Johner Institute

What seems simple, but isn't: What are hazards according to ISO 14971?

With Christian Rosenzweig, Prof. Dr. Christian Johner

Transcript

00:00:00 Speaker 1

Do you also see in audits and TechFile Reviews that the notified bodies are keeping an eye on this?

00:00:04 Speaker 2

Definitely.

00:00:05 Speaker 2

I see again and again, especially how hazards are not described or dangerous situations are missing, right?

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

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Some things seem pretty simple, but when you have to do them, they are quite complicated.

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And this also includes dealing with terms such as endangerment, endangerment situation and damage.

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14971 provides us with a definition for everything.

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But if we then look at what is used in practice, how it is handled, then we come across quite a few problems.

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And if this foundation in risk management is not stable, then the rest of the file often does not become more precise and, above all, more compliant.

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And in this podcast episode, we would like to make a contribution to making it easier to deal with these terms.

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And I have invited Christian Rosenzweig, whom you already know from other podcasts, our expert for the whole topic of risk management, but also I.

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Security.

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Christian, if you report from your experience, i.e. if you have files

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for example, you look at what are the mistakes that you are most often confronted with?

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Yes, one of the most common mistakes is that this description of the risk via the 3 terms endangerment, endangerment situation and damage does not take place at all.

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This means that the tables of the medical device manufacturers do not contain any of the terms at all.

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Either there is no hazard situation or there is no hazard or there is no damage or the damage is wrongly proven, because one does not take the damage to human health, but the damage to, for example, the product itself or the dissatisfaction of the customer in the sense of the quality of the product.

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Then a second problem is often that the terms are not used accurately.

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unfortunately, the norm also has its contribution to this, because it describes the terms in such an abstract way that you don't know exactly what I am assigning to which element.

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Yes, we have to look at that today.

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But before we do that, so is that a problem at all?

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So, what would be the consequences if these inaccuracies were not eliminated, if they were not cleaned up?

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Yes, there are actually 2 big episodes.

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First, the underdimensioning of risk management.

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I just forget about risks because I

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I did not orient myself to the hazards in terms of the approach and then I did not look for the chains of causes that lead to these hazards.

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Or overdimensioning, because if I consider every element in a risk chain, i.e. a sequence of events, to be a hazard, then I can

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thereby creating duplications or multiplications of my described risks in the table and then suddenly I have ten times the scope of my risk management and that is of course an inefficiency, the inefficiency that a medical device manufacturer cannot afford at all.

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K., summarize, so either you overwork yourself and maybe afterwards you can't see the forest for the trees anymore or you were so economical that you don't recognize risks, consequently you don't control them and then the product becomes a problem for you after a field.

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Do you also see in audits and tag file reviews that the notified bodies keep an eye on this?

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Definitely.

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So I see again and again findings such as hazards are not described or hazard situations are missing or that the individual risks are missing.

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Some of the auditors are very subtle and they are very familiar with the matter.

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They are always professionally selected for this medical device and they can then put their finger in the wound and say you haven't found this or that risk.

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K., so for manufacturers it means that it makes sense to deal with this topic and perhaps also to take care of the thoughts that we will hopefully share in a moment.

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So let's jump right in, what's a danger?

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So we have a definition, yes, so a potential source of damage according to 14 971, but it's not quite that simple.

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How would you endanger

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so define, we can't change the definition now, but we can maybe limit it a little bit so that it's somehow more manageable.

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Yes, so you have to say that the standard is a bit inconsistent at this point or rather confused by its explanations.

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So she says endangerment is the potential source of damage and then she puts in Table C.

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1 in Annex C.

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also examples of this and says,

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For example, electrical energy is a hazard or mechanical energy.

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At first glance, this seems like a block of topics or an abstract clustering of these hazards, and one might think that one has to look for the specific hazards for each of these clusters.

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Now, however, the example table C3 in the standard shows that these abstract topics are listed under endangerment.

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That is, for example, in the column Hazard, then chemical hazard or biological hazard.

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That means you stay on this abstract level.

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But my recommendation is to go to a specific level and say that endangerment is one of the elements in this chain of causes, a very concrete one.

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The only question is which one, because when I describe this chain of events, from the triggering event up to the damage,

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then every element of this chain is a potential source of damage and that is the problem with it.

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And that's when we thought it would make sense to always put this hazard as far back as possible, in the direction of damage, so that you can only describe a few hazards and for which you can specifically search for the respective causal chains.

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Were these perhaps 2 examples?

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Maybe 1, you just had the term.

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electrical energy, I think, just mentioned or what do we have to do and then perhaps for an informational danger.

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So maybe we start with an electrical medical device, the chain of causes is, developer had a bad day, didn't somehow design the insulation according to 60, 6 and 1.

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This leads to the fact that afterwards when using the product, an insulation breaks, the strand comes to the

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housing is electrically conductive.

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A patient reaches for this housing and suffers a blow, that is, somehow a ventricular fibrillation, for example.

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So that would be such a chain, what would be the danger here?

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So normally, we had had some development, maybe overtired or not paying attention, then somehow wrong design, then we had the wire or the insulation that broke, then the one the wire on the housing, the housing and the current.

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patient reaches for this housing and then has

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these consequences.

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What would be the danger here according to what you just said?

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Yes, if we really interpret this as the last element, then touching this surface would be quite far back and that would directly cause damage.

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Then I have an electric shock.

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So the present potential or the current flow over the housing would then be the hazard and everything else before that would be the chain of causes.

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So, if we had, as you just said, a energized housing, is the danger.

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A patient who is exposed to this, yes, who is now patting there, would be the danger situation, because that's how it's defined.

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So, being exposed to one or more hazards and then we have the damage, in this case ventricular fibrillation.

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O.K., now we have a second example, namely with the information.

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Sometimes it's a bit more difficult.

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You can tell it.

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to which order the standard brings this.

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Yes, it only begins with these very classic dangers that you just said.

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Yes, in the categories Energy, I'll call it now, and materials and then somehow this information was added.

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Maybe let's make a software that calculates cytostatics, was a developer again, snored, somehow programmed into software bug.

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The result was the

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Dose calculation was implemented incorrectly.

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The result was that the software showed a much too high dose.

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The doctor then prescribed this much too high dose.

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Patient took or was administered the much too high dose and the result was anaphylactic shock.

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Now on this chain, now we have such a chain again, so we now assume a certain monocausality, to simplify it now.

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But if we look at this chain now, what would be the danger here?

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Because, as you said, it would all be a potential source of damage in the first place.

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But let's enter every bug now, because then there would probably be a lot of possible bugs that you can have.

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Where would you put the danger here in this chain?

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Yes, that's quite interesting, because the earlier version of the 14 971 has the 2012 version, which is still

in the example table and at that time it wasn't C.

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1, but A.

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1, she still had the informational

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Danger is included and then you could say, according to the facial expressions, the wrong indication of the medication would be the danger.

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But now they have taken that out in the latest version, saying that there are actually no informational dangers, because they seem to have noticed themselves that this is not expedient and that it contradicts practice a bit

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and that's why I would then ask again for our definition, the last element, i.e. the wrong drug administered or the wrong drug placed or yes, available.

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So we would have again, so we have a danger, yes, so that the too high dose was it in our example, so a wrong drug would of course also have been a danger, but in our example it was just a wrong dose, too high a dose, to be more precise, as long as there are no circumstances,

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under which you are exposed to it, because the thing may be in the medicine cabinet, have a danger, but not a danger situation.

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The moment you are exposed to this drug that is too high, when there are circumstances, that would be the ingestion, for example, in that case we would have a dangerous situation and the damage was now clear in this case, that was then this anaphylactic shock.

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So I think the statement you made earlier is very important here

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in this end, error trees are not so far to go somewhere towards roots or no, sorry to go leaves, as because it frays more and more and afterwards you have so many elements that you could write in the table that you simply have no chance to really manage it.

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It happened to me once.

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I think I also had many 100 entries.

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In my risk table, my auditor came.

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I still had it in Excel at the time,

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The Excel was already very difficult to open because there were so many rows in it.

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Then he scrolled around in there a bit listlessly, closed it again and asked me: ‚Hey Jona, where did you look at this risk?' And of course I didn't find that within these many 100 lines and it didn't matter whether it was in it or not, I couldn't show it and then had my non-conformity.

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And that shows what you said earlier, so more is not necessarily better and so that it doesn't become too much.

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it is helpful to go further back in these chains of causes, as you have just described.

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So, I think that's an extremely important clue.

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There is even another important point that also plays a role.

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The further back I get with the hazards, the more I grasp the entire application context of the product.

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If I were to concentrate only on the edge of the device and say, my my medication system shows a wrong medication.

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Then I might not have covered the case that it shows the right drug, but the user makes a transcription error and still gives the wrong drug.

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And I have to consider that as a risk of my application, my product.

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And then my measure could be, for example: I print out the medication so that the user cannot make a transmission error.

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Absolutely, because you're already plugged right into what I just wanted to ask.

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We have now asked, ultimately, what, what does it make sense to consider a threat?

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And now, which is the logical follow-up question: And what do we do to ensure that we do not forget any dangers or causes that ultimately lead to dangers?

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What are things that would like to be forgotten?

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I think you just told us an answer, namely that you also consider the case that the product does that first.

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what it was actually supposed to do.

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Yes, in this case, namely also consider the case that we have a real complaint, but still a danger, depending on the definition, but in any case in this case a risk.

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That means damage with a certain probability and a degree of severity.

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So, what else should you consider so that you have a higher probability,

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Sustainable Socket is at home here.

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This is actually already defined by the standard through the safety-relevant features and there is also a question, for example, what is the forsible misuse, the foreseeable misuse of the product.

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That would be such a point, for example, or that you just want to use the

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the selection of materials, the design of the product, the packaging, that you also look at the production processes, what can go wrong, the process parameters, we are already in the middle of it, deep in the risk analysis and this risk analysis, of course, also helps you to find new hazards that you may have forgotten to write down before.

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So I, you have now mentioned a few points, let me summarize them briefly, so that was once

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of this safety-related feature.

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Yes, that has something to do with what has to be given so that we don't have unacceptable risks.

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Yes, these can be specifications, for example, which I have a pump tolerance that must be given.

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Then you said the predictable abuse.

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Then you said, also think of things that have something to do with the other intended use.

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For example, storage or maintenance would probably be one of them.

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Transport

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What are other points that you still consider important.

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The purpose of the product itself, of course, what, what do I want to achieve with the product, what functions or medical purposes do I want to fulfill and if these are not given, then of course I also have a danger resulting from it.

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Mhm, so if a dialysis machine does not cleanly remove the substances requiring dialysis, if removed, if an I.V.D.

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shows the laboratory values densely or incorrectly or too late, that would be

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Things that should be considered in the hazard or risk analysis.

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What I still see often are that problems with usability are not sufficiently examined.

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In the meantime, especially of course with more complex products, it is with 1 of the most common causes, afterwards also then really for incidents in the market.

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And what auditors or reviewers also keep an eye on are uncoordinated changes.

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So, that can be with the manufacturer himself.

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Yes, someone is turning something around in production, because it seems to work somehow faster or cheaper.

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Or even with a supplier that changes the process, that he changes something on the product that he supplies on the component he supplies, which no one has on his radar afterwards and then also leads to risks or actually to damage.

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So with that, we have now summarized a few things that should be remembered when we record the hazard and risks as completely as possible.

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want, yes and also have to, that is the requirement, what is the goal of a risk analysis, to have it as complete as possible.

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Perhaps a few thoughts at the end, which I have now also noticed, for example, with the companies that we are currently supporting in the Fit for Future program through risk management.

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That's the issue, yes, what do we do when we have now identified danger?

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So now a very short turn in the direction of measures, there is sometimes in the files

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things like: Measure is biocompatibility test.

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What is your thought on that, Christian?

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These are not measures, they are ultimately the verification of the measures, but the measure itself is not described at all.

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Then you have to be careful not to formulate the risk too abstractly, because then you have no choice but to define an abstract measure.

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Mhm, yes, so if someone says we have a threat from

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biocompatibility, yes, or lack of biocompatibility, it is extremely unclean.

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Yes, you can be more specific.

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We may have a problem due to toxic substances or we may have an even more specific problem due to adhesions that arise in production.

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And the more specific we have this, the more specifically we can define the measures.

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And it is now important to distinguish between measures and verification of measures, as you just said.

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‚Cause if someone were to say now that the

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Biocompatibility tests and toxicity tests in this example, is the measure and one would need a verification of the measure.

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So that doesn't make sense.

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So in any case, separate the measures and the verifications of the measures.

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What I also noticed are and this is also just indicated, so yes, so fuzzy measures.

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Yes, we produce according to the product 13 485 yes, or we develop it according to our S.O.P.

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of course, these are things that are so tangible that we have the same topic again.

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How do you intend to prove the effectiveness of this measure, this general measure?

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That will be very difficult.

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So always, I think an important thought here or is more helpful to consider, I can make a reliable statement knowing this measure about how the severity and/or the probability that damage will occur.

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And if someone says I'm doing it according to S.O.P., I think it will

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hardly succeed.

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If you take measures, perhaps just to finish the idea, if you take measures that have something to do with instructions for use, training, labeling in the broader sense, it is also important to verify these measures.

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And here the summative evaluation of usability is explicitly a means, a method, to prove this.

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And since the user interface is also designed according to the standard

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the I.F.U., i.e. the instructions for use, is also part of the review in a summative evaluation.

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So the thought that some manufacturers may have, yes then we always write in, instructions for use, that's O.K.

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Now we still have to consider that if risks are to be minimised by this measure, then it is also mandatory to prove that they are minimised, and these are then usability tests.

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Christian, your thoughts on top of that.

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Now you've actually said everything that

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What can be said about this?

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Then maybe now one last question, how can you help yourself, what do you offer to really give hands-on support?

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Yes, first of all, of course, we are doing a seminar, a 2-day seminar for people who have not yet had any contact with risk management, but at the same time for those who have already worked with risk management and want to have the finishing touches.

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And then, of course, it is also a good idea to consult

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service from us.

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We do micro-consulting, so that we answer small questions or look over files, up to the complete creation of the files, which I also like to do in the company of the respective manufacturers, so that they then have learning success and look over my shoulder, so to speak, while I create the file.

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Yes, I think that's very important.

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Well, what I like is that you almost do it, just like we learn to operate like doctors.

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pretend more, the others are allowed to watch, then they are allowed to participate, you watch them, then they do it all by themselves and are thus enabled to do these activities, which, as we have seen, are not quite so banal, and also to do them themselves.

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So, it's important to us overall that this transfer takes place and that was one of the reasons why we did this podcast today.

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Christian, I can only thank you very much for the insights you have given us again.

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So, a complex topic, as we have seen, where it helps a lot to work precisely, to deal precisely with all these concepts.

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Thank you very much, Christian.