Johner Institute

Legal Affairs Manager in Small Businesses

With Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

Medical Device Insights, a podcast by the Jona Institute for medical device manufacturers, authorities and notified bodies.

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Here at Medical Device Insight, we deal with regulatory issues all the time.

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But we've never talked to the people behind these regulatory

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topics, namely with the Regulatory Affairs Managers.

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And we decided to invite one today and I would ask one of them to briefly introduce herself very briefly what her name is and what she does, what she does, perhaps in her company.

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Yes, hello, thanks for the invitation.

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My name is Nadine Langguth.

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I work in a small company with about 30 employees.

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which has an active implant for leg lengthening.

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Yes, first I studied mechatronics at the Cooperative State University and was in development and then did further training as a Regulatory Affairs Manager and Regulatory Affairs Manager internationally and since then I have been working in this department or I am exactly this department, so there is only one person in our company.

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Yes, I think it's not so untypical for small companies to have one person.

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I think they often have other tasks as well.

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Then for some, I think, it still radiates over in the direction of quality management.

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But what exactly is it like for you now?

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So, what do you mainly do as a Regulatory Affairs Manager?

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So, what do you spend most of your day doing in this context?

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Yes, the focus for me is already classic, the approval of products worldwide and also the maintenance of approvals, i.e. if there are any notifiable changes to the notified bodies or even certificate extensions, as is regularly the case with active implants.

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That is already the focus.

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Another task, which I think is also quite typical, is the monitoring of the regulations.

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i.e. monitor all changes to regulations, laws, standards and so on and then also ensure that it flows into the company, the changes.

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Exactly, these are the typical focal points and then there are a few tasks that maybe, as we have just said, not necessarily regulatory affairs by definition.

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For example, I am still responsible for the change process, i.e.

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any change requests that exist internally are evaluated and categorized by me, whether they are notifiable and what task activities are necessary to implement these changes.

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That's still a big part and basically just the close cooperation with me still with the development regar-

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yes, any verification tests, I work very closely with development, they are all still checked and approved by me, all the test documents, as well as the clinical documentation.

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And a large part is also the topic of vigilance, where I also discussed the topic of vigilance with my colleagues from Q.

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M.

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Close cooperation.

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Yes, it's all one person, that's unbelievable.

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Perhaps we will take a closer look at this part that you have already touched on.

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No, so some, i.e. regular toy affairs, as you said, a lot is now about licensing issues, also for you.

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This means that you are probably the person who then also submits the documents to the notified bodies or to the authorities.

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What would you have to do with these documents yourself?

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So, so to speak, what might now be said about the passing on of these documents.

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because they are probably not only the mail distribution institution of their company, so where do they have to create something themselves or check or redesign something, can they still report to us?

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Yes, so in the meantime I have fortunately gained a lot of colleagues, which means that I am no longer the one who writes everything, as it really was in the beginning, where the product file is for the most part really

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was written by me.

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Now I have more colleagues in the area of development and also clinical affairs and now my job is to check, I would say, give the framework of what the documentation should look like and then, as I said, a lot of reviews of the documents and then the approvals.

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That's right, so the writing.

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sometimes also the checklist ‚Basic requirements', for example, is still created by myself or co-created.

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But many other documents, such as the verification tests mentioned above, I am no longer responsible for carrying them out, but the specifications are checked and approved by me and also the results.

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Wife, you've already answered my next question almost to some extent, but

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You have already described that you are with many others, you have an interface function.

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If you go through that again very briefly, what are the most important internal and external, yes, role departments that you work with?

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Yes, externally quite clearly, the notified bodies and the authorities where the approval documentation is submitted.

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and internally, as I just said, the development was easy, which creates the complete product file for us.

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Clinical Affairs, which is now also occupied by us, is of course also a close collaboration.

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Quality management in principle is in the direction of vigilance, but of course also certificate maintenance.

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Although I also have interfaces, for example to sales,

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because of course both internal sales and field sales have to meet regulatory requirements here, I'll say, where I support my colleague very much, that the requirements are adhered to.

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So actually across the company with a focus perhaps on development and clinical affairs.

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Yes, that means that if you want to know something that's going on in the company, you come to you because that's where all the threads come together.

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I think it also shows how exciting the task is and at the same time probably how challenging the task is.

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If we were to dive into this a bit, what would you say, what are the biggest challenges or perhaps even difficulties that you encounter regularly?

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Yes, I'd say 22

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2 big topics.

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On the one hand, especially at the moment, the ever-increasing requirements and the then in such a small company, as I said above, almost 30 employees and then an active implant, where the regulatory hurdles are of course very high, here somehow they design the implementation in such a way that you meet the regulatory requirements, but it is also simply manageable in everyday life.

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both financially, so we can't afford big software solutions and so on, as well as of course with the human resources that are available to work through all the issues.

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That's certainly one of the big challenges and that's coupled with the topic that if you're the Regulatory Affairs department alone, of course the exchange is also a bit

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difficult or non-existent, is not possible to simply talk shop with like-minded people and yes, perhaps together with someone who can master the challenges that many other small companies certainly have.

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Yes, so I can absolutely understand that, so we are also trying to be able to act even more as a platform as a platform in the future in order to promote exactly this exchange,

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because yes, many 1000 or 10000, so to speak, of their colleagues are there with us in the context.

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And I think learning from each other is a very, very important thing, yes, so that you don't have to reinvent everything.

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You may have now asked us to follow up very briefly at one point, you said that the regulatory requirements, I suspect also now, what happened to M.D.R.

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came along, which, if you were to name 1 now, what is a special burden for you now.

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you could name one.

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Because with regard to M.

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D.

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R., which is due to the increasing number of reports, which is certainly even more required now, because it really simply depends on personnel and effort to create the many reports.

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So, Post Market Update Report and absolutely yes.

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So, it's definitely time to automate.

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We also try to help with that, because it can't be that you just search for data very hard and then create a report.

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I think that's where computers should help us.

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It could be faster and also cheaper.

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What other measures have you taken now to deal with all these challenges?

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So, you could almost ask, how do you manage your everyday life?

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with all these challenges, I think you can call it yes.

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Or they can also say what else they want to make it work even better.

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So we actually have a large part now in the direction of M.

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D.

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R.

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also managed by simply getting help from outside, getting support, just to create a basis, because to start from 0 and as they said so nicely, reinvent the wheel every time.

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I think that many of the procedural instructions of the referrals, the

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So many companies have to create documents, why should everyone make the effort and that would also be something I thought about, which could really be helpful, especially for such smaller companies, that I might just get such one-man shows, regulatory affairs managers and managers together even more and easily overcome the hurdles together and really have a

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I call it an exchange and not just a theoretical high level, but maybe really sit down together and create documents together, work them out, which everyone then fills with their specific content, but there is just really a closer cooperation, an exchange and maybe as free or inexpensive as possible, because of course that's still a challenge for the small companies, if you

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then still has to pay large membership fees, association fees.

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Perhaps the contribution can simply be that everyone contributes their input, their work performance and you can simply exchange ideas even more and join forces so that everyone doesn't have to reinvent the wheel again and again.

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Yes.

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absolute, that's a capital G.

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D.

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and I can promise them, we will definitely take them up here at the institute.

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What would you say is the best thing about your job?

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So, you are welcome to do a little advertising now, because I think we all need regulatory affairs managers and we also need young talent.

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What would you say to young people, what makes it so valuable and perhaps even satisfying to take them into this job?

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In any case, as you have already heard with the job description above, it is very varied.

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Yes, also the different requirements in the different countries, of course, there is always a lot of variety.

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What I really like is simply the cooperation with the most diverse areas in the company and how you can really see at the end of the day that everything is intertwined and also that there is such a big picture of what works, where you can simply contribute to it.

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that it works well.

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And basically, medical technology is simply a great area, because I think you work on products or bring products to the market that help people at the end of the day and that, of course, makes you happy when you hear one or the other patient story about how you could do something good for someone and contribute to it.

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I don't think I can think of a worse final word.

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Thank you very much, Ms. Langguth, for this wonderful interview and for the insight you have given us into the world of a Regulatory Affairs Manager, in this case from a smaller company.

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And in further episodes of this podcast of Medical Device Insights, we will also knock on the door of a large company again and then you will see the differences.

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Ms. Langguth, thank you very much again.

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With pleasure.