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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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00:00:10,080 --> 00:00:14,240

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

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00:00:15,335 --> 00:00:20,614

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

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00:00:21,094 --> 00:00:23,094

I'm Bob Chew, your host.

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00:00:23,255 --> 00:00:33,670

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

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00:00:33,670 --> 00:00:36,949

trends impacting the pharmaceutical industry.

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00:00:37,590 --> 00:00:44,905

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

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00:00:45,225 --> 00:00:46,905

Thank you again for joining us.

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00:00:46,984 --> 00:00:49,625

And now let's dive into this episode.

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00:00:50,905 --> 00:00:58,184

Our topic today is integration of artificial intelligence in the pharmaceutical industry and FDA perspective.

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00:00:58,759 --> 00:01:03,559

Our guests today are David Churchward and Doctor Tina Kiang.

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00:01:04,119 --> 00:01:09,959

David is head of operations, quality, compliance, and external affairs at AstraZeneca.

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00:01:10,855 --> 00:01:20,935

Previously, he spent seventeen years at the UK MHRA, where he led the inspectorates expert circle, engaging with global

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00:01:20,935 --> 00:01:27,120

regulators and industry in the assessment, regulation, and adoption of new technologies.

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00:01:27,840 --> 00:01:28,240

Doctor.

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00:01:28,240 --> 00:01:35,680

Kiang is director, division of regulation and guidance within the Office of Pharmaceutical Quality, CDER, FDA.

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00:01:36,115 --> 00:01:46,594

She began her FDA career as a lead reviewer at CDRH and over the years has been involved in assessing new technologies, especially software.

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00:01:47,234 --> 00:01:52,650

I will now turn the microphone over to David, who will moderate this discussion with Doctor Kiang.

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00:01:52,650 --> 00:01:53,370

Qiang.

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00:01:53,689 --> 00:01:55,209

Hello, and welcome.

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00:01:55,930 --> 00:02:06,329

One of the great benefits of our ISP community is the ability to share conversations and perspectives with other professionals across a wide range of roles and career

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00:02:06,329 --> 00:02:06,890

experiences.

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00:02:07,694 --> 00:02:13,135

And a really important part of that is the dialogue between industry and regulators.

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00:02:13,854 --> 00:02:24,360

So I'm delighted to welcome doctor Tina Kian to this podcast episode and for the opportunity to explore one of the most significant topics of recent times,

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00:02:24,599 --> 00:02:26,680

that being artificial intelligence.

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00:02:27,479 --> 00:02:27,879

Doctor.

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00:02:27,879 --> 00:02:34,280

Qian joins us from FDA, where she's held a wide range of roles during her twenty years with the agency.

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00:02:35,145 --> 00:02:42,745

So, Tina, I think your career overview and its relevance to your expertise in AI is best described in your own words.

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So, please, could you tell us a little bit about your career and what brought you to your current position as a thought leader influencing FDA's AI and machine

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00:02:53,020 --> 00:02:53,980

learning efforts.

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00:02:54,060 --> 00:02:56,939

Thank you, and thank you for having me on this podcast.

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I started my career at FDA almost twenty one years ago now.

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00:03:03,235 --> 00:03:05,314

I was a reviewer in medical devices.

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I started my career reviewing ophthalmic raw materials and neurodevices, neuromaterial devices.

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00:03:14,675 --> 00:03:19,770

And, you know, through through my career, I've always sought different opportunities.

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So when when time came for me to go into leadership positions, and advancing my leadership positions, I went to, what is what was called the division of

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00:03:30,694 --> 00:03:34,455

anesthesiology, respiratory, general hospital, infection control, and dental devices.

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00:03:34,455 --> 00:03:36,135

So a big, very big mouthful.

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00:03:36,854 --> 00:03:40,134

There was my first exposure to software products.

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00:03:40,134 --> 00:03:45,840

And so, you know, there were many, many products which I jokingly had set had a battery or plugged into a wall.

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And, therefore, you know, software products and exposure to software products and learning more about how to regulate software.

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And so taking that and those many years of experience over there and when I came over to CEDR, you know, there aren't that many people with device experience or software experience here in CDER

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and and certainly not in the area of policy making.

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00:04:08,064 --> 00:04:18,199

And, you know, so when, you know, documents or, prox came across my our desk regarding software or, you

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00:04:18,199 --> 00:04:23,479

know, now artificial intelligence, you know, myself there was a very small number of people who could look at it.

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00:04:23,479 --> 00:04:33,295

And so, you know, myself and there there's a couple of other peoples in in our group that, would look at these, you know, documents or these policy statements and whatnot.

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00:04:33,455 --> 00:04:35,775

And so, you know, it it became a natural fit.

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00:04:35,855 --> 00:04:39,055

It you know, I knew a little bit about software and validation.

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00:04:39,055 --> 00:04:47,170

You know, if you extend it more once you learn about artificial intelligence, you kind of extend those, criteria a little bit more.

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00:04:47,170 --> 00:04:53,649

There's it's slightly different, but, you know, soft what is artificial intelligence, but very advanced software.

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And so those kind of, ideas and the the knowledge that I had was transferable.

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And so now, you know, I'm part of the, CDER AI Council, their policy and review subcommittee.

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00:05:09,579 --> 00:05:19,740

You know, we have a subcommittee in, OPQ, which is my home office, you know, which talks about not only policy with regard to industry, but also how to use it

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00:05:19,740 --> 00:05:20,939

within the agency.

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00:05:20,939 --> 00:05:27,514

So I've been it's been an exciting kind of journey here, to artificial intelligence.

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00:05:28,875 --> 00:05:29,595

That's great.

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00:05:29,595 --> 00:05:38,314

And and what what a great opportunity for us to to tap into some of that experience, as we look towards the the use of AI, in our in our pharmaceutical industry.

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So let's let's dive into the questions, and and see what what comes out of the discussion.

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So if we if we're looking ahead five years, how do you see the integration of advanced AI techniques transforming drug development, regulatory

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submissions, and also manufacturing oversight.

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00:05:58,345 --> 00:06:08,389

So I think I 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

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00:06:08,389 --> 00:06:12,149

know, industry's own control systems to be able to moderate and regulate.

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00:06:12,550 --> 00:06:23,485

And so I think, you know, again, in, drug development and, know, drug development, advanced manufacturing in particular, you know, molecule

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00:06:23,485 --> 00:06:33,724

selection, designing clinical trials, you know, analysis of clinical data, for example, on the drug development and drug testing side, you know, and advanced manufacturing,

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you know, not only, you know, being able to control process parameters, you know, in in an effective way using real time data, for example.

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00:06:42,460 --> 00:06:50,694

And so, you know, there I think there are many aspects and different parts of the drug life cycle where it can be used.

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It can be effectively be used, you know, for example, in kappa investigations if you see a deviation in manufacturing or, you know, deviation in in the final drug product.

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You know, looking back at data, artificial intelligence could be used to analyze the data to see, you know, what those failure points are.

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Because quite frankly, it can, you know, given the right boundary conditions, and this is always the important part, given the right boundary conditions and ask the right questions, the AI

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can analyze the data far quicker than a human being can.

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00:07:23,454 --> 00:07:23,935

You know?

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00:07:23,935 --> 00:07:26,814

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

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00:07:26,814 --> 00:07:36,649

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 using.

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00:07:36,889 --> 00:07:39,610

So I think there there's a there are great opportunities.

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00:07:39,689 --> 00:07:43,129

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 and,

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00:07:53,754 --> 00:07:57,514

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

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00:07:57,514 --> 00:07:59,769
We're starting to use process models.

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00:07:59,769 --> 00:08:03,209
We're used computational modeling in order to do molecule selection.

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00:08:03,289 --> 00:08:06,810
These I think of this as, the next logical step.

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00:08:06,970 --> 00:08:14,444
But, you know, using caution and understanding that you you as the human being have to set the boundary conditions for the use.

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00:08:15,245 --> 00:08:16,045
That's great.

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00:08:16,045 --> 00:08:18,525
I mean, those opportunities are really exciting.

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00:08:18,605 --> 00:08:27,110
I guess, with any new technology, there's always the question relation to guardrails that protect the patient without impeding that innovation.

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00:08:27,110 --> 00:08:29,590
Some of that maybe you touched on a little bit there.

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00:08:30,230 --> 00:08:40,470
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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00:08:41,164 --> 00:08:41,725
Yeah.

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00:08:41,725 --> 00:08:44,924
So, you know, I'm of the opinion, and this may change.

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00:08:44,924 --> 00:08:47,644
This may change depending on, you know, what we see.

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00:08:47,644 --> 00:08:57,690

But currently, I'm of the opinion that the regulatory framework, meaning statute and regulation, are flexible enough to allow for the integration

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00:08:57,690 --> 00:08:58,409

of AI.

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00:08:58,409 --> 00:09:08,644

You know, we went from human beings looking at products to and inspecting products on a process line, for example, to, you know, machinery with a human intervening to

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00:09:08,644 --> 00:09:10,804

now software with human checks.

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00:09:10,804 --> 00:09:16,085

But, you know, you know, software without human intervention that moves that moves across the line.

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00:09:16,085 --> 00:09:21,365

And now AI, again, as I stated before, which is just a much more sophisticated type of software.

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00:09:21,649 --> 00:09:32,129

And so I think because we have been able to use our quality system regulations, for example, you know, the the two ten and two eleven, for g CGMP

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regulations.

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00:09:32,690 --> 00:09:33,009

I'm sorry.

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I said quality system regulations.

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00:09:34,529 --> 00:09:37,034

That was a old device terminology.

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00:09:37,034 --> 00:09:47,115

The, you know, CGMP regulations in order, you know, in order and having these incremental advances throughout the years, this should be

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00:09:47,115 --> 00:09:48,394
able to be fit in.

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00:09:48,769 --> 00:09:51,730
You know, of course, we'll need additional guidance.

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00:09:52,049 --> 00:10:02,289
You know, you know, we've FDA has already published a guidance on AI
develop use and develop in drug development, last January, in January
2025.

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00:10:04,165 --> 00:10:14,404
The CDER has published their guidance agenda, which on the top of the,
CMC quality, list is an AIML

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guidance for pharmaceutical quality and manufacturing.

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And so that will you know, when that publishes, that will hopefully
provide some frameworks on how to think about integration into,
pharmaceutical manufacturing and advanced

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manufacturing in general.

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00:10:28,899 --> 00:10:33,315
So, you know, we always have to look for opportunities for convergence.

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00:10:33,315 --> 00:10:42,274
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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00:10:42,274 --> 00:10:52,460
You know, there are the points, you know, points to consider or just,
general guidelines that we published with EMA, in, last in January.

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00:10:52,460 --> 00:10:55,820
You know, that I think was received really well.

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00:10:55,820 --> 00:11:05,654

And so, I think, again, you know, we have to look across not just within, you know, within the scope of what the FDA regulates.

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00:11:05,654 --> 00:11:15,779

You know, 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

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00:11:15,779 --> 00:11:17,059

this new technology.

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00:11:17,299 --> 00:11:17,620

Yeah.

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00:11:17,620 --> 00:11:19,059

That sounds great.

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00:11:19,059 --> 00:11:29,455

I mean, with with global manufacturing supply chains, that convergence of of regulatory expectations is really important and, you know, totally recognize that it takes time

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00:11:29,455 --> 00:11:31,054

to build some of that confidence.

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00:11:31,774 --> 00:11:35,615

And the obvious challenge in the AI space is speed of development.

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So I I really wish you and your colleagues success in those discussions towards alignment because for industry and for getting some of these technologies to patients, that alignment really matters.

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00:11:48,740 --> 00:11:58,584

We've we've heard a bit about the the different phases of the drug life cycle where AI can have relevance, perhaps we could explore that a little bit.

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

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00:12:09,544 --> 00:12:11,464

models in in those CMC submissions?

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00:12:11,840 --> 00:12:12,399

Right.

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00:12:12,480 --> 00:12:19,519

I think, you know, from that point of view, I think that, you know, we've been dealing with process models for years in the CMC space.

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We're we're starting, you know, with, you know, there was a paper that was published, a few years ago by, you know, FDA, you know, our members in OPQ along

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with, some partners in EMA about how to think about process models.

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And in that process model framework, there was an AI example in in fact, where, you know, it goes through how to think about, you know, credibility

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00:12:44,490 --> 00:12:48,410

assessment and risk assessment, of AI models.

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00:12:48,490 --> 00:12:53,529

I think, you know, as with anything challenging, it's, you know, something is new.

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00:12:53,929 --> 00:12:54,250

You know?

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00:12:55,274 --> 00:12:58,954

There's always challenges of, you know, what what do we need to look at?

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00:12:58,954 --> 00:13:00,634

How deeply do we need to look?

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00:13:00,634 --> 00:13:11,000

But when we're looking at the credibility framework and the risk framework, we I think, you know, we need to make sure that products are well validated, that they're fit for use, that they're correct

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for the context of use, that the risk is appropriate for that part of the system.

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00:13:16,759 --> 00:13:24,075

And that, you know, when looking at it, that there's enough data to provide that assurance that those risks are properly controlled.

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You know, I don't know how much I'm not on the assessment side, I couldn't comment on how much or how little they're receiving in terms of, you know, what's come in in an application

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versus what's come in in, like, a meeting, you know, premeeting or whatnot.

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00:13:39,079 --> 00:13:49,754

But we highly encourage anyone who's wants to file, or wants to integrate, an AI model into their manufacturing to come to our, you know, e

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t ETP program, you know, emerging technologies program, have those conversations.

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Or if it's on the cyber side, the CAT program, to have those conversations early, in order to make sure that and have those conversations early and often

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to make sure that, you know, everyone is on the right track and that we're thinking about the integration and the risk in the right way.

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00:14:12,539 --> 00:14:12,940

Okay.

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00:14:12,940 --> 00:14:13,740

That's good to hear.

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00:14:13,740 --> 00:14:20,475

And good good to to know there are those routes that that we can use also in the in the AI, you know, AI space and and to drop that technology.

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00:14:21,434 --> 00:14:28,475

So an area that's particularly close to my career experience is compliance in in manufacturing operations.

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00:14:28,554 --> 00:14:28,794

Mhmm.

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00:14:29,115 --> 00:14:38,419

And we're already seeing industry working on AI integration into a wide range of of quality operations and supply chain activities.

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00:14:38,659 --> 00:14:41,940

And, you know, I'm sure that those are gonna come under scrutiny during inspections.

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So from your perspective, how should companies prepare for inspections where AI supported decision making is integral to GMP

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compliance?

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

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00:15:02,649 --> 00:15:08,889

So I I'm gonna I'm going to, try to, play into fix some nomenclature.

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00:15:10,554 --> 00:15:19,035

Even 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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00:15:19,035 --> 00:15:20,154

It's providing output.

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00:15:20,795 --> 00:15:22,154

Human beings make decisions.

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00:15:22,554 --> 00:15:32,940

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

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we would still call it output.

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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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00:15:42,034 --> 00:15:45,314

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

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00:15:45,314 --> 00:15:48,834

It provides output on which decisions by people are made.

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00:15:49,314 --> 00:15:59,370

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 loop, that

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00:15:59,370 --> 00:16:00,089

is a decision.

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00:16:00,089 --> 00:16:04,169

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

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00:16:04,169 --> 00:16:07,154

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

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00:16:07,154 --> 00:16:12,995

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

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00:16:13,394 --> 00:16:16,355

Because then you're still thinking about human beings.

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00:16:16,355 --> 00:16:17,875

You're still thinking about record keeping.

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00:16:17,875 --> 00:16:28,250

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 on the other end?

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00:16:28,250 --> 00:16:38,375

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 way

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00:16:38,375 --> 00:16:43,894

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

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00:16:43,975 --> 00:16:54,079

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 making,

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

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00:16:58,254 --> 00:17:03,615

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

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00:17:03,615 --> 00:17:14,210

And, again, if we frame it that way, I think how to prepare for inspection and what what materials and how to think about inspection becomes a lot easier because it still fits within

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00:17:14,210 --> 00:17:15,970

the framework that we have now.

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00:17:16,289 --> 00:17:25,009

You know, we wouldn't expect there to be any additional difficulty because we're using a process model that is a traditionally program process model.

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00:17:25,089 --> 00:17:27,250

It shouldn't be any different just because it's AI.

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00:17:29,144 --> 00:17:30,025

That's that's great.

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00:17:30,025 --> 00:17:34,025

A bit of bit of demystifying there and stripping it back to its to its bare essentials, I guess.

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00:17:34,025 --> 00:17:44,349

So, yeah, it's a really, you know, interesting way to kind of put put that that kind of reality back into into how how some of those view models are being being viewed.

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00:17:44,669 --> 00:17:45,309

Yeah.

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00:17:45,309 --> 00:17:55,309

So, of course, we we can't implement we can't just implement AI across the drug life cycle without thinking about maintaining and developing the AI

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00:17:55,309 --> 00:17:56,029

model itself.

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00:17:56,934 --> 00:18:06,934

So from a regulatory perspective, what are considered to be best practices for lifecycle management of the AI model, and particularly regarding things like

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00:18:06,934 --> 00:18:10,934

change control and revalidation, some of which you kind of talked touched on just a little bit previously?

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00:18:11,589 --> 00:18:12,149

Yeah.

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00:18:12,389 --> 00:18:22,389

You know, I think the the big thing is to understand, you know, when when you're gonna check-in with the AI, and establishing those boundary conditions very early

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00:18:22,389 --> 00:18:22,789

on.

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00:18:22,789 --> 00:18:28,994

Like, when and I think that that goes for any time, anything that you're talking about within with regard to change control.

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00:18:28,994 --> 00:18:33,634

It's just that, you know, depending on the model, changes could be happening.

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00:18:33,714 --> 00:18:40,169

You know you know, if it's an open model, for example, changes could be happening, day to day.

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00:18:40,490 --> 00:18:44,490

And so the question is, how how do you know when to check-in with the model?

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00:18:44,490 --> 00:18:46,009

How do you know when to check-in?

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00:18:46,569 --> 00:18:56,005

And it shouldn't be, oh, there's something happened that's bad, and we had a bad result, or, you know, we have a whole lot of product that it that doesn't meet our quality standards.

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00:18:56,005 --> 00:18:57,044

It can't be that.

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00:18:57,205 --> 00:19:00,484

You know, that's way too late and way too far down the line.

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00:19:00,644 --> 00:19:05,525

And so I think, you know, wherever AI is implemented, you have to think about, okay, what are the boundary conditions?

200

00:19:05,525 --> 00:19:07,924

What are the what are the signals?

201

00:19:07,924 --> 00:19:12,089

What are the triggers that you have in place to say, okay.

202

00:19:12,089 --> 00:19:13,130

It's time to check-in.

203

00:19:13,130 --> 00:19:23,369

It could be as simple as we're gonna check-in, you know, every six months, you know, to make sure that, you know, it's that the output is still appropriate for that

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00:19:23,035 --> 00:19:24,714

unit operation, for example.

205

00:19:24,795 --> 00:19:33,355

It could be, you know you know, product is coming out from a specific unit operation, there's there's testing further down the line.

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00:19:33,595 --> 00:19:43,330

And you have, you know, certain triggers or certain you know, once it gets too close to a boundary condition or specification, you know, something becomes too high or too low, okay.

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00:19:43,330 --> 00:19:45,890

Maybe we need to see if the model is drifting.

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00:19:45,970 --> 00:19:50,369

You know, it could be any number of those things so long as they are well defined.

209

00:19:50,769 --> 00:19:51,090

You know?

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00:19:51,724 --> 00:20:01,805

And that when changes happen and when you when you do need to change something, you know, we have to tweak the model in some way or make

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00:20:01,805 --> 00:20:04,605

a minor change to the model or even a major change to the model.

212

00:20:04,605 --> 00:20:06,779

What what reporting category does it come in?

213

00:20:06,779 --> 00:20:08,539

When do you have to come into FDA?

214

00:20:09,259 --> 00:20:17,499

And so we have to think about it again using, you know, q eight, q nine, q 10 principles on good manufacturing and then q 12 principles on change control.

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00:20:17,819 --> 00:20:19,819

You know, what are what's essential?

216

00:20:20,345 --> 00:20:22,505

And what's essential to report?

217

00:20:22,505 --> 00:20:24,105

What's essential to look at?

218

00:20:24,184 --> 00:20:32,585

What's essential to make sure that the output in terms of in terms of the drug product that you are getting at the end is meeting quality standards?

219

00:20:33,049 --> 00:20:43,130

And having those guardrails in place along the way, just as you do now when you are in a when you're when you're looking at unit operations or the process as a whole, again,

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00:20:43,130 --> 00:20:52,004

I think if you think about it in the same way, you know, along the line as you do now, the principles still hold.

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00:20:52,085 --> 00:20:58,644

You just have to understand, you know, can the AI, in in its context of use, can it change?

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00:20:59,019 --> 00:21:03,659

Can it change on its own, or will it only change because you made a change to it?

223

00:21:03,819 --> 00:21:11,179

And that will help you define the framework and define the boundary conditions and define the triggers for when you have to go back in.

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00:21:11,179 --> 00:21:13,674

But they have to be defined early.

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00:21:13,835 --> 00:21:16,555

You can't define you can't say, oh, wait.

226

00:21:16,555 --> 00:21:23,994

There's there's a lot of product that doesn't meet our standards or and then that's that's the point where you have to go check-in.

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00:21:23,994 --> 00:21:25,515

That's not the way to do it.

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00:21:25,515 --> 00:21:35,639

So I think, again, we if we look at good principles, you know, are the principles that we've utilized all along, and apply it in the same way with the same

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00:21:35,639 --> 00:21:38,440

rigor and not just say, oh, well, it's AI.

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00:21:38,440 --> 00:21:40,999

It'll fix itself because we know that's not true.

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00:21:41,559 --> 00:21:48,065

I think we can you know, people will be able to, you know, be able to process it and think about it in the appropriate way.

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00:21:48,065 --> 00:21:53,184

Again, and always, you know, if you need advice from FDA, come talk to FDA.

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00:21:53,664 --> 00:21:53,984

You know?

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00:21:53,984 --> 00:21:59,579

Is there is, you know, for for this part of the process, we're intending on using AI.

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00:21:59,660 --> 00:22:03,820

We have, you know, a temperature control, you know, further down the line.

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00:22:03,820 --> 00:22:07,579

You know, well, this trigger maybe this trigger may be appropriate, maybe not.

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00:22:07,579 --> 00:22:09,180

There's another test down the line.

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00:22:09,180 --> 00:22:10,140

Is this appropriate?

239

00:22:10,140 --> 00:22:10,619

Is it not?

240

00:22:11,125 --> 00:22:18,164

And, you know, perhaps and it's going to be a process to learn as people are starting to integrate and learn more.

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00:22:18,484 --> 00:22:21,525

So, I guess, building that into a into a control strategy.

242

00:22:21,525 --> 00:22:21,765

Yeah.

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00:22:21,765 --> 00:22:22,325

Exactly.

244

00:22:22,325 --> 00:22:22,884

Exactly.

245

00:22:22,964 --> 00:22:30,359

Build it into your control strategy from the start and, you know, be able to modify that as you learn.

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00:22:30,519 --> 00:22:30,920

You know?

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00:22:30,920 --> 00:22:34,599

And and, again, a control strategy, it's not a be all and end all.

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00:22:34,599 --> 00:22:35,400

This is it.

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00:22:35,400 --> 00:22:42,964

You know, you have to you have to look at it, reassess, come back to it, reassess risk, change the control strategy as you need it.

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00:22:43,924 --> 00:22:44,484

Yeah.

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00:22:44,565 --> 00:22:47,684

So so just kind of thinking about those risk based frameworks.

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00:22:47,684 --> 00:22:57,970

Now as we develop those frameworks for model change management and also the datasets that they use, what level of evidence is required to demonstrate that robust

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00:22:57,970 --> 00:23:06,129

data lineage, governance, and controls when we're actually training or validating the AI models that are used in regulated contexts?

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00:23:06,289 --> 00:23:06,929

Yeah.

255

00:23:07,009 --> 00:23:17,024

I think, you know, with everything, you when when we're looking at data for validation and and especially with an AI model, because it's not a human

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00:23:17,024 --> 00:23:19,424

programming it and then debugging and whatever.

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00:23:19,904 --> 00:23:23,904

It's it's it learns from data, and then it is validated with data.

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00:23:24,460 --> 00:23:33,259

And, you know, when once it's deployed, it's using that body of data in order to do what's functionally meant to do and trained to do.

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00:23:33,660 --> 00:23:44,044

So as with training, and this is where I will make that human analogy, as with training a human being, if you give it bad data, it's going to produce bad data.

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00:23:44,365 --> 00:23:44,924

You know?

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00:23:45,325 --> 00:23:49,404

And so, you know, I you know, we've all heard the phrase garbage in, garbage out.

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00:23:50,284 --> 00:23:58,240

And so I think you have to look at to make sure, you know, the datasets that are used that are being used for training are appropriate for the context of use.

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00:23:58,640 --> 00:24:06,160

You have to make sure, you know and this may or may not be easy, you know, making sure that there's no bias in that data.

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00:24:06,515 --> 00:24:12,595

You know, you have to making sure that that the data, you know, is representative of what you want it to be.

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00:24:12,595 --> 00:24:19,795

I think in manufacturing, you may have less of a chance versus clinical, but there's it's still a possibility.

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00:24:19,795 --> 00:24:29,369

And you have to you have to make sure that the data is such that you're trying to minimize the potential for hallucination if you're you're talking about something that's generative or or something that's,

267

00:24:29,369 --> 00:24:34,329

you know, a learning model that that it doesn't that there isn't a chance to hallucinate.

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00:24:34,329 --> 00:24:34,490

You know?

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00:24:34,865 --> 00:24:39,345

You want the data to be tight and clean as clean as possible.

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00:24:39,744 --> 00:24:40,065

You know?

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00:24:40,065 --> 00:24:41,424

And sometimes that's difficult.

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00:24:41,424 --> 00:24:42,545

It can be difficult.

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00:24:42,545 --> 00:24:43,025

You know?

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00:24:43,025 --> 00:24:54,210

Historical data as it is, you know, can be can have discrepancies in it, you have to make sure that it that that the model can appropriately,

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00:24:54,369 --> 00:25:04,450

when it's trained, not only see what it needs to see and and is able to to move the products to and do what it's supposed to do, but also be able to to identify, oh, this is a discrepancy.

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00:25:04,450 --> 00:25:05,329

This is not good.

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00:25:05,329 --> 00:25:14,904

And so, again, being able to train a model on the data that it's and to perform its duties, but also to be able to to identify, no.

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00:25:14,904 --> 00:25:16,184

That's a discrepancy or, no.

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00:25:16,184 --> 00:25:17,464

That's out of specification.

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00:25:17,464 --> 00:25:18,024

No.

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00:25:18,265 --> 00:25:18,904

You know?

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00:25:18,904 --> 00:25:28,679

So I think that, you know, it's important also to go back to what I said in in our last question about the guardrails.

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00:25:28,759 --> 00:25:31,639

You know, having a human in the loop at some point.

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00:25:31,720 --> 00:25:41,774

You know, it may not be at that particular unit operation, but having a human in the loop at some point, you know, will help, you know, make sure that that

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00:25:41,774 --> 00:25:45,534

the the AI continues to operate the way it's intended.

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00:25:45,934 --> 00:25:47,694

You know, when is that check-in?

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00:25:47,694 --> 00:25:48,815

How often is that check-in?

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00:25:48,815 --> 00:25:50,014

Who is responsible?

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00:25:50,174 --> 00:25:51,854

And having that predefined.

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00:25:52,815 --> 00:25:58,380

So datasets that are designed to to mitigate risks of bias Yes.

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00:25:58,460 --> 00:26:03,900

Making sure that we can have interpretability of of of the outputs, the periodic check ins.

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00:26:03,900 --> 00:26:08,859

All of those things are are kinda are just common themes I'm hearing is that form part of those guardrails.

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00:26:09,345 --> 00:26:09,744

Yeah.

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00:26:09,744 --> 00:26:19,825

And and I think that it's no I think it's not very much different than what we do now, you know, in in terms of of, you know, how how we monitor

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00:26:19,825 --> 00:26:30,200

or I hope it's not very different than that what we do now of how how how, you know, manufacturing is monitored, you know, and and that how the processes are monitored to ensure that

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00:26:30,200 --> 00:26:40,295

the product from unit operation to unit operation risks are controlled and that the quality of product is maintained throughout the manufacturing cycle so that you have

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00:26:40,295 --> 00:26:45,254

a quality and product that meets your specifications and meets your needs for the intended population.

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00:26:45,734 --> 00:26:56,079

And so I think if we continue to think about that that's the end goal, you know, it it becomes, you know, where where to insert, you know, a human being,

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00:26:56,079 --> 00:26:59,919

where to where to find those boundaries becomes easier.

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00:26:59,919 --> 00:27:05,679

And and understanding, at least right now, that AI is not the be all and end all.

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00:27:05,679 --> 00:27:10,955

You can just plug it in and wave your hands at and say, you know, I don't need to look at this.

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00:27:10,955 --> 00:27:15,115

That's that's not, I don't believe that's where we are right now.

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00:27:15,115 --> 00:27:16,954

We may be there in the future.

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00:27:17,434 --> 00:27:25,730

But, again, even if we got there in the future, it's still a human being that needs to sign the dotted line on the paper and take responsibility of everything that's going on.

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00:27:26,609 --> 00:27:27,009

Yeah.

306

00:27:27,009 --> 00:27:27,410

Okay.

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00:27:27,410 --> 00:27:28,289

That's that's yeah.

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00:27:28,289 --> 00:27:34,849

And and wouldn't that be an interesting development if we got to the point of, you know, something perhaps further towards something truly autonomous?

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00:27:36,535 --> 00:27:45,894

How 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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00:27:46,375 --> 00:27:47,095

Yes.

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00:27:47,575 --> 00:27:57,719

Know, we are one of the things we have, you know, a document, an internal document, you know, the, you know, points to consider or, you know, just good practices.

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00:27:57,720 --> 00:27:58,279

You know?

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00:27:58,679 --> 00:28:07,914

And we the big thing is making sure the people the people are still key in the the whole process.

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00:28:07,914 --> 00:28:18,269

Meaning, we we wanna make sure that the people who who are doing, you know, doing the assessments or writing the policy

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00:28:18,269 --> 00:28:28,190

or, you know, conducting reviews or conducting inspections, they are still the training and their skill sets are still essential.

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00:28:28,509 --> 00:28:33,274

Because as with anything, if you're not trained well, you don't know what you don't know.

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00:28:33,755 --> 00:28:34,315

Right?

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00:28:34,474 --> 00:28:44,690

And so, you know, 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

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00:28:44,690 --> 00:28:54,769

has, built, our AI, chatbot or, you know you know, and there are plug ins that can that can be utilized with ELSA to

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00:28:54,769 --> 00:28:59,265

help with certain parts of the review or certain part, you know, looking at policy documents.

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00:28:59,265 --> 00:29:09,424

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

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00:29:09,424 --> 00:29:10,144

all of the Internet.

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00:29:10,829 --> 00:29:13,869

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

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00:29:13,869 --> 00:29:16,910

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

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00:29:16,910 --> 00:29:19,470

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

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00:29:19,869 --> 00:29:24,349

But, you know, but it it was trained on the Internet.

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00:29:24,349 --> 00:29:29,414

So there is information that, you know, could potentially cause hallucinations.

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00:29:29,494 --> 00:29:34,375

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

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00:29:34,375 --> 00:29:37,734

Like, this is our RAG library of quality policy.

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00:29:37,975 --> 00:29:41,015
We want to make a new call policy statement about x.

331
00:29:41,080 --> 00:29:51,240
We can point to that regulatory lock that RAG library so that the output that we get is based on the information that's there and not and won't contain any

332
00:29:51,240 --> 00:29:57,585
of the noise that possibly opinion pieces on the Internet about how certain things should be regulated get seeked their way through.

333
00:29:58,065 --> 00:30:01,264
But that output still needs to be checked by a person.

334
00:30:01,424 --> 00:30:04,625
And, ultimately, that person who is doing the work is the one that's responsible.

335
00:30:04,625 --> 00:30:06,224
And so we have to say, okay.

336
00:30:06,224 --> 00:30:16,419
Do you still have the knowledge and skills to be able to look at this statement that comes out or best analysis that comes out if you're looking at, you know, data

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00:30:16,419 --> 00:30:24,019
or, you know, this this, you know, graph or whatever that comes out table that comes out.

338
00:30:24,944 --> 00:30:29,505
Do you still have the skills and knowledge to look at it and say, yes.

339
00:30:29,505 --> 00:30:31,984
This makes sense, and this is what I want.

340
00:30:31,984 --> 00:30:32,464
Or, no.

341
00:30:32,464 --> 00:30:34,464
This actually doesn't make sense.

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00:30:34,784 --> 00:30:39,664

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

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00:30:40,009 --> 00:30:42,809

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

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00:30:43,049 --> 00:30:53,129

You know, we have work groups to work on prompt engineering to make sure that the output is, you know, appropriately worded or formatted, you know, in this in the, appropriate way

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00:30:53,129 --> 00:30:54,409

for the work that we're doing.

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00:30:54,694 --> 00:31:01,575

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

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00:31:01,815 --> 00:31:03,335

Some of them have been deployed.

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00:31:03,335 --> 00:31:05,494

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

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00:31:05,654 --> 00:31:15,990

And so I think that we we have to keep continuing to improve, you know, what, you know, the and

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00:31:15,990 --> 00:31:26,205

continuing to validate in the same way that we we want you to validate to make sure that the that the outputs that we use, that we could potentially use, are still appropriate

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00:31:26,205 --> 00:31:27,724

for the work that we do.

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00:31:27,725 --> 00:31:37,890

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 in

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00:31:37,890 --> 00:31:41,329

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

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00:31:42,450 --> 00:31:43,089

Yep.

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00:31:43,089 --> 00:31:43,409

Okay.

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00:31:43,409 --> 00:31:43,970

That's great.

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00:31:43,970 --> 00:31:44,609

Thank you.

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00:31:45,009 --> 00:31:55,195

So maybe as we start to think about bringing our our discussion to a close, what future directions or innovations in AI do you believe will have the

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00:31:55,195 --> 00:31:58,875

greatest impact on regulatory science and patient outcomes?

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00:32:00,154 --> 00:32:03,355

You know, I think that there again, I think we're only seeing the beginning.

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00:32:03,480 --> 00:32:06,200

Like I said earlier, I think we're only seeing the beginning.

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00:32:06,200 --> 00:32:14,519

I think there's there is there's a number of there's many, many ways throughout the drug development cycle and post post marketing.

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00:32:14,519 --> 00:32:22,335

You know, once once the product is out there, a product is out there that can where AI could be utilized.

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00:32:22,335 --> 00:32:30,015

You know, we already talked about drug development and and, you know, molecule suction and clinical trials and and, you know, adverse events.

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00:32:31,930 --> 00:32:37,690

But, you know, we've talked about process, you know, throughout throughout, the manufacturing.

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00:32:37,690 --> 00:32:46,585

You know, in addition to, you know, continue advanced manufacturing, continuous manufacturing, can we utilize AI to kind of make it more robust?

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00:32:46,585 --> 00:32:56,585

You mentioned, you know, maybe one day we might get to the point where we have a fully autonomous, you know, autonomous, line where, you

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00:32:56,585 --> 00:33:03,220

know, hopefully from beginning to end with some, you know, obviously, some monitoring along the way, you know, check ins along the way.

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00:33:03,220 --> 00:33:09,299

You know, you go from beginning to end, and, you know, everything that comes out on the other end is is fantastic.

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00:33:09,779 --> 00:33:16,734

But I think, you know, we also have our opportunities, you know, post marketing, you know, looking at patient populations.

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00:33:16,815 --> 00:33:23,534

Because once a medication, a drug goes out into, the the general population, you never know what's going to happen.

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00:33:23,534 --> 00:33:30,349

You know, it's going to touch people, and people are gonna be utilizing it that we're not within that well controlled trial.

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00:33:30,429 --> 00:33:40,744

And so maybe you see, for example, additional benefits that you could look at data, you know, with people reporting, you know, additional benefits and, you know,

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00:33:40,744 --> 00:33:49,625

possibly look into that even further and refine that further and, you know, possibly get another indication based on that kind of real world evidence, for example.

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00:33:49,865 --> 00:33:50,184

You know?

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00:33:51,019 --> 00:33:52,619

You can you you know?

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00:33:52,619 --> 00:34:02,700

And looking at, you know, potential looking at, post market monitoring, looking at potential side effects, you might be able to see, you know, drug drug interactions that you would not

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00:34:02,700 --> 00:34:12,875

have anticipated in development, you know, where, you know, again, an AI can analyze tranches of data much faster than a human being can

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00:34:12,875 --> 00:34:14,235

and find the patterns.

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00:34:14,235 --> 00:34:15,914

And that's the big thing about AI.

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00:34:15,914 --> 00:34:26,039

The AI is the strength of AI is being able to recognize patterns and perhaps recognize patterns more rapidly than a human can because they're able to access all

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00:34:26,039 --> 00:34:28,760

of the data much, much more quickly.

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00:34:28,920 --> 00:34:39,034

And so maybe perhaps, you know, identifying, oh, there are drug drug interactions that we did not anticipate, but we found, you know, this cardiovascular product and this

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00:34:39,034 --> 00:34:44,819

renal product, you know, when these two things are used together cause x.

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00:34:44,819 --> 00:34:47,139

And we've seen it over and over and over again.

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00:34:47,380 --> 00:34:57,380

But someone just analyzing individual adverse event reports may not put those two things together, you know, or a company who are analyzing, you know, reports

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00:34:57,005 --> 00:34:59,085
may not put those two things together.

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00:34:59,085 --> 00:35:03,885
And so I think there are great opportunities to utilize the power of AI.

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00:35:04,204 --> 00:35:07,085
I think we also have to look at just generally.

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00:35:07,085 --> 00:35:08,925
I mean, we talk about risk all the time.

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00:35:09,885 --> 00:35:13,829
You know, when we utilize AI, we have to be judicious.

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00:35:14,230 --> 00:35:18,789
If we utilize AI in this particular situation, are we getting back?

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00:35:18,789 --> 00:35:22,230
Are we benefiting, you know, in a meaningful way?

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00:35:22,230 --> 00:35:27,715
If the benefit is minimal, is it really a good idea to use it there at that point?

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00:35:27,715 --> 00:35:34,515
Or is it what you were using or what you were using right, at the moment previously, you know, still appropriate?

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00:35:34,675 --> 00:35:40,519
And maybe the technology has to advance a little bit more before it's, you know, good to use there.

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00:35:40,519 --> 00:35:50,840
And so because AI takes a lot of computing power, it takes there's an environmental impact, there's a whole bunch of other things about AI besides just, oh, does it give me the right answer

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00:35:50,840 --> 00:35:52,119
that have to be considered?

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00:35:52,505 --> 00:35:55,945

And so we have to balance that as well with risk and benefit.

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00:35:55,945 --> 00:35:58,744

Is the benefit is juice worth the squeeze, in other words?

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00:35:58,744 --> 00:36:01,144

Is this the appropriate use of AI?

402

00:36:01,144 --> 00:36:06,105

Or is it just because it's a new shiny object and we wanna say that we we're using AI for this?

403

00:36:06,265 --> 00:36:14,559

And, you know, again, we can't deny the other impacts that it has besides does it affect our work.

404

00:36:15,119 --> 00:36:15,760

Yeah.

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00:36:16,000 --> 00:36:24,554

I mean, certainly I mean, what a fantastic time for science and technology to really start pushing the boundaries of of what we can do in in in health care generally.

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00:36:24,554 --> 00:36:31,755

So it's it's, you know, certainly something that is is super interesting just to see where this where this is gonna end up taking us really.

407

00:36:32,210 --> 00:36:32,690

Yeah.

408

00:36:32,690 --> 00:36:41,329

And and I think, you know, as with every technology, you know, once there's adoption, I think it tends to move pretty quickly.

409

00:36:42,210 --> 00:36:45,409

I think that it improves more quickly once there's adoption.

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00:36:45,894 --> 00:36:49,894

And I but I think, you know, there's always early adopters and later later adopters.

411

00:36:49,894 --> 00:36:52,215

And I'm not saying one is better than the other.

412

00:36:52,375 --> 00:36:52,934

You know?

413

00:36:52,934 --> 00:36:59,335

I typically, for technologies, I tend to wait till the second version comes around because I don't wanna be a beta tester.

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00:36:59,539 --> 00:37:00,900

That's not my thing.

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00:37:01,139 --> 00:37:01,699

You know?

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00:37:01,699 --> 00:37:10,260

But there are others who wanna be the first out of the gate, and that's okay so long as you control the risks that come with being the first out of the gate.

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00:37:10,900 --> 00:37:11,460

Yep.

418

00:37:11,460 --> 00:37:12,019

Absolutely.

419

00:37:13,125 --> 00:37:14,644

What a great conversation.

420

00:37:14,885 --> 00:37:16,324

I think we're at time.

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00:37:16,644 --> 00:37:20,965

It's been an absolutely, fascinating discussion, Tina.

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00:37:20,965 --> 00:37:31,210

Thank you for for giving up your time to to join me in and giving us some insight into this technology that does bring so much opportunity and yet still right now presents a

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00:37:31,210 --> 00:37:35,130

number of questions that I think we're all still trying to get to grips with.

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00:37:35,289 --> 00:37:45,335

I'm really looking forward to continuing the discussion between regulators and industry as we develop those guardrails that really help us to enable the delivery of innovation for

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00:37:45,335 --> 00:37:45,815

patients.

426

00:37:45,815 --> 00:37:47,494

So thank you again very much indeed.

427

00:37:47,494 --> 00:37:49,015

Thank you so much for having me.

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00:37:49,015 --> 00:37:50,534

I really enjoyed this conversation.

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00:37:50,534 --> 00:38:00,059

In summary, I was excited to hear the innovative ways in which regulators are viewing quality system oversight of these new technologies.

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00:38:00,780 --> 00:38:10,954

My three key takeaways are the strength of AI is in its ability to recognize patterns and provide outputs based on those

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00:38:10,954 --> 00:38:11,755

patterns.

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00:38:12,155 --> 00:38:18,875

It is important to recognize that AI is not making decisions, it is providing outputs.

433

00:38:19,275 --> 00:38:20,875

Only humans make decisions.

434

00:38:22,260 --> 00:38:22,660

Doctor.

435

00:38:22,660 --> 00:38:32,820

Kiang's thoughts on approaching change control from an overall perspective versus trying to use current thinking and methods really shines the light on the way

436

00:38:32,820 --> 00:38:38,865

forward for adoption and innovative application of AI and related technologies.

437

00:38:39,744 --> 00:38:48,625

And lastly, first movers just need to think through how these technologies will be used and apply appropriate risk controls.

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00:38:49,760 --> 00:38:54,800

I'd like to thank David and Tina for their engaging and thought provoking conversation.

439

00:38:55,280 --> 00:38:59,440

I am really excited about the potential these new technologies offer.

440

00:39:00,800 --> 00:39:07,644

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

441

00:39:08,284 --> 00:39:17,724

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

442

00:39:18,909 --> 00:39:22,989

On behalf of all of us at ISPE, thank you for listening.

443

00:39:23,309 --> 00:39:30,850

And we'll see you next time as we continue to explore the ideas, trends, and people shaping the future of pharma.