Johner Institute

Medical devices as autonomous systems

With Dr. Rasmus Adler, 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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More and more medical device manufacturers are not only putting products directly on the market, but also systems of products.

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So, for example, a telemedicine manufacturer launches

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maybe a blood pressure monitor, maybe an app as a diary and possibly some server application.

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Or if we go into the area of classic devices, for example a dialysis machine, then we have a system consisting of the dialysis machine itself, the dialyzer and the tubing set.

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Or other examples would be monitors in intensive care in hospitals, i.e. vital monitors.

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Patient data management system, i.e. an I.T.

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solution and a ventilator.

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And now the question is always what is a system and who puts systems on the market?

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And unfortunately, this term is understood ambiguously.

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And one of the definitions that we have comes from the M.D.R., which refers to a system as a combination of products that are packaged together or

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and that are intended to be combined or combined to serve a specific medical purpose.

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And all the 3 examples I just mentioned serve certain medical purposes and they are also connected and combined with each other.

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But now we have another term and that is the autonomous systems that we have.

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Now we have to see, do they also fall into this class and around this and

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To answer a few more questions, I invited Doctor Rasmus Adler from Fraunhofer IESE to learn more about autonomous systems, about the requirements for these autonomous systems.

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We also want to discuss the regulatory aspects with each other and address a few solutions that will help to make these autonomous systems and systems safe in general, but without unnecessary effort.

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on the market.

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Hello, hello.

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Hello, yes, thank you very much for the invitation.

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Glad to be here.

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Would you like to briefly describe something about yourself, about your role at IESE, so that we understand who you are and in which area you work there?

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Yes, I'm a program manager, autonomous systems is the name of the role, I also did my doctorate at IESE, I've been there for 14 years and my job is also to manage the departments

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A bit to calculate there regarding the topic.

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So that's a very extensive cross-sectional topic.

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So it's about safety, we have the security department, data engineering plays a lot of things into it and to see that the solutions then mesh to cover the topic comprehensively.

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When we talk about autonomous systems, perhaps we should first look at what an autonomous system is, perhaps also, how does it differ from these other systems that I mentioned earlier.

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painted hat.

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Is there already a definition?

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Yes, there is not even just one, there are many and that makes it difficult in some cases.

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I wrote a very long blog post about it, so I can't reproduce everything now, then our time would be up.

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But so roughly autonomous means independent of, yes and it always depends on what you want to be independent of when it comes to definitions, what is important at the moment.

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So with robots it may be that they are independent of the power supply,

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In the military, it may be that you want to be important from external information, i.e. not remotely controlled, yes, because otherwise you will be detected.

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But the program aims to achieve a given goal independently and adapted to the situation, and this is also the general definition of Acatec, i.e. independent of human instructions, i.e. without human control or detailed programming.

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Could you give us an example, maybe even from the

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medical field.

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So first of all, maybe a preliminary remark, we will of course link your blog below in the accompanying materials, so that everyone can take a look at the variety of definitions again.

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But perhaps an example from the medical field anyway.

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Yes, from the medical field it would be autonomous infusions, so to speak, no.

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So when I give infusions

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and then perceive, O.

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K., how many infusions, depending on whether it's painkillers, opiates or insulin, how much is needed at the moment and the difference now in this case to automation or classic automation, which exists, is that you decide very situation-specific and that for the specification would actually only be to say, well, the pain should

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be optimally alleviated, but not so much that you then get into shortness of breath or any unacceptable risks and that depends on a lot of factors and you don't give clear rules as to when it has to be how and that's where the difficulty comes in.

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That sounds a bit like closed loop systems, is it the same thing or are autonomous systems something else?

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Yes, that's exactly what it is.

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So Closed Loop is definitely there.

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but these rules are just not quite explicitly included.

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But that's exactly what goes in that direction and what often swings with it, it's the cognitive loop or 4 steps that you first perceive the situation, predict what can happen if the system behaves this way or that.

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So in this case, for example, if I give such and such an injection now, what would happen if the patient gets into shortness of breath or not

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and then make the decision and implement it.

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And for that, networking is usually necessary.

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This means that these systems are often also networked systems.

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What could that do in the example of your infusion, which which products, what we might say, would now be involved in this overall system?

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Yes, you would need the oxygen content of the blood, for example, which is also decisive.

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with opiates to see how well the patient is still supplied with oxygen and also other values.

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That means you would have to measure all these values and then deduce from them, O.

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K., is he still getting enough air or not?

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That is, if there was an oxygen sensor on one side and the infusion pump on the other, there would be other parts of this system.

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Yes, and you would definitely have a system that integrates all this, all these and you can still imagine that you can also use a

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alarm and so says, well, depending on what the value is, I give an alarm and especially at information points there is also that, so with painkillers there is still the concept that you say, the patient can ask himself again that he has a little more, yes, gets more painkillers, that would just be a schematic structure in this case.

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Yes, now we have described how several products could form a system,

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The people who are now wearing regulatory glasses may see it a little differently.

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It would be possible, for example, for a manufacturer to place this whole combination of products on the market as a medical device.

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Or it could be that different manufacturers market the individual products independently of each other and then configure this system together in the clinic.

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This means that from a regulatory point of view, there are now various

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Playing styles.

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But for you, I don't think that's the point at all, but for you it's all about achieving the goal better with these systems than minimizing the pain in the best possible way in this case or then somehow completely shutting down the patient.

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What difficulties do you encounter or what are the typical challenges when working with such autonomous systems?

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Yes, they are two different things, on the one hand these new algorithms, which

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come into play by no longer being so rule-based when you have data-driven models.

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So the topic of artificial intelligence, what, what do you do there.

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The other big topic is this, this networking and how can the systems work together securely at runtime, especially if there are different manufacturers and then a system is added at runtime or a system goes away or you want to replace a system.

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Oh, I can imagine that, that's of course the

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Nightmare, so many, of many a risk manager.

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This means that risk management unfortunately also refers to M.

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D.

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R.

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First of all, look at the device and its intended purpose.

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And if you now have a purpose that allows so, I don't want to call it vague, but perhaps allows so many combinations of other products that are now configured here together or have to work together, then it becomes challenging to solve all these possible problems

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to identify and actually control.

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So we really have, if I hear correctly, an explosion of combinatorics.

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But I think you have just hinted at other framework parameters that make things even more complicated or even more difficult.

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Can you say something very briefly?

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Yes, exactly, so it's the system, of course the variety of variants in itself, but also the context, which can be completely different.

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So I

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there is still a person present with E.

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in the same room, what is the patient like, so now not only the data in principle, which you monitor permanently, but basically the age of the patient or maybe some other things that you have to enter beforehand.

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So there's a huge range that could still be taken into account and this whole context also makes up the risk very strongly, if you want to measure it in the situation.

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Yes, yes, these are somehow an infinite number of parameters that we have

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Yes, you have now said, type of systems, manufacturers of the systems, which ones come in, which don't come in, how do I connect them with each other, what clinical context do you have.

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Yes, it will, it almost sounds a bit like an unsolvable task.

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But of course you wouldn't be in the podcast here if you didn't already have some ideas.

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How do the manufacturers, before we get straight to that, solve how

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how do they deal with it at the moment when they want to put something like this, such an autonomous system, on the market and now have to live with exactly these combinatorial challenges?

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What is the approach?

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Normally, you always assume the worst case, if you do everything you don't know about the context, so to speak, then you always take the worst case and are thus on the safe side, so to speak.

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And

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of course, this also has the disadvantage that in many situations you simply do not act optimally.

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Yes, or what so many people face as a challenge, so to speak, i.e. set the hurdle so high, yes, if you always come up with the worst case for all combinations, so to speak, that you come up with requirements that you can no longer meet in the end and then the product no longer comes on the market, which would not really benefit the patient either.

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O.

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K., that is, the one who

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the difficulty that we have, but I think I have just described, the approach to solve these difficulties, namely the worst-case approach, is not necessarily the one that leads us to our goal.

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How would you deal with it or what, what is the concept you have in mind to achieve the goal of this autonomous system on the one hand, but then not to expose the patient to unnecessary risks and at the same time to get this diversity under control?

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that almost sounds a bit like squaring the circle.

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Yes, that's true, but there are also concepts, so in other domains there is also the concept called Safety Element Out of Context, which is, if you just have a sensor, really have nothing, then you say, what can I guarantee for it,

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then the problem is that these guarantees and the integration that all this is not model-based, yes, and not formally enough to actually be able to deal with the variants at runtime.

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And that's exactly what we're tackling, that you say you have all this documentation and safety-relevant information that you need to say whether a certain composition, compilation can work together safely.

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They were cast in models like this,

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that what you actually do at design time, when you decide whether the situation fits together, that you do it automatically at integration time.

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And that is in many things, is actually the regulatory side more of a hindrance.

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So, if you now think of someone in another area in a convertible factory or something, then of course the same problem is that you can't initiate a certification of a few weeks after every change.

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And we've already had projects,

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where we had prototypes, where a report was generated and it only has to be signed.

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Could you make it clear with the example of the infusion scenario you described above, what you would describe if you were to use them, that sounds almost like specifications, what such a specification would contain.

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Exactly, i.e. the specifications, they would then have to contain the safety certificate that is already created at design time

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and then, tell me, the aspects that you don't want to assess in the worst case.

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And if then, when an oxygen value is delivered, for example, that you say, under what circumstances of an oxygen device this value is correct, that you simply send these assumptions that lie behind it at runtime and then the receiver can say, yes, O.

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K., with these applications, with these assumptions, I can then live in the concrete context.

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I'll try to describe it in my own words, so that you can check if I understood it.

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So, for example, this oxygen sensor would now not only send the oxygen value, but perhaps the uncertainty that is now associated with it.

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And the other system would now say, is this accuracy perhaps sufficient for us in the given context for the very specific patient or for the very specific combination of several products?

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Is what you're doing right now

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I understood that correctly.

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Exactly, that would be that.

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The question is always ultimately this oxygen value, how comes, how does the sensor come exactly or how does this intelligent sensor come, is already a processing towards the assumption that this oxygen value is so high and that's exactly what you would send along and it can be, for example, that you also have assumptions about the age of a patient or something like that or other assumptions and you could then check them at runtime and this is how you would deal with the different variants.

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Would we then have a central intelligence, i.e. one authority, that would have to ensure that all these assumptions are fulfilled and that the system as a whole is secure?

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Or is it more of a distributed intelligence, where there is no central decision-maker who makes exactly this information or these distinctions?

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Yes, it makes sense to centralize that in a big one.

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so that everyone gives the individual information, so to speak, and the assumptions behind it, and that the central authority can then decide, O.

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K., because of this information base, that's enough for me now.

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Yes, and then it's very contextual, i.e. very situation-specific, when I accept which uncertainty.

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Yes, and then a concrete scenario would also be that you say, O.

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K., if I upgrade now and add or remove new devices,

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accordingly, the behavior would then also be different, then you give the alarm faster or less quickly.

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Yes, because if I don't know something about a situation, if I don't have any value at all, then I'm more likely to have to assess the worst case.

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Mhm, so it would actually not only be an autonomous system as well, but also an adaptive system that would depend on these

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Parameters that you mentioned earlier, as the combination of the products, perhaps also whether it has just failed, reacts in different ways depending on the clinical context you have described.

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Is my assumption correct that a lot of domains, in this case also medical knowledge, must be included in this formulation of these rules?

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Yes, in any case and that is often the case

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So, that's incredibly important and that for the assumptions behind it and even for integration, because in the end it's already expert systems that are already trying to formalize knowledge, the medical, accordingly.

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Yes, and from the technical side and from the solution, i.e. the languages, which are then standardized, there are already ready-made solutions and that is where there is still a lot more to come.

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actually exactly the brainpower is in it.

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That is, it's a framework, I hear, is already there and or what you can offer, I hear now, but what has to be done or what manufacturers could do, what different scenarios of this framework or probably there are already interface specification languages, then actually fill it with domain knowledge in order to achieve exactly the goal, that we have already mentioned, namely to be adaptive in the sense that we are able to

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Achieving a safe state, i.e. minimizing risks and maximizing the benefit for the patient, exactly.

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So it is from the O.M.G.

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even standardized, how such models should look.

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We also have open source things on how to model something like that, but the thing is very application-specific and a lot of domain knowledge is necessary to make the knowledge explicit in the first place.

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And that's a first sensible step anyway if you have to struggle with many variants, even if you don't want to look at them all at runtime and switch back and forth between them fully automatically, but also if you simply have to manage these variants at design time and then have a system again, which is actually similar and then want to use the documentation again and again.

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In any case, this is a first sensible step in this direction.

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That means it makes sense especially if I understand it correctly when manufacturers have a wide variety of products in their portfolio that they want to connect together in different variants and combinations, or do you see it that way?

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Exactly, that's where the approach really comes into play.

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So there is also the idea of the product lines and that's exactly behind it.

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Here you can have a product line in your safety engineering approach, so to speak, and the

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requires a certain modeling and models and if you then work with a lot with Word and Excel or other things, it's just much more difficult, especially because these models also have an indirect reference or all this safety information about the architecture and other models that describe the system.

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And that goes so far that you can even say, if I have a component now, for example, and then a port or omission or you somehow change this component slightly, that you can then say directly automatically, O.

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K., what security requirements and are affected by them and how, what effects do they have?

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Mhm, I think that's what many people could use to describe their risk management in a way that is comprehensible, because most people have the risk management file

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in the case of the regonaries, the linchpin of all the technical documentation together with the clinical evaluation.

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Of course, all this will have such a price, I guess.

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Can you give an order of magnitude as to how long it would take to implement these concepts that you have just presented in yourself?

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And for whom is something like this profitable above all?

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Yes, it is primarily worthwhile for people who have to deal with it more often and

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where there is, where you can again, where there is also a high level of reuse.

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But how, how long it takes now, that really depends very much on the individual case and also where

you are normally already in the normal development, where you can build on it.

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If you already use appropriate modeling in normal development, which is our approach, also architectural modeling for tools, to really integrate the requirements, requirements tools, then our approach is always to really integrate that.

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And not to open up a parallel world with other tools and other models, because that's the problem.

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Otherwise you get inconsistencies between the 2 worlds.

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And there are many solutions and, for example, the effort depends heavily on how much experience we have with them.

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So, we have a free tool that you can use in this way, which works well for Enterprise Architect.

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We already have a lot of experience for Magic Draw.

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When it comes to other tools where we have less experience, it just takes a little longer.

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But the linchpin is also the development itself.

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So, it's not just the tools that matter and you shouldn't pay much attention to it at first glance, because you also have to have a modular architecture in order to create modular safety artifacts on top of it.

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We are now really going back into the middle of this area of modeling.

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I think the big difference is that these are no longer models for any components or for products, but now we really have models of entire systems, in this case autonomous systems.

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Yes, to me it sounds as if we can, so to speak, counter this combinatorial explosion a little bit, so that the files don't even then combinatorially

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explode and the notified bodies increasingly want to have proof, i.e. really almost mathematical proof, that the products are safe.

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And that sounds to me very much like an excellent step to fulfill these wishes.

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What would be your recommendation or what would be your recommendation, what manufacturers could take as a very first step to move forward on this path?

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Yes, the first step would be to call me, contact me, gladly,

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And that we then just talk about where they stand without obligation.

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And where exactly the shoe pinches, because that's always very, very important for us from experience, to really understand the problem first.

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Sometimes there are, there are other solutions.

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Sometimes you can also use ready-made solutions and that would be a first step to tackle this.

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So, would also be my recommendation, if you are interested, just and have complex systems.

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Well, it's certainly not recommended for everyone, but especially when we have a system of many products, have many variants, have different clinical contexts and don't know how to get all this under control, that you go down the path of these models and the contact details of them, we also write them in below.

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So, my tip, just get in touch

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with him and let him give you a first thought.

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Of course, we are always there for you when it comes to regulatory issues.

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So take advantage of our Micro Consulting, which is just as free and non-binding as the offer from Doctor Adler.

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Yes, I think things wouldn't be easier and we need more and more developers, architects, experts in regulations and models.

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but there is no other way to manage the complexity and that's why we have this podcast, where we want to look at and introduce ourselves to exactly such things.

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In that sense, first of all, I thank you from the bottom of my heart and hopefully see you soon.

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Thank you very much.