What does it mean to be a Regulatory Affairs Manager?

With Alexander Beck, Prof. Dr. Christian Johner

Transcript

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Medical Device Insights.

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A podcast by the Johner Institute for medical device manufacturers, authorities and notified bodies.

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This podcast is used by many people in Regulatory Affairs

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Experts and of course they also want to know how things are going with others, how things are going with my colleagues, what can I perhaps learn from them, what are their biographies and it is precisely this curiosity that I would like to satisfy a little today in a conversation with Alexander Beck.

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Alexander Beck is at Richard Wolf in the Regulatory Affairs department, was previously with several other companies and already in a similar area and

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of course, there is always the question of what exactly drives someone into this area, because there are hardly any training courses that lead to it in a targeted way.

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Mr. Beck, what was it like for you, how did you get involved in this regulatory area back then?

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What drove you there, what fascinated you?

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Yes, first of all, thank you very much for letting me be here.

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Yes, you're absolutely right, it's not a classic one

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Apprenticeship where you just pick yourself out at the beginning and say: ‚Gee, in Regulatory Affairs, that's where I really want to go now, even if it's a wonderful, beautiful area.

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It was similar for me.

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I actually come from project management for translation services, but I've always worked in technical documentation or project management for it, and I'm interested in regulation and the question, what's behind it?'

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I got into this area and it was then deepened over the years, then I continued my education, attended further training, dealt with it more and more and then actually got the opportunity to get a taste of the air at another medical technology manufacturer and then got into it, Regulatory Affairs wise, I then supervised the MDR transmission and accordingly ended up with Richard Wolf in Knittlingen.

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Yes, that's great.

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Yes, even a large company, even with critical products, I think you can say, i.e. those that really make a big difference, but which of course also entail high risks.

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And regulatory affairs has a lot to do with ensuring that these products are certainly efficient.

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If you now describe the task you currently have at Richard Wolf, i.e. what are the typical activities you have, who do you work with and perhaps also the question associated with it,

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when will the boss say that they did a good job?

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So, it's definitely a very, very extensive task that we have.

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So, we have interfaces, if we start with it, to almost all departments, right?

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In regulatory affairs, they really come together with every department in some way, in some way.

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The main interface point is usually research and development, because they work with a very, very large

number of documents that come from research and development.

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or

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they work with it and then work accordingly with their colleagues there.

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Then, of course, they have overlaps with quality management, post marketing or

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Post Market, they have a lot of overlap and all the areas around it.

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And if you look at what Regulatory Affairs Manager does all day, it's actually an extremely complex and beautiful task, because we at Regulatory

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To place our products in certain target markets or to enable access to target markets.

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But for that they need documentation, because the target markets they want to enter are usually backed by an authority, which of course wants to know what is coming into our country, what are we going to leave with it or what Richard Wolf wants to allow there, what is supposed to be registered there

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And then they pass on the required documents accordingly.

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No, that's still document-based these days.

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That's a bit of, well, I'll say now, more content-based requirements or possibilities to transport more content are changing than documents themselves and then they are just there in responsibility and hand over this documentation, this information

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but are also on the other hand, if there are questions about this information transfer or the documents, you are also the contact person for this as Regulator Affairs Manager and of course you have to have a bit, well, a little bit of sensitivity and also know how to communicate with authorities and what is really behind it.

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This is not so without and

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Of course, my superiors are always happy when it comes to the certificate or registration.

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If we actually have approval for a certain target market, then of course they are happy, and we in the department as employees are of course happy about it.

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And for us personally, of course, it's also a very, very nice story when, for example, we manage registration or approval with few queries on the part of the authorities.

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That's a very, very

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great story, because it means that our work was so well prepared, or so well adapted to the needs of the authority, the target market, that there were simply no queries that had to be clarified.

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That is, the metric is ultimately how quickly and effortlessly the thing ultimately slips through.

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In other words, how quickly can they get their product onto the market?

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That is what they are measured by.

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So, as you have just described, the interface is between your company on the one hand and the authorities or notified bodies on the other.

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If I may ask again very briefly about the area within the company, they said they had a lot of interfaces, they reported on development, on Q.

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Postmarket activities.

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How do these come about, as long as they are documents, how long, how do these documents come about?

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So, write that your colleagues according to their

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requirements or send the document and they improve it.

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So, what does this cooperation look like, how do you possibly iterate afterwards on documents that then pass well in the approval?

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Mhm, that's a very interesting point, because most documents, they are mainly created for a specific reason, no, that's usually,

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Considerations that arise in the verification of validation, but also in but also in very general documents, such as product description, no, we also have them and they are first initially created by the colleagues in the respective departments, that is often, if you look at the main markets, then you concentrate on EU, MDR, FDA, that's the direction it goes and then of course it may be that you have to pay for certain markets

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You have to go into a bit of depth and take a very close look at what the individual target markets want, so they can, for example, if we look at the area of Southeast Asia, they have different requirements than, for example, the markets in the Middle East, which goes in the direction of product description or something like that

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and then you always have to look at what is actually required and then work up the version of the documents, no, as they said, you have to create different iterations and at some point you come to your result.

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Mhm, so there I confessed, that I ask briefly, that is, there are certain documents, there they say, please write me something like this, I need that now for this target market and then there are other documents that come to you more or less automatically anyway, where they then only do an exam.

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So

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Can you describe this interaction very briefly?

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Exactly, it's just as you described.

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Sometimes we have the need to adapt documents that already exist and that have already been written, and we then adapt them to the target markets, and with other documents, we can then simply pass them on, I'll say in quotation marks.

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No, there are still a few formal requirements that are often still adhered to, but you wouldn't have to adjust them very much, not quite as much.

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Mhm,

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You have described how important it is logically for your company that the products come onto the market promptly, that it does not somehow X.

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iteration afterwards with the authorities and you have described that it will also be celebrated if it works well.

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Of course, one can conclude from this that it is not a matter of course that this always and immediately works.

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What are the typical challenges they have to overcome, with which they may sometimes have to struggle,

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who do not absolutely guarantee that it runs well.

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So what are such typical difficulties in your work?

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So, for example, what happens regularly is when you look at the risk classification in the different target markets, which of course are already roughly based on the E.

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or rather, you can do that quite well as a guide, I'll say,

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but they actually differ in specificity.

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If you then actually go into the details and look at how the risk classes are structured in the target markets, there are already minor differences and then there are always questions.

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This is such a classic, it actually happens relatively often that something is asked for or that information does not seem sufficient.

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But there is not much you can do in advance, because in the end you don't know who the subject matter expert on the other side is and which one

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kind of information need or even how much information need he still has and then they have to adjust a bit and usually these inquiries are superfluous relatively quickly.

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From time to time, of course, it can be that there are more detailed technical inquiries and then they have to.

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exchange ideas with the specialist department and then find a suitable solution so that you can pass it on.

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I have now heard 2 big elements, one of which was, we have different requirements as a challenge.

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You explained this using the example of classification and the second thing is that you don't always have one hundred percent clarity, which is also the individual expectation afterwards, now to see a requirement as proven.

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How to go

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or what, as you described earlier, you try to prepare it as well as possible, what are your approaches with which you can push this uncertainty that you have just described as far down as possible?

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Mhm, basically on the one hand is experience that you bring with you, no, that's in the case if you work in the area of longer or in a target market, if you work on it longer, then you know roughly in which di-

rection the documentation has to go, what

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what is not needed is needed and then you can prepare the documentation a bit.

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Basically, what this whole complex of topics requires is that you know what requirements the guidelines, the regulations basically provide or do.

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which guidelines are needed or

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what requirements, that's what I wanted to say, what requirements

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You have to read very, very much.

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They have to summarize an extremely large amount of information.

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You have to understand the cosmos, the context in which these approvals take place and also the requirements are then placed on you.

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And then you can prepare very, very much information in advance and then send it out, well accordingly to the authority.

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But that's just very, very much, as you say, lagwork.

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So you have to walk very, very much, read very, very much and

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implement the work accordingly.

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Yes, so I can completely understand that.

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Well, we monitor between 6 and 7000 regulations for medicine and E.V.D.

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Manufacturer.

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So I can understand very well that we have to read a lot and stay tuned.

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How do you keep yourself up to date?

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But we now have not only the issue that we have to get the products through approval or conformity assessment, but we have

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maintain compliance in the long term?

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What are your typical tasks, what are the challenges you encounter, and how do you approach them?

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Basically, we try to keep up to date with our target markets.

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No, we have different newsletters, we have different memberships in different associations, where we always try to keep up to date with the latest trends, the latest developments in regulation in different areas

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and then evaluate it accordingly with us.

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There are internal processes on how this has to be done, which departments have to be informed when and how.

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This is all covered within the framework of quality management and then of course it comes in the direction of, if you think in the direction of PMS, for example, then it's back to my business or

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to the consideration, how is my product on the market, what is happening there right now,

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what kind of feedback do we get from this, do we have any insights, perhaps also from other manufacturers, for example, who have similar products.

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So this complete P.M.S.

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Of course, we also keep an eye on the cycle, although it's not primarily in my job as Regulatory First Manager, but it's a different department.

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But of course it always plays a role when they go to another market, there is often too.

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Well, so PMS data is often queried or requested.

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Mhm, yes, so this post market surveillance, we are also observing that, it is coming more and more into focus, also from authorities and notified bodies, so not only premarkets, but also these post market tasks that we have.

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But you have just described, is not primarily your focus now, but rather you are then the premarket commander, i.e. who is responsible, as you described earlier, for the fact that the products flow through quickly, that the products come to market quickly.

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if you were to really dream it now, what would a world look like in which you would most like to live, in which work is particularly enjoyable and perhaps the boss would also be particularly happy, what would be different compared to the world as it is today?

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I think if we could do it, that is, we in the sense of the world, no, everyone, all medical technology manufacturers and authorities on this planet, if we could just have a good,

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We could find a solution for how we could find our information that we have now in the company or also, no matter in which company it is, if you could take this information and play it out in a globally harmonized way, that would be very, very helpful, because in principle we are currently doing nothing more than refining the information that we already have in a wide variety of ways, changing it a little bit

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yes, to change in form.

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But the information core itself remains more or less the same.

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It is very rare that they really have to provide completely new information, but they usually just have different forms in which the information has to be presented.

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And if we could do that, that would of course be a very, very great story, because then very, very much effort, very, very much, I'll say again unnecessary effort, which now lies purely in the formal design of information, would be eliminated.

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Yes, I see it exactly the same way as you do and I think the good news is that this dream will be fulfilled because we are directly involved in it.

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You have actually described very important elements, the these, which lead to this dream or to the fulfilment of this dream, and that in several places already in the conversation.

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So once you said that the time of documents is coming to an end or is changing direction

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Data, unit of information, I don't even know exactly what your term was, i.e. ultimately structured data.

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So I, I think that's an indispensable prerequisite for this and then what these systems have to create, as you just described, it's always the same information, but in different combinations, formatting, even structures that we need and that can and shouldn't have to be done by hand anymore.

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Yes, you just mentioned the diligent work,

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is exactly where we are working on it.

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So we have to work on it with notified bodies, we are with the F.

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en.

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also on it, especially in the context of electrical safety and E.

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So that's where we're going to go down these data models.

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So what makes me very happy is that they confirm that it or even this, therefore see the solution, this way.

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So let's go it together, let us know, maybe we can do it too.

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make some prototypes out of it in order to be able to really do this evidence end to end and to really be able to fulfill this common dream, it must also be said.

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You haven't described it yet or briefly hinted at it in the preliminary conversation, but at the moment it's still one of the most labor-intensive things that of these regulatory affairs jobs.

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How would you

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make this job palatable to young people.

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Why should you change Regulatory Affairs and preferably to Richard Wolf, of course, I think that's clear anyway.

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What would be your advertising block for it?

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Yes, very much, it's a very, very nice job in itself, because you have contact with an extremely large number of people, every day.

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They have, they're a great, they've got a great interface function, in that they really

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Learn a lot.

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Anyone who wants to come into an area that has to do with medicine and who wants to learn a lot and is perhaps also interested in medical technology or is interested in medical technology, is in exactly the right place in the job, because they have extremely complex issues.

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But you can also turn them into a wonderful, unambiguous result.

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You can make it possible for your medical device, your medical devices, whether it is an instrument, a device, whatever, to be approved in a market.

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So, you actually have a meaningful task, right?

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And on top of that, what I personally find to be a very, very great enrichment, you have a very, very great international environment.

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So, I'm in Global Regulatory Affairs, I'm really with all the markets

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It doesn't matter if it's Asia, Africa, South America, whatever.

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They come together with a lot of great people and that's just a very, very, very great flair.

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And if you also enjoy the documentation work, then I think it's a perfect job for anyone who wants to start in the field for the first time.

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So all those who want to work in a variety of ways, in several dimensions, should contact Mr. Beck.

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They had mentioned several dimensions, one global, i.e. geographical, the entire breadth.

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Then they have the whole breadth in terms of content, yes, from technology, law, you could say to a certain extent, medicine, quality, everything is there, other dimensions, through the whole thing.

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Departments, departments in such a company, it is internally and externally.

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So the diversity is given, but I think the prerequisite is also that you want to have this diversity.

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Otherwise, if you want to do exactly the same thing every day, you might not be right.

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And all the others, I would recommend, contact Alexander Beck, his contact details, I have entered them in the show notes below.

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Mr. Beck, it was a wonderful interview.

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Thank you very much for your time.

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I have to thank.