Johner Institute

Notified bodies are upgrading (part 2)

With Dr. Andreas Purde, Prof. Dr. Christian Johner

Transcript

00:00:00 Speaker 1

also a goal at the beginning is definitely to check for formal aspects first.

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I have not yet formulated the goal, now deep drilling A.I.

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moderate, but first of all the formal aspects are covered by an A.I.

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And when we have settled the issue, we will certainly also deal with the deep drilling.

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

00:00:26 Speaker 2

Yes, here we are again.

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I am very happy to have invited Doctor Andreas Purte again and that he accepted the invitation, because I think it is completely obvious to discuss the topic of A.I.

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in the examination of technical documentation, that is really hot at the moment, that is also overflowing with the progress we have.

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And that's why I think it's necessary again that we do a follow-up session with him.

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Starting point, perhaps

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also the observation that we are both making now, when Andreas and I during our A.I.

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supported T.D.

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Exams, we now have more and more mistakes that we can pull out with them.

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So and the question we are actually facing now is, how do we deal with it?

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So once on the side as a manufacturer, but also on the side of a notified body.

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Because if you somehow report a four-digit number of deviations to the manufacturers afterwards, I don't know if anyone is really helped.

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And these are so few topics that we want to discuss today.

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We also want to discuss what is currently the latest status.

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So, what's going on with this mission.

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We also want to shed light on how we can make our A.I.s adapt to human species.

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In other words, how you proceed with such an audit, what kind of teams you have with you, always with the aim that they know what possibilities we have and can then build such things themselves and thus drive up their conformity.

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That may even be

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large frame.

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But for now, Andreas, 1000 thanks for being with us again.

00:01:56 Speaker 1

Yes, very much.

00:01:56 Speaker 1

I'm glad that we can take up the topic again and you have already addressed many interesting points that we want to talk about again now.

00:02:03 Speaker 2

No, yes, but maybe I'm just starting with the problem.

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I don't know if it's a problem, but with the fact that we have very, very many deviations.

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It no longer feels like a random test, but like a full test.

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How do you deal with it

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00:02:20 Speaker 2

So, do you also see this as the full test and what do you do when a three- or four-digit number of deviations blows up in your face?

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Yes, so maybe I have to go back a bit to what the Medical Device Regulation or the I.V.D.R.

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actually want to.

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Well, we all know that we are in the low-risk range, i.e. 2 A.

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and 2 B.

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products, even random samples.

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That means we don't look at all the technical documentation,

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but just a random sample.

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However, once we have taken a sample, i.e. selected technical documentation, there is actually no longer a sample in the evaluation of technical documentation.

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So, I'm not doing a sample of the sample, but we have to de facto meet all the requirements that the M.D.R.

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or I.V.D.R.

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technical documentation.

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So, that means checking all modules, i.e. risk management, usability,

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electrical safety, biocompatibility or whatever is applicable to the product, it is of course also clear that I cannot check every single test, because every single risk of technical documentation in its entirety.

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So perhaps, in order to classify this a bit, i.e. we have to fully evaluate and check the technical documentation.

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As I said, with the restriction that we can't do that, of course.

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can actually do in every last test proof.

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No, maybe that's a bit of a classification and of course I also know technical documentation.

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If I, as an evaluator, had actually written down all the errors that I noticed in the past, so to speak, then I might have had technical documentation that would have been of such magnitude that I wrote hundreds of deviations.

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However, this usually correlates with manufacturers who

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have not yet understood exactly what they actually have to write in a technical documentation.

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And actually, a reviewer in a technical documentation, if he notices that it doesn't fit at all, should actually cancel a review and send the customer back and say, please deal with the requirements of Annex 2 of the MDR again and then you will come back when you have managed to get it that far.

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That would actually be the mode.

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So

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three-digit deviation figures, I know that there are, but should actually be avoided.

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But now we have it at K.

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I. that this happens.

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So that's not an exception either, but probably more the rule now, because we, as you have just described, officially it is then full audits of the files selected as a sample.

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However, the reality and the fact that human life is finite and so is the time of an auditor, leads to the fact that it does happen.

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Somewhere, as you just said, not everything can be checked.

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The A.I.

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doesn't take it into account, she is very capable of suffering and also relatively fast.

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What would you give to an A.I.

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so that it doesn't just overwhelm us now?

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Or the alternative question would have been, if it overwhelms us, what ideas would you have to consolidate it again, so as not to overwhelm the manufacturer quantitatively on its own?

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Of course, you're absolutely right, Christian.

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So to if, if I now have an A.I.

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and would do it unchecked and the A.I.

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maybe also does its job relatively well and actually all errors in the broadest sense, whereby errors are not yet quantified and I'll go into that in a moment, i.e. finds all error inconsistencies of a technical documentation, then of course there can be hundreds relatively quickly, depending on the quality of the technical documentation.

00:06:00 Speaker 1

But this does not help us or the manufacturer.

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If I were to pass on every error that does not call into question the conformity of the product at the end of the day to our customers and thus to the manufacturer, who then has to correct it in painstaking detail, that would not help.

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This means that we must also, I would say, take into account the human behaviour of an evaluator of the A.I.

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somehow convey that the A.I.

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decide whether the error is now so

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I'll put it this way, what is relevant is that it has to be corrected, i.e. that the conformity of the product is in question or that the explainability of the technical documentation is not given, or whether it is actually a minor lapse or a minor error in the technical documentation, but which does not go into the wine at all with these two points mentioned above, i.e. not correlated.

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then maybe I can give the hint, but don't expect any correction at this point, because otherwise I don't think we would be done at the end of the day.

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No, that's what T.

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D.

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evaluator today also and exactly this behavior I would have to admit at the end of the day of the K.

00:07:05 Speaker 1

I.

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Mhm, I have a relatively large number of T's now.

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D.

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s and what you have just proposed is a risk-based approach, you can perhaps also call it.

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And the test criteria that I have in it were ultimately which,

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which were derived from the standards and of course now, how do you implement them, because the standards are far too unspecific to be tested against them.

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Maybe now an example where we can stay close to the norm if a use scenario has been qualified as safety-related by the manufacturer and

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And there is no reason why it is not examined.

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Then that would have been a deviation, which probably also calls into question the conformity.

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Or if there is a risk to which there is something that is not quite small and for which there is no risk-minimizing measure, they will probably also say, hm, that calls into question the conformity.

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What I'm choosing out of is my fear, which I have a bit, is that even if we now proceed risk-based and let's say, all the

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Little things, i.e. hiding formal inadequacies, there is still so much left over that it won't be so easy for the manufacturers afterwards.

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How would you deal with that?

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Would you then raise this threshold even higher until you are left with a manageable number of errors afterwards?

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It's a good question now.

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I don't even know if I can even

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As of today.

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Maybe I have to show that first over time, then later.

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So, we may have 2 approaches to how we currently evaluate, to illustrate it a bit more, at least that's how I personally do it, that I pursue.

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I first go through this way, even once across the technical documentation, by checking whether all the topics that have to be addressed in general have been addressed at all.

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That's part 1 of the review and then

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persevere risk-based corresponding, I'll call it a deep arc, where I actually look at a concrete, for example risk-reducing measure, look at how it is verified, is it verified correctly, that you look at such topics and you don't do that for all risk-reducing measures, but for those that seem particularly relevant to the product at the point.

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So, if I now have an A.I.

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which would now be able to examine all those who

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she would probably find more in total, of course.

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Now the question is, do I then leave each deviation individually or is it then rather a deviation that would read like this: Not all risk-mitigating measures, for example sufficiently tested, example 1, 2, 3, are then more likely to go back to the manufacturer and say, okay, you may have identified a more structural problem due to the higher sample, that you have taken.

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and then gives the task with the manufacturer, OK, please look at risk, the risk analysis again in its entirety.

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Nevertheless, I don't know if we can actually say that we would push the threshold up and say, OK, I, because we get very, very many deficiencies now in the TD through the use of AI, if that would actually happen and then push the threshold further up, I can hardly imagine.

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because then I would question our own work and say, no, no, I can have a maximum of x deviations and then we only take the x worst and all the others we let fall under the table.

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I don't think it should be like that at the end of the day.

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Then I would have to look to the effect that I say, OK, dear manufacturers, we will all see the use of AI in the evaluation of technical documentation.

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This means that I also expect the manufacturers to perhaps make these mistakes in the first place.

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and not come to us with these errors at all.

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And in the last podcast, we had already talked about the fact that the expectation is natural or the call to the industry that of course the manufacturers should also deal with it and, if necessary, check their technical documentation in advance before it is submitted to the tax office.

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And I also assume that manufacturers will then also

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A.I.

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to do that.

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So, that was mega important now.

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So, that's why I'd like to repeat that briefly.

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So, what you said is that tolerance is not necessarily getting bigger because we have a lot of mistakes, but you actually mentioned 2 ways out.

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The first was to get the sheer number down by abstracting.

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So, similar findings just summarized in one and then just exemplary says, for example, how

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found in these examples.

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So then you control the number.

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So it's not quite as overwhelming.

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And the second approach you said is, but at the same time, of course, the level of testing may not be higher, but the one that just the penetration of the test is getting higher and the manufacturers have to react by producing for equality of arms, so to speak, in order to keep up.

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So thank you so much.

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Now a little something else has been added, where I would like to dig a little deeper.

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you have not yet described how people, now in very concrete terms, how you also approach this matter.

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I would like to shed some light on that, because if we know how people do it, we always have a good approach to how we can teach it.

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So the first point with this human analogue would be, how do you go about it?

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So you have already indicated or sketched, you first go into width and then into depth.

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So, how exactly do you have to imagine that?

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Do you go so normatively or I know, biocommunity and usability and software, so let's go across it, so they have anything at all or is it already a bit deeper and then it's like T.

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Stings, how do you have to imagine that?

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Yes, you've already summarized relatively well, Christian.

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Well, of course, I like them now, I'm also just a proven one and we have many, they may all do it a little differently.

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I can only speak for myself now, but it is actually exactly as you have just described, that I first check in a technical documentation whether we have more evaluation modules with us.

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This is not structured according to standards, but rather in terms of evaluation modules, and is relatively strongly oriented towards Annex 2 of the NDR.

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But we also have some assessment modules that do not quite coincide with the chapters of

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from Annex 2 and I just look for each evaluation module, are all the topics that are required there basically available for the time being.

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And if I now take a look at the area of risk management, in the area that is now relatively familiar to me, I say, it just says, OK, I need a risk management plan, I need a risk management report, it has certain areas where certain requirements have to be covered, I first look at them and say, OK, are all the artifacts, the

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are required there for the time being.

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Why am I doing this?

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Well, if they are not available, I don't need to do a deep drilling.

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Then I should ideally feed the technical documentation back to the customer relatively quickly and say, O.

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K., we have larger gaps in the T.

00:14:21 Speaker 1

D.

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and my time is actually a bit too good for me.

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If there are larger gaps, then writing down every single point, that doesn't help at this point, I had already said before, then the T.

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D.

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back to the manufacturer as quickly as possible, so that he can then fill his large gaps

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at this point.

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So, as I said, first go into the width, first to look, is everything there, is my personal approach and if I say, okay, in the width everything is there or I have just identified 23 points where it was not there in width, is also okay, then I just go into these deep holes and then you just look, as I said, individual aspects that seem particularly important to you for the product in question.

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Or also, we also have internal test catalogues.

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After this horizontal basic evaluation has taken place, you have decided, which is good enough to go down into the details afterwards.

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So that means that perhaps also to commission the specialists, then follows again at the end, so then someone comes again who closes this bracket again, for example someone from the clinical evaluation, who looks at the sum again, or is it enough to look at the

00:15:35 Speaker 2

Sum of the individual valuation simply to be placed next to each other.

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Yes, Christian, you, you, you're also talking about a valid point right now, but I also like to assess how it, how it actually works at the moment.

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So in the past it was actually possible for a single evaluator to evaluate the technical documentation in its entirety.

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No, so I used to be able to do all aspects of technical documentation in personal union with me, so to speak

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evaluate, there is less.

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So, if I look at the current tendencies, this is actually still possible in the very rare cases.

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Why also the valuation complexity is written.

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We have experts who deal with the topic I.

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T.

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Security, we have experts who deal with the topic of artificial intelligence when they are in a T.

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D.

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are available and

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to always be the top expert in all areas is something we really can't do anymore.

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This means that we now have dedicated experts for each assessment module, not for all, but for some selected assessment modules, who then look at the topics from their perspectives.

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And that's right, they also have their deviations.

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As a rule, however, they are largely module-separated.

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So it's not the case that I can get too many overlaps or perhaps contradictory statements.

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There are

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sometimes trades where this can happen.

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Instruction manual is such a module, probably everyone looks at it and then has its deviations for the corresponding module.

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The topic of risk management is the second where there may be such overlaps.

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But as a rule, these deviations are already very specifically geared to a certain aspect of the technical documentation.

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If there were topics where a, I'll just outline a case now, the clinical evaluator would say: ‚You, Andreas, have you seen in risk management, they mitigate risks in a very funny way.' Yes, then the evaluator of the clinical module would give me this task.

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So, he would not only question the risk management evaluation module, he would not do that, but we would then remain in communication that it would then also be possible for the

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so-called evaluations of the main part remains to be responsible for exactly this aspect.

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Because otherwise we would perhaps contradict each other on the given side and we do not want to do that out of our own interest.

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Mhm, so there is no one who smooths out at the end, but the respective pillar manager then compares himself with the other areas, but only if that should be necessary.

00:18:12 Speaker 2

O.

00:18:13 Speaker 2

K.,

00:18:13 Speaker 2

Now we have described the approach of the people and it is then again a good role model or model, first of all also for the A.I., i.e. that we approach examinations in a similar way.

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Now we can also consider, after we have talked about the procedure, what kind of people are they now and I now see 2 dimensions.

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One is a technical dimension, as I already suspect your answer, which of course we have to somehow fit for these modules.

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Orthogonally, we would need some kind of character.

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Differentiation, so now perhaps completely acquitted, you might need some kind of formal philistine and then someone who somehow sees the big picture more like that.

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So how, how would you, if you were allowed to put together a team, maybe even without regard to the labor market or any financial restrictions, what kind of team would you put together in terms of these defences, professionalism and

00:19:09 Speaker 2

I don't know if character is the right term, but I think you know what I mean.

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Yes, so I actually think we need them too, both now and in the future, so by which I mean in the future now, perhaps always with the support of A.I.

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it doesn't help if I always let the strictest of all evaluators loose on every technical documentation, then I don't think we'll get ourselves any further in the market.

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but I must, as we said earlier, certainly follow through with the risk-based approach and follow through, persevere, whatever.

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And of course I also need at one point or another, just formalism wins, no, a Declaration of Conformity, it has to be correct, a Bud that may, must be correct and must not look different in one document than in the other or in Intended Purpose, no, I can't do that now, I

00:20:06 Speaker 1

I'll say it, let five be straight at one point or another.

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This means that I have to work very precisely on individual aspects and can perhaps take a more risk-oriented approach to other aspects.

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And of course, a heating cabinet is clinically different from an implant.

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Yes, and I think that at the moment our evaluators have to manage this balancing act, so that they know what kind of product they have in front of them.

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How strictly do I actually have to evaluate certain aspects now, and I also assume that we will have to manage this with AI in the future and, if necessary, apply a slightly different standard for highly critical products, such as products that are now not so critical in terms of risk profile.

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But this is quite a controversial discussion that I have just initiated, I notice when I tell it, because in front of the eye of the law

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there is no distinction between the risk class in the technical documentation.

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Also, die M.D.R.

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assumes that all technical documentation must be correct and conclusive in itself and must meet the requirements.

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There is no distinction between heating cabinet and pacemaker at this point.

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Nevertheless, it is of course the case in everyday valuation that one would of course apply a slightly different evaluation standard.

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depending on the criticality of the product.

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And I think it has to be that way, because otherwise we probably won't get any product on the market at the end of the day.

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Mhm, you've just opened up a third dimension now.

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So I came in with two, namely the technical domain, let's call it now, i.e. usability, risk management, electrical safety and so on.

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The second dimension was the character, i.e. perhaps the degree of formalism, somehow perhaps also the holistic view as examples of this.

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And

00:21:57 Speaker 2

and you have now added the third dimension, namely the understanding of the product class, which still has to be added.

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Yes, we have that, but it makes the space even bigger, so to speak.

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So we are now moving in three-dimensional space.

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I, I dare to ask again, assuming you can wish for 5 people, who, what kind of team would you put together?

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and with them you have to do everything, with the 5.

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Yes, so you do your new purte notified body, I hope your bosses don't hear that now, you open the small purte named body, you can wish for the 5 best people you take with you to your named body, who would it be?

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So don't name any names now, yes, otherwise we'll have a lot of trouble on our hands, but you can invent some now.

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Yes exactly, I'll see if I, if I, if I get to 5, so I can do 3 in any case, no, that I need of course one, one, a person who in principle

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Who has the regulatory knowledge, no, who knows what are the requirements of the M.D.R.I.W.D.R.

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and the corresponding standards behind it.

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In other words, the very strong formalists, i.e. regulatory ones, who simply have regulatory knowledge at this point.

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The second person I always need is the one with the technical expertise, who knows exactly.

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I have a product of this kind, what does that mean technically?

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What does that mean technically for A.I., technically for electrical safety, technically for what do I know what cybersecurity or any topics like that, right?

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And the third person, and we all know this, that the topic of clinical data has become enormously important, not least because of the M.D.R., but of course also very much by the M.D.R.

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So I also need medical expertise, i.e. the doctor or nurse who knows exactly how a product is used, for the evaluation.

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Because that, I'll just say it, as an engineer I don't know, no, period, no, but for that I need the, the, the, the application of the product, the clinic, the, the

00:23:52 Speaker 1

who understand the clinical everyday life of a product, that's the third dimension I need at this point.

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The fourth dimension that we definitely still need at this point is that the customer side understands.

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So we are also an economically minded company and I have to be able to respond to customer needs.

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So we definitely need this perspective at this point and

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I would say I would leave it at the 4 for now.

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The fifth one doesn't occur to me right now, I would rather give another one action or one character trait or give a person I have now forgotten.

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But I think with the four I now have the most important ones, I already mentioned them.

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We have a plan for how our agents can act in the future.

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Which may now bring us a little closer to technology,

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what's new with you from the field of A.I., i.e. new insights, how do you use it, tooling maybe, I know, I can't tell us any secrets, but what is humanity allowed to know that is not secret, where you may be working on it right now, what is on your mind.

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Yes, so we too, is not an open secret, of course we are still at the beginning of it, no, so we have

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A.I.

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in the evaluation, which is already doing its job well, but not yet perfect.

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We are now in the process of overcoming or removing technical hurdles, and we certainly have to get even better in the prompts we currently have.

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As I said, the goal is first of all, we had already talked about the evaluation strategies, not foreseeable in the broadest sense, I'll say, but it's first about how

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I'll say it, completeness check, all aspects are then covered.

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That's the first goal we want to achieve.

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And we have to do that internally, by now covering all the evaluation modules that I have already mentioned, which we have, and of course also the device classes.

00:25:48 Speaker 1

In addition to the evaluation modules, I also have device-specific risks that need to be addressed.

00:25:52 Speaker 1

A baby incubator has other risks than

00:25:56 Speaker 1

Hip implant and the topics we have to try somehow in prompts and in yes A.I.

00:26:04 Speaker 1

verifiable criteria.

00:26:08 Speaker 1

These are the tasks we currently have ahead of us.

00:26:10 Speaker 2

Mhm, have you built up your own infrastructure, how do you do that or do you use normal models?

00:26:18 Speaker 1

Yes, that's a legitimate question, the customers actually ask and also for a legitimate reason, because you don't want the

00:26:26 Speaker 1

Information in the technical documentation then via the A.I.

00:26:30 Speaker 1

into the world.

00:26:31 Speaker 1

We use a commercially available large language model, but it runs in a closed environment.

00:26:38 Speaker 1

This means that it does not learn from the technical documentation and no information flows from this completed, completed L.L.M.

00:26:46 Speaker 1

outside.

00:26:47 Speaker 1

So this is now a

00:26:49 Speaker 1

Open A.I.

00:26:50 Speaker 1

Model, that much I can reveal.

00:26:52 Speaker 1

So that doesn't flow to Open A.I.

00:26:54 Speaker 1

back at the point, but it runs in the cloud.

00:26:58 Speaker 2

Yes, yes, that's how we do it, it's also one of our variants.

00:27:01 Speaker 2

So we also use several, always depending on the task and one is to use these isolated models.

00:27:09 Speaker 2

In some cases, we also have open source models that are also amazingly powerful.

00:27:14 Speaker 2

So, the interesting thing is, in some cases we go back to cheaper models when we use the A.I.

00:27:22 Speaker 2

very well.

00:27:24 Speaker 2

So, of course, that always depends on the task.

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So, for example, I let several agents loose on the matter and then the agents, I sometimes give a cheaper model, like the referee, who afterwards in turn reports on these individual results.

00:27:41 Speaker 2

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00:27:42 Speaker 2

So I have, so to speak, I have an Andreas Porte, he gets the largest model and then I have a few Porte unskilled workers, who then get cheaper models, who then take part in formal exams and where the referee decides afterwards if different answers come back, what do I do.

00:28:00 Speaker 2

So, of course, if everyone agrees, it's easy.

00:28:02 Speaker 2

In most cases, but I now also have that he sometimes vetoes it, yes, that he says, the 3 cheap ones may have somehow

00:28:10 Speaker 2

have not gone deep enough, even in their evidence, and then it may even be that we have a veto.

00:28:15 Speaker 2

So he has so many different types, he can veto, he can do a majority vote and he can do a minority vote or just wave it through and so different models for different tasks.

00:28:28 Speaker 2

Yes, maybe that's just the status where we're working right now.

00:28:32 Speaker 2

Yes, I would say, you can already get towards the end, let's take a little look into the future.

00:28:37 Speaker 2

Have you already

00:28:39 Speaker 2

Considerations on how the M.D.R.

00:28:42 Speaker 2

or the future M.D.R.

00:28:43 Speaker 2

requirement to receive structured data.

00:28:48 Speaker 2

So, is there already a project, are there already data structures, for example, that you have in mind, what is your strategy?

00:28:57 Speaker 1

Yes, so that's a wide field now, too.

00:29:00 Speaker 1

In fact, this is the goal of us, as probably of all other notified bodies, for the time being

00:29:08 Speaker 1

not to have any special requirements for the format of the data we expect.

00:29:12 Speaker 1

That means, ideally, when I look into the future, I still accept the PDF world, which we currently have very, very strongly, as well as when someone says, O.

00:29:24 Speaker 1

K., I'm now coming around the corner with some XML file, where all the data of the technical documentation are in it, I have to get involved as a notified body.

00:29:33 Speaker 1

That is,

00:29:33 Speaker 1

The goal for us is no matter what format comes, we want to be able to process it, I'll say, that's the noble goal we have.

00:29:41 Speaker 1

Whether we succeed in doing that at the end of the day, let's see.

00:29:44 Speaker 1

Nevertheless, there are various projects that are underway to create a bit of clarity.

00:29:50 Speaker 1

There is also this New Horizon project of the EU, which is now starting again at this point.

00:29:56 Speaker 1

I'll look, I don't know exactly what they're going to do yet.

00:30:00 Speaker 1

I can, but could well imagine, that the topic

00:30:04 Speaker 1

structured data for T.

00:30:06 Speaker 1

D.

00:30:06 Speaker 1

should also appear on the agenda.

00:30:08 Speaker 1

If I know who is involved as a stakeholder in the project, I would almost assume that the topic could come up.

00:30:18 Speaker 1

Because I think we all agree that a uniform format is of course easier to master than 100 different formats.

00:30:27 Speaker 1

I believe, Christian, you as a

00:30:29 Speaker 1

as a technician at this point, you can certainly confirm that it would be easier if we had that.

00:30:34 Speaker 1

As I said, but again, what I just said at the beginning, the goal of every notified body should be not to stand too far in a corner, but to accept any formats that have established themselves in at least one market.

00:30:50 Speaker 2

Mhm, that's of course the ideal case for the manufacturers, then they don't have to get too involved with you.

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The challenge will of course be then,

00:30:59 Speaker 2

you have to get into a structure that makes your A.I.

00:31:03 Speaker 2

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00:31:03 Speaker 2

So, because my assumption is, or conjecture or pure speculation, that you are the A.I.

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right now not only give these texts, but also the structures, because you get much better test results for them.

00:31:16 Speaker 2

And then you have the classic classic interoperability issue, which we have with us.

00:31:21 Speaker 2

Maybe a thought about this Horizon project or about a general standardization,

00:31:28 Speaker 2

we actually have the same challenge as we do in the area of legislation and standardisation.

00:31:34 Speaker 2

So that means we have different levels of abstraction, law often the broadest, the most imprecise.

00:31:41 Speaker 2

Yes, that is perhaps what we also expect from the granularity on an I.M.D.F.

00:31:46 Speaker 2

Tape of Content Format somehow.

00:31:48 Speaker 2

It goes into the norms, becomes a bit more specific, but often not

00:31:53 Speaker 2

operationalizable and thus more verifiable.

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That's why the manufacturers always have their Q.

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M.

00:31:57 Speaker 2

systems with their specific specifications on how to implement it.

00:32:01 Speaker 2

And that would ultimately have to be transferred into a structure, because only then are we actually, we have the granularity on the basis of which we can then also make judgements.

00:32:12 Speaker 2

So that's why there will probably be a guess in the long term or does there have to be a framework that

00:32:19 Speaker 2

specificity, concretization and where these extensions, in order to become specific, are then again generally defined.

00:32:28 Speaker 2

So this is a topic that on the one hand has a lot of knowledge in the field of formal languages, but also extremely deep knowledge in the area of domains.

00:32:40 Speaker 2

yes, so how do you do it in the 60, 6 and 1, how do you do it in the 62, 304 or in all these different domains,

00:32:48 Speaker 2

I'm curious to see how that will be, but I think that's exactly where the circles go.

00:32:53 Speaker 2

Yes, and here I am ours, we have already arrived at the end of today's podcast.

00:32:58 Speaker 2

Perhaps very briefly the most important thoughts.

00:33:01 Speaker 2

We first thought about how we would deal with all these many deviations that the T.

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D.

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automated T.

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D.

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test will flush up.

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So, your important tips, summary by abstraction and the request to the manufacturers to retrofit as well,

00:33:16 Speaker 2

Then we thought about how we as humans would approach this topic, perhaps also as a role model for the A.I.

00:33:23 Speaker 2

Once we have thought about it, how do we proceed, in which steps.

00:33:27 Speaker 2

Well, you had called it, from width to depth.

00:33:30 Speaker 2

We also thought about which team we would put together to be able to do that and then took a look at the state of the art today, what you are doing.

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I also said a few sentences about where we are at the moment and at the end we took a look into the future.

00:33:44 Speaker 2

when we may have arrived in the world of exclusively structured data at some point.

00:33:49 Speaker 2

Andreas, as always, was a pleasure with you.

00:33:52 Speaker 2

I hope for a part 3.

00:33:56 Speaker 1

There will certainly be, no, so also from my side thank you very much and I had already said it after the first part and I, as I said, I would like to repeat the call again at this point.

00:34:06 Speaker 1

This is a journey we are on now, the

00:34:09 Speaker 1

Spain may also be scary at times.

00:34:11 Speaker 1

We will see and I think we all have to go through it together, i.e. consulting institutes, notified bodies and, of course, the manufacturers as well, and I believe that this is a common task that we have ahead of us and I believe that we should also tackle it together.

00:34:25 Speaker 2

What a final word, Andreas, 1000 thanks.

00:34:27 Speaker 1

Thank you.