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Hello, and welcome to the ISPE podcast, Shaping the Future of Pharma.

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I'm Bob Chew, your host, and today we have another episode where we'll be sharing the

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latest insights and thought leadership on manufacturing, technology, supply chains,

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and regulatory trends impacting the pharmaceutical industry.

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

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and shaping the future.

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

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Our topic today is the use of AI quality transformation at Sanofi.

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To share more about this topic, I would like to welcome Miguelina Matthews, who is the

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head of Quality Intelligence, Advocacy, and Pharmacopeia Affairs at Sanofi.

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Miguelina gave a presentation at the recent ISPE Facilities of the Future Conference

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on AI transformation at Sanofi.

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Welcome to this podcast, Shaping the Future of Pharma.

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First, before we dive into how Sanofi is using AI, would you give us a bit of insight into

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your role at Sanofi?

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First of all, thank you so much for having me on the show.

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I'm excited to be here.

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So I'm the head of Quality Intelligence, Advocacy, and Pharmacopeia Affairs at Sanofi, and I

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know that's a mouthful, but it's a role that sits right at the intersection of regulatory

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science and quality strategy.

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And increasingly these days, it's also focusing on digital innovation as well.

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So on the intelligence side of things, my team essentially keeps our fingers on the

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pulse of what's coming down the pipeline.

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We're constantly monitoring emerging regulation requirements and industry trends that could

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impact our GXP processes across the enterprise.

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It's like being an early warning system for quality.

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We want to make sure Sanofi is always ahead of the curve.

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For the advocacy piece, we get to be more proactive.

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We work to influence both industry standards and the health authorities on topics that

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really matter to us.

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And one area that's particularly exciting right now is how we can responsibly integrate

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artificial intelligence into our GXP processes.

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It's fascinating work because we're literally helping to shape the future of how the industry

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operates.

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And the combination really keeps things dynamic for us.

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One day we're analyzing guidances, and then the next we're presenting at an industry conference

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about AI and applications and quality systems.

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It's the kind of role where you never stop learning.

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You know, I've been with ISPE for maybe 30 years now, or even more, and it's amazing

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how initiatives and groups such as yours can really drive and influence the direction of

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regulatory acceptance of new technologies.

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But anyways, what do you see as the biggest challenges and the biggest opportunities facing

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pharmaceutical manufacturing in this age of AI-powered technologies?

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That's a really good question, and it's something I've been thinking about a lot in the past

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couple years, especially now that AI is really booming everywhere.

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

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Patient safety is non-negotiable 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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So we think about how do we validate these systems?

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How do we explain what the algorithm is doing?

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When a regulator asks, we need to be able to explain.

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And how do we ensure that AI doesn't drift over time?

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So 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.

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And now AI is introducing probabilistic decision making that can feel uncomfortable to some

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of the users.

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So getting people to understand and embrace the shift while maintaining our rigorous standards

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is a real challenge.

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And then additionally, the regulatory landscape is still catching up.

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We're seeing drafts from different health authorities.

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And we're all figuring this out together, the industry, the health authorities, and

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everyone.

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But there are real opportunities, and they're enormous.

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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

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coming?

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AI lets us analyze vast amounts of process data, and it allows us to spot patterns that

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humans simply can't see as easily.

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There's also the efficiency piece, document review, batch record analysis, deviation trending.

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This takes hours for humans to do manually.

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So AI can compress this time dramatically, freeing up our quality professionals for higher

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value activities.

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And most importantly, there's real potential to speed products to patients.

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So if we can use AI to streamline processes and make smarter decisions faster, that means

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getting life-saving medicines to patients sooner.

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And that's a real win.

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Well, you shared a use case called PLAY, 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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Absolutely.

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So PLAY is a great example of how we approached scaling AI at Sanofi.

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So what we did is we started small and smart.

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The initial pilot focused on one specific use case, where we were trying to automate

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deviations and complaint trending, while providing root cause suggestions.

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So this was traditionally, I think it's the same case in many other companies, where traditionally

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it's a very manual process, where the quality teams spend hours looking for patterns across

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different types of events, and they spend time brainstorming what the potential root

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causes could be.

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But within a few months, we could see concrete results with PLAY, with faster identification

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of trending issues.

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And AI could generate potential root cause hypotheses that allowed the investigators

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to explore further.

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But the difference is, the real difference is that we didn't just focus on the technology.

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From the start, we built change management into the process.

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We involved end users to help design and identify issues with the tool.

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And we were transparent with what the tool could and couldn't do.

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

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we call RAISE.

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So RAISE stands for Responsible AI at Sanofi Enterprise, and it really provides the guardrails

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for how we can develop, validate, and deploy AI tools across our organization.

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So this governance ensures we're addressing risk, ethics, and compliance systematically

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with any new tool.

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So today, PLAY is used across multiple manufacturing sites globally.

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And it's an available toolkit, not only at the site level, but at the global level.

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And really, overall, the lesson was to start focused, prove value, govern responsibly,

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and then scale systematically.

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Well, that sounds to be kind of aligned with a talk I heard recently from an FDA person

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on this same podcast.

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You just work within your existing quality system framework, but you understand what

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the technology can do, and you build it up one step at a time.

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So what allowed this deployment to take place successfully?

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So in my opinion, I think there are really four success factors that allowed us to make

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this work for us.

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So first of all, we had strong support from our leadership from the beginning.

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This wasn't just something that was driven by IT or one specific department.

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It was really all the leaders throughout the company that were supporting this effort and

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could see the potential value.

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Second of all, as I mentioned, that RAISE governance framework was absolutely essential.

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We needed to make sure.

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We're a highly regulated industry, and our patients are in the forefront.

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So we needed to ensure that we had a framework and guardrails around the tools that we were

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deploying.

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Third, we really focused on the user experience.

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So getting the input from the pilot sites and the end users was absolutely essential.

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And we also built some change management into the process to ensure that the users were

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embarked and understood the tools that they were using.

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And finally, we were able to provide the value and the ROI concretely and quickly.

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But honestly, I think the secret sauce was treating this as a quality initiative that

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happened to use AI and not an AI initiative that happened to touch quality.

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So the quality teams were actively involved in deploying the QA platform for Play, for

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example.

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So what benefits are you now seeing through the use of this Play, PL-AI?

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So we're seeing several benefits.

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First of all, there's, 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,

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looking for patterns, that's actually significantly decreased in terms of the amount of time it

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takes.

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

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So AI can help us spot patterns and connect the dots for thousands of data points more

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quickly than a human can.

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And thirdly, there's the consistency piece.

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So human analysis can depend highly on who's doing the review, their experience level,

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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

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analysis.

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So that's a huge benefit as well.

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And it's elevated the role of the quality professionals, in my opinion.

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So instead of spending time on the mechanical work and the manual work, the investigators

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can really focus on the critical piece of assessing the outcome.

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So overall, we're identifying quality signals faster, investigating more thoroughly and

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consistently, and ultimately addressing potential issues earlier.

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Well, that's really great.

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That sounds like a really good buildup and deployment.

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Now in your presentation at the ISPE Facilities of the Future Conference, you talked about

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quality maturity index versus quality risk exposure.

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What exactly are they?

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And how are they complementary?

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And how is AI giving you better insights into these measures?

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Oh, thank you for the question.

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So these are, QMI and QRE are essentially two metrics that help us understand the complete

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picture of quality across our global network.

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So QMI, or the Quality Maturity Index, is essentially a digital analytics tool within

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our platform.

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And it provides dynamic, data-driven, essentially KPIs that we consider to be signals for our

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quality maturity at the site level.

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So in practical terms, QMI will enable us to evaluate specific areas requiring attention.

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So for example, it takes into account deviations, repeat deviations, Kappas, and it also allows

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us to benchmark across different sites.

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So it's essentially a way of monitoring KPIs.

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The difference between QMI and QRE is that the quality risk exposure, it's also a data

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analytics tool platform, but it actually takes into account additional factors, mainly some

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external inspection trends, audit outcomes.

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So it adds an additional layer.

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It also includes, considers the type of processes that occur at a given site.

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So with the quality risk exposure, again, it just takes into account additional factors

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that will then allow us to identify the potential risk at a given site.

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So in short, QMI scores the site's quality maturity from zero to 100, while the QRE considers

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external factors.

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And together, what makes them really powerful is that it allows us to identify where we're

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most at risk and to prioritize actions accordingly.

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So if I understand correctly, QMI is focused on true quality impacting items, whereas QRE

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layers on regulatory, which is supposed to just be quality impacting, but we know that's

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not always the case.

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Do I have that right?

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I think so, yes.

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So you're right with QMI.

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It's essentially the quality indicators that traditionally are tracked, the deviations

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and Kappas.

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But the QRE takes into account, for example, external trends, and I'm just making one up.

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So maybe we're seeing a trend in visual inspection observations.

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And we know that certain sites perform visual inspection activities.

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And if you put those two together, and let's say that site is having a lot of deviations

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at the same time, that could increase the quality risk exposure.

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Okay.

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I hope that's a little clearer.

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So how is AI helping you move complaints and deviations from being a reactive process to

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a predictive process?

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Thank you.

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That's also a really good question.

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So traditionally, the biopharma approach to deviations and complaints has been, as you

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mentioned, inherently reactive.

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Something goes wrong, we investigate, we find the most probable root cause, and then we

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implement corrective actions.

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And it's a solid process, but we're always responding after the fact, after the deviation

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has occurred or after the complaint has been filed.

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So I feel that AI is really flipping this model on its head.

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First of all, the AI allows us to have pattern recognition in place.

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As I mentioned before, it's a little, it's more difficult for humans to see the patterns

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and to do this in a manual way.

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With Play, it can analyze thousands of historical deviations and complaints and identify early

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warning signals that precede major quality events.

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So maybe, for example, we'll see an uptick in a certain type of minor deviation that

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historically has led to more serious issues, or a particular combination of factors.

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

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So that correlates with problems down the road.

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

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So AI is really allowing us to do that.

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Second, we're using AI to do what we call, or what I call, a weak signal detection.

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So not every complaint or deviation is created equal.

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Some are isolated incidents, but others are the first indicator of a systematic issue.

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So AI helps us distinguish between noise and signal much faster.

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So we can investigate and intervene before a trend fully develops.

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And thirdly, there's the root cause prediction capability.

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When a deviation occurs, instead of starting from scratch, the AI tool can say, you know,

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based on similar events across the network, here are the most likely root causes to investigate

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first.

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That accelerates our investigation and gets us to the corrective action faster.

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So 60 years ago, Edward Deming took his statistical quality methods into manufacturing, and in

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Japan first, because they were the ones that would listen.

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And there were control charts.

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I'm sure, does Sanofi use control charts, and is this AI basically allowing you to automatically

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interpret drifts and trends and such that the human eye used to be doing with the visual

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control charts?

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Is that what we're talking about?

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Yes.

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Play is essentially a dashboard, and it does exactly what you just described.

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And what's kind of cool about it is that you can visualize this on your computer, and it's

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also available as an app that any Sanofian can download and look at at any point in time.

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Okay.

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A number of companies, including CAI, where I sit on the board of directors, have created

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AI-powered apps for deviation report writing.

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How is Sanofi using AI for such tasks, and what benefits are you seeing?

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So we're using AI across several reporting functions.

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So, the creation and completion of the investigation reports is definitely a big one.

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So the investigation and reporting can be incredibly time-intensive, especially for

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really complicated investigations.

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So RA tools can help to draft the initial report sections and can suggest investigation

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pathways based on similar historical cases, and it can even help ensure that we're covering

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all the regulatory requirements for the investigation.

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

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internal quality reviews.

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So the AI tools that we're using can pull relevant data from multiple systems, identify

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key trends, and generate draft content that our quality professionals can then refine

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and validate.

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So the benefits are really compelling.

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There's the obvious time savings, but we're talking about reducing report writing, you

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know, 40 to 50 percent in many cases.

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But it's not just about speed.

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The consistency piece, which I mentioned earlier, is also really huge.

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It enables us to follow standard formats, making sure that all the required elements

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are covered, and that we maintain a consistent tone and approach across different authors

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and sites.

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And that's particularly valuable for regulatory submissions, where consistency really matters.

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And then overall, there's the quality improvement aspect.

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AI can suggest additional data points to include.

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It can flag potential gaps in the investigation, and it can recommend similar cases to reference.

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So it's having a really experienced quality professional looking over your shoulder is

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basically what the tool can feel like.

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It's making sure you're not missing anything.

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But the key, I just want to add, the key is that we're not replacing human judgment.

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The tools are really augmenting it.

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So the AI handles the heavy lifting and the data gathering, but it's the human in the

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end that's making the decisions.

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AI is a statistical tool, and the industry relies on statistics, everything from drug

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development and clinical trials.

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Do we think that AI could, given sufficient data, look at a deviation and assess whether

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it was really just operator error or really just an incorrect laboratory result, and instead

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point to the true root cause?

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Or if it was operator error, be able to say, you know, you tried retraining in the past

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and it didn't work.

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Consider process improvement or at least a different approach to operator training.

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So said AI.

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What do you think?

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Yes.

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So in the case of play, it can look across thousands of similar deviations and corresponding

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kappas and say exactly what you just said, Bob.

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It can say, wait a minute, you've attributed this type of event to operator error five

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times in the past, in the past two years, and you've done retraining each time, but

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the pattern keeps recurring.

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So it does alert the investigator that, hmm, maybe it's time to investigate further and

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this isn't really, the kappa wasn't effective or it wasn't really the right root cause.

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So it can flag that maybe that root cause was not appropriate the last time.

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Are you able to discuss additional applications of AI beyond what you discussed in your presentation

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at Facilities of the Future conference?

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So at Sanofi, we have a few AI initiatives underway across the enterprise and it's a

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really dynamic space for us.

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But for today, I think I'd rather keep the focus on play and the quality intelligence

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applications we discussed.

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There's so much depth there and honestly, these are the use cases where we've seen the

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most mature implementation and measurable impact.

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What I can say is that we are using AI broadly and we, like I said earlier, we start with

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a clear business problem, prove the value in a pilot, engage our stakeholders, leverage

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our raised governance framework, and then scale systematically so that
the consistency

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has been key to our success.

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Well, this has been a great story, but let's look at some of the other
presentations from

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Facilities of the Future conference.

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Which ones do you recall as being especially memorable, exciting,
impactful to you?

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Yes.

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So there was one presentation that really stood out to me.

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It was titled Realizing the Potential of Digital Twins in ATMPs.

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And what I found fascinating was how they articulated the unique
complexity of ATMP

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manufacturing.

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You know, the patient-specific execution, the really small batch sizes,
how compartmentalized

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the manufacturing can be with frequent changeovers and manual steps.

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But they explained how digital twins could really enhance and provide benefits to that

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type of manufacturing.

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So they shared how equipment optimization through leveraging digital twins.

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And that was really eye-opening to me.

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They showed how using average growth rates to estimate equipment needs can be grossly

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underestimated.

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But what really resonated with me was their progression from holistic models to digital

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shadows.

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They didn't just theorize.

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They actually showed measurable results.

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And I also appreciated their candor about the regulatory considerations.

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They were clear that while digital twins for supply chain, scheduling, and facility design

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face minimal regulatory hurdles, applying them to manufacturing process

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But I felt that their presentation connected really well with Clay in terms of using digital

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tools for predicting quality.

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Well, I'll give you my personal view of digital twins, both equipment digital twins,

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which by the way, aircraft industry has used for a long time to model jet engines and what

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happens if a fan blade blows and, you know, modeling all of that, that's been used for

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a long time.

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And also, process digital twins.

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I could imagine during startup, you train the equipment digital twin at the factory

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acceptance test.

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You then disassemble the machine, bring it to the site, reassemble it, plug in the digital

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twin, run the machine a little bit, and the digital twin says, this whatever needs a little

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adjustment and this isn't connected properly over here.

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And then you fix that, and then the digital twin says, okay, this equipment is now working

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as it was at factory, and of course, you did all this testing at the factory, and it helps

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you get through the startup and setting to work phase much faster.

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Maybe you can even have it run through the automation and give you an instant qualification

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decision.

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And then transferring processes, again, using a process digital twin to say that, yes, this

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process is producing product the way that it was at wherever you're transferring from,

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from the development site or a sister plant.

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And then you maintain those twins going down in time, and they can identify when the equipment

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needs adjustment or the process is drifting.

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What do you think of that?

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I think it's absolutely fascinating.

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And I think the other thing that digital twins allow for is for operator training, right?

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Operators can practice and learn on a twin rather than the actual equipment or especially

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if product is a limiting factor.

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It's a great way to leverage digital twins, and I really found their presentation fascinating

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and interesting, and the future is coming.

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So where do you see industry and its adoption of AI in 5 to 10 years from now?

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So looking ahead for the next 5 to 10 years, this is what I personally see is coming.

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In my view, in the next 5 years or so, we'll see AI becoming more regularly embedded in

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our quality and manufacturing operations.

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We're already starting to see it now.

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The tools and approaches we're piloting today will become standard practice.

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Predictive quality intelligence, AI-assisted investigations, automated report writing,

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I think these won't be considered innovative anymore.

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I think in the next 5 years, they'll be basically standard use.

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And for companies maybe that aren't using them, they may start to feel a little behind

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if they haven't already started leveraging this.

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I also think that we'll see much tighter integration across systems.

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Right now, many of our AI applications are still somewhat siloed.

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My prediction is that in 5 years, we'll have comprehensive digital ecosystems where AI

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is connecting insights across quality, manufacturing, supply chain, and regulatory, creating a more

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holistic view of product quality and patient impact.

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Additionally, the regulatory landscape should mature within the next 5 years.

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Right now, we've seen a lot of drafts from health authorities, but I expect that within

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the next 5 years, health authorities will have those frameworks and expectations formalized

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and in place, and we'll have a much clearer view of the health authorities' expectations.

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Hopefully, in my opinion, those expectations will be harmonized across the health authorities,

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but that may take a little longer.

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Well, Miguelina, this has been really fascinating.

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I compliment Sanofi on being what I'll call a pathfinder, not a trendsetter, but certainly

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an innovator.

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We talked about your PLAI, your play application, and how it's being used to analyze deviations

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and streamline report writing, but also to pull together a lot more data and analyze

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it statistically than a human could.

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The regulators ought to be head over heels about this kind of thing, where more data,

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more science and risk-based uses of that data is being done through these statistical tools,

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which is really what they are.

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It's not so much an artificial intelligence, it's a statistical tool.

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I think this is really great, and I compliment Sanofi both on its innovation and how it organizes

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itself and starts up and deploys these tools throughout the organization.

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I'd like to thank Miguelina for her time with us today.

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It's great to hear about innovative efforts at a major pharmaceutical company to adopt

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new technologies that promote efficient manufacturing and quality improvement.

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That brings us to the end of another episode of the ISPE podcast, Shaping the Future of

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Pharma.

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Please be sure to subscribe so that you don't miss future conversations with the innovators,

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experts, and changemakers driving our industry forward.

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On behalf of all of us at ISPE, thank you for listening, and we'll see you next time

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as we continue to explore the ideas, trends, and people shaping the future of pharma.