**Ciara Duffy:** Hello and welcome to the RPS Pharmacine Podcast. My name is Ciara Duffy and I'm a member of the English Pharmacy Board.

Our guest today is Rebecca Stanbrook, an accomplished professional with extensive experience in the world of regulatory affairs and clinical trials. Rebecca currently serves as the executive director of regulatory and development policy at Novardis, a colleague of mine. where her primary focus revolves around modernizing clinical trial practices and utilizing digital tools to enhance the field. Rebecca also holds the esteemed position of FPA, European Federation of Pharmaceutical Industries and Association, ICH E6 Revision 3 Topic Lead, and is a member of the Transcellerate Regulatory Council.

Before moving into her current role, she held the position of Group Manager for Inspections at the MHRA. And during her tenure, she held various key positions in good clinical practice and pharmacovigilance, contributing significantly to the development of statutory programs in these fields. Rebecca was part of the pioneering teams that conducted the first statutory GCP inspections in the UK. Rebecca's group at the agency played a pivotal role in creating essential industry resources, including the good clinical practice guide and the good pharmacovigilance guide. We're really excited to have her on the podcast to share her wealth of knowledge and insights into the world of clinical trials and regulatory affairs. Rebecca, welcome to the podcast.

**Rebecca Stanbrook:** Thank you, Ciara. Thank you very much for the warm introduction. I guess one thing I should mention is that these are my own thoughts, not those of my employer past or present, or any other organization that I'm working with or volunteering for, and I'm absolutely thrilled to be part of this podcast series.

**CD:** So let's start. at the very beginning. Can you tell us about your journey to becoming a pharmacist?

**RS:** Yes, of course. It's a very straightforward one, actually. My mother actually worked for a small retail pharmacy near home. So I used to go down sometimes to help out. And both pharmacists that she worked for there were very supportive and encouraged me into the profession. And I guess I was always more interested in how things got onto the shelf. So what was the testing behind them? How were they made? And so...pharmacists always were very encouraging and of course my mum too.

**CD:** Great. You started your career in industry as a pharmacist in clinical trials, is that right? Yes, that's correct. And what was it really that interested you in clinical trials from the offset?

**RS:** Seeing products on the shelf in the pharmacy and interested to know how they got to the shelf. I was particularly interested in, well, what's the testing behind them? How do you make sure that a product actually works? and it's safe. So I guess that was really sort of the interest. And one of the natural routes in for a pharmacist is as a clinical trial supplies pharmacist. And I was very fortunate to be able to do six months of my pre-registration training at a pharmaceutical company. And so part of that was actually working in clinical trial supplies. And it was really absolutely fascinating area, I must say. And so I think that was sort of the inroad into sort of the clinical research field.

**CD:** It's interesting how that first job has shaped your career path, isn't it?

**RS:** It really is because pre-reg is great because you do get to see different aspects of industrial pharmacy in that six months. So very fortunate to be able to get a pre-reg where I had sort of six months in the industry. But I did sort of work in lots of different areas within the industry. So I went to the chemical manufacturing place. I've made tablets, I've made syrups, I've packed supplies, worked in medical information. So there was sort of a good grounding. So you can see all these different entry roads for a pharmacist into the industry.

**CD:** So over the course of your career, you spent 11 years at the MHRA with this convent to the HRA during that time. What were some of the... biggest challenges that you faced during your time working for government and how did you navigate them?

**RS:** I guess working for government is very different in some ways from working for the industry. Besides the fact that I still feel that I have a responsibility for public health, I guess first and foremost you're a civil servant, so you've had to have signed some form of secrets act so you don't divulge information that you shouldn't. Then of course the politics, or should I say the neutrality of the politics. So around election time, course you shouldn't particularly making any parties and statements for one party or another and then also you've got several bosses so you know your immediate bosses within the organisation but you get questions coming from ministers and you've got a set time frame to answer those questions so that can be quite pressurised and during my time at the agency the Freedom of Information Act came in so we then got a lot of questions for inspection reports. which required quite a bit of redacting because of that potential intellectual property issues. So I guess that all went hand in hand with sort of the provision of information. So, you know, that's part of the role of the agency. It isn't just about making sure that the products are safe and effective and that the companies have organised their compliance with any particular registration appropriately. It's also about providing information. So that's why we wrote two books, one on good pharmacovigilance practice and one on good clinical practice. And really the idea was to shed additional light on expectations in legislation around those areas. And also to give practical examples of what happened when we were inspecting.

**CD:** So what were good practice ideas and all you might want to consider if you're gonna be doing that.

**RS:** When UK was still in the EU, of course the MHRA had interactions with the European Medicines Agency. So that was great to liaise with other colleagues from different European inspectors. assessors and also agencies globally when we put on training events. So thinking about working for the HRA, for the last two years I was at the agency, I was two days a week seconded to the Health Research Authority, which was new. So the first year was about helping shape what the HRA was doing and also the interactions they would have with the MHRA. And then the last year, I was bringing in a confidentiality advisory group from another agency that was being made default. And this also has helped me with my role in ICHE6 because that was about using data. And of course, we're also gonna be talking about the use of real world data. So I think navigating government, it's the same as you navigate any job, you just do the best job that you can.

**CD:** Well, you've done a great job, particularly with the publications. Then over the course of your career, you've also held a number of different roles in the pharmaceutical industry. What sort of activities have you got involved in within the various roles?

**RS:** So perhaps I kind of almost go through sort of a potted career history. So I've been a clinical trial supplies pharmacist in that role. I was interpreting the protocols that had been written to conduct the clinical trial and determining a packaging strategy for them. So were the trials blinded in any shape or form? Did we need to source particular materials? So comparators, the packaging that was used. And then would of course determine who was going to pack them and when they were going to pack them. And of course then there's a release process. So you need to make sure that everything you packed is in accordance with good manufacturing practice. And then of course you can't release to the site until you've got the regulatory green light from the documentation at the site so that they've got ethics approval and that the actual trial is approved in that country for being able to be conducted. So it could be quite pressurised because basically, you're the last line before the participants would receive the product. So then I've also worked in clinical quality assurance, and that's where in a number of companies I supported the therapeutic area. So I'd look at the protocol to make sure requirements with GCP were met. But then we'd also get involved in the auditing of investigator sites to make sure that they were conducting the trial in accordance with the protocol and GCP. And then also we had a role in system audits. So you wouldn't be specifically looking at a clinical trial. You'd be looking at the processes that were involved across all trials. So you might sort of look at, well, how is a database locked? Then I've had a role in compliance, supporting inspections. So including inspection preparation. So preparing teams for what to expect during an inspection because not everybody will get inspected during their lifetime. And of course, hosting the inspection. So providing the documents. and keeping inspectors up to date with where people are coming from to come in and talk to them. We also had a role in looking at metrics to determine levels of compliance. And then of course, serious breaches. So where there's a potential breach of GCP which could impact on participant safety or the data integrity, then you need to sort of assess whether that needs to be reported into the authorities. And then laterally, I've been working in the policy group in regulatory affairs. where we've been involved more in this external work that we mentioned, particularly involved in ICHGCP, the International Council for the Harmonisation of the Technical Requirements for Pharmaceuticals for Human Use, which I'm absolutely thrilled to be working on and really appreciate the support of the company with that.

**CD:** For those who may not be familiar with this, can you give us a brief overview of what ICH is and the change from revision 2 to 3 and why it's so significant?

**RS:** Yes, of course. And as you can imagine, all acronyms never have an easy title to them. This one's particularly tricky. The International Council for the Harmonisation of the Technical Requirements for Pharmaceuticals for Human Use. Luckily, we just shortened it to ICH. So this was established over 30 years ago. and it was established by three regulatory founding members and three trade association founding members.

So US FDA, PMDA in Japan, EMA in Europe and their corresponding industry associations. So Pharma in the US, FPA as you mentioned earlier in Europe and JPMA in Japan. And basically the idea was to have some harmonization of standards for medicines across the regions because there were lots of different expectations across the regions.

Now, over the years, this has expanded with more regulatory members, more industry association members, and also other international organisations that might be impacted by the guidelines that are produced. And of course, these regulatory members must implement the guidelines into their legislation. And there is actually a hierarchy of guidelines, believe it or not. And when you join as a regulatory member, the first three that you need to implement are the tier one guidelines. So ICHE 6. which is GCP obviously, Q1, which is about stability, and Q7 about good manufacturing practice for active pharmaceutical ingredients.

So I guess if we look at E6 then, we could actually do a whole podcast on this, Ciara, because of the changes. So in terms of ICH E6, we could perhaps have a whole podcast on that, Kiera, because there are quite a raft of changes. Of course. To put it in a nutshell, we wanted to make it more future proof because you've got all these different types of trial design, you know, these innovative trial design. So platform, umbrella, basket trials. And then you've got trials that are using decentralized or pragmatic elements. And of course, use of real-world data in trials. We also wanted to make the text more proportionate. So if you've got a product already on the market that's in your trial, perhaps there are less risks associated with that because you've gotten... better understanding of the profile of the product. But also we wanted to get sponsors to think. What's the scientific question? How is it best answered? What data do you need to answer that question? And what are the risks and how do you mitigate them? In one word, it's just “think”.

**CD:** What were the most significant impact to patients for the new update?

**RS:** That's really interesting because it's all been part of this GCP renovation. So in 2017, there was a reflection paper coming from ICH. which talked about not just E6, but also about E8, general considerations for clinical studies. So it's broader than your intervention on clinical trials on investigation of product. And the point about patients is E8 came out first and it really talked about involving patients in the trial design or even the development program. So perhaps you don't need to involve patients at every single trial, but at your development program, then involve patients.

Because what you can see is that by involving patients in the design of the trial, you get better understanding of the disease and what's the impact for them on the disease. So we always use the example of multiple sclerosis patients. We were always thinking about the six-minute walk test when actually patients were, well, I'd really like to get a good night's sleep. So it's involving patients. So patients are a lot more engaged in clinical trials than they ever were.

**CD:** Great to see that being championed. So you sat on the Industrial Pharmacy Advisory Group at the RPS. What is this group and how can RPS members get involved with it?

**RS:** IPAG, it's basically a group of industrial pharmacists chaired by Suniyana Shah. And we meet quarterly to discuss matters which might have implications for pharmacy and particularly the industrial side of pharmacy. We might be talking about upcoming general pharmaceutical legislation that is out for consultation at the moment. And if you want to get involved, if you're an industrial pharmacist, you can indicate this in your membership when you're shown what your interests are in RPS. And so you will then get the newsletter that comes from the European Industrial Pharmacists Group.

**CD:** You've held many voluntary positions. How do these roles such as that in the IPG help to shape your career and expand your professional network.

**RS:** Well, currently I'm sitting as Vice President of Technical and Professional Development at the IPG. So I'm responsible for organizing webinars and commenting on consultations which can affect industrial pharmacists. So for me, volunteering is about giving something back to pharmacy. I've had a wonderful career in pharmacy. It's opened many doors, which is why I really want to support others. But of course, there's other plus sides because... you get to meet wonderful individuals who are involved in these voluntary organisations because it is time consuming but it is very rewarding.

**CD:** Yeah, I would agree. It's great to get involved in any voluntary opportunities that you can. So in your opinion, with your wealth of knowledge from regulatory and policy, what are some of the biggest trends and changes we can expect to see in clinical trials over the next few years?

**RS:** That's a really good question. And I don't think you can answer the question without actually mentioning the impact of COVID. Of course, the pandemic killed millions of people, caused disability for many and trauma and hardship in some shape or form for all of us. But it did help speed up the evolution of clinical trials. The industry is notoriously conservative when it comes to embracing new technologies. However, with the pandemic, we were forced to because we'd got participants in trials who we needed to keep supplied with medication. for their own benefit as well as else. So we had to devise ways of making that happen. So as a consequence, we spread out the introduction of home nursing, remote visits, use of electronic consent and even direct to patient shipping of investigational products.

And of course, there's sort of an explosion in digital technologies as well. So many of these in the past, we kind of dipped a toe in the water as an industry but not embraced fully, but then we needed to do that in the pandemic. So it really sort of did accelerate it. So if I've got a crystal ball, I think we're gonna see more of this in the future, more complex innovative trial designs. And going back to your question about patients, I think we'll see lots more patient centric trials. So bringing the trial closer to the participant and also along with the use of real world data as well.

**CD:** Do you have any thoughts on how artificial intelligence might shift trials in the future? That's absolutely fascinating question.

**RS:** And it's actually a question that has been pondered as we speak, because artificial intelligence was used during the pandemic as well. So you can imagine how many spontaneous reports there were of adverse events as a result of the vaccinations, thousands, millions. So actually some of the agencies used artificial intelligence to try and sort of work out where there was a pattern. course, AI can be a bit of a black box. Well, how does that work? And it's how does it learn? And how do you demonstrate what it's doing now after it's learnt something is still appropriate. So I think we're still in a learning phase, but I think you're going to see more and more use of AI across clinical trials as well, not just about trying to look at trends in adverse event reports. There's a few papers out at the moment on AI use in various aspects. I think FDA have now got one out about sort of using manufacturing.

**CD:** Yeah. So who would you say are some of the individuals who have inspired you the most throughout your career? And what is the best piece of advice that you've ever received?

**RS:** Let me answer the last question first. A pharmacist doesn't necessarily know the answer, but they know where to look or who to go and ask. So that's actually a quote from one of my mum's pharmacists, Mr. J.M. Peace. He was one of those people who inspired me on my pharmacy journey. He owned a pharmacy and was so encouraging that in an area outside the dispensary, right out the back where there was no stock, he brought in one day a sheep's lungs, heart and eye, and we dissected it there in the back. So very, very encouraging. And also I have to thank her first pharmacist, Mr. Mounsey, although I was younger then. when he owned the shop. He was always interested in how things were going at school for me and always happy to have me helping out wherever I could.

And then of course there's my mum, Patricia Harvey. Throughout my career she's always been very supportive and I guess without her role as a dispenser I probably wouldn't have set foot in a pharmacy other than to go and pick up some medication. Inspirational people indeed. How would you encourage others inspired by your career path to start getting involved in clinical trials or regulatory policy? I always say that I was lucky that I was in the right place at the right time. But you do make your own luck. And I think my curious nature has kind of like taken me along this career path. So I think a piece of advice I would give to anybody is that you're a long time in a job so make sure it's something that you enjoy.

As for getting into the industry. As I said before, I did six months pre-registration in industry, so I was one of the fortunate ones, but it is certainly possible to get into the industry as there are so many different roles for a pharmacist. I think a pharmacy degree is great because it's so broad, it can open up many doors. I think you just have to need to knock on the door and see what's the other side.

**CD:** And lastly, can you recommend any books, podcasts or other resources that have been particularly helpful to you?

**RS:** I think there's quite a few books on clinical research, but I think the grey guide still stood the test of time. So if you want to know how to conduct a trial, the principles are the same as they were 12 years ago when we wrote it.

But then of course, websites. RPS has got a great website where you can get access to what's happening with IPAG. Then you've got EIPG, ICH, MHRA and EMA websites. So I'd always consider looking at websites for health authorities because there's some great information there. And if you're interested in electronic health records, I can certainly recommend a book called The Digital Doctor by Robert Bacter. Absolutely fascinating read. One of these complete page turners.

**CD:** Sounds like some books that I need to look up. Rebecca, thank you. This has been such a great discussion.

We've covered so much from the starting of your pharmacy career in the dispensary, sparked by your mom's encouragement. And you wondering how the products got on the shelf, to how they were tested and how they were stable. You had great guides such as Mr. Peace, whose quote of a pharmacist might know the answer to the question, but they will know who to ask. It's definitely sound advice.

We covered the differences between government and industry, some of those key differences with the considerations that come along with being a civil servant. interesting to cover the provision of information as a role in that job in addition to patient safety and product quality and efficacy.

We talked about the application of clinical trials and we've gone through a little bit of a brief overview of your career from interpreting the clinical trial protocols to understanding the packaging strategy. You've really had a varied and wide spanning pharmacy career from industry to government and back to industry again. with clinical quality assurance roles in auditing and looking at policy groups to your current great work on ICHE6, but volunteering and how important it is to give back, but also how beneficial that can be for network and knowledge expansion.

We talked about some of the people who have inspired you most and how you would encourage others to get involved in clinical trials and in regulatory policy. And I think a really great piece of advice was to ensure that you choose a role that really ignites your curiosity because you'll be in it for a long time.

And you've talked about the advantage of pharmacy as a career and how you really can go into so many different things. And I think that's really important. Thank you so much for your time today. It's been really great.

**RS:** It's an absolute pleasure. Great chatting with you, Ciara.