TÜV Rheinland & the Structured Dialogue

With Dr. Christoph Ziskoven, Marc Engelhardt Prof. Dr. Christian Johner

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Transcript

00:00:00 Speaker 1

So, it's not that we got the MDCG paper and said, ah, now we have to have a structured dialogue, but it's just that it's actually unavoidable to talk to customers in order to make certain things clear before the conformity assessment procedure, for example, that you can decide on the right thing to do.

00:00:16 Speaker 2

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

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After the big waves of MDR and IVDR introduction, I have the feeling that we are increasingly coming into a balance with manufacturers, but also with notified bodies.

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But that doesn't mean that everyone is super happy with this balance.

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And many manufacturers, and I think also some notified bodies, have the feeling that these procedures will take a very long time until certification, which leads to entire audits and tag file review procedures, and that they do not yet lead to the time-to-market that some manufacturers have in mind.

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And I think the EU was of the same opinion, and now we have this instrument of structured dialogue, which is intended to help us to exchange information more quickly, but also in accordance with the rules, in order to achieve the goal of fluent communication and thus also the most seamless and smooth

approval possible.

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And today I would like to dive deeper into this topic of structured dialogue and have

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experts from TÜV Rheinland had been invited for this purpose.

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One is Marc Engelhardt and Christoph Ciscoven, a doctor and lawyer.

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So I think it's a really great mix that we have with us.

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Let's start with the lawyer, Mr. Engelhardt.

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How did you come to TÜV as a lawyer?

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It's not necessarily what you probably decide to do as a first-semester student when you start this course, to go to the TÜV.

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How was the way,

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how you got there, what do you do today and what does that have to do with Structure Dialogue in the first place?

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Yes, so briefly about my background, in fact the career is not quite the typical legal career.

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In my case, after finishing my law studies in Berlin, I looked for a job in the private sector and ended up there more or less by chance at a medical device manufacturer, based in Berlin and in Bavaria.

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There I applied for the position of Regulatory Affairs Manager without knowing exactly what it actually was.

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I learned that relatively quickly.

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It is about approval law, it is about the interpretation of the laws for medical device manufacturers.

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I did that for the company for ten years, then I worked for a larger American company for ten years, also in Germany.

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and then I was asked if I would be interested in taking over the newly founded position of Head of Certification at TÜV Rheinland.

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And since that fits quite well with my career, I said so.

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And now I've been working at TÜV Rheinland for three years in this position.

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Because it's an extremely important position.

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I sometimes have the impression that the manufacturers are afraid of the auditors and the auditors are afraid of the certification bodies.

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But I don't think that's the case with you now and if it were, Christoph Ziskofen can tell us.

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Now we come to our doctor, who is also on the road at TÜV Rheinland and that is not necessarily the

mandatory path from medical studies to a notified body.

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What was it like for you, Mr. Ziskofen?

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Yes, after studying medicine, I was able to gain experience in clinical practice for 10 years.

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So my background is orthopedics and trauma surgery.

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since I did the corresponding specialist in various maximum care centers and university hospitals and after completing the specialist training, the question simply arose, what happens now and TÜV Rheinland was at that time in the process of relaunching the topic of doctors in conformity assessment procedures and was then very lucky to be one of the first doctors to actually be hired for conformity assessment procedures.

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Tiff Reinhard already had doctors, of course, because we are also a big provider of occupational health services.

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So that means everything that revolves around occupational medicine, but at that time 10 years ago not yet medical devices.

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And then yes, I was asked if that would be something for me and I found it totally interesting and really exciting and then went there and then acquired all the regulatory knowledge in the course of this job.

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and well, from the timeline then the transition from the clinical evaluation procedures under Meddev, at that time still under the directives, to the implementation of the M.

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D.

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R.

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to designate the Rhineland as a designated body under M.

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and later also I.

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V.

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R., to be able to experience all this and yes, this is a very exciting topic, I also did an auditor training and roughly outside, I'll say now, of the clinical evaluation area, i.e. for the entire exam.

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and technical documentation with biocompatibility, risk management and everything that goes with it.

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And for about a year and a half for the coordination of the technical competence centers in a global position and see that we as TÜV Rheinland just correspondingly, no matter whether it's China, Japan, U.

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A., no matter where you ask TÜV Rheinland, we should always have a similar or, in the best case, even identical opinion and an identical view of the requirements of M.

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and I.

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and that's my area, where I then coordinate.

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Great, so I think it's good for all notified bodies if there is uniformity.

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At one point I would like to follow up again, as a doctor there are of course many paths open to you, just like as a lawyer.

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What was the motivation for leaving the patient's bed?

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So, I could also ask the other way around, what attracted you so much to this option, to this one that TÜV Rhein then offered you?

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Well, on the one hand, I have already studied

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During my studies, I got to know areas that were outside of direct medicine.

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So I was also working for a larger German private health insurance company and worked there in product management, so I programmed applications accordingly for the market overview and found out that it was also something that suits me.

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So don't go on now

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patient work, but also outside, I'll say an office job in quotation marks.

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In addition, the topic is really exciting and you have so many new things that happen, where you have to orient yourself accordingly to new requirements of the state of the art.

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Innovative medical products is a topic that suits me and where I enjoy it and that's why yes, so you are often asked, so now resonates in your question like this,

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in the subtext maybe a bit with, don't miss the patient work, but yes, of course it's nice to work with patients, but for me it's just at the named point, it's totally exciting and I don't regret it for a day.

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Yes, I can understand, so you are already on the pulse of the times in any case and you can see medical devices that may actually appear years later at the patient's bedside, I can well understand.

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Yes, we wanted to learn more about the Structured Dialog today

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and I think that's a question that a lawyer can answer best.

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What is a structure dialogue anyway, what is it, what is the goal of this concept?

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Yes, to put it trivially, the Structure Dialogue is basically communication.

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Yes, and since we have a service

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which of course are equivalent to state surveillance, where we have just been authorised by the state, we have to comply with certain rules and these are relatively clearly specified in the Structured Dialogue.

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We are not a free economy and can therefore advertise as we want, but there are certain requirements that we have to observe.

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Yes, and there are a few buzzwords, for example, as a notified body, we are not allowed to provide advice.

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Communication is of course necessary to do business with each other at all.

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Yes,

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This means that we are allowed to talk about prices, we are allowed to talk about steps, we are allowed to talk about the necessary documents that have to be submitted.

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One can talk about the procedure itself.

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What you are not allowed to do as a notified body, however, is to act in an advisory capacity within the framework of this conversation.

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Yes, the Structured Dialog must not take place before a contract has been concluded with the customer.

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Which is a bit like preventing notified bodies from discussing their service with the customer in advance, so to speak, and then entering into a kind of competition.

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This means that the Structured Dialogue actually only has to start when the contracts have been signed and the manufacturer has decided on the said notified body, in order to guarantee that this relatively complex approval process, which in principle means that

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to be able to successfully complete the proof of compliance of the manufacturer's medical devices with the general safety and performance parameters, as they are just reflected in the law, which then leads to the so-called CE marking.

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And for this, the Structured Dialogue with certain framework specifications should form the background.

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In the introduction, I advertised that it contributes to better communication and thus ultimately to faster marketing of the products.

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Would you

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sign that or is my speculation correct?

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I would be cautious about that.

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So, of course, communication should help to ensure that the procedure itself runs as smoothly as possible.

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Yes, but that depends very much on how the structured dialogue is conducted and

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very interesting point.

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I mean, you can start right away with the manufacturer as a customer.

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Yes, there are customers who approach us and say, yes, we have now signed the contract.

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It is now a matter of certifying the first medical device.

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What should we do?

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So and then, answers to these questions are expected as part of the Structure Dialog.

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Is it good if we do it this way and that?

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Yes, so you can

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not engage in dialogue.

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The fact is that the obligation to comply with the legal requirements naturally lies with the manufacturer.

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This means that the manufacturer must work out how he wants to proceed within the framework of the approval process, how he wants to implement these requirements.

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What he can then do within the framework of the Structure Dialog is that he tells us that we see this and that specification, we have classified our product, we have assessed the risk, we have built up technical documentation.

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Does that correspond to

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we can then take a closer look at their ideas.

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This means that the suggestions on how to implement the legal requirements clearly come from the customer.

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The customer has to decide for himself.

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What we can do within the framework of the Structured Dialogue is that we just go there and say, yes, that seems sensible to us.

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The path that has been taken actually meets our expectations, yes.

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And we accompany

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the customer on the way to certification.

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What we don't do is tell the customer how to do it.

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This is an advance payment that clearly has to come from the manufacturer, but that is the point where we then get involved and where we then also try to constructively complete the procedure that was then initiated with the customer.

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I understood you that way, that is, the strategy that ultimately comes from the customer and you stand by him and answer more questions: Does it fit like this?

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So, you're not the one who says, the shared flat goes like this and that, do X, do Y, but customer says, I'd like to do X and Y and then you say, yes, that makes sense to us.

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Can you do it like that, have I summarized it correctly?

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Perfect, yes, I would have, I needed a lot more words, but in the summary just right.

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Now the Structure Dialogue is called structured.

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What is the structure now?

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So are there certain sequences that have to be followed?

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Are there certain formal boundary conditions?

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Are there predefined communication channels?

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So what is the structure in this Structure Dialogue?

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In principle, the structure is already in the fact that it should be constructive, yes, without leaving the framework parameters.

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And frame parameters are exactly what I said.

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So

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Non-competition clause in the sense that you just advertise your service and say, if you start this structured dialogue with us, then and perhaps then pay extra money for it, then that has a positive one.

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effect on the approval of their medical devices.

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This is not the case.

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The Structured Dialogue is based on the legal requirements.

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So it can't be bought somehow, yes.

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You also don't get any advantages by just going there and saying we want to have a technical meeting now.

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We are prepared to pay X in the hope that this could possibly speed up the approval process.

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If it actually comes to a technical meeting, which we also offer, then

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this goes according to the price list and then of course we hope that the manufacturer will take as many positives as possible with it in order to be able to continue the proceedings.

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But simply because you pay money, you won't be able to expect any advantage.

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The same applies to counselling.

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We do not provide advice.

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Again, I have already emphasized this, yes, we are looking at how the manufacturer intends to proceed.

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We can then judge it and say, yes, the path seems right to us, it all has hand and foot.

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If necessary, we can point out that there are legal provisions that may not yet be properly taken into account

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They have been, but still have to be adhered to.

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But we don't act in an advisory capacity and we also make sure that the laws are actually complied with.

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Christoph, you would like to add.

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Yes, of course.

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So, I think it's just very important to emphasize, which you have also done, that the structured dialogue.

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So, it's not a value in itself, but that it's really about the content.

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So the fact that we have a structured dialogue with the manufacturers is a certain format for a conversation, for communication, and having that is very useful and important.

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But of course, within the structured dialogue, it is at least as important to deal with each other in a goal-oriented way, to set the right expectations accordingly and

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That's just when manufacturers come and ask for structured dialogue, which, by the way, they have already done before this term even came along.

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Well, the inquiries are not new or only since the corresponding M.D.C.G.

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paper in the world, but even before that there were manufacturers who said we just need appropriate communication with the notified body before and during the procedure and I really think to focus on targeted communication on meaningful content,

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that's really what brings in the additional efficiency, not just that you just say, I have a structured dialogue and that's it, but that you really say what we're talking about and that's where they also said, what can manufacturers do, define the questions, really with a preconceived list of questions, perhaps, what do I really want to know from the notified body, where are the points that are still unclear to me as a manufacturer, to really have a clarity about it and to have that in the

00:14:32 Speaker 1

in the best case, then also to the notified body before the technical meeting, so that we can of course also find the right experts who then sit at the table.

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If the problem is more the clinic, we need the clinician.

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If the problem is rather, what is the right classification for a software product, which is a typical question, then the software expert would be more likely to be there and that's good if we are told about it before the meeting, so that we can get the right people together.

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Mhm, now you've already gone into the first best practices.

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Let's conclude the legal part very briefly, Mr. Engelhardt, if you will perhaps also briefly tell us the legal basis right away, so that you can also read again what I have just heard, so it is a structure in the sense that there is now a very strictly predefined process of who has to say what when and in what order.

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So this structural concept is not to be understood that far here.

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But what you have just reported, Mr. Cisco, reminds you of this F.D.A.

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Presubmission Meetings,

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where you define a clear objective in advance that you want to achieve, and also clearly specify the topics in order to be able to involve the respective experts.

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I hope I have reproduced them correctly.

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If we may let Mr. Engelhardt have his say again very briefly, so that you can once again give us the legal framework so that all those who are listening right now could read again what these boundary conditions are, which you have just described so wonderfully.

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Yes, in principle there is not that much detail.

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I would simply point out very briefly that a lot is directly regulated in the regulations, in the MDR, in the IVDR.

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Yes, when it comes to the tasks and obligations of the notified bodies, but also the tasks and obligations of the customers.

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There is then a document that describes the Structured Dialog in more detail, and that is the so-called MDCG Document 2022-14.

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The

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which was actually published in 2022 and which, because of the difficulties in switching from directives to regulations, went and said that the Structured Dialogue should be used effectively as a means of communication in order to speed up the process.

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So you can definitely refer to that.

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I mean, the bottom line is that it's just like this: Talking is better than not talking.

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Yes, that is emphasized a bit.

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It is that the challenge

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right now, as far as the legal framework is concerned, yes, I mean, the changeover from directives to regulations is the first time in the EU, yes, this is a project, so to speak, it is a challenge that affects both manufacturers and notified bodies equally, it is a common challenge that has to be mastered for the benefit of the industry and in that sense, of course, it also makes sense, that you talk to each other, that you communicate with each other, that you try to eliminate the stumbling blocks, to avoid them, yes, in

order to be as efficient as possible

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process, which then also lies in the certification of the medical devices according to the regulations.

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So I would like to underline that very much.

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Incidentally, this is also how this document came about.

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It was the World Medical Device Summit here in Konstanz on 22 May and the EU Commission, ministries, but also doctors, which was very important, notified bodies, sat together.

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And that's when we noticed that there was no communication and no

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common understanding of the whole problem and suddenly you realized what you had done.

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At that time, we were also able to show figures such as how the registration figures collapsed for us and then the thing got rolling and realized, yes please don't tighten it up, because at that time we had recognized that the EU had decided something, then it tended to be tightened again by the German authorities and by the

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and further tightened by the individual auditor.

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And everyone thought that we were doing something good with the whole system, with the result that we might not have done so much good, because you can't even get the products into the markets.

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And this M.

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Document that followed was exactly the wish or expresses this wish, hey, talk to each other and don't outdo each other in any artificial

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requirements that are not documented anywhere.

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So maybe that means as a little story that was hidden behind it.

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But now we are in the present and we have this document, we have already had many of these Structure Dialogues and Mr. Cisco, if you would perhaps tell us, what are the experiences you have had with it so far, what has proven successful, what are the

00:19:07 Speaker 2

maybe the things where they would say, hm, we don't necessarily need that now, what does it look like in practice?

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Yes, I just wanted to make a very brief comment on what has been said so far about the background, namely what is in focus, what is important, the patient.

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So at the end of the day, we do the whole thing in order to be able to provide patients with medical devices that are safe as well as powerful and

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I think that's just important and the MDR may not have given sufficient consideration to certain aspects,

as you have already explained.

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We are talking about products for rare diseases, we are talking about extremely innovative products.

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There are currently working groups for both as a result of the same MDCG paper.

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We have an MDCG paper for the orphan, for the rare products.

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Where I was in the working group, there is a working group for the innovative products.

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I am also involved in this on behalf of the notified bodies and I think that as a further pillar the structured dialogue, that you get into communication and that it is really the case that communication is officially permitted, because that was a very big problem, that there is simply no uniform interpretations not only among the notified bodies, but perhaps also among the notified bodies, well, regulating bodies.

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What are notified bodies allowed to do, what are they not allowed to do?

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And there are also some very strict approaches, that you just said, well, you are allowed to talk to the customers at all and on the other hand, of course, it is quite understandable that you have to talk to each other.

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So it's not that we have the M.D.C.G.

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paper and said, ah, now we have to have a structured dialogue, but it's more the case that it is actually unavoidable to talk to the customers in order to make certain things clear before the conformity assessment procedure, for example, that you have to decide on the classification

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which of course then also results in the correct conformity assessment procedure, under certain cir-

cumstances.

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If you only notice this during the review, after the application has already been submitted, that, for example, because it is a combination product, you may have to consult the EMA and other Competent Authority for Medicinal Products, that is of course very late in the process.

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This means that clarifying such things in advance makes extreme sense and of course it is not expedient to refrain from doing so when you talk about rapid certification and about bringing the products to market and replacing existing, safe

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to keep functioning products on the market.

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And that shows that it builds a bit of a bridge into, what are best practices, what can be done.

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I said earlier that preparing for the meeting is very important, so that really as a manufacturer, when you ask the notified body for a meeting, and that's also important, that you actually do this request, that you say, I want to talk to the notified body and schedule a corresponding meeting, that you really go there and say, I'm going to go to the notified body now, I'll ask for it

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And that's, so that's the first step.

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And once you have taken this step, asked the notified body for the meeting, have an appointment, that you are then also well prepared, have a corresponding list of questions, what are the points that are really still open and that should then be clarified accordingly.

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So that always helps us enormously in advance, yes a

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Paper, a presentation, whatever the format is.

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So it's not so structured that we say, there has to be a certain format now, but it makes a lot of sense to have that, a list of the contact persons accordingly at our customer and yes, what is the topic and then also plan an appropriate time for the conversation so that we can then sit down together, either on-site in a face-to-face meeting or online via Teams.

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So that's from the

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The way we do this, according to the way it suits best for those involved, also possible in a hybrid way.

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So that means that we are not in such a way that we say that there is still this one format and that it always has to be like this.

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But what actually happens with us, and Mr. Engel has already said this earlier regarding the regulatory requirements, so we need a contract in some way, of course.

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So we can't do this now without the fact that we have at least concluded a framework agreement beforehand, but this is of course also very clear from the customer's point of view, because we are talking about confidential things.

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So that means things like confidentiality, objectivity, independence,

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it just makes sense and is valuable that before you have such a meeting with which you talk about content, maybe also have relevant information that concerns the product, exchange, that you create an appropriate basis and therefore of course a contractual basis and an aspect that may not always be in the foreground in the discussion, is a lot that is also said, structured dialogue, this is a company that has a new product and

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that comes then, is planned for the market launch, we have a structured dialogue beforehand.

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In reality, however, it is very often different, we have quality management certificates for non-high-risk products.

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This means that we have been looking after the customer for perhaps 20 years earlier under the directives, now under the regulations, and this customer has a large number of products with us that are within the scope of various certificates and are now

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If this customer plans to introduce a new product and extend the scope of the certificate to this product, then we already have a contract.

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This means that this customer is already our customer within the framework of the quality management system procedure and it is of course very unproblematic to be involved as a notified body at an early stage so that the customer then clarifies appropriate questions about this product with the notified body so that the procedure can then run efficiently at the end of the process.

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Those were a lot of tips, I have to summarize briefly, otherwise it will fall on the stack.

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So first tip, please only do it if you have a contract, otherwise it won't work at all.

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Second tip, don't limit yourself to topics that have something to do with new products, but use this tool for other issues as well.

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Third tip, have clear questions that you want to ask the notified body, so have clarity about what the goal of this conversation is and

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And the fourth point I have heard, and please provide the necessary background information so that the notified body can prepare properly.

00:25:07 Speaker 2

These were, I think, the four tips that I hope to have distilled correctly.

00:25:11 Speaker 2

What are typical questions that pop up in your mind?

00:25:15 Speaker 2

Maybe also the most common questions, but you can also report the funniest ones.

00:25:19 Speaker 1

Yes, so the most common question is, of course, we all know that, that's where the shoe pinches, is the clinical evaluation.

00:25:25 Speaker 1

This means that the requirements between M.D.R.

00:25:28 Speaker 1

and between M.D.D., the directives and the regulations have changed significantly and there are of course correspondingly many questions to be answered.

00:25:38 Speaker 1

But it can also be the classification.

00:25:40 Speaker 1

So in other words, especially with software products, Rule 11 for software products is relatively, yes, I, I'll say now, worthy of interpretation, for which there is then again a corresponding M.D.C.G.

00:25:51 Speaker 1

Paper.

00:25:52 Speaker 1

where you can then determine the correct classification for software products.

00:25:57 Speaker 1

There is the question, is my software medical device a medical device at all or is it a wellness app?

00:26:03 Speaker 1

So these different borderline borders, boundaries between really medical device and perhaps not medical device, although I say that quite intentionally, not medical device, because we are responsible for medical devices as a notified body.

00:26:14 Speaker 1

We don't tell the manufacturer, you have a drug or a cosmetic here, we look at the question, is it a medical device, yes or no.

00:26:21 Speaker 1

and of course that's something that may also be a point that you have to talk about before we get an application, accept the application, draw up a contract, everything and then find out, it's not a medical device at all, of course it doesn't make sense to proceed accordingly, but the question, do I have a medical device, yes or no, or maybe another product, is also, I'll say now, something that we have discussed several times, demarcations.

00:26:45 Speaker 1

And yes, Marc, you can add something to him.

00:26:49 Speaker 3

I wanted no, so

00:26:51 Speaker 3

To say this almost a little more generally, the questions we often hear are: Can I do it like this and does it then lead to approval?

00:26:59 Speaker 3

Yes, these are popular questions and they apply to all kinds of things, starting with classification and so on and so forth.

00:27:07 Speaker 3

The statement that you make there, well, these are questions, of course, they are obvious.

00:27:11 Speaker 3

Yes, the problem is that the answers often cause disillusionment, because the answer to them can only be: Yes, you can do it like that,

00:27:20 Speaker 3

yes, no one forbids you, that leads to the goal, we don't know.

00:27:25 Speaker 3

We cannot guarantee that there will be a roadmap after the Structured Dialogue and if it is adhered to in

such a way that it will then lead to the approval of the product, yes.

00:27:33 Speaker 3

What we can do is exchange ideas about which ways seem to make sense and then we actually get detailed questions,

00:27:40 Speaker 3

That's just the constructive approach to the whole story.

00:27:43 Speaker 3

But we can't say that if you do that, you'll get approval, because in the end it will always depend on how it is implemented.

00:27:51 Speaker 3

If you really think about it, the approval of a medical device is actually not difficult in principle.

00:27:57 Speaker 3

All you have to do is prove that the product complies with the general safety and performance parameters, or as it used to be called, the essential requirements, by mapping the corresponding supporting documents in the technical documentation.

00:28:10 Speaker 3

File, clinical evaluation, description of the product, quality management system, the points.

00:28:17 Speaker 3

Yes, the documentation, it has to be conclusive.

00:28:20 Speaker 3

That is, we can talk about whether

00:28:23 Speaker 3

which chapters in the technical documentation should perhaps be given more weight than others.

00:28:28 Speaker 3

Yes, it is, what would you expect in the context of the clinical evaluation, but we can't say that if you do it that way, then you will also get approval, because that can only happen when the entire technical documentation is checked by our product specialists and they come to the conclusion that the message that is supposed to be in there is actually fulfilled.

00:28:46 Speaker 1

Yes, I can maybe do that again with a bit more illustrative also an example, so the clinical evaluation is coming yes

00:28:53 Speaker 1

more often like this, for example, is the number of cases in a planned clinical trial sufficient?

00:28:58 Speaker 1

So I have a clinical study as a manufacturer, I want to do it because I have a class 3 implant, novel product on the market, requirement to carry out a clinical study.

00:29:07 Speaker 1

The question that arises is, are 300 patients in this study enough or is that too few, would the notified body accept that?

00:29:13 Speaker 1

That's just a question in this level of detail, which is of course difficult for us to judge in such a meeting, because on the one hand we know

00:29:22 Speaker 1

from an hour of meeting not the entire technical documentation of the product and the intended purpose of the product is now, let's say, a draft up to the conformity assessment procedure and until the completion of the conformity conformity assessment procedure, the intended purpose may change again.

00:29:39 Speaker 1

Indications are added, inclusion, exclusion criteria.

00:29:42 Speaker 1

Contraindications.

00:29:44 Speaker 1

This means that if we were to say in such a meeting, 300 patients and the study, that fits, but afterwards something changes in the intended use, for example, or the contraindications are expanded or perhaps some that are still presented in the meeting are omitted, it may be that the study what is in the technical file at the end of the day,

00:30:04 Speaker 1

is not sufficiently supported.

00:30:05 Speaker 1

Whereby it is then just the case that we now say, this fits so far later, but then say, it doesn't fit after all, because something may have changed or we had insufficient access to the file at the time of this meeting, because we can't bring forward the conformity assessment procedure and have a real statement, that's okay, actually results from the entirety of the submitted documentation and not from a small spotlight that you might see in such a meeting

00:30:29 Speaker 1

and in addition, the determination of 300 patients is something that is carried out in a case number analysis by a biostatistician.

00:30:37 Speaker 1

But that's actually a good example.

00:30:39 Speaker 1

So as a notified body, we would then already give the feedback, yes, if you have a certain number of cases in your study, we would expect that it is justified accordingly, scientifically validly justified and ideally from a person where you have ensured within your quality management system that this person

00:30:55 Speaker 1

is sufficiently competent to carry out this sample number analysis properly.

00:30:59 Speaker 1

And then the question of whether there are 300 or 315 or 285 patients is not what we are sensibly discussing in this meeting, but the question of what are the regulatory requirements for clinical trials and what is also important with regard to the documentation to be submitted afterwards, because the manufacturer then hears

00:31:17 Speaker 1

this sample number analysis by the biostatistician is important to the notified body afterwards.

00:31:21 Speaker 1

So we submit the biostatistical assessment report and not only the final study report, but also the study plan.

00:31:27 Speaker 1

To sum it up, we also have these common questions right now, what needs to be submitted, what is the

scope of documentation for our customers already prepared on the homepage, let's say now, whitepapers.

00:31:39 Speaker 1

These are checklists that tell you which things have to be submitted for which parts of the technical documentation

00:31:47 Speaker 1

And for me, this is also structured dialogue, not only synchronous communication in meetings, but also asynchronous communication via our question and answer lists if we have questions during the process.

00:31:58 Speaker 1

Also our white papers, where we then give the manufacturers a best practice, what are the documents we need to make the process work.

00:32:06 Speaker 1

So this written way is also very important and then of course supplemented, especially when we talk about the questions and answers, i.e. about the queries during the procedure,

00:32:15 Speaker 1

because in writing, sometimes, when you get a written question, you don't understand what you really meant by the other person at the end of the day, that you have the opportunity to talk about it again, so a technical meeting, what was really the reason to ask this question, what is really there, what is the regulatory reason, the occasion, the starting point, to ask this question to the manufacturer in this way, so that the manufacturer does not understand something completely different and then does something that in the end does not advance the process, but is a lot of work.

00:32:42 Speaker 1

So I think it's really very important to talk about it, because they have this exchange and that helps us accordingly, so that at the end of the day the procedures can also be shorter.

00:32:53 Speaker 2

You have already answered 2 questions that I have not yet asked.

00:32:56 Speaker 2

One was the question of the binding nature of the statements and the second question again, what is Structure Dialogue?

00:33:02 Speaker 2

I just learned the first one, so the commitment globally cannot be given.

00:33:08 Speaker 2

That was what Mr. Engelhardt said, you can't make a statement about

00:33:12 Speaker 2

the success of the approval, because it did, they rephrased it again and said, it's not an early conformity assessment.

00:33:18 Speaker 2

So that's a restriction, the next one they had, she had called it, a statement can only be made naturally on the assumption that certain information provided is correct and also no longer changed, because otherwise the basis is missing afterwards and a bit also resonated, of course it can only do things

00:33:37 Speaker 2

that can also be answered in the scope and thus also in time in scope of such a meeting.

00:33:43 Speaker 2

So, for example, a calculation of the number of cases is one thing where biostatistics often sits on it for hours or days and that would not be the case, so you don't get the commitment out of it, but you may get a commitment with regard to the procedure to arrive at this number of cases.

00:33:57 Speaker 2

You could get a commitment, that was the scope restriction of this structure dialog and then they had Cisco from just another

00:34:05 Speaker 2

opened up the playing field, what is it actually and said, it's not just this conversation that we have there, this one-hour one, for example, but the structure dialogue also includes asynchronous communication, F.A.Q.s are also part of it, an asynchronous communication exchange is part of it and I think we have now, I think, already got a pretty good overview of this topic.

00:34:30 Speaker 2

What would be the things you would recommend,

00:34:33 Speaker 2

to get into the Structure dialog, once A.

00:34:37 Speaker 2

for the company manufacturers who are not yet customers with us and B.

00:34:40 Speaker 2

for those who are already manufacturers but have not yet done something like this.

00:34:44 Speaker 2

Who is a good contact person for you?

00:34:46 Speaker 2

I'm unsure.

00:34:47 Speaker 3

I would just name the basic requirement very briefly.

00:34:52 Speaker 3

Yes, as I said, you should know the rules,

00:34:56 Speaker 3

that you want to fulfill.

00:34:59 Speaker 3

You should be firm with the regulation, the requirement of the regulation and the accessories.

00:35:04 Speaker 3

And you should have a strategy.

00:35:06 Speaker 3

Yes, I think that's very important.

00:35:07 Speaker 3

One should know how one intends to be able to prove this proof, which is required by the regulation.

00:35:14 Speaker 3

If you go there and say, we don't really know, we've had a look at it, we're something there, we can do it either way.

00:35:21 Speaker 3

That will not lead to the goal.

00:35:22 Speaker 3

So

00:35:23 Speaker 3

You actually have to know the rules and you have to have a very clear strategy for the product in question.

00:35:29 Speaker 3

Which starts with the fact that you have worked out the intended purpose of the product very clearly, that you know for which target markets, that you know which risks have to be considered.

00:35:38 Speaker 3

I think that is imperative.

00:35:40 Speaker 3

Otherwise, it will be difficult to actually carry out this structured dialogue.

00:35:44 Speaker 2

Who will you turn to specifically?

00:35:47 Speaker 2

Is there a contact person or is that the respective project manager at your company?

00:35:53 Speaker 3

Yes, I'll say it, I would perhaps look at it differently.

00:35:57 Speaker 3

We are actually talking about customers now.

00:35:59 Speaker 3

I mean, if there are no customers yet, they come in anyway via Marketing Sales and the inquiries are then forwarded.

00:36:06 Speaker 3

Dr.

00:36:06 Speaker 3

Ziskoven has already said this quite nicely: Most of the customers we have are certified over time, not only for the products, but starting with the 13-485, i.e. the quality management system.

00:36:17 Speaker 3

So, and in this context you have your contact persons and you can then express the desire for a Structure Dialogue.

00:36:23 Speaker 3

This means that as a rule, customers have direct contact persons to whom they can then turn to them.

00:36:29 Speaker 3

We don‘t have a staff unit for the Structure Dialogue, but that will actually be taken up and further worked on and answered.

00:36:37 Speaker 2

Mr. Ciskoven, you had just nodded, was there anything else to add?

00:36:40 Speaker 1

No, from my point of view, Mr. Engel has reproduced this very comprehensively.

00:36:44 Speaker 1

So of course, the customers we have have their contact persons and would then point out at this point that they now need a conversation for a new product, whatever.

00:36:54 Speaker 1

In most cases, it is actually the lead auditor, because we, i.e. the lead auditor for this company, because he also carries out the corresponding planning of the audits and the corresponding and

00:37:05 Speaker 1

is known to customers as a contact person for technical questions.

00:37:07 Speaker 1

With the new customers, it is our sales department that would of course prepare appropriate offers and

then establish the contacts.

00:37:16 Speaker 2

Yes, this also makes the call to action clear.

00:37:17 Speaker 2

So dear non-customers, get in touch with marketing and sales.

00:37:21 Speaker 2

Dear customers who want to conduct a structure dialogue, use your contact person, typically your lead auditor.

00:37:27 Speaker 2

And then gets the ball rolling.

00:37:29 Speaker 2

All the tips that you should then follow, namely clarity about the intended purpose, which Mr. Engelhardt has just emphasized again, the listeners now know from this podcast episode.

00:37:40 Speaker 2

Yes, I have learned a lot from you.

00:37:42 Speaker 2

Thank you very much for giving us these insights.

00:37:47 Speaker 3

And for contacting us, we can refer to our website again, everything is in there, yes, for interested parties certainly not there, I think you can find exactly the channels that you have to write to, will be linked, thank you very much for the good conversation, yes thank you very much