a team, and the importance of this just to everyone within an organization. So thank you both so much for joining us here on the podcast today.

Spencer Zawasky: 37:37
Sure. Thanks, Tyler. It was a pleasure talking to you.

Trisha Bouthot: 37:41
Thank you, Tyler. It was a lot of fun.

Tyler Kern: 37:42
Absolutely. I enjoyed the conversation a lot, so thank you both very, very much. And thank you to our

listeners today. We appreciate you joining us for this episode of Making Bright Ideas Work, a podcast from Sunrise Labs. Of course, we'll be back soon with more episodes of the podcast. But until then, make sure you're subscribed on Apple Podcasts or Spotify, to stay up to date with everything going on in this industry. And we will see you soon with those new episodes. But until then, I've been your host today, Tyler Kern. Thanks for listening.