How Bad Process Adherence Injured Us for Life
presented by Joseph Anderson, President, IpX
at the 10x Medical Device Conference – San Diego 2019

Joseph Anderson: This is my son. This is Josiah Wyatt Anderson; he was born in 2009.

Is ecosystem calibration really needed?

There's a hole in his left hand, and that's the first issue we'll discuss today. This was two days after his birth. He was born with a mitochondrial disorder. He was having some issues, but he really wasn't having anything major at this time.

As you can see, two days in, he's got a little thumbs up. He's saying, "Dad, I'm good." But on that hole: Let's talk about the process and the people side of the healthcare industry.

A traumatic birth
A very traumatic birth. He was in a NIC unit for six months. Being in a NIC unit for the first time is a traumatic experience for a parent, and a child. If you've gone through that, or if you know people that are going through that, be a support network because it's an experience.

So I walk in and I see my son, second day, and I'm being me. I'm trying to joke with some of the parents and help them out because, as of now, my son's condition is okay; it's manageable. They're saying maybe a week or two. But I notice, when I walk in, he's squirming a lot.

I mean, he's really squirming. And he's moving, and I make eye contact with him. And when I make eye contact, I realize he's in pain. I mean, my son's in pain!

One thing they do in NICU, especially for large boy they call "The Moose" – because normally NICU children are pretty tiny (Josiah was 10 pounds) – is tape the IV down pretty well. Then, they gauze that and tape it. So the child is practically in gloves, so they can't pull those off.

Well I realize he's squirming, and they keep putting more tape on because they don't want to pull the IV out.

I look at the nurse and I say, "Well, what's your process to really make sure he's okay? Because it looks like, to me, he's saying, "My hand hurts." "
He's not trying to pull something out. He's shaking his hand. So they unwind this tape, because I make them, because now I'm a dad, and I'm becoming a real dad, and I'm saying, "You're going to take that tape off his hand, or I'm going to do it."

Long story short, they burned a hole halfway through his hand. So the process mistake one, people mistake two.

They didn't have the right processes to ensure that the meds going in, internally, that are fine, but when they come out on the external, they burn through the skin. They weren't monitoring that; they had no processes.

Guess what, I'm a process guy. I always have been. At this time, I was working for Rolls Royce in the MOD department. So second day, people in the process failure.

Okay, now we're getting ready to get real.

Is ecosystem calibration really needed?
That's operational excellence, but I'm making it real. You have to know who you are – people, processes, tools, and data – because what you do could change the life of someone. It's important. We all know that.

So is it important, is it really needed? That's what you got to ask yourself. "Is operational excellence just a buzzword?"

No. It's not.

Here comes day three. So this is my son, day three.

What in the world has happened?

A lot can happen if you don't take it seriously. What happens if you don't have the right processes; if you don't have the right org structure; if you have a bureaucratic process where you make a mistake and the only thing you know how to do is panic?

Even in the healthcare field, we still have protocols that are non-existent. So this situation you're looking at right now, this is a little boy that has had the wrong feeding tube placed down his throat, and,

You want to know what happens when you put an adult feeding tube down a newborn's throat? It changes their life.

So now he's in a NIC unit. He can't eat; he's lost two pounds. He's struggling to breathe. And you also want to know what happens? You aspirate.

So what happens when you're aspirating and you need food? You have to get a feeding tube. You have to get a G-tube. And then, it goes down to a whole other line.

So this is day three, and this is, again, people, processes, and, now, guess what?

The wrong tube

We had a product manufacturer that didn't have interchangeability processes on their tubes. You want to know how they control their children and their adult tubes? By rev.

They had the same part number, two different revs. Guess what happens when you're a new nurse and you don't understand that Rev B is for adults, and it accidentally got into the NIC unit because the sorter on the tubes didn't catch it, because they saw it by part number.

So we've had failure across the supply chain within day three, on my son.

We didn't think...
He had a mitochondrial disorder, but that's all manageable. All of this, right here, is because we didn't take what we do seriously.

> We didn't think about the enterprise impact.
> We didn't think about the supply chain.
> We didn't think about the operators, the core nurse.
> We didn't think about the product stocker.
> We didn't think about the serviceability.

What can happen if you don't take this seriously?

This can happen. This is pretty bad, this is rough. Imagine seeing this on day three. You burn a hole in my son's hand, and now he's going to have to have a tube.

So, I don't want to beat up the med device world, or the healthcare, because – What can happen if you do take it seriously? You could save people's lives.

Out of NICU
So here's my son, out of the NIC unit. So he has a feeding tube, which we discussed. So now he's being kept alive by what?

A medical device.

Now you're going to see some funny things here. Again, as a product manufacturer and designer, although all this is great, it's kind of clunky.

You see this apparatus up here, that's where you put the food and that's also how you allow a child to burp, to exhale, so you have to let air in and out. But it gets kind of complicated.

Can you go imagine going to a restaurant with this thing? Can you imagine the looks I got?

"Do you have to do that here?"

Yeah! I'm feeding him! This is **exactly** what I have to do here. You happen to have a mouth. He can't use his.

But from a medical device perspective, what happens if we really think about the impact of the ecosystem?

What if we really think about the usability? What if we think about the processes?

What if we think about the parents that are going to have to feed their children every three hours? And for the hour in-between, you have to burp them.

How can we make that better? How can we make it easier on them? Because I tell you what, that little machine up there beeps constantly; it gets real annoying at 2 a.m. The first thing you want to do is turn it off, but you can't.

So how can we build better products?

Building better products
For us at IpX, the [Institute for Process Excellence](), for which I'm president, we challenge companies to think differently.
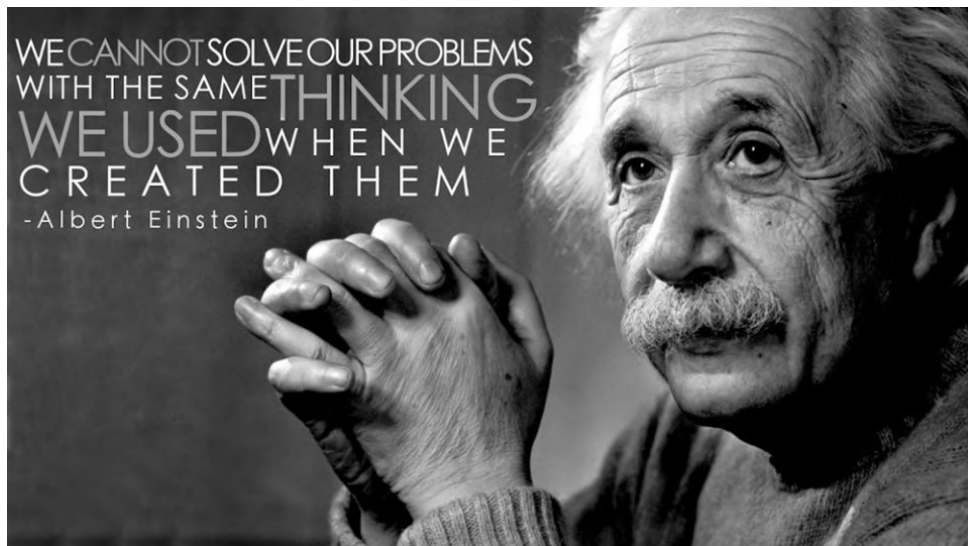

You have to think about your entire ecosystem. That's your users. That's the service field, the field group; that's your operators; that's the people in direct line of your customers, of your users, of those little children; and you also have to have very clear, concise, and valid processes and requirements.

"Clear, concise and balanced" has been IpX's trademark statement for over 30 years. You hear a lot of people say, "Clear, concise, and," or, "Clear, concise, and...." That's from us. It's very simple.

It's a very practical approach to understanding your data, to understanding your workforce requirements, to understanding your user requirements.

All of us right now, most large companies and small companies, you hear PLM, QMS; you hear big data analytics; you hear cloud utilization; you hear integrated & enabled products.
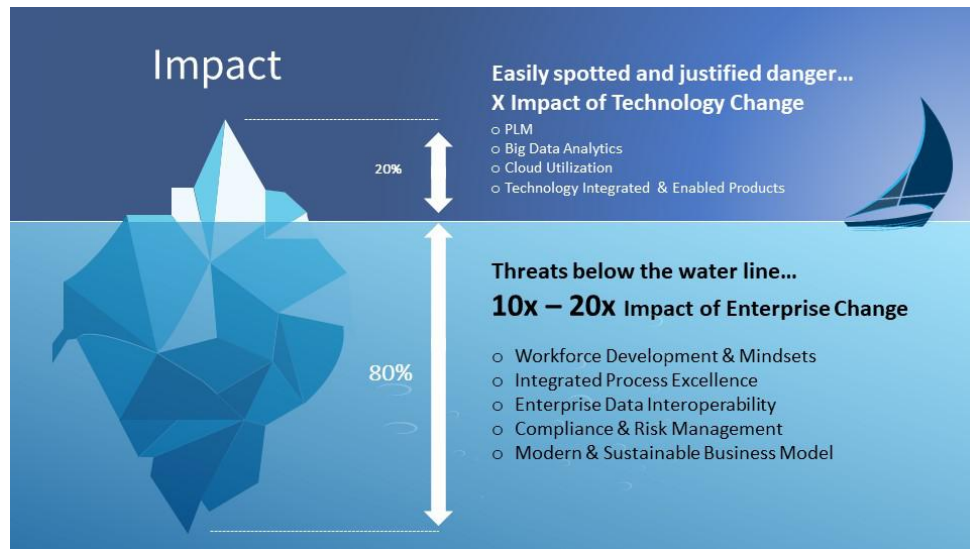
This is where we're at. This is where the margins are. This is the future right here. It means nothing if you're still operating on legacy processes.

It means nothing if you're still operating with legacy mindsets, right?

So what we challenge companies to do is look at the big picture. Look at the ROI for an ecosystem, if you combine them both.

You modernize your workforce, you actually have Integrated Process Excellence.

What's that mean? We're not so engineering-centric that we forget about the enterprise, the touch points.

This design, if we put it in the field with the same part number, what's the hazard risk on that? It's pretty, pretty high.

So if you don't have sound processes, if you don't have enterprise data interoperability, if you don't embrace compliance and risk management, you're putting your users at risk.

Then, you have to have a modern and sustainable business model. What's that mean?

That means you can't act like you did 30 years ago. You can't model yourself after a company that's been around for 40 and has really never invested in any of this.

If you have a company today that's not investing in training, not investing in workforce development, not looking at their processes, and updating those as fast as they are with big data analytics, you're in trouble.

Because that data is going to be garbage, absolutely going to be garbage. Your systems used to support that data, they're going to be inefficient; they're going to be ineffective; your users aren't going to be able to use them.

You got a QMS system that nobody could use and has bad data in it. What's that going to do for you? Where's your margins there?

So for us, it's about seeing the full impact. We call it the True North Calibration model.

True North Calibration

What makes IpX stand out from any other service company that talks about transformation?

We come in and we do a full ecosystem assessment.

The first thing is you need to know who you are. We need to know who you are. What's that mean? We look under the rugs, we look in the closets, we find out how you truly operate regardless of what your processes say.

How many of you today have processes that you don't follow?

You don't have to raise your hand if you don't want to, but we all know it. You have all these processes, but... There's that 'but.' "That's not **exactly** how we do it."

That's a pet peeve of mine. You can imagine why. "Well, we have this process, **but …**"

Well, we have to find out who you are. So we do a full assessment.

Some of those could be as simple as five days for a small company. For large global enterprises, a multi-site, it could be anywhere from 90 days plus.

But we know everything about you. We know your org structure, all your processes, all your systems, how you're using your data.

And we build out a true report. So we identify the strengths, the weaknesses, the opportunities. And what that does is, it gives you a roadmap for change.

We talked about change. You can't change if you don't know who you are.

It's like going to gym. How many of us have tried to get in shape on our own? How many of us have failed that?

It's because you don't really know what to do. You know you're out of shape. You know you need help. But, sometimes, arrogance gets in the way.

You want to get in shape, get an expert. Get someone that can evaluate who you are now, and give you a roadmap for change. And that's what we do.

Part of the calibration model identifies workforce development needs. We are the industry standard for changing configuration management for across the enterprise.

> *It's not just engineering change. It's not just engineering configuration management. You've got to involve marketing. You've got to involve manufacturing and serviceability.*

We have our **RISE** platform, which is **R**etention through **I**nclusion, **S**ervice and **E**quity.

It's a practical and functional approach to getting the right people involved at the right levels within your organization, regardless of race, regardless of gender, regardless of belief.

But we cover the spectrum. So, regulatory compliance, systems engineering, all of the workforce needs to make you a really sound, scalable company, we provide.

And then, enterprise roadmap for transformation. Most companies skip these four verticals.

Business engagement: How are you going to relate to your users? How are you going to market this internally? What are their needs?

Organizational change management: A lot of companies talk about it, but they don't do it. A lot of companies say they help you, but they don't know what they're talking about. Because if they don't know who you are, how are they going to help you change?

Process excellence: Time and time again we see it, companies will invest in a new shiny new thing.

I need a new QMS, I need a new PLM system. I need Cloud, I need big data, I need analytics. But at the end of the day, you also have to update your processes. You have to do that work. It's paramount for success.

And then we could talk about the shiny things.

We could talk about **digital transformation**. We hear that a lot. "We're a company. We want to digitally transform, but we want to skip all of this." This becomes sunk cost then.

If we don't invest in workforce development, process excellence, organizational change management, digital transformation, all those fancy initiatives that you're investing in becomes sunk cost.

You have to invest in all this for this to be successful.

You could do some in parallel, but at the end of the day, if you shoehorn in legacy processes to your systems, you get bad data. You get inefficient systems.

And then, continual improvement as performance monitoring.

You have to have phases. We talked about that. You can't do everything in big bang.

So for us, this is the transformation model of the future.

Ecosystem Excellence: Product Development Future

More essential than individual success in each discipline is the digital connection between the disciplines; the connected tissue, the digital thread

Otherwise its merely digitalizing the workgroups, speeding up the silos, but retaining the barriers between reinforcing the traditional organizational structures

Again, all these initiatives require a closed-loop change and configuration management process, and it's all integrated.

Big data is integrated to your design, from design all the way to decommission.

All those requirements, all those end-user requirements, all those regulatory requirements, environmental requirements, you must have those integrated to be successful.

CM2 – Closed-Loop Configuration Management
Now, to the Institute for Process Excellence and CM2.

True North - Empowering your Ecosystem

Core business processes and their enabling systems represent the major organizational activities and functions used to perform work and conduct business.

These instances of conflict or redundancy will have a negative impact on the operational efficiency of an enterprise.
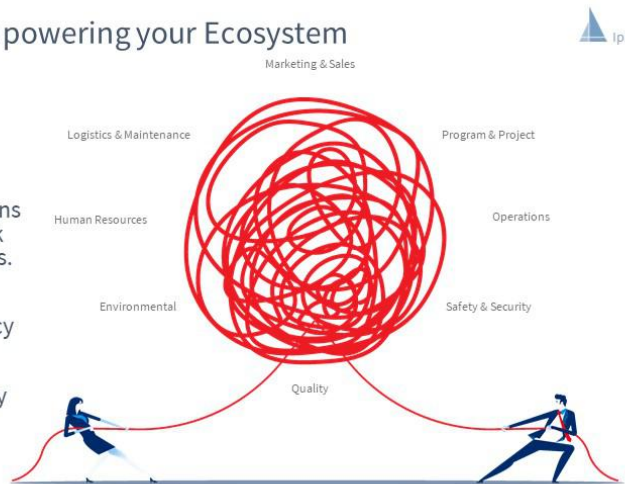
Empowering your ecosystem. Many companies operate like this.

A lot of companies will want to say, "Well, we're a siloed organization."

No, you're a big ball of a knot is what you are. You don't operate, you don't talk, you don't understand what the other one does, you don't respect the other competencies.

You need to, you need to untie this.

You need to think about that ecosystem, and that's what we do. That's what we help companies do from the organizational restructuring to actually integrating these processes.

For us, this is what excellence is. It's people, processes, and tools, and data.
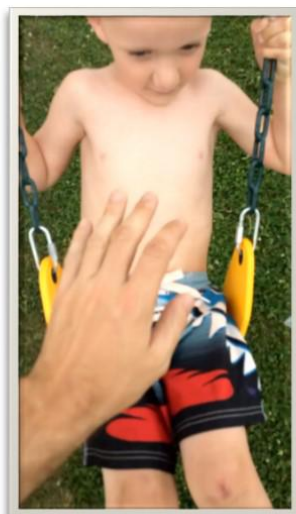

The people and processes for us, that's the True North Business model. That's a modern business model.

Then the tools and data, that's a robust digital platform.

And this is what it means.

[Plays video of Josiah laughing on a swing.]

It starts with you. All of you are here because you're in the medical device industry, or you support it in some way.

What you do is important. Don't get so lazy. Don't get so greedy that you forget about what you do.

If you could see this little boy now, he's got five scars here. He had to have a Nissen, a giant scar on his left hand. He has two little hearing aids. But he's a happiest boy in the world, because he's had some of the best healthcare providers.

He's had some of the best medical devices that have given him what he needs to thrive.

And as you see now, he's a 10-year-old boy. He's just like his dad.

He's laid back, he's funny. And he would tell you it's no big deal.

But I'm telling you what you do is a very big deal, and it all starts with you, and these little kids, and the adults you're trying to help.

So thank you very much.

[applause]

Questions from the Audience
Joe Hage: I've had chance to get to know Joe over the last year, and you are one of the most human people I know. So thanks.

Your presentation was touching. The last slide wasn't fair, and I understand your value prop better now than I have ever before.

My marketing mind working and thinking how to tell that story, I don't know if this imagery works for you. I thought of a house in complete disarray, or a hospital ward with debris everywhere, as "Before," and then "After" IpX is the pristine, because things are in place.

Joseph Anderson: Spot on.

Joe Hage: It makes so much sense to me now. Two things: One is, among all the people I know who do this and that, all of them are necessary, but somehow you sit on top of all of it.

I mean, well maybe not a head of marketing, I mean, I say that joking, but without a value prop you can articulate, you don't really have an enterprise.

But if you do have an enterprise, and you don't have all the processes, so that you can keep children out of NICUs....

Joseph Anderson: Eventually your house crumbles. And then we see that with large companies, even outside med device. If you think about the Sears, the stores our parents and grandparents probably thought would never close.

Joe Hage: I know you do medical devices, of course. You do other verticals as well. Are there any verticals you don't do?

Joseph Anderson: Nope, we cover them all.

Joe Hage: And how many employees do you have?

Joseph Anderson: We have just under 50 global employees, and we have a partner network.

Joe Hage: Okay, do we have questions in the room?

[Rob Kisfalusi](#)**:** Rob Kisfalusi, I work for Wondfo, specifically in charge for a brand called Preview Diagnostics. But in my former profession, working for a competitor of ours, I sold one product and I sold it very well because I got to the heart of the matter.

You touched on all of the key points that I utilized in my previous role as a sales rep. When you walk into a physician's office, and we heard some stories over the past couple days about people, they don't even look at you because you're the 40th person that's walked in the door that day, and they have their head down, and they just say, sign up for a luncheon, and they don't even acknowledge that you're a person, and that we are all charged with tasks that we do.

We get so focused on our tasks. We're all doing the job of three people, and as companies try to cut costs, and get rid of people that are focused, we have blinders on our focus every day.

But when I get involved with these organizations, and I start doing the training, and the in-service, and getting them to choose the right product that is usable by the patient.

The reason you're not getting a return, is because patients don't want to do this. I'm giving you something that patients do want to do. You're going to get a better return rate on it.

My message to them is always like a pep talk, because I'm in front of the entire company, everybody is in the company in this all-hands-on meeting, and I told him to stop worrying about their tasks that they have to do every day, and focus on what is our job.

Every single one of us that work in healthcare, every single one of us that make medical devices have two jobs: Save lives. Make the quality of life better.

We get so focused on our tasks, that we often lose sight of what our job actually is, and I just wanted to say thank you for bringing that out.

Joe Hage: In closing, just in the interest of time, if I could put on my marketing hat again for a moment. I'm concerned about what I perceive to be the relative lack of awareness of the importance of your role.

I shared, I've known you for a year. I understand it better now than I ever have. Who has a budget for Process Excellence?

I'm sure some do. But most is like, yeah, I know, we should do more, you know, do we really need a consultant for that?

How do you think we break through that obstacle to lift awareness of the importance of the disciplines in which you and your team are expert?

Joseph Anderson: Go to recalls.gov and look at all the recalls, across all industries.

> *More than 90% of recalls are from change or configuration management. It's a process issue. So every company in the world has money to have modern processes, and a workforce that's actually trained, they just don't do it.*

If you think about marketing and branding, the last thing you want, I would assume as a marketer, is for a product that you've been marketing and pushing to go in and fill, and then there would be a recall.

Joe Hage: They have the money to handle the recall but not the money to avoid the recall.

Joseph Anderson: Right. So all that money you spent on marketing and branding, all of the money you're doing on damage control and liability – if you would have invested it up front – you, as a marketer, would have had a product that's sound and guaranteed.

You never have to worry about recalls.

Unfortunately, we get called in, we're the triage group. We're M*A*S*H, we go in and like you said, we're here, we're going to fix you.

The companies we work with that are best in class, the Amazons, the Apples, they've been working with us for a long time. It's a competitive advantage. They want to release things that are solid, and that are good, and definitely don't hurt anybody, because they care about their brand.

If you care about your brand, now and 50 years from now, you invest in these type of things.

Joe Hage: You there in TV Land, you can find him at Joseph@IPXhq.com.

Joe Anderson everyone.