Johner Institute

Notified bodies are upgrading

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

Transcript

00:00:00 Speaker 1

What would you recommend to the manufacturers in this regard?

00:00:03 Speaker 1

Should they also start investing in AI to create a level playing field?

00:00:10 Speaker 2

I think they have to.

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To put it quite simply and clumsily at this point, they have to.

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I don't think we can close our minds to the topic of AI, whether it's a notified body, manufacturer or, at the end of the day, perhaps even an authority.

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Medical Device Insights.

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

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All those who have followed me in recent weeks know how much the use of AI is on my mind right now.

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Be it AI in checking technical documentation or automating many tasks that we have here at the institute.

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Tasks we perform for the manufacturers of medical devices and IVDs.

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I have someone from a notified body with me today, namely my old colleague Andreas Purde.

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He was what most people don't know, he used to be my Kapo when I was at TÜV Süd.

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For example, I was also allowed to go on software audits with him.

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He is a very experienced man.

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Today we want to talk about what is happening at a notified body in terms of AI.

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You will probably suspect that something is happening there.

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Because you can't escape the trend.

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And the issue of efficiency is not limited to manufacturers or consulting firms, but this also affects the notified bodies.

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And that's why I'm super happy that Dr.

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Andreas Purter is with us today.

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Andreas, I've already said that on the one hand you also have a software background, but I know that it's much, much more.

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And if you could give a very brief rundown of all the tasks you have in your organization at TÜV Süd.

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Hello Christian, thank you very much for the invitation.

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I am pleased that we can talk about this issue for a few minutes today.

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I have been working at TÜV-Süd in the field of medical devices for 20 years.

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I actually studied electrical engineering, have a relatively strong software background and am currently

part of the management group in Germany.

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In other words, for the business that we look after from Germany.

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I may

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At TÜV Süd, we can also deal with the digitization projects that we are doing in the field of medical devices.

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That's the way it is, I'm roughly resaying what I'm currently doing.

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But I'm obviously aware that I've caught the best here, because that's a rare combination, part of the management team.

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That means someone who also has a say in decisions and at the same time the one who takes care of digitization issues.

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Bull's eye.

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We'll get right into it,

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as areas of application of AI at a notified body.

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So I had teased a bit about the background motivation, certainly has something to do with efficiency, but maybe also conformity.

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But I don't want to take anything away now, Andreas.

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What are the topics that you are currently exploring or where you may even be directly involved, where you want to use AI?

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Yes, of course.

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So actually, from my point of view, there is

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an insane number of applications.

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I think I would like to highlight a few times because they are simply the most important for us at the moment.

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First and foremost is certainly the topic of evaluation of technical documentation.

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This is one of those ways where we believe that AI can actually bring relatively many advantages.

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The second is the topic of level 1 audit.

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I'll explain why in a moment.

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Or the third point, which I would simply like to explain to the auditor in the audit.

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as the lead auditor in the audit.

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As I said, I am also happy to explain why.

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So the TD area, and I think we all know that, is a big part of the work we do.

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So I guess 60 percent or more is somehow searching, matching and summarizing.

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This is an activity where I can imagine that AI can support us significantly.

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The second topic I mentioned was a bit of the topic of Stage 1 Audit.

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So when a customer is contacted for the first time with a notified body or even

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contact a certifying body, you have to do a level 1 audit.

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And in the level 1 audit, we actually only determine whether the QM system is complete in itself.

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It is not yet about detailed questions that go into depth, but rather only about completeness.

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That's also the case, when I think about it, a task that can be wonderfully prepared by the AI at this point.

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The third topic I could imagine is a bit of managing the auditor.

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When I'm in the audit and I'm visiting a customer that I haven't visited that often, I could imagine it being quite cool if the AI was telling me in the background: „Well, based on the audit results of the last audit, ask in that direction, dear auditor, because there have been findings there in the past.

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Maybe you can follow up on that again without me having to spend hours dealing with the results of the previous audits." I could imagine it that way.

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those from an external point of view, i.e. what our customers would perceive, are the areas of application that we are currently exploring a bit.

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And of course, we also have an internal use of AI.

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So I don't know, screen MDCG documents and work out relevant questions.

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These are all topics that we naturally use internally to increase our internal efficiency, of which the customer does not notice so much.

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That's why

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I have now turned my focus to the topics that are more outward-looking, i.e. T.

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Assessment and audit.

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I can fully understand that, these are also the points with which I have worked a lot, especially with the T.

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Review, so we now have a booth where you can say that it has a human level, at least from the junior, I would guess now, consultant, junior, auditor reached and we also have very good experience with level 1 audits,

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already done.

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When it comes to managing auditors, that's a great idea, and I'd like to take that up as well.

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My idea had been to take a kind of anamnesis of the respective manufacturer and then actually make a little bit of what you do in these risk-based audits.

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This even goes so far that you could almost select customers according to the priority for

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unannounced audits, because you also go back into this history.

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So I find a mega idea, where I also have experience, but not quite as good, is in analyzing MDCG documents.

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So you have to be a bit nice to AI, because these documents are sometimes a challenge even for an AI.

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Because the .

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I mean, you can only find structures in it that are also in there.

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There are some documents where even the AI is confused afterwards.

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But that's a personal assessment.

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You have already mentioned three topics.

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Very briefly about the repetition through the TD review, stage or stage one audit.

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And this guidance of auditors through the audit process, especially with customers and manufacturers, where they may not have so much experience.

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If you were to prioritize it or put it in an order, how would you go about it?

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Or what is your planning?

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Yes.

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So indeed, we are also an economically minded company and we actually take the things that have the greatest leverage first.

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Because at the end of the day, the investments you put in there have to be worthwhile.

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And it costs money and effort to do all this.

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currently assumes that the topic of TD valuation will offer us the greatest increase in efficiency.

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And increasing efficiency is now also a bit of the first reason why we are tackling the whole issue.

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But that's not the only one.

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So the topic of standardization and also the consistency of evaluations are other topics that simply follow the efficiency directly.

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To sum it up, yes, we start with the topics that have the greatest leverage.

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In my view, this is currently the topic of TD valuation.

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followed by the two audit topics I mentioned.

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As I said, I had already said that at the same time, of course, we also use AI internally to increase internal efficiencies, so to speak.

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But this actually runs in parallel, in order to get a bit of annoying work that you have to do at one point or another, I would say, to get support for it.

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Later, we may have to take a very brief look at what this also means for the manufacturers.

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Because if you give the TD to the AI to check, then the AI doesn't do a random check, but a regulated full test.

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Maybe we can share a thought about it later.

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But in order for this to work, and that's why I'd like to discuss it with you first, these are not banalities, what you're planning, and I can also report it from my own experience, it's not trivial.

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What do you think you have to do

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What requirements do you have to have fulfilled for such a TD exam to reach a quality that actually helps you.

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So a check that contains too many false positives, a check that leaves too many errors undetected and therefore justifies a lot of rework, could even cause more work in the end.

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So what do you have to do, what requirements do you have to meet to achieve this level of quality that you think is necessary?

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Yes, that's an absolutely good and valid question.

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I would like to start it with the statement that I say that AI is not a sure-fire success.

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We've already tried that, but it wasn't particularly successful.

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If you just shoot into the blue, the result is not good either.

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We still need a very high level of domain knowledge for the use of AI.

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And what we have to achieve in our organization is that we have the experts who have the domain knowledge and who then ideally also deal with the topic of context engineering.

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that we bring the two topics together.

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Because this group of people then has to do the preparatory work, bring the topics together, so that they can then be used accordingly by the other colleagues.

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What we also need is, I would say, a certain set of governance rules.

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So where can AI support, where can it not support, where are human examinations, decisions,

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Absolutely necessary?

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Where can I perhaps trust an AI verdict in the first instance and then only intervene when there is actually an indication to do so?

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I need very clear rules.

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And of course, if you want to use AI, we also have to determine how well AI actually delivers the results?

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We need to validate the issue somewhere.

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Again, that we just don't blindly

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that AI delivers the right results.

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In summary, I would say that AI is a tool.

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And like any tool, you have to be able to operate it.

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That's what we have to achieve as an organization.

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And so does every individual who is part of the organization.

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I couldn't agree more.

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When it comes to domain knowledge, you can even distinguish between regulatory knowledge.

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Here you really have to understand regulation down to the last detail.

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also all the slight contradictions that we have, the different levels of abstraction on which rules are published and on the other hand also the domain in the sense of what I call risk management or biocompatibility and so on.

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So I can fully underline that, because otherwise you can't tame the AI at all or make such precise specifications that it then delivers the results in the necessary quality.

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So completely communicates itself completely

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my experience, also with regard to this topic of governance.

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We always have such IP protection, which we also want to take into account.

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And you had addressed another aspect for which I do not yet have a final solution.

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Namely, you said that we also have to determine what the quality criteria are in the end, against which we will then also compare later.

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And I find that an astonishing or surprisingly difficult task to find out.

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You can see that if you were to give different auditors the same task, they wouldn‘t always come to the same conclusion.

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And I don‘t mean that in any way disrespectfully.

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It‘s similar to doctors, who would never come to the same diagnosis.

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And it forces us now to formalize these rule sets and thus also to arrive at metrics that are then somehow recognized.

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So we can no longer hide behind this

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fluffi root.

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Yes, that‘s what the expert said, but now we need scientific metrics and working them out was more difficult, at least for me, than I would have thought.

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So in agreement with everything you just said, the prerequisite is domain knowledge, even in a double sense, governance rules and also clear guidelines, to be able to define quality metrics, without that it will not work.

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If these prerequisites were not met, then

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there are certainly some risks involved.

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What do you see as the priority and how do you deal with it or how do you plan to deal with it?

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Exactly, so excuse me, risks is also a question that I personally ask myself, of course.

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So not only the organization, but not me personally.

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One point you just mentioned is the issue that AI, like every employee who can also make mistakes with us and

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Too much blind trust in the results of AI should not actually happen.

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Of course, we have to prepare as an organization so that this ideally happens in as few percent of cases as possible.

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But we probably can‘t rule out errors in the use of AI one hundred percent.

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That‘s why we have to have clear rules.

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how we have to deal with it and where a human expert still has to make a decision at the end of the day or not.

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This is certainly a domain that we have to look at.

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The topic of dealing with AI errors is a risk that we will have methods to get it under control afterwards.

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But there are also other risks that may not have too much to do with the rules now.

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And they certainly affect you personally.

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Well, I would already assess myself now that I .

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is open to technical innovations.

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But I also notice that this pace of development, especially in the field of AI, is so fast that I sometimes find it difficult to keep up.

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Because there are things that didn‘t work last week, then this week and always staying up to date with all the information is actually a challenge.

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What remaining work is left for the colleagues who are still working?

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Is it all highly intellectually demanding work?

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At the moment, it looks like people like to give the AI the activities that are annoying, but on the other hand, of course, they are also relaxing in a certain way, even though they are annoying.

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At the end of the day, that still means that the work that remains with you

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is rather the highly exhausting, detailed, difficult work that then remains on the human side.

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And if I want to speak for myself personally, I can't do eight hours a day of highly mentally strenuous work, but need breaks in between or sometimes activities that may not be so strenuous.

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And that is certainly also a question that you then ask yourself personally and, of course,

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the organization or society will have to solve how to deal with this concentration of work.

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Mhm, we have that, we are already observing in the medical field, so in the radiology field, for example.

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I had talked to the radiologist,

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she described something similar.

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She said, in the past we just had patients and some were non-critical patients, some were completely clear that it was something and around the middle third, you really have to make an effort to get a clean diagnosis, he always had time to recover a bit, because the patient has to go to the M.R.T.

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and so on.

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And she says, in the meantime you sit in the back of the room and only get these critical cases presented, which is similar to what you just described, such a work intensification and

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thus ultimately lead to an overload.

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And I don't think we all know exactly what the effects are yet.

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With that you have now described 3 risks to us again, namely the blind trust that one may be inclined into the A.I.

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or, on the other side of the medals, the misclassifications that can prevail in the results.

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You had described that the speed at which everything is developing can be very overwhelming.

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And that there is also an overload due to the fact that the work is so condensed or threatens to condense into such a way.

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If we now take a step back and see, what does this mean for the manufacturers, who are of course also exposed to these 3 risks.

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But I now see an additional change in that their notified body, i.e. you, is also changing, yes, in the sense of higher efficiency, in the sense of full testing

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Partial examination.

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What would you recommend to the manufacturers in this regard?

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Should they also start investing in AI to create a level playing field?

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I think they have to, to put it quite simply and clumsily at this point, they have to.

00:18:01 Speaker 2

I don't think we can close our minds to the topic of AI, whether it's a notified body, manufacturer or, at the end of the day, perhaps even an authority.

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the topics will simply come and I think the companies and companies that do not deal with the issue will

not survive at the end of the day.

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I am firmly convinced that all market participants must deal with the issue at this point.

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Mhm, that was now the one very concrete line of action, what would be your wish, as far as togetherness is concerned, yes, that means now, now I just have a bit of maybe one of those

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warmongering expression equality of arms, but we don't want to fight each other.

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What would you wish for the future, how to deal with each other in the A.I. age?

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I actually wish that all market participants at this point, i.e. manufacturers, notified bodies and authorities, that we tackle this challenge together and also deal with each other in partnership, even in the age of A.I.

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and also

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like to exchange ideas together, learn together, try to solve the challenges that lie ahead of us together.

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And I think we will certainly manage that or we have to do it.

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I'll say, also about locational advantages, Europe et cetera P.

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, we have to deal with the issues and we can only do that together at this point.

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I couldn't have wished for a more beautiful final word.

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That's why I just say thank you Andreas for being there.

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that you have revealed to us today what your thoughts are on the use of AI by notified bodies.

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But, and I found this particularly touching, it also means what it means socially and what it means for the cooperation between manufacturers and notified bodies.

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Thank you very much, Andreas.

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With pleasure, it was a pleasure.