Johner Institute

Risk Management Tools

With Christian Rosenzweig, Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

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

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In this podcast, we would like to talk about 1 of the most central topics that exist in the entire field of medical devices, namely risk management.

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More specifically,

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Let's talk about tooling in risk management.

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The reason for this podcast is a notified body that contacted us and said that they would have a hard time with the market leader a la risk management tools, namely Excel, and had already wanted to declare non-compliance for a manufacturer.

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We now have to take a closer look at whether a notified body is allowed to demand or prohibit this at all.

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But before we go that far, let's first look at the question: When does a tool make sense at all?

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So a dedicated tool, I don't mean Excel.

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And to discuss this topic, I once again called Christian Rosenzweig, our risk management expert.

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And if there is anyone else who doesn't know Christian, then maybe he will introduce himself again very briefly.

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Yes, thank you very much.

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My name is Christian Rosenzweig.

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I have been a consultant at the Jona Institute for 4 years, mainly dealing with risk management and IT security and.

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I have known the market of medical devices from the inside and outside for more than 20 years and have experienced a lot during this time.

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Yes, and above all, many a risk management file has been written, reviewed, improved, brought through approval and many tools have been used.

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That's right.

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Yes, you, now let's start with a question, before we go into the notified bodies and their requirements, when do you think a dedicated risk management tool makes sense at all?

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So, the first question is, how complex is my product anyway?

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If I have a very simple product, such as an orthopaedic shoe insole or a manual clinical thermometer, then the risk management file is very manageable.

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But if I have a complex product where I have various trades in it, such as software, mechanics, electronics, then I may still have to look at service activities extensively.

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I have an extensive production with a high level of vertical integration, I may have involved many suppliers, then I have an incredible number of sub-modular risk analyses,

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which I have to look at and which I somehow have to consolidate together into the big whole risk table according to ISO 14971.

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And then, within this risk table, I have to maintain the many links to measures that then go out again, i.e.

go into product requirements, into production, into certain tests, or at the organizational level, for example, concern personnel training, or even

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suppliers and then the whole thing becomes unmanageable.

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Then I can no longer keep track of all this traceability with a simple Excel tool.

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K., that's very helpful.

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If we now perhaps briefly return to the introduction, if someone now takes an Excel and you have already talked a lot about links, everything we have, what is the stomachache, what do they have with them or what do they want to be sure?

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At the end of the day, MDR is about me recognizing all risks, identifying them and minimizing them as much as possible.

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And if I don't have an overview of what all my risks are, for example, that appear at the very bottom of production or that appear in my IT security area, then I'm missing something.

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And it can happen that individual risks are lost during transmission.

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And I urgently need this clarity and comprehensibility of the individual elements and how they relate to each other.

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Ah, OK, so that means that a lot is also at stake here, I'll call it now about the topic of traceability, which you have.

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Yes, so you have to have them between the, you said earlier, also the risks or hazards from the various trades and that this manual process can be a problem, I think you can understand that.

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And if you then link that in Excel, then possibly, but you're telling us, topics like C.S.V.

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Computerize System Validation on top, am I right?

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Yes, exactly.

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So first of all, the question is, do I need a tool at all, does it make sense and then the

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Question, what is the tool actually supposed to achieve, what, what is my objective and traceability is just one objective, but then other objectives can also be added, such as, how do I work in distributed systems with my suppliers or with other branches of my company and other departments of my company such as production or development.

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K., so now you have shown a bit, in which cases does a tool make sense, in which cases

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you can really get by with a normal Excel.

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I suspect that the majority of our listeners are no longer with the very simple products.

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So that is, the probability that a dedicated tool is necessary is relatively high.

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That means you have to choose 1, what should you look out for?

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Or I could also ask the other way around, what do many people do wrong when choosing such a tool?

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Yes, that's actually something very interesting, because you can do a lot wrong.

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So

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On the one hand, there is always the question, have I even described my risk management processes in such a way that I can live them well and can I then find a tool that I can use as part of my processes?

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It can't be the other way around, it can't be that I have to adapt my processes to a tool and that happens

very often, that the manufacturers look for a tool, find out that their processes no longer fit and then they just live as the product specifies and then they may even run into non-conformities.

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That's why.

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Yes, that is a very important point.

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Well, I really want to emphasize that, because I've often observed that myself.

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We are not only concerned that it fits the processes.

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A tool does not replace competence.

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I think there is a lot to the saying ‚Fool with a tool is de la fool'.

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That you might put this belief aside right away: ‚I'm going to buy something and I've killed the topic with it.' So, thanks for this important hint.

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So, the first thing you said is: Make sure that the tool supports your processes, otherwise it's the wrong tool you choose.

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What are others?

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Criteria to pay attention to when choosing a tool.

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Yes, perhaps we will go into this point in more detail.

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For example, if I use a tool that does not comply with the MDR, is not ideally tailored to the MDR and ISO 14971, then I just run into traps.

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Example: The ALARP principle, which has been in force in risk management for a long time, which is still propagated via the 14971,

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I can no longer apply this for reasons of the MDR, because it says quite clearly that every risk must be minimized as far as possible.

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I can't have a green area where I don't need any more blanket measures.

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And if the tool specifies this in exactly the same way and says, wonderful, you don't have to implement any measures, because you already have everything green and I then stick to it as a manufacturer, then I have immediately created a deviation against MDR again.

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We then have a tool-supported deviation.

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So to speak, exactly.

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Yes.

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Then another point, the license costs.

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This is often misjudged, because people say, OK, the license price per participant or per user is quite low, we can afford that.

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And then you realize in the course of the project that there are more people who need access to this tool, who need access to some extent.

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If we think of the post-market sector, for example, which also has to work with the risk management file, then it can quickly happen that the license costs exceed the entire financial framework every month.

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And if I only realize that at the end after the introduction,

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then I've created quite a lot of inefficiency, because then I have to roll back again, in the worst case.

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Yes, another problem is that the tool is simply too complex to use and has poor usability.

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This is also something that you may only notice after the introduction, so it is advisable to do a sufficiently long pilot phase to test first, I can work well with the product in practice.

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Another problem, these tools that

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they need interfaces, because I have to continue working with this information that is generated there.

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For example, I have to translate my measures into product requirements and I have hosted my product requirements in another tool, for example.

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How do I now exchange the information so that I don't have to transfer everything manually?

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Are there generic interfaces through import-export or is there even an online interface where I can exchange data in real time?

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These would be questions.

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So it is recommended in any case to carry out a comprehensive

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catalogue of requirements for the tool, then also to make a weighting.

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What is particularly important to me?

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And then to decide on the basis of which tool to use.

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You have just said one thing indirectly.

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It must definitely support distributed working, because at least different experts must be able to access it in different phases.

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Yes, you just mentioned the post-market phase.

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But a product manager probably has to be able to access it.

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security expert, who may have to compare this with the NIST database.

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The risk manager, the context experts, the development, that's quite a range.

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People who don't necessarily always sit in the same place.

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Exactly, and now comes the next problem, because there are so many stakeholders who will use this product, they all want to have a say in the tool selection.

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So they put all their requirements for the tool on the table and in the end you can't find any tools at all because the requirements are simply too heterogeneous.

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The costs for the tool introduction may also be out of the ordinary, because then specific adjustments to the product will be necessary and the

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Whole can also extend the process of implementing the tool of the project incredibly.

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Yes, there you are already at the next point.

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So, it's very important what you say, so that we might also separate it, so to speak, the first task package that we've talked about now, what do we pay attention to when choosing tools?

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Yes, you talked about things like customizable the individual processes, specificity for the medical device world with M.T.R.

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and ISO 1491:70 topic cost.

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Topic of usability, topic of interfaces, topic of distributed working.

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Now let's assume that we have found 1.

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Now you've already opened the door for the next question, what do we have to pay attention to when we introduce this.

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Yes, assuming we have the tool, what are the stumbling blocks that we should definitely avoid so that we don't fail at the next hurdle?

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This is almost obvious and happens incredibly often that people say, I have now chosen a commercial tool, I can install it at the push of a button and then I get started and.

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that's how most projects are started and then you realize that it's essentially a change management process that I'm carrying out in the company, that I have to take the people with me, that I have to create the structures accordingly.

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And the whole thing cries out for a control of this project and that's why I would strongly recommend always starting a project.

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And such a project must therefore have clear budget specifications, it must have a completion date and there must also be a project manager who is responsible for it and who controls it all.

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Yes, and

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then, what else can go wrong with the introduction of the tool, that the users of the tool are not sufficiently involved, that they only realize later when using the tool that it does not meet my requirements at all, I cannot use it in practice, that's why it's so important to get them on board at the beginning or that you don't start a pilot project and immediately roll out this product throughout the company and is therefore inefficient in the introduction.

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then what you have already mentioned, every tool that is in any way quality-relevant or affects the safety and efficacy of a medical device must of course also be validated accordingly, keyword computer system validation.

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And this also applies to risk management, because there you basically determine the risk profile of the product,

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defines measures for the design of the product and this is a very important step or an essential activity in the life cycle process.

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And if I don't have the software behind it under control, then measures that I have defined at some point can slip through my fingers.

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Or the traceability does not work and the measures do not arrive in the product requirement profile.

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That's exactly why I have to validate it and these validation efforts, they must not be misjudged and that's what happens

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often also that at the end of the project a quality manager comes up with the idea that you have forgotten computer system validation, now you have to do it quickly, but this quickly turns out to be a six-week project with considerable costs and effort.

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Yes, and you can't fall for it, at some point promises, yes, they buy a validated tool, so there will certainly be a pre-validation, but the obligation therefore remains unaffected to validate this tool again in the actual environment and with the actual users and configurations.

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Yes,

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Exactly, what else can go wrong with the tool introduction?

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For example, it is said that the risk management team, which otherwise implements operational risk management, is now fully involved in the tool introduction.

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Yes, then they don't have the time for operational risk management.

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That has to be compensated for somehow.

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That would be a wonderful occasion, for example, to call us to support them, either with the tool introduction or even with the operational implementation of risk management in the meantime, while your own team is now taking care of the tool implementation.

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Because is so through the disaster, to introduce a tool, the products were more insecure.

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That would probably not be entirely in the spirit of this whole initiative.

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Exactly, do you see any other things in the introduction?

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Yes, even such small things that you forget, for example, to take the I.

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department, because this system, i.e. this tool, must then be integrated into a system, must be hosted, must be maintained and maintained and there is of course the I.

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department, its own I.

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department.

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For example, who makes a backup of the data that is stored with

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can be created in the tool.

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Who takes care of training, who takes care of licenses, licensing and password and role management and then you need someone who is responsible for it.

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Yes, and the most important point, as I have already said, is change management.

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Tool implementation is not only a technical activity, but it is also about people who use these tools and you have to take these people with you accordingly.

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Absolutely, yes, that's a bit of a

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system where work instructions may have to be adapted.

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Yes, then it is no longer called Form X.

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Y., but or Excel, but enters it into it.

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This also needs to be accompanied.

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You have already told us that this is somehow not just a download, a click on an executable and everything is good, but this is a real project.

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You even called it a change management project.

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Is it possible to somehow combine time frames or somehow perhaps costs with it?

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I know it depends on you now on 1000 parameters, but if you maybe at least use these parameters

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which have an influence on the duration and costs.

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Yes, exactly, as you say, the costs of such a project depend on the complexity and that depends very much on the tool and the framework conditions.

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What can be listed as framework conditions, for example, is, do I have a ready-made tool that I buy commercially off the shelf and can use from day one in the same way as I bought it, or do I have to adapt it,

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how much configuration work do I have to put into it or do I even have to put programming effort into it?

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So configuration effort, that would be, for example, if I use a system like Jira Confluence and then have to define specific code shares or configurations, then that creates effort and manpower, which also costs.

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And if I have to program interfaces, possibly even by an external service provider, then the costs naturally quickly skyrocket.

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Then the license costs are of course also an issue, which is included in this

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the entire tool implementation cost issue plays a role or even the content processing if I then have to adapt the processes again.

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So, if, as you say, I have to adjust the individual S.O.P.s again, then it is also part of it and there are also expenses to be justified.

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So, I'll summarize that very briefly, because it will have a lot that you gave us.

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So that was the cost of the tool, and the cost of integration with existing systems.

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So, it goes as far as interface programming.

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I have not yet mentioned the costs and expenses for the configuration, but presumably it is also part of it, expenses for the training that we want to have, then the license costs themselves.

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So, these are all things that you want to take into account, plus of course the opportunity costs, i.e. especially the costs for the people who are involved and then cannot do anything else during this time.

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Yes, exactly, and that's why it's advisable to make a project out of it, so that such a project plan is drawn up at the beginning, the costs are estimated and then we look at it.

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Am I even within the budget I have available for this project?

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You've already exorcised it all on your own body, so to speak, or accompanied customers.

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Where could you help concretely if someone is now faced with exactly this question?

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So should I introduce 1?

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If so, how should I introduce it?

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How much does it cost me?

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How do I clean up the project?

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How could you support these tasks?

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Or you and your team, you would have to say, of course.

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So, of course, the first thing we do is look at how the risk management process according to ISO 14971 is implemented at the moment.

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This means that we check it for conformity, for efficiency and once the process is in place and secure, it is compliant and also works and people can live it, then we look for the appropriate tool for exactly this process.

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This means that we then look for each other or first create a list of requirements for this tool based on the current processes and the other framework conditions.

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And we then compare this catalog of requirements with the available tools on the market.

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And we may then also consider having in-house productions, i.e. a tool developed in-house, tailored to their own requirements.

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And then you have to look again at what the cost situation is, whether that is possible.

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This means that we would support tool research, including the consideration of whether a self-written

tool is possible.

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Yes, and then we do project management during the implementation.

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This means that we would then really act in this function as project management and would accompany it with everything that goes with it.

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To the end then to Computerized System Validation.

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You just said, in-house development, I mean, Anna, but correctly, do you start at 0 or are these things where you can build on the basis of existing A.L.M.P.L.M.

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systems?

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Yes, exactly, there are plenty of A.L.M.P.L.M.

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Systems on the market that are more or less generic, I can do them.

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and then the share of in-house development, this adaptation of such systems as Jira Confluence, for example, which has proven to be a relatively widespread medical device sector, would be the means of choice.

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Wow, let me briefly summarize this episode.

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Well, the starting point was Notified Bodies,

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Look very critically at the market leader Excel, especially if you have distributed or trades for which you analyze separate risks or hazards and then merge them in a risk management file afterwards.

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So, that's where the problems come in.

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This in turn speaks for the use of a tool that can do something like this exactly, that supports something like this.

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And we have now clarified, so to speak, when does it make sense, what do you have to pay attention to when choosing a tool.

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Once you have found a tool, what do you have to pay attention to when you implement it?

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What does the whole project ultimately have to be able to do and achieve?

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We had talked about the topic of cost drivers and now at the very end you had also nicely explained to us where you and where can support your team so that these projects do not change like many other IT projects in a disaster, but really help to simply work faster, to identify and eliminate risks quickly and comprehensibly and

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ultimately simply to make better medical products.

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Because I think that's what it's all about at the end of the day.

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Mr. Christian, thank you so much.

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As always, it was a wonderful conversation.

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Thank you very much.

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With pleasure.

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Bye.