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GREG HORNE: Hello, and welcome to *The Health Pulse*, a podcast exploring how analytics in the health and life sciences industry is growing and the convergence that's impacting all our lives. My name is Greg Horne, and I am your host for the series. And as always, we'll be joined by my expert guests to discuss a topical subject.

And on this week's episode, we're going to turn our attention to the pharmaceutical supply chain, with our guest Grainne Lynch. And she is a senior manager and traceability lead at Accenture. And we'll get into more of that in just a minute. But before we do, we still want to hear more comments and feedback from previous episodes. We've been covering a fairly wide range of topics around the health and life sciences spectrum. And we like getting feedback at thehealthpulsepodcast@SAS.com. So please, keep those comments and questions coming. It is helping us shape the future of the series and where we're going with this. And so just a reminder, it's thehealthpulsepodcast@SAS.com.

So without further ado, let's move on to this week's guest. Grainne, welcome to the podcast. Thank you for joining us today. Could you just do a quick introduction, please?

GRAINNE LYNCH: Sure, Greg. Well, thank you so much for inviting me today. It's really super. I love all opportunities to talk about the work that I do. I'm very passionate about transparency and traceability, so any opportunity to talk about that, and myself as well, I do appreciate. I think we have plenty of things that we can spotlight in our supply chains. So that's wonderful.

So maybe you can tell by my accent, I'm Irish. I live in Ireland. I live in Cork, which is in the south part of the island. And I live in a small village near a town, near the city of Cork. I have a window outside where I can see green fields and trees. And I'm extremely, extremely lucky.

So I work for Accenture, by way of an acquisition. In fact, the company I was working for in Cork, which is involved in manufacturing execution systems, called ESP, was acquired by Accenture a couple of years back. And so Accenture now has a bolt-hole down in Cork city, in a wonderful place, which is surrounded by some manufacturing companies in the pharmaceutical and health care sector. So we're in a really great space to help pharmaceutical companies to look at their processes and try to get digital and do lots of wonderful work. So that's me, in a very small introduction.

GREG HORNE: Fantastic. And as always on the podcast, we like to find out what do you do when you're not working with Accenture. So Grainne, tell me about a hobby or an interest or something that you have outside of work.

GRAINNE LYNCH: Well, we could be here all day talking about those things, because that's where life happens, isn't it?

GREG HORNE: Yeah.

GRAINNE

So I mean I've got a family. So they take up plenty of my time. But what I'd love to tell you about a new passion I've found. So Ireland is an island. And one thing that has massively changed in the last 12 months is the amount of people going into the sea to swim. So I've hopped on this bandwagon. And I've started sea swimming. Not a very strong swimmer, so I've decided to take lessons. And last night, I took, I think, my eighth lesson. And tonight is my ninth. And it's just amazing. I just don't think I could go back into the swimming pool. It's not warm. I wear a wetsuit. I sometimes wear gloves and boots and a hat. I wear goggles, even in the summertime. But it's lovely, because what do you feel? First, you feel the buoyancy of the water. Feel the freedom of the-- you can feel the wind. And you can see things change as you swim along. The landscape changes as you move from one place to the next. So it's been amazing. And it's about discovery of what's on my doorstep. So that's what I wanted to share with you.

GREG HORNE:

That's fantastic. I have swum in the Irish sea. And I can vouch for the fact that it is extremely cold. So, yes, fantastic. And I've seen an uptick here, actually, swimming in the Great Lakes. So interesting times for exploring where we live. But that sounds a really interesting hobby. So thanks for sharing that with us.

So I want to go back now a little bit and think about your life before the world of coronavirus. So for a lot of people listening today, this idea of traceability and supply chain in pharmaceuticals is going to be very new. So talk to me about what you have always done in the past and what does the concept of traceability really mean?

GRAINNE

LYNCH:

Sure, and that's really helpful a way to start a conversation. So for the last, say eight years, maybe a little bit more, I've been helping pharmaceutical companies to simply become compliant with supply chain legislation. And that legislation is related to preventing counterfeit medicines from entering the supply chain. In different countries, it's been called a few different things. But this legislation has been evolving from country to country.

But ultimately, has a couple of very common capabilities that it calls out. It's been asking for pharmaceutical manufacturers to mark their products in some way with a code. And for that code to be unique to that pack. And for some sort of checking to take place, to make sure that their pack is authentic, so that it can be verified to make sure that it is where it's come from. That it's a genuine pack.

So in the United States, we have some legislation in that space called Distributed Supply Chain Security Act. In Europe, we have the Falsified Medicines Directive. And I've been helping companies to comply with that. And that was really quite-- OK, well, here's the legislation. Here, after some time of deliberation and discussion through the industry, some requirements have dropped out. And they've become solidified. I've helped companies to interpret them. I've been helping companies to comply with them, to meet their deadlines, et cetera.

So that was my world prior to COVID-19 coming out. And that introduced a capability around track and trace, at a unit level. So at an individual box level.

GREG HORNE:

That's fantastic, Grainne. That's really interesting. And I think our listeners now have a good foundation to understand what kind of some of the issues are. So let's think about this idea of coronavirus. Now, everybody has become an expert in Pfizer and Moderna and AstraZeneca. And they supposedly feel they know all about how cold chain works and the rest of it. But from your perspective, how has coronavirus changed your role? And what have you been doing in that space in the last year, 18 months or so?

GRAINNE

LYNCH:

That's a great question. Previously, I was using serialization, track and trace, as basically a license to operate capability. Something that was just work that I was doing just to meet legislative requirements. But now it's changed. What we're seeing is now that the industry has come to deliver on those legislative requirements. And they're now compliant. It means that now what we can do is we really need to start looking at end to end traceability. So that legislation was really for finished goods, saleable units of pharmaceutical product going out to a patient, in a pharmacy, or in a hospital, primarily.

And now what that has prompted me to do is to start to think about track and trace throughout the whole supply chain. And by the whole supply chain, I mean end to end, cradle to grave. I mean from the time that a product is imagined, especially in the pharmaceutical industry in our clinical trials processes, when we start to think whereabout raw materials for those products need to be sourced. How planning is done. How those products are produced and manufactured. How fulfillment is done. How distribution is done, et cetera. All the way out to what is the reverse supply chain looking like? What is a reverse logistics solution? And also what is end of life looked like for that product?

And by looking at this transparency path, by looking at transparency in each of those buckets, which is a pretty typical supply chain, what is now being required. Which what we're seeing is a huge trend, not just in pharmaceutical but in other types of industries, is we're seeing increased trends by consumers, by customers, and by buyers in certain places, to request, not just the product that they're buying, but the history of that product.

So the history of that product is, in fact, it's traceability information. So where the product has come from, where was it manufactured, when it was manufactured, how it was manufactured, where the materials were sourced for that manufacturer, for that product. And by what process was that pharmaceutical product approved, et cetera. And what does that entire journey look like? And that's becoming more and more--

In fact, pharmaceuticals is a leader in this space, because we already have GxP requirements. We already have so much information. And it's held on record for a long time. Our auditing processes and our validation processes are such that we can actually give that information. And we can give the information of the reassurance of the provenance of the product as it's developed. We can do that. But it's a trend, now, coming in to other industries that information now needs to be provided to buyers, to purchasers of products, even in other industries, such as food and beverage and consumer goods products.

So what's changed for me is that a simple license to operate capability that was driven by legislation, where I worked for many years, has now become so much broader and so much more impactful across a number of different industries. I'm seeing that track and trace legislation-driven requirement moving end to end in supply chains. And I'm seeing it moving into other industries across the globe. And I think it's been driven by people, by consumers, who want to know where their products are coming from. And it's been driven by another thing that I haven't mentioned yet, which is that it's been driven by the need for companies to become much more responsible, in terms of the types of products they're producing. How they're producing them. And how they're going to look after their entire lifecycle.

GREG HORNE: Fantastic. That's great. There's a lot there to digest and consume. I think one of the things I want to pick up on straightaway is this idea of data. You talked about data in there. So we've had a few people talk about, now, it's not just good enough to have data, you have to know what data, and the right data, and remove bias from that data. So can you just tell us a little bit about that piece as well?

GRAINNE LYNCH: Yeah, that's a really interesting question. So we don't have any problem with data. Sure, we don't. Greg, like we really don't have any problem with the amount of data that we can get from any particular source. Let me just think about supply chains again, because this is my space. So we're thinking about supply chains, ingredients are moving, materials are moving into processors and in and out of systems. And we have no problem with generating lots of data points around that.

What we do have a challenge with is really figuring out what is the most interesting information that we can derive insights from in that data. So we've got IoT devices that can tell us about movement of product. We know about conditions of products, such as temperature. We can know when doors were opened and closed. And we can know who opened and closed doors. But what does that even mean, when it comes to ensuring-- in biopharmaceutical processing, for example-- what does that mean when we look at the quality of the product? Does that mean that the product is within the required quality or not? And what do we need to derive from the data that gives us information that allows us to take action in advance of an issue happening?

So let me just give an example of that. So no problem with access to data. When we're in a, say, a manufacturing environment for a biopharmaceutical product, they tend to be cold environments. They need to be kept at certain temperatures. Products are typically kept within large fridges. Time out of refrigeration is something that is managed extremely rigidly and rigorously, by quality and by manufacturing personnel. So we've got a lot of devices that helps measure that information. And of course, products need to be outside of refrigeration for certain amounts of time. But, obviously, that needs to be managed, so that doesn't extend beyond and be wasted in some way. So there are tolerances to the amount of time that products need to be out of refrigeration. So we've got IoT devices that can measure all of that.

But the IoT device is just going to be recording a particular temperature at a particular time. So we need to derive insights into that. We need some software that sits on top that will actually tell us, this is time in, this is time out, and you have this many minutes to make a decision, take an action, and put that stuff back in the refrigerator. And if you don't do that, then we need to derive understanding from that as well, which means that the product will be spoiled in some way.

So that's what we're seeing, really, in terms of biopharmaceutical processing. And that's what I'm seeing, in terms of the integration of the manufacturing processes, the physical flow of product as it moves through manufacturing, and the insights that can be derived so that products can move faster and not be wasted.

GREG HORNE: Brilliant. That's great. And that leads us I think into our final question, which is the future. What is next? Where do you go in supply chain traceability? What's your big focus area for the future? And the next however long?

GRAINNE LYNCH: Yeah, sure. So if you want to stay within the biopharmaceutical industry, I think that data-driven solutions are absolutely going to be top of mind. We've got a huge amount of capability in science. And there's an awful lot of unmet need when it comes to patients getting different types of medicines that can meet their need in terms of-- cell and gene is one area, actually, which is very specific to individuals, because it's based on their specific DNA.

But there's a huge amount of growth in biopharma. We're actually seeing now that the future is this growth. Just to give you a little data point on that. Accenture did some research, and we project that biopharmaceutical industry will grow in revenue by 81% over the next five years. And overall, like not just biopharma, but in pharma alone, will grow by 61%. So that means that we have a huge amount of capability for growth. But at what expense this revenue is going to come?

So if new products are being developed, and it needs to be accessible to people. It needs to be at price points that are affordable, in some ways, because there's-- These products can be very expensive in some ways to try and repay for the amount of study, and the amount of development, and the years and years of innovation that goes on behind them. But simply just charging the highest price point isn't necessarily a sustainable way to move forward. So I think that there really probably needs to be a shift in how we think about the shared value of these incredible capabilities and this incredible technologies that we have, that are both new in terms of biology, but also new in terms of science and data exploration for developing them. So that's one thought.

Secondly, just to go back to the idea of transparency and traceability, what I'm really, really seeing now is that, as we develop more and more products, there's more and more confusion. There's confusion, not only at patient level, which I can relate to very well. But I'm sure there is quite a lot of confusion amongst health care professionals. There's increasing numbers of products out there. There's increasing amounts of issues that can happen with interactions of product. And for sure, a lot of the doctors that we deal with, especially, say in Ireland, are general practitioners. They don't necessarily know about the interactions of products.

So I think probably the folks that understand this are really going to come to the fore, in terms of helping people to understand and simplify. And in order to do that, they need to be able to trust in the product they're getting, the information, the veracity of the information, the simplicity of the information, how easy it is to follow, is a really important space. So I think that what we're going to see is an increased amount of effort put into enhancing customer experience.

And I think in the pharmaceutical industry and in health care, we have-- to my mind anyway-- we've two types of customers. We've got patients are customers. And we've got health care professionals themselves who are customers. Because they may be involved in putting a kit together to help with the administration of a product. I think we really need to get clear information to those folks about interactions, about how to use the product, about how much the product is going to cost now and into the future, and also enable ways that information can be fed back in ways that can help to continually improve the customer experience.

And in order to do that, I actually think then we have to build systems and improve systems that already exist, that enhance the information about where products come from and where they're going to. Overall, enhance end to end visibility and transparency across our supply chains to help to build that trust out to those types of health care professionals and patients. That's what I think.

GREG HORNE: That's great, Grainne. Thank you very much. And thank you again for joining us on *The Health Pulse* podcast. It's been a real pleasure to speak to you and to hear a lot about the supply chain, which I think many people just would not have even understood or had prior knowledge to. So thank you for joining us today.

So all that remains really then is for me to wrap up. So thank you very much for listening. Remember our email address is thehealthpulsepodcast@SAS.com. Please feel free to drop in any questions or thoughts based on today's episode. And anything that you may have heard in previous episodes as well, always welcome.

Last thing for me to do is to say I've been your host, Greg Horne. Thank you very much for joining us. Please like and subscribe to get future episodes delivered direct to you. And we look forward to another episode in the near future. Thank you very much.

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