



**FDA Recalls: Fewer But How Many Near Misses?**  
Presented by Joseph Anderson  
at the 10x Medical Device Conference – San Diego, 2022

**Joseph Anderson:** We are witnessing, and we're experiencing what I like to call a "powder keg of issues", that have decimated and can decimate your organization or your partner.

Doesn't matter if you're a joint manufacturer, contract manufacturer, contract design, venture capitalist, these types of issues, and the blink of an eye can change your organization.

**Note:** The following was auto-transcribed by [otter.ai](https://otter.ai) and got probably 80+ percent correct without edits. Interpret accordingly.

**Joseph Anderson:** Thanks for having me, Joe. I think this is my fourth, fourth event to speak and...

**Joe Hage:** What it says in your nametag?

**Joseph Anderson:** Four.

**Joe Hage:** Then it's your fourth!



**Joseph Anderson:** Four. But for me, it's an honor to be here. And I'm going to talk about that at the end. And Joe and I, since we've met, we always kind of have this back and forth, what are you going to speak about? What's the title gonna be, and he doesn't like my titles, I don't like his. I don't say it, he tells me he doesn't like my titles. So he just picks one and then I just choose what I'm going to use. So we're still gonna get to the point.

But for me, you know, there's just been a lot of great presentations, a lot of great discussions, I hope that bookend some of that, and tie it together to what we're doing IPX. Because the world's changing, if you've heard me speak anywhere at a prior event, I'm even before the pandemic, we've been forecasting this for a while, you know, companies are going to struggle, you know, innovators are going to struggle, if you don't look at your processes across the board, if you don't look at your operations across the board, if you don't have the right supply chain partners, and we've seen that, right.

And then in the medical device industry, really in any industry, I don't care, I know why we're here. But if you make a product manufacture product, you design a product, these outliers can really cause failure to your business to your dream. And that's what I want to talk about a little bit today. So IPX, we work with everyone from small companies to Fortune 500, fortune 10. And we are professional services and education provider and owner the industry standard for operational excellence.

So if you think about quality management platform, if you think about configuration management from that as needed idea to as service as decommissioned, that's kind of the standard, the CMT standard, but I won't bore you with that. For us, it's anywhere from we say new nutrition and nuclear to automotive outer spaces who we work with. I want to skip through all these do the name drops. These are great companies we work with, we have a quarterly leadership panel where we just get together and see what the trends are going and what's happening. And we were able to forecast because of some things going on in Asia Pacific in 2018, there was an issue, there was something going on it was going to impact us all I'm going to talk about that.

We all know now there was a pandemic brewing. We have a cross industry congress that we meet with once a month they submit changes to us they submit this request to us for curriculum and or services. Anything from you know buzzwords, digital transformation, industry forro, we've heard people



mention digital or other digital twin in here over the last couple of days, and all those have been come heavily marketed. There's a lot of value to understanding what those terms mean. And that's what this group does that we work with, we're really trying to identify what the future is going to be for industry. But why I'm here today. And this is important.

We are witnessing, and we're experiencing what I like to call a powder keg of issues that have decimated and can decimate your organization or your partner. Doesn't matter if you're a joint manufacturer, contract manufacturer, contract design, venture capitalist. These types of issues, and that blink of an eye could change your organization and that's really what I want to talk about because we all know who this company is typically, I don't mention names but really don't care today it was peloton. Peloton what happened that made them go from \$108 a share on June 1. Two as of yesterday, it was 1290. Part of it was supply chain absolutely. Part of it was poor design. There's a lot of other ones we can aim off, gyms are opening back up, gyms are opening back up. We're missing one arrogance.

Air gets leadership arrogance because the leadership knew about their supply chain issues. The leadership knew about the design issues, but they thought they had a lifestyle brand. CEO admits it was a mistake not to recall the product earlier in the process. This burns me that statement burns me should burn all of you as a consumer. All of you as manufacturers service providers, service professionals, design engineers, manufacturing engineers, this kind of statement should burn you. If you find an issue, bring it to the table, don't hurt somebody, don't be somebody at risk because your company, unfortunately, and they claim some over software, and some of it was, but they knew about it. Right there. They knew about these issues, they knew about the design flaws, they didn't know they chose not to do anything about it. They knew about supply chain issues, they knew the market was changing. They didn't adapt. They weren't flexible. There were a lot of companies over the last two and a half years. And guess what, they weren't ready to be flexible, they weren't ready to adapt. I've seen a lot of peers with a title founder, President, CEO, in the last two and a half years become manager, right, or they're now part of a workforce because their organization was spread so thin, they weren't able to maneuver around the pandemic.



I cut my teeth, teeth in the automotive world. 20 years is brutal. This is a very brutal industry to work in from a manufacturing perspective. And the one thing that I really, really hope you take home today, as we have a lot of people here that are experts in quality and lean manufacturing. And we heard just in time the other day, and that one always baffled me because there was never just in time because there was never enough. All these initiatives can be great. But if you apply them wrong, if you bring in the wrong resource, you're in trouble. And you've got to be able to adjust, you have to take some of that pride away as a leader, as a contributor. And go, you know what this isn't working for us. We hear this continuous improvement mantra all the time.

Another one that annoys me, it should be continual improvement. Look at the difference. In a word, I say this, pretty much every time I speak somewhere, continual means we're going to monitor how we're doing, we're going to measure that, then we're going to improve again, continuous means you never stop. So you have all these initiatives, and you're just burning through money, Six Sigma, lean, I've been there burning through money, if you're not monitoring why you deploy what you implemented, that's actually causing you more headaches. So as you're doing these initiatives as a company, you got to think about all these and this is a big one that's gonna happen to anyone. We saw it with Boeing. We see in med device, we see it with Abbott, you know, these are ones that actually made the public.

But what about the near misses? If you really want to check in and assess your supply chain, you got to look at everyone. You got to look at everyone. And that's not easy to do. These challenges, right? A company's reputation and its financial, financial success, you got organizations must assess their entire ecosystem. What's that mean? You hear a lot of companies talk about operational excellence, but they're just focused on manufacturing, operational excellence, it's end to end. So don't forget that write that down. Operational Excellence is end to end. It doesn't matter if you fix manufacturing, if all the inputs in the manufacturing are poor. If you really want to assess your suppliers or assess yourself, look at your deviation and waiver data.

That's the first thing I asked for when a CEO or their board asked me to come in and evaluate them. They tell me what they think their problems are. They identify their objectives. And then I shocked them and I say, well, show me your data. Show me your change records. Show me all your change data, your



corrective action changes, show me your deviation data. How many manufacturing waivers are you running on? How many of them have been incorporated back into product development? These are things you need to assess. So as you're thinking about partnering with a supply chain, or a manufacturing contract, or a defense contractor or design contractor, regardless of where you're at, in the med device world, and on the defense side, it's just another level of complexity. You've got to assess these things, you got to understand all of that. Proactive organizations that invest time and resources to assess and adjust will avoid product crisis. That's just the truth. You got to be ahead of the game.

We've heard a lot of great things Dr. Dave talked about innovation and all the steps he has undertaken and is undertaking to get to commercialization, a lot, a lot of steps. That's a first big step to being a real company. And that's one thing that we don't really work with our start-ups on, which is, so you got a great idea. You've validated it, you know, people are going to buy it, but how are you going to sustain it? How are you going to scale that? Alright, sustainability and scalability, it's a big thing. For a startup, you got to think about all of those, because otherwise you're gonna, your mind is gonna be taken by the VCs, your equity is gone, your control is gone. And all you see is a little bit of your dream. And it just hanging on. You've got to think about this whole supply chain, the whole ecosystem of I have an idea. I got to validate it, I got to make sure I could sell it marketed, and then how do I ensure that I sustain and grow? I'm not going to talk about ABA. It's all on the news, we all know product cost, is what it is.

And we see it as it's it outweighs the risk, right, the benefit outweighs the risk, the risk is death. For injury, that's what they don't want to say that, right? They don't want to say, that, for the greater good. We're gonna do this, or we're gonna take that educated risk and hope no one gets hurt. But that's, that's what it means that risk is injury or death. So we have a, a duty, and what we do to make sure once we release a product, it's good goods, we have to take the time. And that's the big mantra of mine quality needs to come back. And I think it is coming back. There used to be a day where a company stood on its quality. And now we're standing on where innovative or innovative, Yeah, but here, you're releasing stuff that's making people sick, or it's or it's enduring young children, or it's killing adults. That's not quality. And that's not innovation. That's just laziness. So for me from an IPX perspective, we work



with organizations and make sure these types of things don't happen. And they shouldn't happen.

So for us, it's all about traceability. It's all about sustainability, scalability and quality. And for us, again, as I mentioned earlier, there's a lot to accompany, it doesn't matter if your startup doesn't matter. If you're a large fortune 500 organization, you have to know everything about your organization. The data is interoperable across all your systems, or processes based off a legacy mindsets guarantee a lot of fortune 500 companies, you'd be shocked if you actually went in and read some of their policies and procedures, their administrative processes. It's baffling that they're able to operate, but because they have their cash rich, they're able to survive. But as we know, that catches up to you. Right? Anybody remember a company called Sears? My grandfather rolled probably rolling over in his grave every day. Thank not know, you know, knowing Sears is gone. You know, that was the company. You know, Sears was everything, just mismanage.

So it's very important for startups, it's very important for your large global corporations to be able to understand everything from as needed to as service to as decommission. I know, we're going to talk about returns your RMA process a little bit later this afternoon. How do we manage that customer satisfaction? How do we get that included back into product development? That's where a lot of companies struggle, believe it or not, they have this amazing RMA process on how they get the return. And then they don't feed that back into product development. That's one area we work with. What are you doing with that data? What are you doing with all that data?

You have your data rich, and we talk about earlier? Artificial intelligence. And that's, that's what RCM two baselines are and I'm not gonna go into a sermon about this, but artificial intelligence, and we kind of dance upon it earlier, you have action based, right, which is robotic. We've been doing that for a long time, then you have autonomous which we all we've been inundated with autonomous capability. But what what we're not saying is that cognitive the adaptive intelligence, so we're gonna give it a bunch of rules, we're gonna give a machine a bunch of rules that's in the field, whether it be a drone, a boat, a car, a robot, healthcare system, that's a robot that's coming soon, we're gonna give it a bunch of data. This is where companies struggle, it's how they manage data, we could build the best robot with the



greatest software and sensors that know how to handle a newborn baby to an elderly patient, we could do that.

But where we need to get better as all of this data, especially when we start talking about the cognitive side, when we talk about adaptive intelligence, that's where we that's where you're going to see more and more companies really start to struggle. And one thing I didn't bring up earlier, when we were talking about, sorry, I don't know your name, you brought up the artificial intelligence on a conference here. It's also about liability. You want to know why they don't want to answer your question. Because as soon as they make that choice, as soon as they program their software to take a life, guess who's liable for that death now, the manufacturer? That's why no one's answering that question. So this is all about how you manage your data, how you manage your changes to that data in the field.

So this is a very, very complex thing. If you're dancing in the world of artificial intelligence, make sure you have control of your data. And for me, it's about ecosystem. Understand your entire entity, your entire operations from cells, all the way into service and support. And the last thing for me, and this is the important one, this is my fourth time here, and this is the challenge to myself as well. I want you to identify and I want you to write it down. This is a challenge. I want you to write it down. All of you somewhere in this room have to make money. I don't know what you all do. You have to survive, right? You're in business. A business, I want you identify three or four people that you meet today that you can figure out how to work with in some way that's mutually beneficial.

And come back next year, and have that testimonial, because that's why we're here, we always use the word networking, and I haven't been great at it, it's more about collaborating. So I want you to figure out how you can use somebody utilize a relationship here for the good of both of your entities. And I think if we all do that, we'll have some great testimonies next year. And my last challenge is we got to make sure this advance stays around. I'm putting that on my shoulders, too. That's a good event. I've been at events where there's 1000 people and guess what ability to really collaborate small, a small event like this, that boutique where you can network and collaborate, it's very important. So my challenge to all of you is let's figure out how we can scale this and grow it a little bit and make sure it's around for another 10 years, or 15 years. So, Joe, thank you.



**Joe Hage:** So first, did I tell you, and second, who here can work with him and leverage his network to ensure more quality in your systems and processes because I regret people say, Joe, do you know someone who can give me a job, I can raise some money will help me some more product. And no one has ever in a decade asked me hey, Joe, do you know anyone who could help me have better quality? It never even comes up? And so my question for you is, do people reach you when they really screw up? Is that your entire business model wait for people to screw up? Or of course, spread the word and events like this so that they proactively find you. But is it really just a? Yeah, I'll indulge the expense of engaging your team. When I really have a problem. Is it bad?

**Joseph Anderson:** I'd say it's 50/50. So we're definitely professional firefighters, we get called in. When there's a major issue when there's a spill the other side of the house and I authorize say for example, Apple, we've helped them with quality. Now they want to get innovation out the door faster. So they've brought us in because when you look at who we are in our framework, we get things out the door faster.

**Paul D'Souza:** Everything is said and done and locate the budget from which people pay you when you when they ask you to come in and help is it from the innovation budget is it from the budget they typically use for Lean Six Sigma project because they're thinking of constant improvement, things like that. And I've been involved with Lean Six Sigma Institute as an example. The CEO is actually here in San Diego lives here. But it matters where the budget comes from. Because I'd love to bring you in we've you know, we've got a lot of people in our database in the sense of not just on my personal Rolodex dating myself, but it matters when they call you and how they pay you. So could you shed some light on that?

**Joseph Anderson:** Yeah, that's a great question. There's a lot of variants to that. So I can't give you a you know, straight one, I give you some case studies, we get a lot from engineering, engineering improvement, a big part from operations improvement, and then the continuing education. And then the fourth one, the fourth one actually is at the board level, or the C suite level, which is we need to bring someone in. That's not just here to give us philosophy, philosophy. But here's all our objectives. And they set aside a dedicated when you do it that way, when you have that top, very top line support, then these initiatives, everyone knows it's important.





When you start kind of out that education, your work your way up that, that bottom side up, it's a little more difficult. But we've tried to get at least at the VP level. So either it's from engineering and manufacturing, it could be from service, but I like to get straight from the C Suite.

**Joe Hage:** That'd be awesome. You mentioned earlier that you haven't been great at networking. ironic, given your role. Would you share ever so little bit just enough to give color about? Why are you so hard to get a hold of?

**Joseph Anderson:** I work a lot. I think it's I you know, I spoke at a university two weeks ago, we young young students, great students in Houston, they all they all have a dream, they all want to be entrepreneurs. And I told him, you're being lied to. Because everyone says they want to be a leader, you can buy a class for 229. But if you really want to be a leader of an organization, a global organization, you're going to work a lot. You're going to work a lot, and the people that work for you guess what? They depend on you. So the reason I have a hard time networking at these events is because as soon as I'm done speaking, I have to work because I have customers I have clients I've employee that supply chain. And on my level, this is something that was never told to me.

Once you assume a true leadership role. That's your job. Your job is to lead. Your job is not to sit back and push everybody else to do it. But to set an example on a lead so for me it's I'm doing my role.

**Joe Hage:** And if you would, for those who are joining us for the first time and may not have seen your content ever quickly, what did you cover last time about quality and what inspired you to be in the business you are in.

**Joseph Anderson:** So for me, it was my son, my son was born spent a lot of time in NICU unit has a rare genetic disorder. And during his time in a NIC unit, he was injured from some some issues with poor process and poor medical device and poor quality control. And all those things, you know, seem like they're trivial when they you know, you now he's 13, you know, so when you look back, you go, "Oh, it's no big deal." But those things matter, you know, had he not live which happens every day, and then NIC unit because of the processes have gone on better, but quality control, grab control, foreign federal function, all these things a lot of companies take lightly, I don't take



lightly form fit or function and new part numbers and part control are very, very, very important.

And you, you can't just say we're not going to because cost because as soon as you start getting in that gray work grey world, you lose control. So for me it was it's personal. And I'm I just don't I don't accept someone releasing a product to enter someone. Accidents happen. But when you're dropping planes out of the sky because of software and sensors, that's a bunch of BS when you're releasing food into the market that's contaminated because you don't have proper quality controls or processes. That's a bunch of BS. I mean, it goes on and on.

**Joe Hage:** In your case, as I recall, the packaging difference between the adult size two, and the NICU tube to stick down your infant's throat was not delineated clearly enough. So the wrong one was playing.

**Joseph Anderson:** Correct. They are controlling it by revision, not part number.

**Joe Hage:** And that did what?

**Joseph Anderson:** Caused them to have a permanent speech impediment.

**Joe Hage:** Could have been avoided.

**Joseph Anderson:** Yep, absolutely.

**Joe Hage:** So any final thoughts? That's my friend Joe. Thank you.

