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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, thought

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

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You

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shared a use case called Plai, p l a I, at the ISPE conference.

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And I understand this tool is used at scale, at Sanofi.

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Can you share how the tool was taken from pilot to at scale?

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The

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initial pilot focused on one specific use case, where we were, trying to automate deviations and complaint trending while providing root cause

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suggestions.

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Traditionally, it's a very manual, process where the quality team spend hours looking for patterns across different types of events, and they spend time brainstorming what the potential

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root causes could be.

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But within a few months, we could see concrete results with play with faster identification of trending issues, and AI could generate

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potential root cause hypotheses that allowed the investigators to to explore further.

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And what it also enabled us to, bring this tool to scale was our, governance frame framework, which we call

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RAISE.

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So RAISE stands for responsible AI of at Sanofi Enterprise, and it really provides, the guardrails for how we can, develop, validate,

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deploy AI tools across our organization.

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Please

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tell me about Open Biopharma Research and Training Institute.

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How did it get started, and what is its scope of services today?

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We

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like to do that bridge between, you academia and industries since there's often a gap between them.

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We wanna make sure that, you know, there are folks who are coming out of these academic institutions who are right, ready to work, ready to and and not just ready to work, like, ready to work at a at

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00:01:56,580 --> 00:01:57,380

a certain level.

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One of the goals of our of our nonprofit, you know, because Open Biopharma Research and Training Institute is a nonprofit training institute.

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And we also have, you know, we have a we have a core lab services.

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We have our, you know, our polypractical production space, and we have our our training services that we we offer, and we also host as a venue as well.

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00:02:14,975 --> 00:02:23,280

So we have often a host leading training services and training come training from different organizations who are have industry ready training.

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And though we often bring do we often work deals with them to have a a channel for all of our, apprentices and interns to be able to access that training.

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So this way, then when they come out, third, that's how we say when they're industry ready.

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00:02:34,835 --> 00:02:42,355

They're they're able to do all of these other things and actually try out these different elements, work on the core lab services, and really get a real well rounded level of experience to understand

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where they best fit.

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Because oftentimes, it can be difficult when you're in college trying to figure out exactly what you wanna do.

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00:02:48,035 --> 00:02:51,930

And then that never really matches with whatever industry is about to do because it always changes.

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00:02:51,930 --> 00:02:55,370

You know, two years, five years, that's difficult for these things to work.

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So that's Open BioPharma in a nutshell.

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And, yeah, we're we're happy to be here, and it's a great it's a great organization.

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How

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do you see the integration of advanced AI techniques transforming drug development, regulatory submissions, and also manufacturing oversight?

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I

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00:03:12,355 --> 00:03:22,060

think there are many different ways that AI could be used, You know, some of which would be actively regulated by FDA, some of it which, you know, is within your own, you know, industry's own

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00:03:22,060 --> 00:03:24,940

control systems to be able to moderate and regulate.

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Given the right boundary conditions and ask the right questions, the AI can analyze the data far quicker than a human being can.

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00:03:32,855 --> 00:03:33,815

You know?

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00:03:33,815 --> 00:03:36,615

But ultimately, you know, a human being has to check it.

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00:03:36,615 --> 00:03:45,940

A human being has to make sure the boundary conditions are set correctly, that the parameters are set correctly, and that, you know, whatever comes out makes sense within the context of what you're

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00:03:45,940 --> 00:03:46,500
using.

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00:03:46,500 --> 00:03:49,380
So I think there there's a there are great opportunities.

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00:03:49,380 --> 00:03:53,300
With opportunities, there are risks, and you have to control for those risks.

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But I don't think that we should shy away from those opportunities in the same way that we haven't shied away from adding or using newer technologies

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and, for example, manufacturing or molecule selection that we have in the past.

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00:04:07,415 --> 00:04:09,655
We're to use process models.

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00:04:09,655 --> 00:04:12,695
We're used computational modeling in order to do molecule selection.

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These I think of this as, like, the next logical step.

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I've

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been with, ISPE for maybe thirty years now, or even more, and it's amazing how initiatives and groups

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such as yours can really drive and influence the direction of regulatory, acceptance of new technologies.

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But anyways, what do you see as the biggest challenges and the biggest opportunities facing pharmaceutical manufacturing in this

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age of AI powered technologies?

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On

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the challenge side, I think the biggest hurdle is trust.

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00:04:51,570 --> 00:04:54,130

Patient safety is nonnegotiable in our industry.

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So when we talk about bringing AI into GXP environments, there's natural skepticism there.

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But we think about how do we validate these systems, how do we explain what the algorithm is doing.

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When a regulator asks, You know, we need to be able to explain, and how do we ensure that AI doesn't drift over time?

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That's one of the biggest challenges on the challenge side.

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There's also the cultural piece.

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We've built our quality systems on deterministic rule based thinking for decades, and now AI is introducing probabilistic decision making that can feel

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uncomfortable to some some of the users.

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Predictive quality is definitely, something that's part of the future.

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Instead of reacting to deviations after they happen, What if we could actually see them coming?

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AI lets us analyze vast amounts of process data, and it allows us to spot patterns that humans simply can't see as easily.

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So if we can use AI to streamline processes and make smarter decisions faster, that means getting, like, receiving medicines to patients sooner,

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and that's a real win.

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Those

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00:05:59,285 --> 00:06:01,125

opportunities are really exciting.

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I guess that with with any new technology, there's there's always the question relation to guardrails that protect the patient without impeding that innovation.

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00:06:09,680 --> 00:06:12,160

Samantha, maybe you touched on a little bit there.

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What do you think are the opportunities to update regulatory frameworks to keep pace with the rapid AI innovations that we're seeing, in the pharmaceutical sector?

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We

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always have to look for opportunities for convergence.

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We have to have conversations with our fellow regulators across the globe to make sure that there's, you know, as much of a singular voice as possible.

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You know, there are the points, you know, points to consider or just general guidelines that we published with EMA.

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We have to look across not just within, you know, within the scope of what the FDA regulates.

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You know?

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We we have to use our regulatory partners to make sure that we are giving the the industry a consistent message on how to integrate, this new

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00:06:56,415 --> 00:06:57,135

technology.

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00:06:57,135 --> 00:06:57,535

Tell

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00:06:57,535 --> 00:07:03,695

me how your use of AI, is improving how you are training your students.

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So

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when it comes to AI, we started working with it very kind of oh, and not really early on per se because, you know, AI has been around since nineteen forties, technically speaking.

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Right?

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00:07:15,180 --> 00:07:21,395

But what we're talking about when we use AI is, generally speaking, we're using, we started using generative AI.

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00:07:21,395 --> 00:07:30,995

So what that means in our case is that in 2000 in 2023, all of our we started with our, apprentices, and we went, okay.

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00:07:30,995 --> 00:07:36,810

How do we make sure to give them the readiness they need to work in the in the in the future for the future workforce.

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Right?

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00:07:37,290 --> 00:07:40,570

And so what we did was we started identifying.

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We saw there was a there was a paper from the federal from the Fed that explained what the strong suits and weeks and weaknesses of are these are these tools.

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And we said, okay.

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Well, it seems we're weak.

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00:07:50,335 --> 00:07:52,095

Research is a bit of a weak point.

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Why?

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And we knew that research is a very critical element, these students are learning, and these apprentices are learning how to really conduct appropriate research.

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And so we wanted to really test that.

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So we started doing what's called a parallel project where everything that they would do, they would have the they would train what, what we'll call an AI assistant to do at the same time.

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And so they would iterate this forth back and forth, and they've been doing this for years at point.

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So every cohort that comes on does the same thing.

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00:08:17,775 --> 00:08:22,335

And so everything that they're doing, when they do it, they do it in parallel with the actual AI assistant.

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00:08:22,335 --> 00:08:23,615

They create the assistant.

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They build the elements in there.

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00:08:24,735 --> 00:08:32,920

And so that this way, what they're doing creates a little bit of that that tacit record kind of gets a little bit more under better understood.

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Because it also means that when, inevitably, the apprentice or intern leaves because we are an institute that takes in apprentices and interns on in six month, year, two

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00:08:42,915 --> 00:08:44,355

year, they differ.

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00:08:44,355 --> 00:08:46,995

And so a project, you know, might suffer from a gap.

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And so this allows the next person to kind of pop up

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00:08:49,635 --> 00:08:50,275

and go, oh, look.

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00:08:50,275 --> 00:08:50,435
Here's

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00:08:50,435 --> 00:08:50,995
the assistant.

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00:08:50,995 --> 00:08:52,595
Let's let's help them kinda carry along.

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00:08:52,595 --> 00:08:54,195
It ends up kind of carrying these gaps forward.

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00:08:54,195 --> 00:09:00,280
And so it ended up being a really useful tool to kind of carry along this tribal knowledge that normally kind of can get a little bit lost along the way.

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00:09:00,280 --> 00:09:08,360
It also meant that in this way, they were also testing their own critical thinking skills because that was one of the elements that they found out early on is that it was bad.

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00:09:08,360 --> 00:09:18,095
Early generative AI in in in 2023 was, you know, maybe at best, had to hit about a 10% ratio in terms of the

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success rate to actually get the link and the name and all the rest of materials right.

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Now maybe it's about 40%.

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It's getting better.

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00:09:25,020 --> 00:09:26,220
And this is off the shelf tool.

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00:09:26,220 --> 00:09:28,780
So when you really hone something, and that's what they learned.

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00:09:28,780 --> 00:09:31,180

When they really honed something, they managed to make it better.

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00:09:31,180 --> 00:09:33,020

But we're not just using it there.

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00:09:33,020 --> 00:09:39,075

So that's what we started working with it there to make sure that all of our staff have a really good understanding as well as all of our apprentices.

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00:09:39,075 --> 00:09:47,075

Anyone who really walks through our doors, we wanna make sure that they're a little bit better off, you know, understanding what the AI landscape looks like and how to integrate it into their

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00:09:47,075 --> 00:09:47,875

workflows.

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What

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00:09:48,195 --> 00:09:51,475

allowed this deployment to take place successfully?

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But,

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00:09:53,050 --> 00:10:01,130

honestly, I think the secret sauce was treating this as a quality initiative that happened to use AI and not an AI initiative that happened to touch quality.

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00:10:01,130 --> 00:10:08,905

So we the quality teams were actively involved in, deploying the the QA platform for play, for example.

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Several benefits.

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First of all, there's the, of course, the speed and the efficiency piece.

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So investigations, for example, which used to take hours or even days with manual tasks, that's actually,

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significantly decreased in terms of the the amount of time it takes.

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00:10:27,590 --> 00:10:31,750

And beyond the speed, it's also the insights for quality.

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So AI can help us spot patterns and connect to the dots for, you know, thousands of data points, more quickly than a human can.

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And thirdly, there's the the consistency piece.

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So, human analysis can depend, highly on who's doing the review, their experience level, and even what time of day it is.

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The play tool brings a level of standardization to how we approach trending and root cause analysis.

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From your perspective, how should companies prepare for inspections where AI supported decision making is integral to GMP compliance?

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You know, are other new expectations for human oversight, for failure mode analysis, or or for real time monitoring?

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Even

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though we use the terminology of AI decision making, we have to remember that, by definition, AI is not making a decision.

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00:11:22,880 --> 00:11:23,920

It's providing output.

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00:11:23,920 --> 00:11:25,280

Human beings make decisions.

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00:11:25,280 --> 00:11:35,055

And so, you know, when we look at our regulations, you know, we're we're never if software had an output and that output was used without

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00:11:35,055 --> 00:11:37,615

human intervention, we would still call it output.

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00:11:37,615 --> 00:11:44,735

Just because AI behaves more human like, we kind of start using this this nomenclature of decision making, but it's still output.

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00:11:44,735 --> 00:11:48,470

And so, you know, ultimately, AI is a tool.

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00:11:48,470 --> 00:11:51,990

It provides output on which decisions by people are made.

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00:11:51,990 --> 00:12:01,695

And, you know, whether or not, you know, the output that is given by the AI is used without any additional human intervention or human in the

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00:12:01,695 --> 00:12:02,255

loop.

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00:12:02,255 --> 00:12:03,295

That is a decision.

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00:12:03,295 --> 00:12:07,375

That's the decision, not the output that the that was given by the AI.

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00:12:07,375 --> 00:12:10,335

And so I think that distinction needs to be clearly made.

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00:12:10,335 --> 00:12:16,140

And if that distinction is clearly made, then then the thought process about inspections becomes easier actually.

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00:12:16,140 --> 00:12:19,420

Because then you're still thinking about human beings.

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00:12:19,420 --> 00:12:21,020

You're still thinking about record keeping.

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00:12:21,020 --> 00:12:30,955

You're still thinking thinking is our is the output being given by this very advanced software still appropriate to maintain the quality of the product that comes out at the other

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00:12:30,955 --> 00:12:31,435

end?

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00:12:31,435 --> 00:12:41,320

The quality unit is ultimately responsible for the end product and for making sure that along the way, all the parts of the processes are operating the

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00:12:41,320 --> 00:12:47,080

way they should be, whether it's validation, whether it's, you know, the specifications, whether it's the output, etcetera.

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00:12:47,080 --> 00:12:56,755

And, you know, so I think, you know, once we frame the the use of the AI in the appropriate way, like, AI, yes, AI decision

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00:12:56,755 --> 00:13:01,395

making, quote, unquote, it seems like it's making a decision, but it's really AI output.

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00:13:01,395 --> 00:13:06,515

It's AI output and human decision making on what to use with that out how to use that output.

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00:13:06,515 --> 00:13:07,170

In

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00:13:07,170 --> 00:13:16,610

your presentation at the ISPE Facilities of the Future Conference, you talked about quality maturity index versus

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00:13:16,930 --> 00:13:18,690
quality risk exposure.

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00:13:18,690 --> 00:13:21,075
What exactly are they?

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00:13:21,075 --> 00:13:23,475
And how are they complementary?

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00:13:23,475 --> 00:13:29,235
And how is AI giving you better insights into these measures?

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00:13:29,235 --> 00:13:30,035
QMI

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00:13:30,035 --> 00:13:38,710
and QRE are essentially two metrics, that help us understand the complete picture of quality across our global network.

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00:13:38,710 --> 00:13:48,695
So QMI or the Quality Maturity Index is essentially a digital analytics tool, within our platform, and it provides, dynamic

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00:13:48,695 --> 00:13:57,975
data driven, essentially, KPIs that we consider to be signals for our quality maturity, at the site level.

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00:13:57,975 --> 00:13:58,455
Many

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00:13:58,455 --> 00:14:08,430
times, a deviation gets resolved, quote, unquote, by saying, well, it was operator error, and

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00:14:08,430 --> 00:14:10,590
we retrained the operator.

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00:14:10,590 --> 00:14:11,310
Yes.

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00:14:11,310 --> 00:14:12,030
Okay?

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00:14:12,030 --> 00:14:21,615

Now, so the training was inadequate to begin with, and we're gonna retrain the operator on a training system that was

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00:14:21,615 --> 00:14:23,295

inadequate to begin with.

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00:14:23,295 --> 00:14:25,215

That's the logic that I see here.

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00:14:25,215 --> 00:14:32,850

But would your AI be able to kind of cry foul and say, wait a minute.

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00:14:32,850 --> 00:14:37,330

The human error was either, okay.

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00:14:37,330 --> 00:14:47,305

The individual really screwed up or the training was not good enough or the SOP is confusing or there's

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00:14:47,305 --> 00:14:52,425

some other root cause in the manufacturing system that needs to be addressed.

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00:14:52,425 --> 00:14:52,665

Yeah.

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00:14:52,665 --> 00:14:56,185

Do you see AI getting us to that place?

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00:14:56,185 --> 00:14:57,010

Oh,

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00:14:57,010 --> 00:14:57,730

I mean, absolutely.

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00:14:57,730 --> 00:14:59,490

That's exactly before.

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00:14:59,490 --> 00:15:08,930

So so one of the things one of the first projects, you know, that because on the side, my brother and I, you know, we we we do consulting for generative AI.

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00:15:08,930 --> 00:15:14,075

And one of the things we did was one of the first projects we did was on deviations, was around deviations.

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00:15:14,075 --> 00:15:18,155

And the thing is, you know, this is something that we see commonly now.

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00:15:18,155 --> 00:15:26,880

All of the big players all have AI built into looking at their deviations because it is just it's it's a great way to summarize a lot of elements and reduce a lot of the the the hours.

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00:15:26,880 --> 00:15:29,440

It's a pretty low hanging fruit, generally.

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00:15:29,440 --> 00:15:34,880

But the thing is that part that you touched on was is not something I hear a lot about.

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00:15:34,880 --> 00:15:36,415

They always hear about, hey.

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00:15:36,415 --> 00:15:39,135

I'm moving it, but they're like, ah, but we don't wanna solve the problem, though.

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00:15:39,135 --> 00:15:39,295

That

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00:15:39,295 --> 00:15:40,255

that part is a

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00:15:40,255 --> 00:15:43,295

bit absent, which is unfortunate because I think it's such a missed opportunity.

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00:15:43,295 --> 00:15:44,495

And I think you're right.

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00:15:44,495 --> 00:15:53,510

I and I think this is one of the areas where, you know, we're going to see our when our deviations come out come into play, and we see that element that says, hey.

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00:15:53,510 --> 00:15:54,790

This is a human error.

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00:15:54,790 --> 00:15:59,350

We happen to have the training record that's very transparent, that's very that's very traceable test.

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00:15:59,350 --> 00:15:59,830

Oh, look.

217

00:15:59,830 --> 00:16:04,790

Looks like they're we see right here that they're missing this specific pipetting skill.

218

00:16:04,790 --> 00:16:09,645

What we see now why this did not work, well, because they're not doing very well in this.

219

00:16:09,645 --> 00:16:15,565

Let's go back and retrain them on this specific area so we don't have to waste time with all the rest of this because this is the real weak point.

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00:16:15,565 --> 00:16:19,120

Focus on that, and then we'll probably see a lot better results.

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00:16:19,120 --> 00:16:23,680

Now I say probably because we haven't instituted that yet, but we will see that happen in the future.

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00:16:23,680 --> 00:16:23,840

I'm

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00:16:23,840 --> 00:16:24,400

certain of it.

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00:16:24,400 --> 00:16:34,205

How is AI helping you move complaints and deviations from being a reactive process to a predictive process.

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00:16:34,205 --> 00:16:35,645

It's

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00:16:35,965 --> 00:16:41,245

more difficult for humans to to see the patterns and to, do this in an in a manual way.

227

00:16:41,245 --> 00:16:51,100

With play, it can analyze thousands of historical deviations and complaints and identify early warning signals that proceed major

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00:16:51,100 --> 00:16:52,220

quality events.

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00:16:52,220 --> 00:17:00,620

So maybe, for example, we'll see an uptick in a certain type of minor deviation that historically has led to more serious issues

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00:17:01,835 --> 00:17:05,195

or a particular combination of fact of factors.

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00:17:05,195 --> 00:17:09,675

For example, equipment, product line, shifting of time.

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00:17:09,675 --> 00:17:12,315

So that correlates with problems down the road.

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00:17:12,315 --> 00:17:16,280

So humans simply can't process that volume of data to spot the patterns.

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00:17:16,280 --> 00:17:18,920

So AI is really allowing us to do that.

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00:17:18,920 --> 00:17:19,480

Thinking

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00:17:19,480 --> 00:17:29,480

about the regulatory filing, what are the most common challenges that reviewers might encounter when evaluating AI driven evidence or models in in

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00:17:29,480 --> 00:17:30,520
those CMC submissions?

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00:17:30,520 --> 00:17:31,215
As

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00:17:31,215 --> 00:17:34,655
with anything challenging, it's, you know, something is new.

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00:17:34,655 --> 00:17:38,815
There's always challenges of, you know, what what do we need to look at?

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00:17:38,815 --> 00:17:40,495
How deeply do we need to look?

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00:17:40,495 --> 00:17:50,450
But when we're looking at the credibility framework and the risk framework, we I think we need to make sure that products are well validated, that they're fit for use, that they're correct for

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00:17:50,450 --> 00:17:55,010
the context of use, that the risk is appropriate for that part of the system.

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00:17:55,010 --> 00:17:55,490
A

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00:17:55,490 --> 00:18:04,175
number of companies, including CAI, where I sit on the board of directors, have created AI powered apps for,

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00:18:04,655 --> 00:18:06,575
deviation report writing.

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00:18:06,575 --> 00:18:13,855
How is Sanofi using AI for such tasks, and what benefits are you seeing?

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00:18:13,855 --> 00:18:14,175

RA

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00:18:14,175 --> 00:18:23,910

tools can help to draft the initial report sections and can suggest investigation pathways based on similar historical cases, and it can even help

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00:18:23,910 --> 00:18:28,390

ensure that we're covering all the regulatory requirements for the investigation.

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00:18:28,390 --> 00:18:37,265

But we're also applying this to regulatory submissions, quality assessments, and even internal quality reviews.

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00:18:37,265 --> 00:18:47,260

So the AI tools that we're using can pull relevant data from multiple systems, identify key trends, and generate draft content that our quality professionals

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00:18:47,260 --> 00:18:49,660

can then refine and and validate.

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00:18:49,660 --> 00:18:50,220

How

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00:18:50,300 --> 00:18:59,305

is the FDA addressing concerns about things like bias, transparency, and explainability in the models that are used for regulatory decision making.

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00:18:59,305 --> 00:18:59,785

The

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00:18:59,785 --> 00:19:08,425

training and their skill sets are still essential because, as with anything, if you're not trained well, you don't know what you don't know.

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00:19:08,425 --> 00:19:17,370

While we use tools, some tools, we have I think, you know, everyone knows that Elsa is the tool that's used, that that FDA has,

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00:19:18,090 --> 00:19:28,025

built, our AI, chatbot or, you know you know, and there are plug ins that can that can be utilized with Elsa to help with certain parts of

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00:19:28,025 --> 00:19:31,065

the review or certain parts of looking at policy documents.

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00:19:31,065 --> 00:19:40,540

We have a number of RAG libraries with documents where, you know, you can focus your inquiries so that there isn't, like, kind of this hallucination from all of the

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00:19:40,540 --> 00:19:41,180

Internet.

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00:19:41,180 --> 00:19:44,460

Although I'm assured that, Elsa is blocked off from the Internet.

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00:19:44,460 --> 00:19:47,500

So if we upload a document, it's not going out into the wide world.

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00:19:47,500 --> 00:19:50,060

So I wanna make sure that people do understand that as well.

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00:19:50,060 --> 00:19:57,305

But it was trained on the Internet, so there is information that could potentially cause hallucinations.

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00:19:57,305 --> 00:20:02,265

And so we have other tools where we can use it, where we can focus it on a RAG library.

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00:20:02,265 --> 00:20:05,305

Like, this is our RAG library of quality policy.

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00:20:05,305 --> 00:20:09,070

We want to make a new call policy statement about x.

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00:20:09,070 --> 00:20:18,955

We can point to that regulatory that RAG library so that the output that we get is based on the information that's there and not and won't contain

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00:20:18,955 --> 00:20:25,515

any of the noise that possibly opinion pieces on the Internet about how certain things should be regulated get seeked their way through.

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00:20:25,515 --> 00:20:29,115

But that output still needs to be checked by a person.

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00:20:29,115 --> 00:20:32,555

And, ultimately, that person who is doing the work is the one that's responsible.

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00:20:32,555 --> 00:20:34,040

And so we have to say, okay.

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00:20:34,040 --> 00:20:43,880

Do you still have the knowledge and skills to be able to look at this statement that comes out or this analysis that comes out if you're looking at data,

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00:20:43,960 --> 00:20:47,240

graph, or whatever that comes out, table that comes out?

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00:20:47,240 --> 00:20:52,725

Do you still have the skills and knowledge to look at it and say, yes.

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00:20:52,725 --> 00:20:55,205

This makes sense, and this is what I want.

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00:20:55,205 --> 00:20:55,685

Or, no.

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00:20:55,685 --> 00:20:57,685

This actually doesn't make sense.

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00:20:57,685 --> 00:21:02,005

And, you know, perhaps we need to change it or maybe I have to change my prompt.

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00:21:02,005 --> 00:21:05,250

And so there's a lot of prompt engineering going on.

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00:21:05,250 --> 00:21:14,690

You know, we have work groups to work on prompt engineering to make sure that the output is appropriately worded or formatted in the, appropriate way for the work that we're doing.

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00:21:14,690 --> 00:21:21,865

There are different tools for different assessors, for different stages of assessment that are currently being developed and tested.

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00:21:21,865 --> 00:21:23,705

Some of them have been deployed.

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00:21:23,705 --> 00:21:25,785

Some of them, you know, are still being tested.

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00:21:25,785 --> 00:21:35,610

And so I think that continuing to validate in the same way that we want you to validate to make sure that the outputs that we could potentially use are

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00:21:35,610 --> 00:21:37,850

still appropriate for the work that we do.

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00:21:37,850 --> 00:21:47,695

But it comes down to whoever is the one who's who's utilizing that AI still needs to have that background, that historical knowledge, the training

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00:21:47,695 --> 00:21:51,135

in order to make sure that the output is appropriate for the work.