Johner Institute

Regulatory Intelligence

With Dr. Jochen Jäger, Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

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

00:00:18 Speaker 1

In this podcast, we have often talked about the topic of regulation and how you can actually meet all these regulatory requirements.

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In this podcast, we now want to go one level higher, a level of abstraction, and let's see what a regulatory affairs manager actually needs to keep an eye on in order to be able to keep up with all these regulations and to be able to control all things properly.

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And I invited Doctor Jochen Jäger from Roche and Jochen, I think it would be best if you briefly imagine that people have an idea of what you do, what your role is and then we dive

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even more into your activities.

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Yes, thank you very much, I am very happy to do so and thank you for the invitation.

00:01:02 Speaker 2

My name is Jochen Jäger, I am the Head of Translational Policy in the Regulatory Intelligence Department of Roche Diagnostics and I have been in this position for 2 years now, 15 years at Roche.

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Now you've already mentioned this title, i.e. Translational, and can you give us a bit of background, what does such a person do, what does such a person have to keep in mind in order to do justice to their role?

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Well, I like to classify it, because you are always asked a lot, what does translational mean?

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This is not, or not only, about translating different languages, i.e. getting a regulation in French or Spanish and having to translate it into English, but translational in this sense means understanding what the regulation actually means for us, for our company, for Roche, for the functions concerned, for the affected roles, and then to translate that and then really translate it into one of a can also be from English to English, but from a

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let's say translating official language into a language that the engineer, the engineer, the marketing manager concerned, the business head in question understands, translate all the requirements that are given to us into a language that we also use in our Roche culture, so that it is clearer what is to be done.

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That's the translational and perhaps also a classification of where we sit.

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We are in the field, as I have already said, of regulatory intelligence.

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So it's all about regulatory

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forward-looking analyses, what do we need, what is coming in the near future.

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And that also helps us to understand, if I now know what is coming in the future, how can I classify the whole thing, how do I perhaps have to translate these requirements, also with regard to what is to come and with regard to what we have already implemented in our own country.

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And as I said, there are also people regulatory, we still distinguish between regulatory intelligence and regulatory affairs.

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Regulatory intelligence is the upfront.

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This means that we take care of the regulations either in the preparation phase, where we comment and also communicate with the authorities and then translate them into local processes.

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Regulatory affairs is the downstream thing, for example, when we have to submit our products to a submission, when we have to submit them to the authorities, when we follow up, postmarket, all of that is regulatory affairs for us.

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You actually had 3 things differentiated from the 2, if I understand correctly, were part of your activities.

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One was a look into the future, so to speak, the second was, when these regulations came in, to translate them into the, I'll call it technical jargon of the respective business units, and the third, when it has arrived there, which is no longer your area, is to orient yourself according to these rules of the game.

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Can you say that?

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Exactly, yes, that's how you can sum it up wonderfully.

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Can we perhaps use your two

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Now take a closer look at the area.

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So you have already said that in one area it is about looking into the future, perhaps also exerting influence.

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Can you describe it a little more in detail what you do, what opportunities you have to find things, what opportunities you have to exert influence?

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Yes, first of all, you have to know what comes naturally and what you can influence.

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I now differentiate when an authority already has something planned and communicates this either through a pre-draft or at congresses

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or in certain industrial associations.

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So, we are members of various industry associations, such as Aquamed or Medtech Europe or Mecomed.

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And in these, for example, it is also discussed that an authority plans to either update certain regulations or bring them up to date or adapt them to new technologies.

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And then members of the industry associations or even individual industry representatives

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bring in their comments there, that's what we'll do.

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The second thing is to exert influence when the authority has no plans at all, but we see that there is an absolute need for us to talk directly to the authorities and say, wouldn't it be time or would it be appropriate to do something, especially if one authority is clearly behind other authorities.

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So not all authorities worldwide are on the same level and not all of them worldwide are equally wide.

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And these are the 2 areas, I would say, where we

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Regulatory Intelligence.

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So one is cooperation on predetermined drafts from the authorities and the second is really active with the authorities on new collaborations.

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I suspect that this active participation also takes place in the standards committees.

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So I don't just suspect that, but I know it, because I've already come across representatives of yours.

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So that means you would also give suggestions, not only how norms can be improved, but if necessary where they are missing.

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Yes,

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So, of course, we are represented in some standards committees, work there.

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This is also important work for us.

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If we notice that something is still missing, then we would certainly suggest that something new be created.

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Mhm, that's what a company of your size can do quite well now, of course.

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I imagine this is now a bit more difficult for smaller companies.

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of course, they also have other associations or, I hope, which ones they represent.

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We also try to do that a bit, but you can see how they, as well as you, have economies of scale that you can benefit from.

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So of course, smaller companies can also exert influence by, as you said, replacing themselves together with other small companies.

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So these are the groups, there are also certain industry associations, which is why I mentioned the industrial administration at the beginning.

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there you can exert influence, even as a small company you can work there and then also bring in the comments accordingly.

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Of course, it's a question of resources, because as a small company you can't be represented in all standards committees and all industry associations, and neither can we, by the way.

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So there are also our limits, logically.

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So we choose that, depending on the business needs and also according to the size and importance of the standards.

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Mhm.

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Yes, then let's take a look at the second area.

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That was this translation.

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So, as you said, this is not primarily a question of translation, but rather a question of translation from one language to another, but rather a translation, yes, from one style to another or from one, as you said, from the official language to the user language, specifically for your respective business units.

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Is there, can you describe it, how you go about it?

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Well, you have, so to speak.

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several inputs and several outputs, how do you manage that, so to speak, like a kind of thing, I imagine it, like a freight station, where the trains come in or leave there, how do you manage to make sure that everyone gets these regulations presented in their language in an understandable way?

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Is it more of a pull or a push, i.e. you push things out or are you more of a kind of hotline, how do you have to imagine it?

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So short answer is both, but I would start a little earlier to understand what we are doing.

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So we,

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Of course, we translate the technical language, but first, which is almost more important, we also filter what is important.

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So the first thing for us, the big block is monitoring.

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We first have to know what new regulations there are.

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Then comes the identification, identifying which regulations are available for us and in what priority and importance.

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So this is a big filter where we reduce from many hundreds of regulations per month to a few or a few dozen.

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And then comes the third important one, then we come to the Assess and the

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What does that mean for us, we actually call in the experts.

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So that means we try to work together with a team, we call it a squad, in the agile sense, a team of a regulatory affairs expert with a person affected by R&D, for example, or clinical affairs or from the field of operations, so that the regulatory affairs manager can explain or the regulatory specialist can explain what that means.

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and then be able to decide in the conversation how that would be translated in the SOP or in process.

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So here it's very important, especially if it's very specific things, even the regulatory affairs manager may not know what kind of influence it has, then he needs the knowledge of the subject matter expert and the subject matter expert may not understand the technical language of the regulatory area, then he needs the regulatory specialist.

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So we are really in small teams and

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The difficulty is always to find the time, because we don't have any number of experts on some specific topics that can be found promptly, put together with the Regulatory Effect Specialist and they then decide together what that means and what are the actions that we have to take out of the end.

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00:09:33 Speaker 1

K., that means it's much more than just translating now, but it's such a facilitating, you could perhaps also call it, that you bring people together.

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So these are probably also very banal things, which are important, that you find a time together, that you choose the right people and then find out in the conversation, O.

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K., is that clear to you, do you know what that means for you, and then, and you have already hinted at it, you usually find some kind of reflection in a specification document like an S.

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and everything you have now described, I would say, is what you mean by regulatory intelligence.

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So, that's how we set it up in Roche and that's how we would do it internally, that's the case again, every company has its own culture and probably the more specific terms will be defined a little differently.

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So, we would have defined it like this, Regulatory Intelligence is set up,

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That we not only do the preparatory work, what new regulations are now coming in and how do we do the advocacy, i.e. the shaping and co-design of regulations, but also how do we implement and translate them into our products and ourselves?

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specific requirements.

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That's how we would have defined it.

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It may certainly be defined differently in other areas or other companies.

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No, but it makes perfect sense.

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So the term belongs to me too, so I think you have to use the American intelligence here, because I think that's intelligence in the German sense, I think it's more in the sense of maybe a C.I.A., ‚ne Intelligence Agency, namely the collection, processing, evaluation of information and that's exactly what you've described wonderfully.

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How can digitalization help you with all these tasks?

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Yes, so of course it's important for us if we now, I said, the first step in translational is monitoring and I also mentioned that there are several 100 regulations in our area.

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There are probably perhaps even thousands of regulations that are now being created in all areas about space travel, the automotive industry and so on, which are really being created every month now.

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To keep this under control, I have to have an overview.

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I don't want to have all the duplicates.

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I don't want to enter everything several times.

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I also have to know where I can classify it, to which subject matter expert.

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So I need a good overview, I need a good search engine, I need a structure, I need support in a workflow that can then tell me which area is now affected.

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Maybe also, if I have a new regulation, what exactly is the difference between the and two regulations.

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So digitization is one of the core

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Hopes, I'll say now with us, where we can really get a grip on the masses and it will be possible to get more and more regulations under control.

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That goes even further in digitalization, of course, that's first of all management, the structural, but at some point we will also be supported automatically.

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Then it's off to the A.I.

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Machine learning, there are already certain topics, where where and where are on everyone's lips at the moment, can I perhaps communicate better with the system in the natural language, let's go into the G.P.D.

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or similar technologies.

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or do I need better structural measures, attribution or preliminary analyses, automatic translation, so all the things if, if I, if I were to start with paper documents and I now had all the hundreds of documents only in paper form, I would need a whole armada of people who analyze it and with digitization it is more or less manageable.

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Mhm, yes, so I can confirm that, because with the Regulatory Rater, I think we have three and a half thousand regulations right now in the

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in monitoring and with our team, that's not possible at all, to monitor three and a half thousand regulars and see what has changed where and how without digital support.

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What you just described was ultimately this complete workflow that needs to be supported.

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That's how I understood it, so really from the search, evaluation, but then you told yourself even more, namely then really the tracking and

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the point with the chat G.

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probably also up to the answering of questions from the specialist departments, which then arise from this, and then we would have end-to-end support of everything that you as a Regulatory Intelligence Manager are probably not the right term, but as the person responsible for this area really has to have afterwards.

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It is, of course, the dream that we have the whole cycle of the

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Creation of regulatory documents, evaluation, implementation into product specifications, then into the products and then track the products over time until they are eventually withdrawn from circulation.

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The whole cycle is not only in Regulatory Intelligence, the postmarket area is now in Regulatory Affairs, but of course we as Roche have a great interest in this entire cycle being covered in as few tools as possible.

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Absolutely, so that's the realization we've come to, that's why

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the Post Market Raider also runs exactly on the platform, because it's always the same data, it has to be said, product master data and so on.

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If you could wish for a cockpit, where you, as a great manager of this whole area, could see what is happening in your universe, so I'm deliberately describing it so broadly now, what would this cockpit have to show you, what information would you need on it?

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So of course I have a cockpit, so we have also made a small cockpit for our solution at the moment and we also get inquiries from our business partners again and again about what they would like.

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I think it's a bit of a wishful conort, I'll say now, but I can say what I'd like to have.

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Of course, in the area of regulatory intelligence, I would like to know what are the hot topics, what are the big searches, for example, what are the Google trends in the area of advocacy, in the area of regulatory, because we know what's coming.

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then, of course, I want to know which countries are as active as possible at the moment, in which area, what are they really active right now, so not the future, but the current topics, where they are at the moment, what will be focused on in the near future, then we go into IVDR, for example, what's coming, when do I have to do something, then, of course, if I may wish, I would have broken it down according to our product portfolio.

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We have different products, we have

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pure cloud products or software products, of course we have machines or instruments, we also have consumables and in all areas there may be different regulations and then I come in, when I am in the cockpit, if I really have a wish concert, then of course there would also be the post-market area, what is happening there, have what is currently available from the authorities, where is the focus on it, what are the recalls, where are the weak points.

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Mhm.

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K., I can completely understand that.

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such a favor is also a good requirement specification, so to speak, because I suspect that most manufacturers would share exactly these wishes, if they already have it at all.

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I think you're a bit ahead of the curve, but you may have also awakened wishes in others.

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In any case, we are doing everything we can to meet them.

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Let's perhaps take a step back from the topic of digitization and finally talk about wishes, but not wishes for digital products, but wishes

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to regulation.

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You are also taking part in the World Medical Device Summit.

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We will go there on E.

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Commission, meet ministries at all levels, F.

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What would be the wish or what would be the most important thing that needs to be done differently in this regulatory area?

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Mhm, so we also have, let's say, regulatory intelligence divided into different areas and also have position papers on different topics.

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what is very high up for us is that it remains management worldwide, because we have a proliferation of regulations, some of which are difficult or different to interpret or even contradictory.

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That's why two topics immediately come up in my mind now.

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On the one hand, this is reliance, that authorities can really rely on other authorities, that I don't have to do clinical studies twice in countries with the same groups of people.

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And the second is Convergence, that

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the regulations adapt across the countries, so that, for example, certain ISO standards are also recognized and that national standards are not actually created again in a slightly modified form.

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This is now the worldwide FEO.

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If I now go more to Europe, then it is natural that there is clarity, what do I have to do by when, that the authorities are also prepared to process what they demand, that the notified bodies are ready when we are ready and it is not there, the

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Also in I.W.D.A.

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Of course, some things didn't go ideally now, I'll say, you might not have known before, but you should certainly avoid that something like this happens again and that this is also the legal clarity for the manufacturers, when comes what and what do I have to do by when and everything is then available.

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So that's from testing, that's for the certification of all the other things that we are also dependent on and if they are not there, then we have a big problem for the patients, because then maybe possibly.

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products that would be necessary are not on the market in time.

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Mhm, I'll summarize briefly, so you once had this worldwide view, so to speak, where you said, we have to make sure that we have a mutual recognition, that of the evidence documents, for example, and also and the second was ultimately a harmonization of the requirement that they don't even contradict each other in the worst case.

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And in the European area, you are now very much aware of the feasibility of the regulations

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Some things, I think, could have been predicted.

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We simply lack Diregulatory Science.

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We are talking about regulatory intelligence right now, but diregulatory science is what is somewhat underdeveloped, if I may say so.

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As a quick reminder, at the last World Medical Device Summit, the F.D.A.

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Representatives said, yes, that they only have 150 to 180 people in regulatory science.

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The E.U.

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Representative said they have exactly 0

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And I think that says a lot and a lot can be easily calculated.

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So you can model.

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But now perhaps one last follow-up question on this, again with a focus on Europe.

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So you said it has to be understandable, it has to be implementable.

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Do you see the regulation as it is currently designed in a position to follow future trends?

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So do we have the right regulation at all, i.e. apart from the comprehensibility and the feasibility?

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I have the feeling, and this is a feeling now, that it is a very reactive regulation that is several years behind, behind the reaction.

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And of course, if you look at how technologies are changing more and more rapidly, then we are not yet where we should be.

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If I look at it now, I already mentioned it, Machine Learning A.I.

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Technologies, that is simply much faster the developments than the authorities can keep up and we have already started with the

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historical or existing products have a certain gap.

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So we then have a certain emergency in terms of security and clarity as to how it is to be implemented.

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And when the new technologies come and it is not clear and M.D.C.G.

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Guidance is not clear, do I have to do it now, when do I have to do it, do I have to do it immediately, that can't be.

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You certainly need more, more security and clarity.

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Jochen, thank you very much.

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You gave us a fantastic insight into this whole world of regulatory intelligence, the digitization of this world and finally something about regulatory science.

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I think that was a wonderful conclusion.

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Thank you so much for being there.

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I am very much looking forward to seeing you again next week at the World Medical Device Summit.

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Yes, thank you very much from my side and thank you for the invitation.