Johner Institute

Recommendations from a Certification Body

With Dr. Peter Diesing, Prof. Dr. Christian Johner

Audio File: DIESING.MP3

Transcript

00:00:00 Speaker 1

That's my top number one mistake, but it's actually not in my head yet.

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Namely, the MDR says in the basic safety and performance requirements that it includes A under point B methods and C standard.

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Medical Device Insights.

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

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Our legislators, in particular Brussels, but also our standards committees, are still quite busy publishing regulatory requirements.

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So you may be thinking about the new specification on the subject of electronic user manuals.

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But nevertheless, I have the feeling that the system is slowly settling down a bit and that they are already readjusting the consequences of the whole switch to M.D.R.

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and I.V.D.R.

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And so it's time to take a look at this whole system, to see where we stand, where are there still problems at the moment and how can we tackle these problems so that manufacturers can get through all these approval procedures, I'll call it in quotation marks, particularly elegantly.

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And it is precisely for this reason that I have invited someone today who has an overview of this system and also knows the problems very well, because he is the deputy head of the certification body at Berlin Zert and that is the

00:01:24 Speaker 2

Doctor Peter Diesing, whom I would like to welcome here and I know from him that he has a technical past, if I may call it that.

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Well, he has a doctorate in mechanical engineering and you can ask yourself the question, how do you get from such a mechanical engineering background to a notified body afterwards, how do you become a certification center manager, how did it go for you, Mr. Diesing?

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Yes, as is so often the case in life, of course, coincidence always plays a role.

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After spending a few years in industry, I went back to university and did my doctorate there.

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Then there was simply a change of job one floor higher at Berlin-Zart.

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also involved and associated with this change of job was the establishment of the certification body for management systems.

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So I came to Berlinza in 2006, where it was primarily a test laboratory.

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So that means there were approaches to going into management system certification, but it was really still in its infancy.

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There were 2 customers, one of whom then dropped out again, the accreditation was not yet completely through.

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So from that point of view it was a challenge where I got into this topic

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area with a steep learning curve, but for quite a while it was allowed to operate and yes, from the 13485 certification to Appendix 25 and 6 under the old MDD and then later actually with the M.D.R.

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was then also allowed to accompany this process.

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So, you are a man from the very beginning, with all regulatory requirements, but also very specifically with your notified body.

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You just talked about the doctorate.

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Can you perhaps say one or 2 sentences?

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I think we even have a few points of contact there.

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Yes, I studied biomedical engineering and was also there as part of my doctorate in the field of medical technology at the Technical University of Berlin and

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there test procedure for products against decovitus, i.e. such a mattress pillow, sounds like simple

products at first, but as always, if you go deep enough, you realize that everything becomes arbitrarily complex and for this I have developed test procedures, which have then also been used for a long time in the context of yes approval to the list of medical aids and from that point of view I had the whole time just the reference to medical technology, That I never lost.

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I thought I had read somewhere that they had also been in the field of hemodynamics, but that was something else obvious.

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That was my industry experience, which was the one before.

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Well, I used to be with B.

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Braun measurement and was there in product management in the hemodynamics department.

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So everything that concerned blood pressure measurement, time volume measurement, but also electrophysiology, I was a product manager there with a relatively close connection to development.

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So it was a very

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education-oriented product management activity, but in the end it was marketing and I'm just a technician from the core and so at some point it drove me back into an area where I'm a little closer to technology.

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I believe that immediately, especially after they have described that they helped develop their own test procedures.

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Of course, this is something very technical and of course also fits perfectly into the context of such a notified body.

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Yes,

00:04:51 Speaker 2

Yes, and there you are, deputy head of the certification center.

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This means that you have an overview of many conformity assessment procedures that you carry out with and for your customers.

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And we would like to benefit from this experience and this overview today.

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What are deviations, problems, non-conformities that you see particularly often?

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So, do you see any patterns there?

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and perhaps also the question of what consequences these deviations that they observe have for the manufacturers and for the conformity assessment procedures.

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Yes, so I actually see the patterns in the close reading and the close tracking of regulatory requirements.

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These things are actually all written somewhere and is the M.

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D.

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R.

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not exactly a work, which is due to

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It is noticeable by a very clear structure, but there are different requirements in a wide variety of places.

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This is actually difficult for manufacturers to understand all these requirements, especially when their everyday work in small and medium-sized companies.

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just not the reading of the M.

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D.

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R.

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but it's about customers, it's about customer satisfaction, it's about good products and production.

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And the other is often something that small and medium-sized manufacturers have to do, but where they often don't put their heart and soul into it.

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Therefore, reading exactly what is actually in it is often the first one, which is the first starting point and

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then we often have cascades like this in the MDR.

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We have cascades of requirements, which are then perhaps still observed in the first line, so to speak, but are then already lost in the second and third cascades, because you look at the first one and then don't go into the second and third level and so you always lose something.

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So that's a bit

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a, a, a, a pattern that I actually recognize.

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Could you give us examples?

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So, what you have just given us was the ability to read precisely and to draw precise conclusions from them and not to break off too early when reading, namely to be able to understand exactly these cascades.

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Do you have any examples of where things are overlooked or where the cascade is not tracked with sufficient accuracy?

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Yes, so an example is the inspection obligation of the U.D.I.

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allocation.

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So the first thing is that many people are already looking for the word U.D.I.

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and say we have to U.D.I.

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and it's done.

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In fact, Article 10, Section 9H provides for the review of the allocation of the U.D.I.

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So that's already something where the first.

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the first mistake happens.

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Then there is also Article 27, Section 3 and the information provided under Article 29.

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The whole thing is not shown in 13485, so it's a special topic.

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If you then go in after 27, pass away, section 37 then also refers to Article 31 again.

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So that's a cascade where I first have to find myself somewhere

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to see how I form that in my Q.

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M.

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system.

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And there is just it to the abort, to the abort before sometimes even when not reading closely, it's about U.

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D.

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I., but what, what, what kind of inspection obligation is it actually about?

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That's, that's actually something that runs through.

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This example now makes it clear that it is not only about technical documentation, but also about the quality management system, where exactly such procedures

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just described.

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How do you recommend or what do you recommend that the root cause of this problem be eliminated a bit?

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So now just to say, read more closely.

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So I think that would be very helpful.

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Do you have any other tips on how much we should tackle?

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So that you have a higher certainty that you haven‘t missed anything, that you haven‘t missed any element of this cascade.

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Yes, so of course everyone has to find their own way.

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As a technically oriented person, I first think of databases, ultimately of this molecular structure that I have there in the MBR.

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That means I have requirements, these are my atoms, so to speak, and I can remove them from them and then I have my QM system opposite them

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Where I can contrast these atoms or molecules, if I have there in the cascade, for example, then also with them.

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Of course, I can do this in the form of an Excel file, of the Word file as a table, but actually it is an ideal aspect to build up a database.

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but basically the atoms are really to be identified first.

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This is often the crux of the matter, if I don't know the atom, i.e. the individual or singular requirement, then I usually don't have it in my Q.

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M.

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S.

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depicted.

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Mhm, this is of course a very demanding task that our manufacturers are giving it, now both quantitatively and qualitatively.

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So by that I mean that on the one hand we have an extremely large amount of regulatory requirements that

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at all.

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So for example, I think we now have almost 10,000 regulatory documents that we monitor for manufacturers.

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Well, that's an incredibly large number.

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Side notes are over 3,000 changes that we report to the manufacturers per year.

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Well, it's quantitative, so it's a really thick board.

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And what you have now given us, I find almost even more demanding, because the first can perhaps still be slain with hard work.

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But distilling these molecules, as you have just described, I find that an extremely challenging thing, because we do not find a uniform structure for this requirement in all the regulatory requirements.

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They move on completely different levels of abstraction.

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Yes, these are requirements, they are very general, like this, take care of this topic, up to and including please have a procedure or sometimes just down to the

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measurable requirements, these are the things that manufacturers often like best.

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Yes, if it says what I have to say about the war distance must somehow have 2.4 millimeters, you can check that well, you can get it out easily.

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But I think it's a difficult thing to get all these meta requirements into a common construct and it's probably one of the skills that companies and their regulatory people have to have here as well.

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You had just given this U as an example.

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D.

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I.

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topic.

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Can you give us another example of such a recurring deviation?

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Maybe we can find a similar root course there.

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So indeed, this is a bit simpler and it's about the languages in the operating instructions.

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This is also something where it is very often very practical.

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So that means I get a request from Portugal and

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I am then immediately ready to deliver my products there.

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But what I have to make sure beforehand is that the language requirements are also ensured.

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And on the one hand, there is the knowledge of the requirements.

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That means there is this.

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Overview of Language Requirements from the EU, which is a very, very helpful document because it just catches these things together.

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But to bring it into a practical process.

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So it's different from the UDI, where I go very, very far somewhere in the depth of the MER, it's about the requirements that I have to anchor in the organization in the first place.

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Yes, we see again and again that there are challenges there, especially with low-class products.

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So with the higher-class products it is part of the technical documentation check, but with class 1 manufacturers it is often something that is not really implemented consistently in the QMS.

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Mhm, how do these Class 1 manufacturers get to you?

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So, these are class 1 star manufacturers, so to speak.

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No, they have a normal 13485 certification.

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Well, I would say that this is exactly the case, that about 60 to 80% of all manufacturers who have Class 1 products also have a certification.

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And of course, they have to explain how they actually implement the MDR requirements within the framework of this second word, which then comes up again in 13485, as well as regulatory requirements.

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This runs through many places.

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And that's why that's a point that we find there again, especially because it wasn't checked beforehand in the technical documentation review that it was consistent overall, so that it was consistent.

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Have you already started to cluster these deviations a bit according to the type of manufacturer?

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So we now have this issue of multilingualism, including all the accompanying information, you said, the main issue now is that the manufacturers also have Niederklassiker products.

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Are there any deviations from manufacturers who are now Class 2 B.

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for example?

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Is there also such a pattern where you would say, yes, we find that very regularly with them too?

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Yes, so

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that's my top number one mistake, but it's actually not yet in the one in the head, namely the M.

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D.

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R.

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says in the basic safety and performance requirements that they are A.

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under point B.

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Methods and C.

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Standards

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And there is often no precise differentiation.

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A standard is often a container of different methods, there can be verification, validation, process elements, all kinds of things.

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And there I read clearly from the MDR that 4 point B is a method and then 4 point C is a norm that I have to name.

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So I'll give you an example.

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packaging validation according to standard XY.

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That would be a method, packaging validation according to standard 4.c.

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And this is often not worked out precisely enough.

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I also have the feeling that I rarely see anything about it, but I've seen one or the other on LinkedIn who have also reported on it.

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But that's something that often hasn't really arrived yet, that there is a method and that there is a standard.

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Mhm.

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Takes us back to what we just had earlier.

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I really like your concept of the container.

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So, I think that's a very positive way of expressing it, you could also say that there is a certain conceptual non-integrity that we find in these regulatory documents, that we not only have different levels of abstraction, but also demands on different, I'll call it concepts and a concept can be, a product, a concept can be, a documentation, a concept can be,

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a process or a procedure.

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And if you don't keep them apart in your head and somehow call it all a regulatory requirement, which it is, but then of course you have completely different checks.

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A procedure is probably tested differently than a product and if you don't follow through with this integrity, conceptual integrity, then it will probably all be a bit of chaos and you will notice that again.

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And as I have just learned from you, also with the manufacturers of higher-class products.

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Exactly, so these are challenges that they all have.

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Of course, the more time and resources are thrown into the area of regulatory affairs and QM, the lower the probability becomes.

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But these are consistent topics that also need a certain diffusion period until they have actually arrived in the market.

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You have just mentioned a possible solution to reduce the deviation and the probability of the deviation somewhat.

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That was more resources.

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You mentioned in the area of regulatory or quality.

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Of course, this lever can only finally be expanded now, because at some point the company can no longer pay for it and the focus on innovation may then be lost a bit.

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What else can companies do to be smart

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and by that I mean really efficiently and effectively minimizing the likelihood of regulatory problems, except throwing more resources at it.

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Yes, so I also come to a deviation that still occurs again and again, although it is not new at all.

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This is the whole topic of Kappa, i.e. 8.5 of the Kappa Method standard, and there is often a weakness in the topic of Railroad Cause Analysis.

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This means that if I look closely, and the topic of lack of knowledge is often a level that is hit somewhere, but where you don't necessarily always react adequately, because we find the same thing next year and the year after that.

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So a good root cause analysis is actually the key to developing as a company.

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Especially in the case of small and medium-sized companies, we often see it as a chore rather than actually taking advantage of the opportunity behind it.

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And that would actually be the case, there are deviations in audits, are aspects that come out of the audit.

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There are deviations in the audit and if you look closely and really come up with a concept of how such deviations can no longer occur,

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then, I think, you are already a clear step forward.

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But that's actually in the Kappa process, this this connection between error and correction and cause and corrective action, that's often, is often not really pursued to the extent that it then also comes to a reduction in deviations and follow-up audits.

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Mhm,

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Ultimately, they give us as thoughts what the, I think, the aircraft industry has mastered very well, to go down to the root course over years and decades and then learn from it and get better and have now managed to have the lowest, I think, death figures per flown or per kilometer traveled.

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So, that's a consequence exactly, I think, of this continuous improvement process, of continuous learning from the

00:19:41 Speaker 2

Mistakes, so I think that's a lot, so it's a feedback loop that you just described and you have already mentioned a root course, namely the topic of competence.

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So that is, an important one, so you have now named 2 important parts, 2 important answers to my question, yes what should you do now, except simply throw more resources at it.

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Firstly, to make sure that the resources you have are competent and secondly, to take advantage of the opportunity to

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to systematically learn from these mistakes and thereby become better every day.

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Also see the area of automation, digitization as a lever to bring efficiency and also compliance to the top.

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Yes, for sure.

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So the topic of automation, but also the topic of A.I., is certainly a game changer, whether every small manufacturer with 10 employees

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down to the last comma somewhere, but especially the topic of AI can already make a lot of difference there, but that also requires new methods.

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The AI likes to hallucinate and we have examples ourselves, because we also have questions about our IAF documents and our standards from time to time and sometimes interesting things come out of it, but they have nothing to do with reality.

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So from this point of view, the use of AI is also tied to:

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finally methods such as the correct formulation, then the verification of the results and then as a third then the implementation of these results in a concept also present in this way.

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In general, digitization is a double-edged sword, because it takes time, it takes quite a while to have a concept there.

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Pure digitization without sense and reason leads nowhere.

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So I see it again and again in companies that have grown and

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who then introduce new tools every three months, that often doesn't help.

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So that also means digitization without structure, without thinking about how I digitize, is actually more of a step backwards.

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So the structure as such is, it stands at the front and then you can see how I can map this structure with a digital model.

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I couldn't agree with you more.

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So these are exactly the observations that we also make.

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This applies to both, i.e. to digitization in general as well as to A.I.

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So, we notice how we can improve the quality of the A.I.

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results can really dramatically increase if we give the A.I.

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the structure.

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For example, data structures in the form of JSON or YAML files, because then the A.I.

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suddenly concepts with which she can work.

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You also limit the solution space to a certain extent, so if you just say.

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please look for the requirement, classify it according to one of these characteristics, yes, where that comes in now.

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Or a requirement is an entity that consists of a requirement, acceptance criteria, relevance, and so on.

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These are all data models, then you achieve completely different results and also dramatically reduce this probability of hallucination.

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So we, we do this all day, that's why I'm sharing, so I'm excited about what they're saying, because these are exactly the things we just do.

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, so it actually needs even more formal understanding than you already needed and it was already a topic before.

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That is, the automation and I would recommend the A.I.

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often needs fewer people, can really catapult efficiency upwards, but the prerequisites, you really shouldn't underestimate them.

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And I had just mentioned 1, with this what you mentioned, with the one with the structure, yes, with with data models, for example.

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A second point, which you should perhaps also pay attention to, because otherwise it will end up back with you, is as soon as I A.I.

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, I have a computerized system and with it all the requirements, for example 416 for Computerized System Validation and that is with A.I.

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Sometimes it's not so easy to do that.

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I think that's going to be a thing that will probably become much more common for you soon.

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on the table.

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Yes, how do you deal with code being generated?

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How is code generation by A.I.

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of a test code generation by A.I.?

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Because that is certainly to be looked at in a completely different way.

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So there are some exciting questions ahead of us.

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As the head of the certification centre, you are sometimes a bit condemned to criticise there.

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So that means picking out mistakes, and you have just talked about deviations in particular, what possibilities

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Nevertheless, you see what you have to say to the companies not only that you can't do it that way, but that you can somehow get them on a good path.

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So, how do you go about it, what can the Berlin Zert do in particular?

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So, of course, here is the audit.

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and I've heard that from some manufacturers.

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We are not allowed to advise, but every audit is of course a source of information that can help companies if it is perceived accordingly.

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And the mindset is certainly crucial, that I also think about what the auditor says there and what can I do, which may not be a deviation, what can I actually take away because we are

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the auditors are not machines that just rattle off question after question, but actually hand over certain topics through the conversation.

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That's why the audit is always a source at least once a year and I've heard from many that they, that they

say they learn from things, even from deviations, something they wouldn't have otherwise.

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In addition, there is this Structured Dialogue, which is now also being developed by the Commission

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was also funded, so to speak, and we are quite capable of not providing advice now, but of conducting a structured dialogue with the manufacturers.

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We have a measure, for example, which is our MDR consultation hour, which is always on Fridays every two weeks, the link is on our website and that is also a good opportunity, on the one hand also with the customers

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to stay in touch, but on the other hand, without advising, to simply explain certain things.

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And yes, there are different formats, there are also these 1 to 1 formats, as they also come into play through the structured dialogue in connection with the creation of the and especially the view, the technical documentation.

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So there are a whole range of things that someone can actually use.

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That means you gave us 3 things.

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So of course only as examples, namely the first: Use our question time, there you will get answers.

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Second: Use our Structure Dialogue, because that's a framework, as you just said, D.D.U.

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and this does not get anyone into trouble, yes, because of alleged advice.

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Or 3.

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listen pretty carefully to what we report to you in the audit or what is also included in these audit reports, because there is a lot there.

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Information back in for improvement and this brings us back to our topic of Kappa, which you saw as one of the essential levers, in addition to this competence topic and in addition to the digitization topic.

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Mr. Diesing, it was a great pleasure that you pulled the curtain aside a bit, gave us an insight into the problems you encounter, that you were able to give us a few tips on how to avoid these problems, and in this way, I believe, we can all contribute to ensuring that our

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The medical device ecosystem does not regulate itself deadly, but that we can continue to supply our patients with good and helpful products.

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Thank you very much.

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With pleasure.