

Regulatory strategy

With Luca Salvatore, Prof. Dr. Christian Johner

Transcript

00:00:06 Speaker 1

Medical Device Insights is a podcast from the IONE Institute for medical device manufacturers, authorities and notified bodies.

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After the MDR and IVDR more or less brought the system with the notified bodies to a standstill,

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Especially for young companies that do not yet have a notified body, the question now arises again, what to do?

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Should we first go to other countries and put our products on the market there before we try to do that in Europe?

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This is a question that many are facing and that has to do with the regulatory strategy.

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And that's exactly why I invited our expert at the Institute for Regulatory Strategies, Lucas Amotoro, to join us today.

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so that we share exactly these tanks, so that he helps us to understand how to make a logical strategy.

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There are good sequences in which I go to the countries, how can I avoid having unnecessary duplication of effort in the respective approval procedures and simply letting us benefit from his wealth of experience.

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So this as a short preface perhaps to the topic as a whole, but Luca, maybe you can tell yourself and that you

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give a very brief overview of yourself and your work.

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Thank you very much, Christian.

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Exactly, yes, I take care of regulatory affairs worldwide at the Jona Institute together with my team.

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This means that we help medical device manufacturers with product approvals and certifications so that they can master them efficiently.

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And at the beginning there is always the big question of a good strategy, yes, so that you can really

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sense of a reasonable time despite the amount of complexity of regulations.

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And you've been doing that with us for many, many years.

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So, you are also our man for international approval, I think you can say.

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Exactly, so we mainly take care of the topic of E.U.

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Admissions, Admissions to the M.D.

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sub-countries and there especially U.S.A.

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and also China.

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Very good,

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So, Luca, maybe let's jump right in.

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If you're being asked questions like this right now, what do I do now?

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What are the things you observe that are done wrong over and over again?

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So, why slide into trouble?

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What are these difficulties that you encounter?

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What are the consequences?

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Even if you don't set up such a regulatory strategy properly, you could just do it or our listeners especially.

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give a little rundown about what the typical traps and typical difficulties are that you should avoid.

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Yes, so often it is really the case, there is a lack of a mature regulatory strategy in the sense of a mature regulatory strategy.

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Well, it is often not even there.

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It often happens because you don't do thorough research, that you may choose the wrong or, in the worst case, the wrong approval procedure

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or misclassified.

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Yes, these are one of the first steps, so to speak, and it is also very important there so that you can determine a classification properly in the first place, or can you determine, are you a medical device at all or are you perhaps exempt from approval by the F.D.A., that you have defined a very precise purpose here, right at the beginning?

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With that, you have already answered the question of what a regulatory strategy is anyway.

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So if I'm listening to you correctly, it's of course the question of which markets I go to, in what sequences and also, how do I have to design my product so that it might fall into the right class now.

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And if I have understood correctly, the topic of qualification, i.e. the decision as to whether it is a medical device and the classification of these products, is of course also part of this task.

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Can you say that?

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You summed that up very well, Christian.

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So, it's really about, yes, determining how the product is to be qualified, classified, but also about determining the regulatory requirements in the countries.

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In other words, not only the laws, but also normative requirements, guidelines, the policies of the individual authorities in the countries and thus also to be able to determine what a

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possible or a suitable authorisation procedure.

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Sometimes you have options, just if you formulate the purpose in one way or another and adapt it accordingly, yes, then you may only have a limited purpose, but you are faster on the market.

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Yes, there are often several options.

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Yes, that's very important now, because what you said between the numbers is that we can also have such a field of tension between business and between

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Regulatory could be, but perhaps also between business and business itself, namely the question, do I prefer to be in the market quickly with a limited purpose or do I want to have a little more time and then maybe I can achieve a larger sales volume because I have a broader purpose.

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So would you also include in this pot of regulatory strategy?

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Yes, of course, definitely.

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Sometimes that can be a good way,

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you first limit the purpose that you get on the market in the first place and then it is often easier to ex-

pand the purpose later, because you can register with the F.D.A.

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can often be compared with one's own product in the context of a Five Ten K.

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Admission.

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Mhm, so I'll bring in a twist now.

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So it can be

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not only is it possible to adjust the purpose smaller or larger, but it can also be a small shift, so that you agree particularly well with a predicate device.

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Yes, so what not only those who know what has to do with small or wide or narrow purpose, but maybe also a little bit where their focus is.

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Can you say that?

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You can say the same thing.

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Sometimes that depends, now again F.D.A.

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as an example U.S.A., that yes, that you can

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possible comparison product, but you have actually formulated the intended purpose further and that you then limit yourself for the time being.

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And so, in the first step, you may also avoid a necessary clinical study and then, if the product is already on the market, you can carry it out with the approved product.

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Yes.

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Mhm, with that you have already spanned the arc from the problems to the solution space.

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But maybe let's close a problem room very briefly.

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So what you said, what you see, is that you go into it with a certain blindness or unpreparedness, so you don't realize at all what options you have for action and then possibly make decisions, be it purpose, be it approval procedures, which then don't allow you to achieve the business success that you could achieve.

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Yes, and now

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we might switch to the solution room with it.

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To a certain extent, you have already hinted at what needs to be done, namely to be aware of these degrees of freedom.

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You also hinted earlier that it is of course extremely important to have properly researched the regulatory requirements, which do not consist of laws.

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What do you see as other important points?

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So another important point is definitely to get in touch with the authorities at an early stage.

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Well, I just went back to the F.D.A.

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website, it is almost, this is the case every year, about 70% of the submissions are criticized with a so-called Additional Information Request.

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This means that there are major deviations from the demands of the F.D.A.

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and many of these deviations can be prevented, on the one hand by a thorough research of the regulations, but above all by a timely,

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by contacting the F.D.A. in good time.

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Yes, it is the case that the F.D.A.

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offers various ways of contacting us.

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One is the so-called pre-submission meeting.

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There you can join the F.D.A.

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ask very specific questions about all areas, be it biocompatibility, clinical data, a planned clinical trial.

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And you get right there

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A detailed response from the F.D.A. within 70 days, depending on how well this presubmission meeting has been prepared by the manufacturer.

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And the F.D.A.

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even provides further hints or or even gives tips on other topics.

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So this is really definitely recommended and the whole thing is free of charge.

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That's a difference.

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Behind the notified bodies are not allowed to advise at all.

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And I don't think anyone has ever accused them of being free.

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That's you.

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Of course, that changes a lot.

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In other words, this focus.

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So back to the summary.

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So that was researching regulations at an early stage, consciously choosing the approval procedure, and carefully choosing the intended purpose accordingly.

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Now you have added to get in touch with the authority at an early stage, now in this case the FDA.

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What are the most important tips that our listeners should know or is there more?

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Yes, definitely.

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Of course, when it comes to submission, it is important when compiling the submission file, where you can also make formal mistakes.

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Yes, that's annoying, then it is noticed quite quickly at the F.D.A., also through an automatic check.

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But more important are the content problems and there, as I said, are the points that you have just summarized again, such as thorough regulatory research,

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a yes a contact with the F.D.A.

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quite early in the process.

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But also the technical documentation or the submission file, you just have to be clean, avoid inconsistencies, because that's where the F.D.A.

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Reviewer very carefully, if the intended purpose in the instructions for use is different from the one in the form Intended Use, which the F.D.A.

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demands.

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Yes, and that too

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This then immediately leads to delays and that can be prevented.

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Now we have already addressed the topic of registration documents.

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One question in the regulatory strategy was, which countries do I go to, in what order?

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Now we have just had a very strong US focus.

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What would be a tip on what manufacturers can do so that if they now want to go to several countries one after the other, they don't even have to do the same work over and over again?

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Exactly, that's where it's important to start this regulatory strategy, with research, right at the beginning, ideally at the very beginning, of the product development process.

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That means bringing regulatory affairs on board, because it may be a good example at Funk,

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medical devices.

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There is a U.S.

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specific requirement on the subject of wireless coexistence and behind this is also an American standard.

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If you haven't taken them into account during product development, in the worst case it can lead to you having to change the design in the end.

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Yes, that's why you should analyze the requirements, the regulatory requirements of the target markets as early as possible at the beginning, because they can have an influence

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also on product design.

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Yes, so that means, regardless of the order, you recommend very early on to decide which markets you want to enter in the first place and then ultimately to consider the unification set of these requirements.

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Can you, is there a rule of thumb somewhere where you could say, starts in the following sequences and if not, what would it depend on in which order you proceed?

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Yes, man, so

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roughly speaking, can you say that you can call U.S.A.

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certainly or at least M.D.

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Sub-countries, they also have their own specific regulatory requirements in contrast to countries that are not so heavily regulated.

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There, the approvals are often based on international

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regional certificates, i.e. an MDR certificate, will then be recognised.

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This is then more of a formal bureaucratic process.

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Yes, so that surely U.S.A.

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or E.U.

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is certainly a good starting point.

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Here you can make it depend on where it goes faster.

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Yes, so you can, if you are perhaps exempt, in the best case in the U.S.A.

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or can we go a Five Ten K way, which can now be faster than MDR certification, for sure.

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Or do we have to go to the U.S.A. for a de novo trial?

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This sometimes takes a year and a half and often requires clinical studies.

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Yes, and if you then plan studies, you should also plan the studies in the same way that you can

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also covers the requirements of the target markets.

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Yes, not only in clinical studies, but also in usability studies, for example.

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Yes, he has the F.D.A.

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specific requirements and so you should really plan cleverly here so that you don't have to carry out studies several times, among other things.

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Mhm, absolutely.

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That's why we do our, many of our usability studies for our customers in the U.S.A., exactly because this swearing-in quantity

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requirements.

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Now we have talked a lot about regulatory considerations.

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Of course, business must never be forgotten.

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Regulation should ultimately serve the business and the business should serve the patients.

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This means that of course other considerations play a role, such as market size, perhaps also things like quickly find a retailer, which also decide on the order.

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Would you agree with that?

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Yes, definitely.

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So, I've only looked at the regulatory aspects, but of course that the topic of reimbursement, reimbursement is certainly also a relevant topic for business, yes, what needs to be considered.

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Yes, but yes, I think our strength is precisely this regulatory area.

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How can we help your team now, of course, to make the right decisions and to ensure that

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that medical device manufacturers can overcome these hurdles in these individual countries as quickly as possible with as little unnecessary effort as possible.

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Yes, so certainly it is necessary to get a good overview of the worldwide regulations.

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Yes, we also use our Regulatory Radar, for example, our service, which we use to monitor these regulations worldwide.

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That is,

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Our software automatically informs us of any changes, whether to the law, to guidance documents or at the normative level.

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This is also an important input for us in our daily consulting practice, in order to keep us up to date.

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So now you have my question was, how can we help?

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Now, of course, you have talked about our software-based services, so to speak.

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How does your team specifically help with such regulatory strategies?

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Yes, we really help from the very beginning, so the sooner the companies approach us, the better.

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That is, as a typical process is, that we start with the strategic workshop, that we really talk together about the purpose, that we have a precise

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Formulate a purpose or even possible options.

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And then, however, an extensive research effort is necessary on our side, for example, that we research comparable products in the databases, then possible approval procedures.

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And that's exactly how we support our customers.

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So we can really define a complete regulatory strategy for our clients.

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This is

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typically, which we always start with before we then compile and submit an admission file.

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So you're completely involved, including presubmission meetings.

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Exactly, we also support the presubmission meetings, where we have also gained a lot of experience with the F.D.A.

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and feedback is really positive throughout.

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So

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Experience with the F.D.A.s really, I can really rate as very positive, which may be reflected in the E.U.

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is not quite the case.

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Yes, often make it unnecessarily complicated and difficult.

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O.K., but well, I think the good news is that if someone goes to the U.S.A.

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and has a product that is safe and efficient, then we bring everyone into the market and that in a very finite time.

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So there

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Feel free to contact Luca.

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We include the contact information in the show notes, so that you always have an alternative to the European approval path, which is currently still somewhat obstructed.

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Yes Luca, I have to thank you very much again and I'm looking forward to seeing us do another session soon.

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Thank you, Christian.

