Podcast – Jo Merrifield interviewing Lorn MacKenzie

Transcript

Jo Merrifield speaking with Lorn MacKenzie

Time	
0:10: (Jo)	*Welcome to today's episode of Clinical Research Career Conversations brought to you by Edinburgh Clinical Research Facility. My name is Jo Merrifield, and today I spoke with Lorn MacKenzie, a Quality Assurance Manager in ACCORD, which is a joint R&D and sponsorship office in Lothian. We discussed the role of QA in research and Lorn's journey to become a QA Manager. Enjoy.*
0:40: (Jo)	*So hello. Today I'm with Lorn MacKenzie. Thanks for joining me. She's kindly come in before we deliver a Good Clinical Practice (GCP) course today, and I thought it'd be a great opportunity to speak to you and again, this podcast is all about careers in clinical research. So it'd be really nice to hear your story if that's OK.*
0:59: (Lorn)	Yeah, of course.
1:00: (Jo)	*I've introduced you as a quality assurance manager in ACCORD, which is the Joint University of Edinburgh and NHS Lothian Sponsorship and R&D Office. So could you start off by talking about what is the role of a quality assurance manager and why is it so important to have people like you working in clinical research?*
1:20: (Lorn)	Yeah, sure. So the role of a QA manager is, I guess we're essentially there to make sure that clinical research is being conducted to an established protocol, to GCP and to any applicable regulatory requirements. So there are a number of ways that we fill that role within QA. So most QA managers have responsibility for a quality management system. So that's having procedures, policies in place that kind of start off with trial set-up and go all the way through to the reporting of results. So a big part of the job is kind of overseeing that quality management system and the procedures, and an element of that is also training, so we do a lot of training on those procedures too.
2:08:	And also a big part of the role is risk management. So what we do is we try and identify potential issues before they become serious issues. In ACCORD, we have a risk-based audit programme. So this is an audit schedule put together and in QA we come in and we will audit our internal systems, so making sure that the safety reporting system, the monitoring system is in compliance.
2:38:	We do facility audits, so this is where we go out to any labs, for example, that are analysing clinical trial samples, making sure they're running as they should be. We might go to scanning facilities, we might go to manufacturers of drugs, and then we also go into clinic areas, who are actually running, doing the work and kind of making sure that they're complying to everything.
3:00:	Another element of that is we might do for cause audits. So if we identify an issue, we might then go into an area and do a bit of a poke around and see what's going on.
3:10:	And then I guess another aspect is we are responsible for hosting MHRA inspections, so they're the UK regulators authority in the UK, but that will involve getting staff ready for inspections, preparing any procedures, policies they need to do, hosting the

actual inspection itself, and then working with those inspectors to close their actions and then implement actions.

3:36: So it's quite a varied role, but I guess the reason that QA is so vital is we are effectively there trying to safeguard the participants and also making sure that the results that are being generated from these research projects are of the highest quality, because ultimately, I mean, that's what we're basing future medicines on. So that needs to be robust.

4:00 (Jo): *Yeah, of course. And it sounds like a huge mountain of work that you've got, and I know in Lothian there's hundreds of studies ongoing aren't there?*

4:10 (Lorn): Yeah, hundreds.

4:11 (Jo): *And I can imagine they're of different complexity as well. So some will be, you talk about this risk, some will be very low risk studies, but then with the new advanced therapies etc, we're going into really quite risky areas, which is still important to carry out, but it's about mitigating that risk, isn't it?*

4:26 (Lorn): Exactly, yeah. I mean we do see, when you're looking at thousands of projects and we have your huge complex platform trials right down to your staff surveys, student projects, which are still really important, but you have different risk proportions attached to those.

4:42 (Jo): *Yeah. Wow, so your head must be quite full of regulations and policies, and I guess it's about knowing where to look, and…*

4:51 (Lorn): That's part of the challenge of the job, is knowing what information to pull from, certainly, yes.

4:56 (Jo): *Yep. But it must also be really interesting in having been involved in some of these different variety of different trials, and I guess every day must be a bit of a school day learning what's…*

05:06 (Lorn): Yes, and that's why I'm quite suited to this role because I do like to continually learn and keep abreast of things that are going on. So the role does fulfil that in that you are constantly learning and trying to interpret how different pieces of guidance and legislation all fit into a real world situation, and I enjoy doing that.

5:27 (Jo): *Great. And I've asked a few people this and I tend to get the same answer, so I wouldn't be surprised if you say the same, but is there a typical day and what might it look like if there was?*

5:39 (Lorn): So a typical day… It's predominantly an office-based role, unless we are going out and auditing facilities or clinic areas, but it starts off like most people's days, which is checking emails. We do get a lot of QA queries into our mailbox, and we are there to provide regulatory support and resource to research teams. So yeah, a portion of my day is spent answering those QA queries from different teams and guiding them on best practice.

6:10 I guess also I'm checking compliance with procedures, protocols. We've talked a lot about risk management and making sure that if we're running a regulated trial that those risks are identified, we put in mitigations and we put in an audit plan for that.

6:28 But yeah, it is quite a varied role. I mean, some days I could spend the whole day preparing for an audit or getting my teeth sunk into a new protocol. Other days I could be focusing on quality improvement, which I also quite enjoy doing. So it is quite a balance of problem solving, collaborating with other people and then trying to fulfil those QA activities.

6:51 (Jo) *And so you say it's quite office based, but there is times where you have to go out. Has that changed since the pandemic? Are you…?*

6:58 (Lorn) Yeah, certainly, I mean the pandemic changed things for everyone, but we switched to doing a lot of remote desk-based audits as part of that. So before, we would maybe always go on site to look at systems and procedures, but because technology has moved on quite a way with Teams and other ways of sharing documents securely, it means that we can do it remotely, which is… good things, bad things about that. I mean, I feel sometimes when you go on site and you're actually speaking to somebody, you can get a lot more information out of them. And when you have a document set in front of you, it's a lot easier sometimes to kind of pull that thread and then see where it takes you, where if you're doing that remotely, it's just a bit different and they actually take longer to do them remotely. So I try and do them on site where I can, but yeah, it's kind of a mixture at the moment.

7:48 (Jo) *And what would you say your favourite aspect of the role is? What do you enjoy most?*

7:53 (Lorn) So I guess what I like most about the role is probably the exposure to all aspects of the clinical research life cycle. I'm quite fortunate that I get to be involved with the very beginning of the trial where we're designing protocols right up through to reporting results. So it's quite nice to see that trial for the course of the cycle when we go through that process. I'm also quite lucky that I get to work with a lot of different organisations and individuals, so whether that's investigators, lab staff, it's other QA professionals. So I feel like you get to learn a lot of different perspectives.

8:28 I like answering QA queries. There's something quite nice about being the go to person, about how you interpret the regulations or guidance and providing clarification to other teams, which is quite fulfilling.

8:40 And also, because I do work for an academic sponsor, we're quite lucky in that we have a lot of research running across different therapeutic areas. A lot of the big commercial companies focus on maybe one therapy where, because we're dictated by our investigations locally, it's kind of what they're interested in, so that kind of keeps it fresh.

9:00 Yeah, I think ultimately it's fulfilling knowing that in a small way that you're contributing to improved healthcare patient outcomes, which is why I get my motivation from.

9:11 (Jo) *Yeah, yeah, sure. That's great. So, why did you choose a career in QA? Did you choose it or did you just land in it? How did you…?*

9:20 (Lorn): Yeah, to be honest, I'm not necessarily sure I chose a career in QA. I probably did fall into it. After my undergraduate degree - so I did a life science degree in neuroscience - so after that, one of the first jobs I got out of university was working for a commercial Phase 1 company. So they were focusing on cancer treatments. So I was working in the data management team, which was a great first exposure to clinical research, but I knew quite quickly that data management, it just wasn't for me.

9:49: So I did what any sensible person did and panicked and quit my job. I got on a plane and flew halfway round the world. So I ended up in Australia for a period of time and I worked for a medical legal consultancy firm. So they were providing independent support to people who had workplace injuries and were trying to claim compensation.

10:12 (Jo): *And that was in Australia?*

10:14 (Lorn): It was in Australia, yeah, so it was in a clinic, so it was working with other doctors and staff within that role, but I was part of the patient support team. So I got to kind of work closely with the patient and kind of guide them through the process that they were going through. And I enjoyed doing that and what it made me realise is when I was working in that commercial Phase 1 company, which was in a business park on a motorway in the middle of nowhere, you kind of forget when you read protocols that there are patients at the end of those protocols.

10:44: I think working clinically, I mean not clinically, but kind of working in a clinic in that setting, you got an idea that, well there are actually people behind these. There are people going through research, procedures that It's quite nice to support them, so that was quite nice.

10:58: So when I came back from Australia, I kind of thought that I knew I wanted to stay in research closely. I wanted to do something that was helping others. So I got a role in the research governance team in NHS Glasgow, and then I got a similar role in NHS Lothian. And then it was just by chance that an opportunity came up in the QA team, because from all the jobs that I had, what I liked most about those jobs was fixing issues and driving continuous quality improvements, kind of finding gaps in systems and how you can improve on things. So I kind of slotted quite well into QA in that sense, because that is a big part of the job. And also, as I said before, I do like continuous learning, so having to keep abreast of all the regulatory updates just in the UK alone - we do global trials as well - so that's more relevant to be on top of. But yeah, I think that's one of the parts I like about the job.

11:52 (Jo): *And can you just quickly - you say you were doing a clinical research governance role - can you talk a little bit about what the differences are there? What is involved in clinical governance?*

12:02 (Lorn): Yeah, so clinical governance is more about setting up the study and going through that approvals process. So it's about ensuring that there's Ethics involved, you're getting authorisations from the MHRA. It's about ensuring that the study is kind of ticking along – I guess all the right procedures. So in QA you're essentially overseeing that that's been done. In research governance you're the one doing that process.

12:29 (Jo): *OK, that makes sense. Thank you. And you said that you liked the opportunity to learn and constantly develop on the job. Is there any formal training that you've had to go through for a QA role or you've had the opportunity to do?*

12:45 (Lorn): Yeah. I mean, first off, to have a role in QA, a good starting point is to have a life science degree. When you're reading protocols, it's quite useful to have a bit of science background to understand the mechanisms of how certain drugs could be working. But in terms of having a life science degree, I guess you just really need to have an understanding about GCP and how that applies in the real world setting.

13:08 (Jo): *So that's Good Clinical Practice?*

13:09 (Lorn): Yes, sorry.

13:10 (Jo): *No, no, that's perfectly fine.*

13:12 (Lorn): You get used to it just rolling off the tongue. But yeah, I guess in terms of skills, attention to detail is always a good one, being able to work with others, analytical thinking, they're all good skills to have. In terms of what I've done, when I joined ACCORD, I was quite fortunate that I got to go through the University of Edinburgh Clinical Trials Masters course. So this is perfect for anyone who wants to do a deep dive into clinical trial design, looking at conduct, analysis of results, and it's a flexible course. So I did this part-time over three years, which meant that I could continue to work whilst advancing my career. So I really enjoyed the course, so much so that I actually came back and taught on the course.

13:57 (Jo): *Oh brilliant.*

13:58 (Lorn): So, yeah, I led on the QA and monitoring module. So I taught that and then also did a tutor role as well.

14:05 (Jo): *Yeah, great. And if someone was to want to follow in your footsteps, maybe they're listening and think, oh, actually that's something I might be interested in, what kind of advice or tips would you give them?*

14:17 (Lorn): One thing about QA is to be naturally curious and try and not be afraid to ask questions because that's where you get a lot of the answers from. It's not really just about knowing the regulations, but understanding why they exist and how you apply them. And I guess also key is building good relationships. It's definitely a relationship-building job. So yeah, I think if you approach with the mindset of adding value rather than just policing compliance, you'll go quite far.

14:48 (Jo): *Yeah. And then just a final - thank you, it's been a really, really interesting conversation - from a personal point of view, what is the best piece of professional advice you have ever received in your career?*

15:00 (Lorn): So the best piece of advice I've ever received, I guess in relation to my role, would be to trust but verify. So I guess in QA it's not just about catching mistakes, it's more about trying to build confidence in that process, and what I've learned is that compliance shouldn't just be a roadblock. I guess you want to make sure that everyone is working to the highest standards so that the data that you're generating is reliable and robust. But yeah, I guess in QA it's not just about ticking boxes, it's about that collaborative approach.

15:35 (Jo): *Yeah, that's brilliant. I think that's a really nice place to finish and highlight that QA is part of that process. It's not that roadblock, it is very much about supporting and ensuring the highest quality patient safety and the data integrity.*

15:51: *So thank you so much for joining me today and yeah, thank you very much.*

16:02: *Thanks to Lorn for a really insightful discussion about her quality assurance role. She discussed the importance of QA in ensuring compliance with regulation, safety of participants, and quality of research results. She highlights that it's very much a supportive mechanism with the need for close collaboration with research team and support departments to help facilitate excellence in research rather than being seen as a policing kind of role. She also outlined her career journey to this point and spoke about the development opportunities she has been able to pursue. I hope you enjoyed this episode and found out a little bit more about what it is to be a QA professional in clinical research. Until next time, bye.*