Johner Institute

Career as a Regulatory Affairs Manager

With Martin Schoedel , Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

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

00:00:19 Speaker 1

In this podcast, we deal with the topic of regulatory affairs in almost every episode.

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Today I would like to go to the meta level with you and

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let's take a look at what a regulatory affairs manager has to do, especially in a leading role, what does he have to be able to do, what does he have to keep in mind and how can he perhaps also serve as a role model for young colleagues in this field of regulatory and quality.

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And for this I had invited a very high-ranking regulatory expert, executive, namely Martin Schödel and Martin, if you could tell us something very briefly about yourself, yes who you are, where you might come from,

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then our listeners could sort it out well.

00:01:01 Speaker 2

Yes, very much.

00:01:02 Speaker 2

So first of all, thank you very much for the invitation here.

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I'm very curious to see how the format is and how it goes.

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Yes, my name is Martin Schödel, I have been working in the regulatory environment for 25 years.

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I started at Dräger ages ago, there were 20 years of my professional life.

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In medical technology, Dräger means ventilators, anesthesia machines, incubators, monitoring, everything is great.

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2 B products or 2 A and 2 B products.

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Most recently, I was responsible for Quality and Regulatory for the entire Dräger Group and then switched to dentistry 5 years ago and then continued to deal with Class 2 A and 2 B products.

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Means treatment units, what is commonly referred to as a chair, turbines and contra-angle handpieces and X-ray machines, no.

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In other words, everything the dentist needs.

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to carry out his treatment and of course a big part of it is diagnosis and trading planning software.

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And so in the part-time position I was involved in the board Z.

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V.

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I., board member of electromedical technology, to contribute a little bit of my knowledge there as well.

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Mhm, since you have now been to several very large companies and have also headed a large department,

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the question arises, what are the topics that occupy someone at your altitude, i.e. have occupied them in recent years or are currently occupying them, what do colleagues of yours have to have on their radar?

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What has always concerned me is product quality.

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That's just a constant in the 25 years,

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Why?

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We always talk about very complex devices and when I say complex, I mean a long bill of material, then always an interaction of software and hardware and in medical technology that simply means a very high level of complexity, a technological complexity, but always very small quantities.

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So from somehow three-digit to a maximum of four-digit and if you‘re lucky, maybe even five-digit, but it‘s always very, very small.

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small quantities that are then produced per year and that simply brings with it many, many difficulties, both on the development side and on the supply chain side.

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That means that this has actually always been a topic and I think that remains an issue and looked a bit at complexity when you look at such a

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Treatment Center treatment unit, then all the media you can think of are available in such a treatment center.

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They need water, then there is also the wastewater, so you have to think about what we do with amalgam, which can then also be in such wastewater, depending on what the treatment looks like.

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We have compressed air, we have electricity and of course we also have modern communication in there.

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So really everything you can imagine is in such a treatment center and that‘s just one.

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quite a good example of complexity.

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Yes, of course, all the standards that I think you can only imagine are now striking, from electrical safety to biocompatibility, but also outside the medical device sector, environmental standards that are certainly used there.

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You have separated software, usability is central there.

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So the full program, I think, you can say.

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So you've started now.

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So an obvious and very important point is to ensure product safety despite this complexity.

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that's not the quality view, if you still put on the regulatory view or the regulatory glasses, what are the really big topics and construction sites?

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Yes, this immediately leads to market surveillance and follows the reports from the authorities.

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I think we are already very strong at the interface.

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Of course, the biggest topic in recent years has been the M.

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D.

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R.

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I forgot to mention that both companies are multinational and I had responsibility for

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for a wide variety of locations both in Europe and in the U.

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and China.

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And that means everywhere for everyone, for every legal entity or for every C.

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E.

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Marking Entity, as we say, M.

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R.

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Setting up projects and bringing them to successful certification.

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That was in the last 6 years, I would say,

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which is the biggest part and it remains the biggest topic for anyone who deals with Quality Regulatory or with Regulatory and, in my opinion, and in my opinion it is still underestimated, even though we have been learning more and more about the M. for 5 years now.

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That means that the biggest topic, the most interesting topic for me is Software the Medical Device, which then also

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What suddenly has completely different requirements is moving from the practice or from the clinic to the cloud, and with it the interface between Software as a Medical Device and Software as a Service.

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We can probably talk about it a little bit in a moment.

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Software, i.e. medical device in the cloud, no, then the question arises, who actually operates the software, are we on the side of the operator regulation, yes, and there are completely new questions that are being dealt with, no.

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So so the most interesting topic for me at the moment and then the last thing to mention here is the path to digitization, we started a project together with the Juna Institute, digital approval platform, which

has the idea

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to bring all the data available in companies directly into an approval platform and thus relieve the regulatory affairs specialists of a lot of paperwork, which is not very value-adding.

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And what doesn't make the job attractive either.

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So in this respect, there is a lot of data available to bring it into a structured format via an interface and we have also used the expertise of the Johner Institute very, very strongly, which can pray tech files up and down in all facets.

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And the idea of this digital approval platform is that the notified bodies are also on the other side and can also access the same data.

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These were the biggest topics in the last few years

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and these are also the topics that remain.

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I think everything will remain in the next few years.

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The topics will not necessarily change.

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One thing, also absolutely important, is the monitoring of the regulations, which are constantly changing, and to stay on the ball, to understand what is relevant and what is not relevant.

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A topic that always has to be done and managed.

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Mhm, so you have now opened up 2 major topics, one that passes on from the past, namely that is all with the topic of regulations.

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You have now added various sub-points again.

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On the one hand, there was monitoring and staying on the ball, so to speak, being able to assess what these changes mean for the company.

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Then you mentioned the complexity of international approval.

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You said you have a lot of C.E.

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Entities, and of course also entities for the various markets.

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And you said that the topic of M.D.R.

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has kept you or you very busy and that you shouldn't think that it's all ticked off somehow, but that it will continue to occupy you.

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And an example you gave of this was also this whole area of post-market surveillance up to vigilance.

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So with that we have staked out the field of activity of an expert like you, so to speak.

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What would you say?

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So what, you don't have to praise yourself, but what distinguishes an expert, like you or if you were someone maybe to put it a little more neutrally, if you were someone who had to hire you in your position, what would you look for in this person or what are the success factors or the success factors or the characteristics, that such a person should bring with him?

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Yes.

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Well, I would never call myself an expert.

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I think there are very, very different ones.

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But it also brings the answer immediately.

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At this point, as the person responsible for regulatory, I believe that one must succeed in bringing these sometimes complex issues to the.

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To mediate in the board or the management, right?

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That means you have to be able to present it in a way that is understandable to the target audience.

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No, that's the one essential stakeholder group, if they just don't understand M.D.R., then there won't be the appropriate support.

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I believe that this is very, very essential and with it also the possibility that.

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other stakeholders below the management.

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In my view, it is not from top to bottom, but you always have to take your peers with you there.

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So very, very strong communication skills and for me, the central interfaces are always, so at the very beginning, development, most of the work is simply in development.

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Medical device is first and foremost the physical product, but also the

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All the documentation, the whole verification level, that's not necessarily loved by developers.

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That means that you would have to appear again and again as, let's say, as an itinerant preacher and, of course, also production and product management.

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These are the 3 main stakeholders.

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Which you have to take with you again and again.

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For me, these are the key skills and therefore not so much an expert, but to penetrate the topic sufficiently and convey it to others.

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I believe that this is the model for success.

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for such a position.

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Mhm, what pushes the bar even further, i.e. the hurdle or even further up, because what you said is that this person not only has to master his business, yes, so the Regulatory and Quality business, because he now has to choose again, like you and a lot of people, but what you said, that's probably the basis, but in order to be successful, the

00:11:27 Speaker 1

I think was the word you used, because in the end you have to make sure that they really work according to the quality and regulatory specifications, that you don't block them or even be perceived as blockers.

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Yes, there is a lot that goes into it, namely an understanding of their tasks, of these processes that you have.

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Then you mentioned the skills, the necessities to communicate, but also probably the ability.

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To be able to adapt the process in such a way that on the one hand they are helpful for those who have to live them, i.e. effectively and efficiently, but on the other hand, of course, they all meet the regulatory requirements.

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And then you bet on top and I think that's often forgotten.

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All of this will only work if the appropriate funding is there and the funding, you get it from the board or from the board, depending on how the company is structured.

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And then you said that it is crucial,

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to be able to communicate, what has to be done, why do you need these funds or these funds and what does the company also get out of it, I guess it's not just about getting a C.

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sign or approval, but probably then also safe products and then avoid negative follow-up costs.

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So that's really a very big area of responsibility that you have described.

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It's a long way to get to where you are now.

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Regulatory or Quality

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Affairs managers recommend that they manage the path you have taken so successfully.

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I'd like to go into 1 of what you just said.

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It must be possible for quality and regulatory to be perceived as problem solvers and as part of the company's core processes.

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No, if we are perceived as roadblockers, then no one comes to us, but quality and regulatory are only asked when it is too late.

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No, and that.

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Of course, it multiplies the costs and the time-to-market.

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Yes, so insofar as that's actually also Key together that develop processes.

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Of course, who owns the process, it is not always quality, but rather rarely quality, ensuring that the regulatory requirements are already integrated into the processes.

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Yes, and there are always gray areas that can be used, unless we are really talking about patient safety.

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Yes, there is only black and white, that's clear.

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but really the key is to be perceived as a problem solver, then people come to you early and you can find solutions even then.

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Yes, what advice would I give to young Quality and Regulatory Managers or experts?

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Maybe what, what do I find so exciting about the task, that's this

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this diversity, you have to deal with all areas of the company, you have to deal with all functions, you don't really know in the morning what the day will bring you.

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I find that very, very exciting.

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I guess you're a plate juggler, he has so many plates in the air, you have to see who falls down right away and has to give a little bit of start-up financing again.

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So I find that very, very interesting.

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That may not suit everyone.

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So that motivates me.

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You get

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but of course also a very big insight into the company's processes.

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I think there are few people who understand companies as well as people who also deal intensively with processes in the company.

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These are 2 functions, this is Quality and Regulatory and these are all those that make up the I.

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and that's exactly what I find very, very exciting about the area.

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What advice would I give to young Quality and Regulatory Managers,

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In any case, look at the stakeholders.

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Who are the stakeholders?

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And also seek communication there.

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Sometimes the door is locked, so you have to come back again and again.

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I think that's very, very important.

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What is also relevant is that you will be noticed if you understand the technology well enough, not like a developer, but you have to be able to talk to developers there and they must have the impression that you understand the product sufficiently.

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Yes, otherwise acceptance is quickly no longer there.

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You are not accepted if you know Articles 97 to 103 by heart.

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Yes, you are accepted if you are at least once at eye level, but in sight

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can communicate about product and technology.

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So you actually had 2 or 3 you could almost say areas addressed, directly or indirectly.

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One thing, of course, was to understand the trade, i.e. to familiarize yourself with the field of regulation, to continue your education, so that you really stay up to date.

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That's something extremely non-static anyway, as you said at the beginning.

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And then you addressed 2 other areas.

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One was the interest

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And again, the willingness to think about the company and its processes, to really understand them, otherwise you can't help shape it.

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And the second thing is to think about the products of this company and now probably not, or you even said it explicitly, now not only in their purpose and general application, but really also in their technology.

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So that means understanding how they are developed, how they are produced and it then sets in alongside this processual knowledge.

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yes, you have a certain basic technical understanding, because otherwise you are not the partner at eye level or are not perceived as such.

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Of course, this is also a big challenge for these boys, but I think it also makes it clear that it's not the people we need, who lock themselves in the closet and just check documents somehow and move them back and forth, but we rather need outgoing characters who are willing and probably enjoy it,

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to communicate with others in the company, because this pure diligent work and with this we may now come back to this digitization for a very short time, which will hopefully also take over such platforms in the future.

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Could you describe your dream, where should a Quality Regulatory department perhaps be in 5 years and in particular, what would be the dream state that will be achieved through digitization and probably more of a digital transformation?

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Yes,

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so as a dream target image, the Regulatory Affairs Specialist actually spends, I would say, 80% of the time in the discussion with the system architects and the product managers, discussing market access strategies with the product manager and system boundaries with the system architect.

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And means a lot, a lot of thought work.

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The 20% are still documents that you have to generate, of course.

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The essentials, or most of them, should actually also be available, as I have just outlined, via yes, via such a digital registration platform.

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If you then think further, such as a digital approval platform, which then also maps the product.

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Then I can quickly think about the fact that I also have a link to a regulatory radar.

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What is changing in the world?

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Then I imagine that such the relevant changes are already displayed in this platform.

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In other words, any data fields that need to be checked may then be stored.

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That is, this one.

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Regulatory Affairs Specialist sits in front of the mixing desk.

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I think mixing console comes from the 70s.

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I don't even know if it still exists, but maybe the picture still helps.

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Yes, he sits on the mixing desk, sees where, where things also need to be checked, adjusted.

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He also sees when you see the.

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look at the approvals, the status of the approval, we're talking to a digital registration platform, yes, hopefully not only about the M.D.R., but then also about other target markets, so that I then also know where is my approval, for example in Singapore, is it now in-house, is it with the colleagues on site, she is with the Competent Authority that I also have such statuses and can also report and have a good transparency about what, what is there.

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But

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the essential thing for me is really this work together in the development departments to develop the right product for the company, which also complies with the regulations, no, and where the system boundaries have also been drawn very intelligently, very intelligently.

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Mhm, with that you have now mentioned 2 actually big aspects.

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You once described,

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What is the vision of digitization and on the other hand, what are the positive effects on the team?

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So firstly, digitalisation and we are working on it together.

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So that's why we have a common vision, so that this topic of approval is no longer a real issue, but that all this diligent work is taken over and then the information, then it is no longer documents, then automatically ends up at the corresponding end points and you automatically know where we stand.

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And then you don't have to manually chase after them and the positive effect you have when you free your resources from these hard work, which is not always so fun, and I found that extremely important to give the people in regulatory a whole new perspective.

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Then it's no longer the badly expressed document pushers or the formatters from E.U.

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according to F.D.A., but suddenly there are strategic partners in the company who help to define regulatory strategies.

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and I think that's a very, very nice vision for the people who work in these areas.

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I don't think you can find a better ending for the podcast than this very, very positive outlook in the role, which is often perceived quite differently at times.

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And I thank you very, very much for making such an important contribution to making all this possible.

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And of course I thank you very much for being part of the podcast, Martin.

00:21:45 Speaker 2

Thank you very much for the invitation and it gave me a lot of pleasure.