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Welcome to the ISPE podcast, shaping the future of pharma, where ISPE supports you on your journey, fueling innovation, sharing insights,

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00:00:09,840 --> 00:00:14,160

thought leadership, and empowering a global community to reimagine what's possible.

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00:00:14,160 --> 00:00:15,895

Hello,

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00:00:15,895 --> 00:00:20,295

and welcome to the ISPE podcast, shaping the future of pharma.

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00:00:20,295 --> 00:00:22,375

I'm Bob Chew, your host.

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00:00:22,375 --> 00:00:32,230

And today, we have another episode where we'll be sharing the latest insights and thought leadership on manufacturing, technology, supply chains,

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00:00:32,310 --> 00:00:36,310

and regulatory trends impacting the pharmaceutical industry.

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00:00:36,310 --> 00:00:44,125

You will hear directly from the innovators, experts, and professionals driving progress and shaping the future.

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00:00:44,125 --> 00:00:49,165

Thank you again for joining us, and now let's dive into this episode.

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00:00:49,165 --> 00:00:59,120

Our topic today is the upcoming twenty- twenty- six ISPE Annual Meeting and Expo, featuring the topics, tracks, and key

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00:00:59,120 --> 00:01:04,720

highlights of what you can expect from the educational content and agenda.

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00:01:04,720 --> 00:01:14,565

To share more about this topic, I would like to welcome the Chair of the Conference International Program Committee, Connie Langer, regulatory intelligence

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00:01:14,565 --> 00:01:23,845

lead, pharma quality, safety, and environmental operations at Pfizer Global Supply, and the committee executive chair, José

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00:01:23,845 --> 00:01:29,390

Caraballo, founder and principal, JCO Global Advisory LLC.

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00:01:29,390 --> 00:01:31,950

Welcome to the podcast.

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00:01:31,950 --> 00:01:39,950

The twenty- twenty- six annual meeting and Expo theme centers on ensuring that innovation ultimately reaches patients.

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00:01:39,950 --> 00:01:49,815

What does 'from science to systems to patients' mean to you personally, and why is this message especially important

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00:01:49,895 --> 00:01:51,575

for the industry right now?

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00:01:51,575 --> 00:01:52,455

Sure.

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00:01:52,455 --> 00:01:52,615

Thank

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00:01:52,615 --> 00:01:55,815

you, Bob, for the question, and happy to be here.

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00:01:55,815 --> 00:02:05,100

And that theme for the conference, really, for me, it embraces the full arc of innovation.

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00:02:05,100 --> 00:02:14,795

If you think about it, we discover things in the labs, we develop them in development, then we figure out the facilities or the systems

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00:02:14,795 --> 00:02:20,155
or the processes that are needed to execute that process and to produce medicines.

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00:02:20,155 --> 00:02:23,755
We'll still need to get them delivered to the patient.

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00:02:23,755 --> 00:02:32,330
So there's a supply component, involving all that is the complexity of new innovation, data, and digital.

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00:02:32,330 --> 00:02:40,475
So, the conference theme really covers the full arc of innovation from discovery to bedside.

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00:02:40,475 --> 00:02:47,035
And we wanted to make sure that any topic under that umbrella had a place in the conference.

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00:02:47,035 --> 00:02:49,995
So it's very inclusive and very comprehensive.

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00:02:49,995 --> 00:02:50,475
Well,

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00:02:50,475 --> 00:02:59,050
that sounds really fantastic, and it certainly is a well stated theme for the industry today.

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00:02:59,050 --> 00:03:07,930
And that allows us to go into this year's program, which is organized around five interconnected tracks.

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00:03:07,930 --> 00:03:14,365
First, from breakthrough to bedside, systems that deliver reliability.

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00:03:14,365 --> 00:03:19,325
Second, digital data and decision integrity.

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00:03:19,325 --> 00:03:25,220
Third, people, capability, and the workforce of delivery.

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00:03:25,220 --> 00:03:31,860

And fourth, Governance, risk, and readiness.

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00:03:31,860 --> 00:03:38,855

Now, how do these tracks work together to address industry's most pressing challenges?

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00:03:38,855 --> 00:03:39,655

Connie?

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00:03:39,655 --> 00:03:40,215

Well,

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00:03:40,215 --> 00:03:40,855

thank You, Bob.

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00:03:40,855 --> 00:03:45,735

I think that's really a good way to frame it, because they aren't five separate conversations.

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00:03:45,735 --> 00:03:51,170

They're really one connected story about how we get innovation all the way to the patient.

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00:03:51,170 --> 00:03:58,530

So starting with breakthrough to bedside, that's really discovery, the science, and the development side.

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00:03:58,530 --> 00:04:04,875

And how we take that discovery and get it to something that can actually be manufactured, scaled, and delivered.

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00:04:04,875 --> 00:04:11,115

Then moving to systems that deliver reliably, that picks up right where that breakthrough to bedside leaves off.

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00:04:11,115 --> 00:04:17,900

The manufacturing, supply chain, and technology backbone that has to perform every single day.

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00:04:17,900 --> 00:04:23,980

Moving to digital data and decision integrity is where AI and analytics come in.

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00:04:23,980 --> 00:04:28,335

How we build trusted data into better, faster decisions.

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00:04:28,335 --> 00:04:37,775

Then we have people capability and the workforce of delivery, and that's about making sure our workforce has the capability and the upskilling for this AI.

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00:04:37,775 --> 00:04:41,610

enabled world, and not just about the technology itself.

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00:04:41,610 --> 00:04:46,410

And finally, the governance and risk and readiness, that ties everything together.

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00:04:46,410 --> 00:04:49,930

That's the oversight that keeps the whole system in control.

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00:04:49,930 --> 00:04:58,145

So a breakthrough doesn't really mean much without a workforce that can execute it and the governance structure that keeps it inspection ready.

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00:04:58,145 --> 00:04:59,585

It

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00:04:59,585 --> 00:05:07,585

was last week, I think, the news broke about the pancreatic cancer drug, and that is amazing.

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00:05:07,585 --> 00:05:17,040

I don't know if either of you have any inside knowledge about how that was developed or any of the manufacturing challenges, if

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00:05:17,040 --> 00:05:17,600

any.

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00:05:17,600 --> 00:05:25,245

It looked like it was a tablet, in fact, which is pretty amazing in and of itself.

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00:05:25,245 --> 00:05:28,045

Any comments that you all wanna make on that?

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00:05:28,045 --> 00:05:28,285

I

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00:05:28,285 --> 00:05:38,205

don't have any specific insight, but obviously, I'm pleasantly surprised that discovery still happens and that is meeting different patient needs.

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00:05:38,205 --> 00:05:48,100

So, you hear about these discoveries and you almost want to applaud and smile and say thank you for

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00:05:48,100 --> 00:05:50,260

keep doing what we need to do.

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00:05:50,260 --> 00:05:58,985

I think the point is also that once it's discovered, there's still a lot to work on, right?

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00:05:58,985 --> 00:06:04,900

How to manufacture it in sufficient quantities that it reaches patients on time consistently.

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00:06:04,900 --> 00:06:13,220

But it's always pleasant to see these discoveries and, realizing that you're part of an industry that makes that happen.

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00:06:13,220 --> 00:06:15,620

Yeah.

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00:06:15,620 --> 00:06:15,700

And

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00:06:15,940 --> 00:06:17,140

I would just add to that.

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00:06:17,140 --> 00:06:26,975

That one really touches me personally because, we lost my mother-in-law last year to pancreatic cancer, and she was diagnosed late and only had a

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00:06:26,975 --> 00:06:27,935

short time to live.

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00:06:27,935 --> 00:06:32,575

So it's really exciting to see that they are making progress in this space.

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00:06:32,575 --> 00:06:33,535

Well,

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00:06:33,910 --> 00:06:41,830

it certainly is wonderful to know what this industry can produce in terms of miracle therapies.

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00:06:41,830 --> 00:06:51,035

Artificial intelligence, advanced analytics, and digital technologies are transforming pharmaceutical

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00:06:51,035 --> 00:06:51,835

operations.

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00:06:51,835 --> 00:07:01,430

How can organizations leverage these capabilities to improve decision making and performance while maintaining trust,

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00:07:01,830 --> 00:07:04,630

oversight, and data integrity?

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00:07:04,630 --> 00:07:05,110

So

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00:07:05,110 --> 00:07:11,510

I think this connects to several of the sessions across many of the different tracks that we've built into the agenda this year.

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00:07:11,510 --> 00:07:19,615

And, personally, at my company, we're investing heavily in training and in giving teams access to a lot of these new tools.

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00:07:19,615 --> 00:07:29,490

We are partnering with some universities to prepare general training that's mandatory, and it helps really level set us so that we're all understanding the language and the

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00:07:29,490 --> 00:07:31,810

risks and the capabilities of those tools.

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00:07:31,810 --> 00:07:40,130

And if you want to take that further, colleagues also can opt in to take graduate level classes and get a certificate in the management of AI.

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00:07:40,130 --> 00:07:47,325

And I think one of the challenges is the Pace of change is so fast in this area.

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00:07:47,325 --> 00:07:50,845

It's not enough just to roll out the technology.

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00:07:50,845 --> 00:07:55,020

You really have to build in that literacy and the trust that goes along with it.

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00:07:55,020 --> 00:07:55,340

Thank

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00:07:55,340 --> 00:07:55,660

you.

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00:07:55,660 --> 00:07:58,060

Yeah, Connie, I totally agree.

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00:07:58,060 --> 00:08:01,180

And AI is pervasive, right?

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00:08:01,180 --> 00:08:03,020

And we still haven't seen all of it.

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00:08:03,020 --> 00:08:06,140

More ideas will come in as it goes.

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00:08:06,140 --> 00:08:14,935

So I see it as a tool that, for example, will help us be more efficient in things that are standardized.

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00:08:14,935 --> 00:08:15,095

Right?

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00:08:15,095 --> 00:08:22,055

I was reading the other day the approach of AI that it's taken to create code.

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00:08:22,055 --> 00:08:22,375

Right?

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00:08:22,375 --> 00:08:31,620

So who would imagine that coding could get benefit from AI and be more efficient about it?

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00:08:31,620 --> 00:08:38,115

So that's a standardized task that AI probably can do faster and better.

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00:08:38,115 --> 00:08:47,795

But then there's the other parts of the judgment calls, the different decisions, the understanding that really requires still a human to make that call,

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00:08:48,035 --> 00:08:49,955

because they're accountable for many things.

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00:08:49,955 --> 00:08:59,530

So I see it as a tool to gain efficiency, and then we'll have more time to tackle the harder questions.

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00:08:59,530 --> 00:08:59,690

Right?

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00:08:59,690 --> 00:09:01,370

The better the size.

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00:09:01,370 --> 00:09:02,890

So it's a shift.

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00:09:02,890 --> 00:09:10,485

I also agree that if our workforce is not upskilled, sufficiently, that technology will find a wall.

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00:09:10,485 --> 00:09:15,605

They will not be able to be adapted or adopted, in the day to day.

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00:09:15,605 --> 00:09:20,890

So those are important points, as well, upskilling our workforce.

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00:09:20,890 --> 00:09:21,370

Both

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00:09:21,370 --> 00:09:28,730

of you emphasize that success depends not only on technology and systems but also on people.

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00:09:28,730 --> 00:09:38,475

What skills, leadership capabilities, and workforce strategies do you believe will be most critical for the next generation of

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00:09:38,475 --> 00:09:40,155

pharmaceutical professionals?

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00:09:40,155 --> 00:09:41,195

Yes.

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00:09:41,195 --> 00:09:41,755

I

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00:09:41,755 --> 00:09:45,275

always start with, the idea of being curious.

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00:09:45,275 --> 00:09:47,000

Be curious, right?

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00:09:47,000 --> 00:09:49,240

That opens the door for so many things.

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00:09:49,240 --> 00:09:58,375

If you're not curious or you're living in your bubble thinking this would not impact me, you're probably betting on the wrong bet.

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00:09:58,375 --> 00:10:04,855

So being curious is a large priority for our quality and pharmaceutical professionals.

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00:10:04,855 --> 00:10:10,615

Then the second step will be a little bit of courage to learn something new, right?

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00:10:10,615 --> 00:10:18,000

Open the door, enroll in some class, take advantage of the company's trainings.

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00:10:18,000 --> 00:10:25,440

They will get you closer to this technology, and you will be able to manage your day to day and your tasks.

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00:10:25,440 --> 00:10:28,735

With the help of the technology, right?

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00:10:28,735 --> 00:10:31,215

Not against the technology or afraid of it.

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00:10:31,215 --> 00:10:34,895

So, courage to learn something new is always good.

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00:10:34,895 --> 00:10:41,460

And, for me, my journey was a little bit of playing with it for some time, getting used to it.

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00:10:41,460 --> 00:10:42,420

What are their capabilities?

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What I can trust It and what I cannot, right?

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00:10:46,340 --> 00:10:56,285

So that understanding of what it can do for you, it can only come from practicing with it, embracing it, touching it, asking the questions.

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00:10:56,285 --> 00:10:58,605

So I think those are very good strategies.

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00:10:58,605 --> 00:11:08,480

In the future, each professional should be, some way, data savvy, right, to be able to navigate this new environment of

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00:11:08,480 --> 00:11:11,840
everything being digital and or digitalized.

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00:11:11,840 --> 00:11:12,880
Connie,

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00:11:12,880 --> 00:11:14,960
you have any additional thoughts on that?

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00:11:14,960 --> 00:11:15,520
I

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00:11:15,520 --> 00:11:25,205
agree with what Jose is saying, and I think one of the most valuable things that we can do for the next generation is to help them not only

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00:11:25,285 --> 00:11:30,325
build their deep domain expertise, but to pair that along with all these new digital tools.

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00:11:30,325 --> 00:11:40,280
I think AI can give you an answer really fast, but it can't tell you whether or not the answer is right or discern if there's any Gaps or

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00:11:40,280 --> 00:11:41,160
anything missing.

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00:11:41,160 --> 00:11:48,725
So, that accountability still needs to rest with the people who understand the science and the process and the regulatory context.

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00:11:48,725 --> 00:11:58,725
So, I guess my hope for the workforce of the future is that we develop that generation of professionals that can have that combination, that technical fluency

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00:11:58,725 --> 00:12:00,940
plus the strong critical thinking.

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00:12:00,940 --> 00:12:04,460
And I think that's really what's going to set people apart.

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00:12:04,460 --> 00:12:07,260
Well,

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00:12:07,340 --> 00:12:09,500
that leads us to governance.

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00:12:09,500 --> 00:12:17,575
And governance, risk management, and inspection readiness are recurring themes throughout the program that's coming up.

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00:12:17,575 --> 00:12:27,015
How are leading organizations moving from a reactive compliance mindset to a more proactive,

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00:12:27,620 --> 00:12:32,820
risk- based approach that supports both quality and business continuity?

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00:12:32,820 --> 00:12:34,100
I

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00:12:34,100 --> 00:12:42,755
think that everyone- industry, academia, and regulators are all moving in the direction of that more proactive mindset.

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00:12:42,755 --> 00:12:48,595
One example that I think of is this FDA quality management maturity pilot.

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00:12:48,595 --> 00:12:55,580
QMM pilot that's going on right now, the purpose of that isn't just another layer of oversight.

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00:12:55,580 --> 00:13:05,260
It's meant to foster this real quality culture, and to recognize organizations that are already operating at that mature level, and even help

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00:13:05,260 --> 00:13:07,260
identify where there's some more room to grow.

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00:13:07,260 --> 00:13:15,755

So I think, ultimately, we're all working toward the same goal of protecting this reliable drug supply for the patient.

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00:13:15,755 --> 00:13:25,010

And then another thing that I can think of, at my company we're really engaged in developing and using the tools that are available to us through ICH quality

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00:13:25,010 --> 00:13:25,810

guidelines.

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00:13:25,810 --> 00:13:35,250

So we have pharmaceutical development and quality by design, quality risk management, an effective PQS, and leveraging some of the

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00:13:35,250 --> 00:13:38,290

lifecycle management strategies that are now available.

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00:13:38,290 --> 00:13:46,485

So I know those aren't new concepts, but I think used together, they can give us a real framework for building quality in.

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00:13:46,485 --> 00:13:47,445

From the start.

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00:13:47,445 --> 00:13:48,005

Yeah.

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00:13:48,005 --> 00:13:48,245

I

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00:13:48,245 --> 00:13:50,245

would like to add also on governance.

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00:13:50,245 --> 00:13:54,250

Some people react to governance as a bad thing.

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00:13:54,250 --> 00:13:58,010

But when you have to manage complexity, which is what's happening.

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00:13:58,010 --> 00:13:58,250

Right?

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00:13:58,250 --> 00:14:04,650

All these new technologies and data, tools, add some complexity to the organization.

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00:14:04,650 --> 00:14:11,705

Then you need some kind of rules, some kind of governance to make sure that what's critical for you is well taken care of.

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00:14:11,705 --> 00:14:21,140

I compare this with early companies where they may have one product and they may have one

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00:14:21,140 --> 00:14:24,740

customer, and the operations manager can manage everything.

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00:14:24,740 --> 00:14:32,260

But then as you keep adding products and jurisdictions and customers, the complexity gets to a point that you need help.

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00:14:32,260 --> 00:14:39,835

So I think governance is a word and a concept that is being embraced now more than ever because of the complexity.

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00:14:39,835 --> 00:14:43,195

And then, one Comment on the readiness.

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00:14:43,195 --> 00:14:51,580

Obviously, everyone has plans, we get ready and we get upskilled, but readiness also includes being able to demonstrate that you can execute, right?

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00:14:51,580 --> 00:15:00,540

So there's something about readiness that talks to me about practicing what you learn, making sure that you challenge what you think you know.

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00:15:00,540 --> 00:15:07,705

That will help you be ready for inspections or other difficult tasks.

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00:15:07,705 --> 00:15:08,985

Artificial

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00:15:08,985 --> 00:15:16,080
intelligence is really highly complex, sophisticated statistics at work.

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00:15:16,080 --> 00:15:26,000
Do you know of organizations that are using AI to actually drive a more

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00:15:26,080 --> 00:15:35,455
quantitative approach to quality risk management, as opposed to what has typically been more of a

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00:15:35,455 --> 00:15:36,575
qualitative?

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00:15:36,575 --> 00:15:38,975
You get people in a room and they...

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00:15:38,975 --> 00:15:41,135
Yeah, it's a high risk.

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00:15:41,135 --> 00:15:43,010
It's a five.

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00:15:43,010 --> 00:15:45,090
It's not a four.

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00:15:45,090 --> 00:15:45,810
All right?

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00:15:45,810 --> 00:15:55,730
And they're using their judgment, which is valid, but there's really no quantitative

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00:15:55,730 --> 00:15:56,690
basis for that.

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00:15:56,690 --> 00:16:05,315
Are you collecting information at some points and feeding it into AI to identify

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00:16:06,275 --> 00:16:11,955
cases where the risks might have been hidden, and there's additional risks to manage?

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00:16:11,955 --> 00:16:17,720
Or where we thought this was a risk, but it's pretty well controlled.

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00:16:17,720 --> 00:16:19,000
We're good.

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00:16:19,000 --> 00:16:19,320
Yeah.

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00:16:19,320 --> 00:16:19,880
That's

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00:16:19,880 --> 00:16:21,240
very interesting, for me.

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00:16:21,240 --> 00:16:26,280
It's a very active area of investigation for many of us.

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00:16:26,280 --> 00:16:34,915
How I look at it is that the model, what it can do, I think we can think about it and assign it properly.

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00:16:34,915 --> 00:16:38,835
But what data you use to train the model, I think is so important.

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00:16:38,835 --> 00:16:48,460
So, if you train a model to help you categorize risks and you only train them on the good stuff and never on the failures or what

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00:16:48,460 --> 00:16:52,540
lessons were learned, then I think you're missing the point.

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00:16:52,540 --> 00:17:00,145
Also, operations is so dynamic that for me it would be very important to keep that model updated, right?

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00:17:00,145 --> 00:17:03,905
So that it doesn't assume that only three things can happen.

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00:17:03,905 --> 00:17:13,370

The fourth thing also can happen is just that we haven't seen it, so don't assume that it's impossible to happen.

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00:17:13,370 --> 00:17:23,015

So to the extent that the model is well trained with good data, good and bad, and that somehow it can

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00:17:23,015 --> 00:17:26,935

detect when the limits have been reached.

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00:17:26,935 --> 00:17:27,095

Right?

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00:17:27,095 --> 00:17:29,895

You're asking me a question that I cannot answer with my data.

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00:17:29,895 --> 00:17:31,815

I think it will be more useful.

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00:17:31,815 --> 00:17:38,590

At the end, as you say, Bob, there's a judgment call from an expert says thumbs up, thumbs down.

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00:17:38,590 --> 00:17:38,830

Right?

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00:17:38,830 --> 00:17:40,590

It's a four or a five.

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00:17:40,590 --> 00:17:42,270

I think that's also valuable.

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00:17:42,270 --> 00:17:51,585

But what AI also brings is the capability of data analytics, identifying signals that then an expert can investigate further,

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00:17:52,465 --> 00:17:56,385

or maybe even bringing up relationships.

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00:17:56,385 --> 00:18:06,280

Between data that a human never saw because the amount of data is so immense that you will never have a chance to answer that particular question.

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00:18:06,280 --> 00:18:11,160

So those are also good uses for AI and risk management.

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00:18:11,160 --> 00:18:11,720

Well,

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00:18:11,720 --> 00:18:20,255

one of the strengths of the twenty twenty- six ISPE Annual Meeting and Expo is bringing together professionals from science, engineering,

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00:18:21,295 --> 00:18:27,215

quality, operations, regulatory affairs, technology, you name it.

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00:18:27,215 --> 00:18:36,800

Why is this cross- functional collaboration more important than ever, and what unique perspectives can attendees expect to

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00:18:36,800 --> 00:18:40,720

gain from these interactions with their fellow attendees?

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00:18:40,720 --> 00:18:41,280

Yeah,

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00:18:41,280 --> 00:18:48,025

no, it's a great question because I myself benefit from these interactions.

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00:18:48,025 --> 00:18:48,265

Right?

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00:18:48,265 --> 00:18:57,625

If you go into a room full of different perspectives, experts in design, suppliers, with innovative ideas and

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00:18:57,625 --> 00:19:07,460

products, maybe academics that are studying some area in the science, you will never know about these unless you start connecting, asking questions,

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00:19:07,460 --> 00:19:09,460
and understanding the other perspective.

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00:19:09,460 --> 00:19:12,660
So regulators also are in the room.

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00:19:12,660 --> 00:19:18,885
So it's a great convention of minds to figure out and solve problems.

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00:19:18,885 --> 00:19:28,885
And each one has a different perspective, and innovation will happen as soon as you connect the dots, right, and say, wait a minute, I didn't understand the problem from that perspective.

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00:19:28,885 --> 00:19:30,165
That's interesting, right?

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00:19:30,165 --> 00:19:31,685
And you follow-up after the conference.

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00:19:31,685 --> 00:19:41,670
So it's a great place to engage, to build relationships, but also to understand and

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00:19:41,670 --> 00:19:42,550
solve problems.

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00:19:42,550 --> 00:19:44,470
So it's excellent in that sense.

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00:19:44,470 --> 00:19:48,945
I invite everyone to visit the suppliers, the exhibitions.

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00:19:48,945 --> 00:19:55,745
Each one of those exhibitions has a solution for a problem out there.

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00:19:55,745 --> 00:19:58,720
So it's just a matter of making the connection.

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00:19:58,720 --> 00:20:00,160
I've

241
00:20:00,160 --> 00:20:04,320
been going to the ISPE annual meeting for about thirty five years.

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00:20:04,320 --> 00:20:05,760
I hate to admit that.

243
00:20:05,760 --> 00:20:15,535
And I've always Come away with a number of new ideas, thoughts about how we could do

244
00:20:15,535 --> 00:20:16,655
things differently.

245
00:20:16,655 --> 00:20:26,290
For someone considering attending this annual meeting, what conversations, what emerging trends, what breakthrough

246
00:20:26,290 --> 00:20:28,690
ideas are you most excited about?

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00:20:28,690 --> 00:20:32,130
You're familiar with the speakers and their topics.

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00:20:32,130 --> 00:20:32,530
Right?

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00:20:32,530 --> 00:20:37,410
And what do you hope participants will take back to their organizations after this event?

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00:20:37,410 --> 00:20:38,535
Connie?

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00:20:38,535 --> 00:20:38,855
Yeah.

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00:20:38,855 --> 00:20:39,015
I

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00:20:39,015 --> 00:20:44,055

think one of the things that I'm really excited about this year is how broad the session topics are.

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00:20:44,055 --> 00:20:46,695

I think there's really something for everyone to take home.

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00:20:46,695 --> 00:20:52,775

But if you want to know what I'm personally most looking forward to, it's actually hearing from the patients.

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00:20:52,775 --> 00:20:59,100

Every time that I go and I hear these patient testimonials, it really touches me deeply.

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00:20:59,100 --> 00:21:03,820

It's an instant reminder of why we're doing all this work.

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00:21:03,820 --> 00:21:13,795

And, no matter how many years I've been doing this work, that connection renews my energy, and it, you know, helps me to keep pushing hard to bring these new medicines to

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00:21:13,795 --> 00:21:15,155

people who need them.

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00:21:15,155 --> 00:21:23,710

So my hope for the participants is that they leave not just with some new knowledge, but with that same sense of renewal.

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00:21:23,710 --> 00:21:32,830

Whether it's something that they hear from a patient or something that they see, like some incredible work happening across the industry, that it renews their sense of purpose.

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00:21:32,830 --> 00:21:33,950

You

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00:21:33,950 --> 00:21:43,215

know, a few, a few years ago I heard a story from the stage, and it was told by a schoolteacher mother

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00:21:43,455 --> 00:21:45,215

about her son.

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00:21:45,215 --> 00:21:49,855

And the son had a huge brain cancer tumor.

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00:21:49,855 --> 00:21:57,890

And it was actually Pfizer, and I think it might have been somebody from your site, Mike Arnold maybe,

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00:21:59,490 --> 00:22:09,255

who was actively involved in getting the compassionate use authorization from FDA to take what was pretty Take

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00:22:09,255 --> 00:22:15,255

an adult experimental therapy and apply it to this kid who was seven or eight at the time.

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00:22:15,255 --> 00:22:21,730

And the mother describes how it really worked.

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00:22:21,730 --> 00:22:28,130

And then the kid walked up on stage, and there wasn't a dry eye in the house.

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00:22:28,130 --> 00:22:30,465

I don't know.

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00:22:30,465 --> 00:22:34,145

Were you there when that was talked about?

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00:22:34,145 --> 00:22:34,385

I

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00:22:34,385 --> 00:22:42,705

don't remember that exact story, but there's just so many of those things that you see at conferences.

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00:22:42,705 --> 00:22:43,825

Amazing stories.

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00:22:43,825 --> 00:22:51,600

But even just when your child has a fever and you give them Tylenol and they're feeling better right away, that's amazing too.

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00:22:51,600 --> 00:22:55,840

But the story you just shared, Bob, is really good.

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00:22:55,840 --> 00:22:56,560

First

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00:22:56,560 --> 00:23:00,985

of all, what to take back home is the patient, right?

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00:23:00,985 --> 00:23:02,105

Patient centric.

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00:23:02,105 --> 00:23:03,385

That's why we do it.

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00:23:03,385 --> 00:23:06,905

At the end, if you think about it, there's a patient waiting.

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00:23:06,905 --> 00:23:08,345

for this miracle to happen.

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00:23:08,345 --> 00:23:16,140

So, hopefully, the conference gives you that sense of purpose that the patient should be always in the room.

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00:23:16,140 --> 00:23:20,620

I think the other message could be, that AI is pervasive.

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00:23:20,620 --> 00:23:27,900

Even if we don't have a track on AI, you will see presentations on AI because they're applying it in different solutions.

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00:23:27,900 --> 00:23:36,345

Some of the most interesting presentations for me is when they try to apply technology and the lessons learned.

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00:23:36,345 --> 00:23:43,800

So that could be a good opportunity to find who is applying the technology so that you then can ask questions.

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00:23:43,800 --> 00:23:45,240
Was it good or was it bad?

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00:23:45,240 --> 00:23:49,800
And, my final message would be maybe to embrace innovation.

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00:23:49,800 --> 00:23:51,240
Learn all you can, right?

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00:23:51,240 --> 00:23:52,360
Bring it back home.

293
00:23:52,360 --> 00:24:01,905
Try to use it because these are really tools and ideas that can help you
do your job better and

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00:24:01,905 --> 00:24:02,625
faster.

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00:24:02,625 --> 00:24:04,705
Summary,

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00:24:04,980 --> 00:24:09,540
let me go back over those five interconnected tracks.

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00:24:09,540 --> 00:24:19,345
The first, breakthrough to bedside, we talked about the discovery
process, and then, systems that deliver reliability, how

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00:24:19,345 --> 00:24:28,865
we're gonna actually produce the drug, digital data, and decision
integrity about how we keep track of all the information,

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00:24:29,665 --> 00:24:39,550
people, capability, and the workforce of delivery, how we need to train
our workforce, both young, and upskill those

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00:24:39,550 --> 00:24:43,550
of us who are old dogs that have difficulty with new tricks.

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00:24:43,550 --> 00:24:53,485

And then, governance, risk, and readiness, and how all these new technologies really have to be put together

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00:24:53,485 --> 00:25:03,140

in a responsible way with appropriate oversight, and human intervention, review,

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00:25:03,220 --> 00:25:04,580

and approval.

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00:25:04,580 --> 00:25:14,455

So in summary, I'd like to thank Connie and Jose for their time with us today and for sharing more about what we can look forward to at the twenty- twenty-

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00:25:14,455 --> 00:25:16,935

six ISPE Annual Meeting and Expo.

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00:25:16,935 --> 00:25:23,175

It takes place, October 18 through the twenty first in Washington, DC.

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00:25:23,175 --> 00:25:25,400

Be sure to register.

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00:25:25,400 --> 00:25:32,040

Be sure to get your hotel room before they all sell out, and we'll look forward to seeing you there.

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00:25:32,040 --> 00:25:40,675

That brings us to the end of another episode of the ISPE podcast, shaping the future of pharma.

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00:25:40,675 --> 00:25:50,435

Please be sure to subscribe so that you don't miss future conversations with the innovators, the experts, and the changemakers driving our industry forward.

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00:25:50,435 --> 00:26:00,318

On behalf of all of us at ISPE, thank you for listening, and we'll see you next time as we continue to explore the ideas, trends,

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00:26:00,318 --> 00:26:03,358

and people shaping the future of pharma.

