Johner Institute

How ROCHE is tackling EU digital regulation

With Dr. Pascal Hofer, Prof. Dr. Christian Johner

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Transcript

00:00:00 Speaker 1

Last week there was a leaked version of the EU's digital omnibus document.

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

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The listeners of this podcast have probably already noticed how the EU delights us with more and more acts.

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Recently, especially in the digital sector,

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Yes, I see the E.H.D.S., the European Health Data Space, for example, there is the Governance Act, we have the A.I.

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Act and I asked myself the question, how do large companies manage to keep all this on their radar, how do they manage to implement all these requirements that are raining down on them.

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And it is precisely for this reason that I have invited Doctor Hofer from the Roche company today, who is a top lawyer in this

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and Mr. Hofer, I'll come directly to you.

00:01:02 Speaker 2

How does a top lawyer get into such a position, what drove you?

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You could have become a judge or a lawyer and now you have a position where you have an overview of this entire digital area at such a huge corporation.

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What was your motivation there, how was your path there?

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Of course, thank you very much for the invitation and I look forward to discussing this with you.

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Well, I think all in all, almost most of us did indeed start out in the law firm in the classic way, from different directions.

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For me, it was medical law.

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Well, I had a certain soft spot for it early on.

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I had a constitutional lawyer at the University of Cologne, Professor Höfling, whom I thought was really great and he has a bit of a niche field, but he did transplant law at the time and I did my doctorate with him, so I thought that was just the case

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super exciting, then I did a lot of medical products right, a lot of medical liability and then at some point there was indeed a newspaper ad in the classic way, you can hardly imagine nowadays, but that was a newspaper ad, then Roche came around the corner and asked if I would like to work for them in the field of medical law and that appealed to me quite a bit, because as exciting as it is in the law firm, but there you are more

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often there selectively, even in firefighting mode.

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And I was attracted by the prospect of working for a large global company, but this opportunity and the prospect of working more strategically, and it has also come true.

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So really accompanying products and projects from start to finish, of course not only legally, but gives a very exciting holistic view and that appealed to me very much.

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Mhm.

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I think most people can imagine what such a judge does.

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With lawyers, it may be a bit thinner.

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But when it comes to a company lawyer, the understanding is perhaps even less pronounced.

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Could you give our audience an idea of what the tasks, what the responsibilities of someone who, like you, has such a management function, as Head of Legal and for Digital and I.

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T., what

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because it's on the table every day.

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You have already talked about strategy.

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Could you briefly describe what strategic tasks look like?

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Mhm, very much.

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So I think one sub-area is indeed very, very comparable to the classic external lawyer.

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Then there are really normal legal questions or or contract reviews, contract negotiations in our environment, then a lot of I.

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Contracts

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and the like.

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So that's very, very comparable.

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The difference is indeed, as you mentioned, then in the strategic area and that is also highly exciting, because then it is often the case that our, our, our approach and fortunately is also seen by business in such a way that we do not sit somewhere at the cat table, but the lawyer is also seen as an equal business partner, so that we also sit on the governing bodies and are involved at a very early stage, which is

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really has immense advantages, because we can use the projects, the big strategic projects, how do we get to that later, for example, the implementation of an E.U.A.I.

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Acts that can see very early, can address very early, can accompany very early.

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Conversely, with very product-related topics, I also noticed, well there is a new product coming and what are possibly special legal topics and yes, so this early involvement is simply very important.

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Very helpful and also very exciting.

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No, I think that's the big difference.

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How do you set boundaries or how do you work together with the regulatory affairs experts?

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How do you divide it up?

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That's really good, good team play with us.

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So it is, they are of course much closer and much more precise in the individual

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Details, but when it comes to, let's say, put a certain altitude on the market, for example, i.e. these classic, but then very legal issues again, then they come to us and then we tackle these issues together again.

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So and vice versa, we then come up with approaches, such as in the E.

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Heck that we can then

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there and say, you have to put this in your Q.M.S.

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then implement and take into account with the quality people.

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Who then does the monitoring, all these regulatory requirements.

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That's also, I think systematically, not I think I know, it's systematic with the Quality Regulatory people,

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As I have heard, they also have a tool that is currently coming from you, the Regulatory Radar, so that what is coming is systematically recorded.

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And we have these classic legal channels via newsletters and the like, association work and so basically a little bit of this legal landscape monitoring comes in.

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Well, of course, I know that well from my own experience.

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So we then

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At that time, we monitored it for the first time for our customers' products, and of course also for those where we were once involved in the project.

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But now we are so overwhelmed with these requirements.

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So now, I think, we have exceeded the 10 thousand mark of regulatory documents with several 1000 changes per year.

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I don't see any alternative to how this could not be done automatically and that's why we do it

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Exactly the same.

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One is recognition, so when there is a signal, there is something new, something has changed, but the second is of course always, what does that mean?

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Yes, that's not enough to say, yes, something has changed, but what does it mean concretely in the company afterwards, for example, we have to get to the products, we have to get to the quality management system, be it S.O.P.s or work instructions.

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and sometimes the direction to the direction of business also has an effect and that, I think, is exactly where a good interface is necessary between those who monitor, perhaps already give initial tips and later on the other hand, who then implement it, like them and their teams, in order to achieve this conformity in the long term.

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Yes, and a current example was once again the

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Act, we can perhaps go through it just with the example, so of course they have now of course had it on their radar without us.

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How did they approach it, no, such a, yes, that was a big work, yes, which now refers not only to the products, but to the entire company.

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What was their strategy, what were their considerations, how do you cut this elephant into digestible pieces?

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Yes, that is indeed not easy.

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So there were various challenges.

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One is, as you mentioned, the E.U.A.I.

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Act itself is already complicated.

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It has also not been entirely successful in many respects, because it leads to ambiguities, because it is very, which is nice in itself, very ambitious, but then it has become too complicated and, due to this horizontal approach, it has also led to many frictions and perhaps we will come to that, especially in the case of

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MBR, IBDR.

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So that was one challenge, that we have a body of legislation that is difficult and complicated in itself,

implying legal uncertainty.

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And the other thing is, of course, that as a global company, we cannot rely solely on the UAI Act, but we have to somehow make sure that we find a mode, establish a governance model, which then

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hopefully it will work in the rest of the world.

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So those were the 2 big ones.

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And how did we do it?

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First of all, we took the Euway ICE as a starting point, as a center.

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Why?

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Because it is the most comprehensive, the strictest, but then nevertheless tries to build in a certain flexibility, in such a way that we

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at that time, there were these interim measures and Gen A.I.

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and then we have Colorado A.I.

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Act taken from the USA.

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So basically 3 hotspots of the world and with the approach of saying, well, if we fulfill them, can fulfill them and how we do it, I'll get to that right away, then there is justified hope that we can also drive the

rest of the world with it in an approach that is good for us as a company.

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How did we do it?

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So, we then took a look, of course, what are the requirements under the EUAI Act, but how can we simplify it for ourselves in a certain way.

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And I think we benefit from the fact that Roche is not only a pharmaceutical company, but also a large diagnostics company.

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In other words, we have seen, well, there is an area for products that we commercialize and they are then also allowed to be high risk under the EUAI Act,

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because we have a QMS under NDR, IVDR anyway and then the requirements under the EUAI Act can basically be met.

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There are data governance issues, is there any retention for log files and the like.

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So of course you have to look at certain points in the QMS, but that's manageable, it works.

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versus, that was the other area that we tried to simplify, for which internal IT solutions, tools, it would be very unfortunate if you basically had to meet these exaggerated, in my view exaggerated high-risk AI requirements.

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That would completely paralyze IT or lead to really very high requirements, where you have to ask yourself: Is this still in an appropriate, in an appropriate balance?

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I, we said that we want to take an approach that ensures in the governance model, when these solutions

are implemented, that we mitigate them to so-called this low-risk area as Low Risk A.I.

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System and have noticed that it works well and by the way, the requirements that then take effect and there are not many left, that's at least a good point with the E.U.

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A.I.

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Act that then

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there are only basically transparency requirements and this technical watermarking, these are almost global requirements anyway.

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So here we come back to the point that this is also an approach that is then globally viable, because almost every legal system that is now being established in the world often has these transparency requirements, this technical watermarking, this labeling, for example in China.

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So these are approaches that work well.

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So we divided the world in two.

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In one world, we can live well with high risk, and in the other world, we try to simplify in such a way that we stick to low risk.

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I think that's roughly this approach.

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Okay, I'll summarize very briefly.

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So with the medical devices you don't really have a stomachache, because it can be brought together quite well with MDR, IVDR and in the role of the

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Deployers, in order to use the technology, make sure that they remain outside the high-risk area and also see the requirements that the AI Act places on high-risk products, i.e. also on the deployers.

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but a bit too high and that's why they try to stay out of it.

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Exactly, that's exactly the approach and exactly, Mr. Jonah, I would of course also be very interested in how you deal with it in consulting, when companies come along now and then it will probably be different companies, different sizes, different setups, how you go into such a consulting situation and what your advice is, to set it up well.

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Yes, so since the

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that's a relatively broad spectrum that we come across and it also depends a bit on the larger form of organization.

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So with the largest companies, we sometimes see that this is driven from 2 corners, namely from a, let's call it, corporate legal level, which puts a very strong focus more on the deployer role and where you somehow know, yes we also have medical devices, but.

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Nevertheless, this is somewhat demarcated and thus also a problem and then, so to speak, parallel to it, those who then act from the medical device sector.

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And then, in the worst case, you have 2 projects that are not coordinated.

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So we observe that more often.

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So although most people are aware that it is an issue that affects the whole company plus products, these initiatives are not particularly well coordinated.

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So that's where we regularly come across.

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Then there are sometimes some ISO 42001 initiatives between these two worlds, which are then started by one or the other.

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So it may be that it comes from development, because they have heard, ah, South Korea, for example, now wants this to be mandatory.

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But it can also come from this corporate corner.

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So that's an observation we're making.

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The second is, if we now look a little more in the direction of medical devices, that

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the companies only through this A.I.

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Act to become aware of what it actually means to use artificial intelligence and mostly machine learning in their products and first of all to meet the requirements of the MDR and I.V.D.R.

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Yes, that means they somehow treated the products like everyone else

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also and this of these A.I.

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Aspect has fallen down there.

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Yes, for example, the A.I.

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specific risks or that you also have the entire data processing chain that you then have to train the models to have them properly under control.

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And so these A.I.

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Act projects, how can I put it, also used like a little Trojan horse to clean up these old burdens.

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Yes, that means somehow 90% of the work that you then

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under this A.I.

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Act roof or you could also say A.I.

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Act Budget, because and that's what it's usually about, done that it is actually contaminated site removal, which would have been necessary by the MDR and IVDR long ago or 13 for 85, i.e. entire medical products anyway.

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And actually, we get to maybe 10% of the A.I.

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But the apology for tackling the issue and the budget opener is there

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in fact, the A.I.

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So that's what stands out and, interestingly, that's not only with smaller companies, but also some medium-sized and larger, i.e. have had an astonishing ease when it comes to meeting these regulatory requirements.

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This is also due to the fact that a lot of it comes from the research context somehow.

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Yes, then you have, where does the data come from, know from larger clinics, university hospitals, for example, these are research partners,

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Partnerships or they have development partnerships and then somehow it is forgotten that there are also regulatory requirements, also in terms of quality management, which should somehow also apply to them.

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We are not allowed to have black holes there and we come across these black holes surprisingly often.

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So, that's an observation that we now have in the direction of medical devices.

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Well, I had just described, so to speak, these competing or uncoordinated projects globally.

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I had just taken a little look inside, primarily in the direction of development or product-specific scope.

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And when we get into this deployer view again, I sometimes observe the opposite.

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So there is almost overfulfilled or over-anxious action, which makes the use of the L.

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So you somehow know that you have to do something, but you don‘t know exactly,

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what to do now and then always looks in the A.I.

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Act the requirements.

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But actually, the really relevant requirements that are set out in the A.I.

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Act to the deployers, at least if there is another product with a further product context, but they can be found, for example, in the 13 for 85.

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Yes, that is, then they somehow mess around with Article 50, yes, and and and car marketing, what do I

know what they want to do.

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but forgot that this, that it is tools, software, that can be found in Q.

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system and are therefore subject to validation if necessary.

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And that's very, I would say very heterogeneous, how you approach it.

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So mostly, I would say, in the vast majority of cases we observe, it always tips over to an extreme.

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So you destroy yourself,

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with any validations or you ignore the topic altogether.

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So I think a little pragmatism could help and that's where we do our best in counselling to get this pragmatism back in.

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So we can, we don't earn our money with regulation, but with our products and we always have to look at what is actually the goal of the whole thing and the goal is that we produce safe and efficient products and if something can stand in the way of that,

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yes, because we are doing our data handling uncleanly, for example, you have to take care of it, but otherwise we shouldn't meet any requirements that don't even exist.

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So that was perhaps in 3 points, what we know in practice in context A.

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Yes, yes, exciting, is also something I would have expected at this point, that such a law, which is just

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from my point of view, leads to exactly that, either over compliance or under compliance, but not basically especially in terms of innovation.

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What it might have intended, at least it was always emphasized again at the end.

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You also want to promote innovation, but that's not enough at this point.

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I am also surprised how long this topic was ignored by some and is still ignored to this day.

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I mean,

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the first parts are in force, so you should take care of it now.

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And I also observe a relaxation with other European regulations, such as the Data Act.

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Maybe back to you, you have it on your radar, I know that.

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How do you go about that?

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Yes, it's maybe a little bit more in the future than A.

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Act, but still something that will of course affect you directly.

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Yes,

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Yes, also an exciting topic.

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It is highly exciting, especially in terms of the objective, and perhaps in the end we will also have time for the EHDS, the European Health Data Space.

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But I personally welcome this goal, but also companies like Roche, of course, which we welcome, because these

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Ambitions to say that you want to use data more, especially for secondary use, you want to open it up for research and so on, for secondary use.

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That's, that's great, but again at this point the question of how it was implemented in terms of craftsmanship.

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But let's start with the Data Act.

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I think if I have the numbers right in my head, Bitkom once did a survey to find out how many companies are willing to do it, how many are ignoring

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this share of ignorance and don't quote me now, but that was significant.

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That was between 2040% of companies, have said, Data Act, yes maybe heard, but not really in such a way that it, that you can say you have prepared for it.

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Due to the fact that we are of course recognized as the market leader in the field of I.V.D.

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have many, many networked medical devices,

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the topic was important to us, so we took care of the implementation.

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And from the company's point of view, there are two very big issues.

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One is that now, and many lawyers really call it a revolution, you need a data license.

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In the past, you could say that data is not personal data in any case, it doesn't belong to anyone, it isn't

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there are no real property rights.

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A few jurisdictions are maybe a little bit closer, I mean France for example, but most jurisdictions don't have ownership rights to data, but that's not really changed by the Data Act, but brings it a little closer to the shape that it says, well, who wants to use this data, these machine-generated data from, among other things, medical devices, from the owner, the so-called data holder,

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he now needs a license and we have just implemented this in our customer contracts in such a way that customers agree that such data is used secondarily, but which, by the way, in the end, if things go well, of course also benefits the customer again, because what is it used for, the data of course for improving the product or the service.

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Yes, that's the primary reason why you want to use this data.

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So, that's one big thing and the other thing is, what the Data Act also does, is that it gives the user and in our case these are clinics, doctors of networked devices, but they can also be patients, but they are basically already covered by the General Data Protection Regulation, more or less.

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But now new.

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then also such people as hospitals via networked products, they have data access rights, and then as a company you have to position yourself as a data holder in such a way that you can also make this data available when the data access request comes.

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So those are the 2 big points.

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Of course, it is now very exciting to see how this flies in practice.

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So the post-hat child was clearly the automotive industry, so I see enough starting points for the

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Insurance companies and the like are interested in how people drive, what kind of data is collected and so on.

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In other industries, I don't quite see it yet, but we'll wait and see.

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So whether that, whether this concept, which I don't think is so successful, that everything revolves around the user.

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I think the EHDS is much more successful, the way it is conceptually designed.

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But yes, we'll see.

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How do you deal with the Data Act in your consulting practice?

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Is this an issue for your clients or not?

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So, we have that, but we have it even more so in the Health Data Space, because we have the issue of interoperability at the top of both legal acts, and both times as well.

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So there are also small differences, but of course also with the aim of promoting a data economy.

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to promote new business.

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At the E.R.D.S.

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we have of course explicitly included the research.

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Yes, this is not so pronounced with the Data Act.

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And of course we also have the big idea that patients can also take their data with them through Europe, which is also the care aspect of care, which differentiates it a bit.

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If you look at something, what does it mean for the manufacturers?

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It has a lot to do with

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technology, with interoperability, and we will expect to see more precise specifications for all these semantic and syntactic standards in the Health Data Space.

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So they haven't been listed yet, but they will probably be passed on to some other Delegation Acts, where they will be specified.

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And that's where they're slipping now, it's now for production from a few points, it's becoming a real challenge, it's exactly where we also support.

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The first challenge is that they will be the very technical companies, i.e. where machine data, if I may call it that, have not only patient data, but also machine data, they are now entering a world for the first time where they have to think about semantic standards.

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So far, this has been driven exclusively by development, making it highly proprietary.

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And now we suddenly get into the area where we think, hm, how can we replace this?

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Because, of course, we never understand our own semantics outside the company, and sometimes you don't even want someone outside to understand it.

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So these are questions of how we can get this implemented, i.e. how do we get interoperability created.

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This is one of those areas where we support, and really also that you look again at what are syntactic aspects, what are semantic aspects, what are organizational aspects, because

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especially when they talk to developments again, they are very much on the format level.

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But don't even think about what that means semantically.

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So now perhaps for the listeners, if I may give an example, they are someone who works with laboratory values all day.

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But now a laboratory value is not a laboratory value.

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Yes, a hemoglobin is not a hemoglobin, but it just depends, which differs in which state you are.

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It differs how it has been measured.

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There is a whole cloud of context around it.

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and if you don't have that, then you can't compare the hemoglobin values with each other, it's simply worthless.

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This means that now we have a mixture of contextual medical understanding, which in turn must also be understood by the technology, because otherwise it cannot create interoperability.

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So, that's one of those types of advice.

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The second is when you open, you are suddenly open and the capsule of the product is broken open.

00:27:00 Speaker 2

Yes, of course that's exactly what the law wants,

00:27:03 Speaker 2

But from risk considerations, it is of course again provided with a certain stomachache.

00:27:08 Speaker 2

That is, all of a sudden we have topics like this again I.T.

00:27:11 Speaker 2

Security on a whole new level.

00:27:13 Speaker 2

So as soon as there is any interface, says the F.D.A., then it counts as interoperable.

00:27:18 Speaker 2

This means that you are suddenly involved in the whole area of cybersecurity and these are areas in which companies do not necessarily always feel safe.

00:27:27 Speaker 2

That means that the topic of risk management, cybersecurity, that's really a Pandora's box that you open when you open the products, that needs to be weighed very carefully.

00:27:40 Speaker 2

Of course, there are also business risks, and of course business opportunities, we sometimes help with that, but that's not necessarily always our focus.

00:27:50 Speaker 2

So these are topics that we have with us.

00:27:52 Speaker 2

What else do we have in the area of interoperability?

00:27:55 Speaker 2

A.,

00:27:56 Speaker 2

Of course, interoperability now serves to make data available to unknown third parties, but the companies themselves are also in the situation where they move from the product to the solution.

00:28:09 Speaker 2

Yes, that means that they are even interested in no longer just seeing the individual box, i.e. metaphorically speaking, the tin box as the product, but what do we actually need in the clinical context.

00:28:23 Speaker 2

That means we have whole

00:28:25 Speaker 2

a solution that consists of multiple products, medical devices, not medical devices, to provide a service.

00:28:32 Speaker 2

So maybe an example from a completely different context, Dental.

00:28:36 Speaker 2

If you have dental, then you have some products that you might have to use to measure the patients.

00:28:41 Speaker 2

So you have to segment them, then comes an A.I.

00:28:44 Speaker 2

on top of that, then you have to do a treatment plan, then you may have to have another tool, not medical devices, is the whole cost calculation for the patient, treatment plan created and so on.

00:28:52 Speaker 2

That is, it is a whole

00:28:54 Speaker 2

Chain or a whole system of different tools that have to interact with each other.

00:28:59 Speaker 2

And now we are suddenly in the situation where medical device law is leaving us.

00:29:04 Speaker 2

Man, medical device law does not know the concept of the system, apart from the system and the treatment unit, but there is no thought, what is risk management, for example, or clinical evaluation for this interaction of this whole network.

00:29:19 Speaker 2

And

00:29:19 Speaker 2

and that's highly complex, because then you suddenly have questions about what belongs in which file, how many redundancies we might have to have or how do we avoid redundancies.

00:29:28 Speaker 2

If we have common documents, we then bind the release cycles of these individual components too closely to each other.

00:29:36 Speaker 2

Yes, that is ultimately a regulatory strategy and these are also topics in which we are providing support.

00:29:42 Speaker 2

So perhaps to sum up, I think we are all convinced of what great

00:29:48 Speaker 2

opportunities we have when we make truly interoperable products, even if this can have superficial disadvantages.

00:29:56 Speaker 2

I've talked about risks, both technical and business risks, but whenever we've opened something, it's actually almost like a bit of tariffs, so I don't want to get too philosophical now, but if we openly, if we let it flow, then usually there's always something better for society, in our case for the patients, came out.

00:30:15 Speaker 2

and to make it possible.

00:30:17 Speaker 2

These are things that also drive us.

00:30:20 Speaker 2

What is your wish, if we now perhaps dare to take a little look into the future, what do you wish for how this will continue, be it now regulatory, perhaps also technically?

00:30:32 Speaker 2

What do you see in store for us and what would you perhaps also wish for?

00:30:37 Speaker 1

Yes, what I wish for and I think I can already see that in rudimentary ways, at least last week there was a

00:30:44 Speaker 1

a leaked version of the EU's digital omnibus document.

00:30:50 Speaker 1

Of course, I would like to see the goal done well by hand.

00:30:55 Speaker 1

In other words, that one thinks about it and that has probably already been done in this paper, how successful, opinions differ, I still have to look at that myself in detail, but

00:31:05 Speaker 1

In any case, these different, but fragmentary and friction-leading different regulations that we have, we have so many Ds.

00:31:13 Speaker 1

Acts, that you merge them and you probably do that, or they try to make it together into a data code, because that simply, I mean, it helps the consulting guild a lot if we have different fragmented orders.

00:31:30 Speaker 1

But now thinking as an EU citizen, I would of course very much like to see

00:31:35 Speaker 1

really the one of the objectives, which is good, yes, but which is also really better implemented in the sense of innovation, really promote this free flow of data and in such a way that the legal practitioner can then also understand it in a legally secure way.

00:31:51 Speaker 1

And you can only do that if you bring together these different acts that we have really well, because they're too complicated at the moment,

00:32:01 Speaker 1

too fragmentary, too leading to friction.

00:32:05 Speaker 1

Therefore, that would be my wish and it seems to have arrived.

00:32:09 Speaker 1

Now it just has to be implemented well.

00:32:12 Speaker 2

So this wish, I also share it with the consultant's glasses.

00:32:16 Speaker 2

I would even go a step further in some places and say that some things are not necessary at all.

00:32:20 Speaker 2

So an A.

00:32:21 Speaker 2

I.

00:32:22 Speaker 2

Act for medical devices, I think we could all have done without it.

00:32:25 Speaker 2

I don't really see that we have created additional security for the patients, but

00:32:31 Speaker 2

whatever the side effects are, is that we are now affecting less but putting medium-sized and smaller companies under pressure, that the energy is lacking, that the resources are lacking to do what they should actually do, to produce good and safe products.

00:32:46 Speaker 2

And of course, every quantum of energy that is now going into unnecessary regulation, that is missing elsewhere and we are observing that and that gives us a stomachache.

00:32:55 Speaker 2

And there are no winners, neither on the consultant nor on the manufacturer nor on the patient side.

00:33:01 Speaker 2

Herr Dr.

00:33:01 Speaker 2

Hofer, that was a wonderful interview.

00:33:03 Speaker 2

Thank you for letting me participate, for sharing your thoughts with us.

00:33:08 Speaker 2

Thank you so much.

00:33:09 Speaker 1

Thank you very much.

00:33:10 Speaker 1

I was very pleased.