

AI Act – A Practical Report

With Carmen Bellebna, Prof. Dr. Christian Johner

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Transcript

00:00:00 Speaker 1

We are all in Europe and each notified body acts a little differently in this respect.

00:00:06 Speaker 1

Of course, they also have to build up their competence in AI first.

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Where is it supposed to come from?

00:00:12 Speaker 2

Medical Device Insights.

00:00:15 Speaker 2

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

00:00:22 Speaker 2

Now that we have largely digested the MDR and IVDR, new ones are emerging

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regulations and one is the A.I.

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Act, and now it's time for us to gain experience, to talk to people who are already in the process of implementing it.

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And that's exactly what I'm planning to do today, namely with Ms. Balena, who is responsible for Regulatory at Deep Eye.

00:00:50 Speaker 2

Could you briefly tell us how you got into this regulatory area

00:00:57 Speaker 2

and what types of products you make.

00:01:00 Speaker 1

Good afternoon, Mr. Jonah.

00:01:01 Speaker 1

Thank you very much for the invitation to this podcast.

00:01:04 Speaker 1

My name is Carmen Belebner.

00:01:05 Speaker 1

Well, I am a biotechnologist by training with over 20 years of experience in the field of life science and regulatory affairs, both in the pharmaceutical and medical device industries.

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She also worked as an auditor at various notified bodies for 8 years.

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Yes, and since 2023 I have been working at Deep Eye Medical in Munich

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and we develop A.I.

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Assistant to Therapy Planning Assistant in Ophthalmology.

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Yes, I head the Regulatory Affairs department and accompany our product on the way to approval.

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We are currently in the final stages of our C.E.

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Marking.

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We have gone through the complete conformity assessment process, audit and T.D.

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Review and now we are eagerly awaiting our M.D.R.

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Certificate.

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What are you like as a

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biotechnologist in the field of regulatory.

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That's not necessarily what you've studied.

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What inspired her, what drew her there?

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Yes, that's quite interesting.

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So right after my studies, that was very, let's say, genetic engineering and more bioprocess engineering.

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But I also had computer science, so I also had to learn programming, which was really the main subject at that time.

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And I basically started in a start-up laboratory, also in the genetic engineering sector.

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The company went bankrupt after a year and I actually slipped into the pharmaceutical industry in the regulatory area by chance, I would say, simply because that was of course the greatest need at that time.

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And I just got stuck, yes, and I noticed, O.

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K., all these regulatory things, also in connection with technology, no matter what kind, so I have all kinds of

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Stuff qualified, validated, really from equipment, computer systems, according to CAM 5 guideline to sterilization validation.

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I just took part in everything that was offered.

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So for a few years now, since ChatGPT, I'll say, I've just been enthusiastic about the topic of A.I.

00:03:04 Speaker 1

immensely and

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In 2023, I had the opportunity to start working for a company that offers A.I.

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based medical products and I struck right away.

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So I couldn't help but grab it.

00:03:19 Speaker 2

I can understand that well.

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So because you bring everything with you, you bring the medical-biological knowledge with you, you bring the regulatory knowledge and you bring the technological knowledge with you.

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So there is your company is to be envied, someone like you found

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And with the Fable for computer science, with the Fable for A.I., you may be predestined to take care of this A.I.

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Act, because it is particularly relevant for the type of products you have.

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What are you doing right now in concrete terms to meet the requirements for this A.I.

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products?

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Of course, on the one hand from M.D.R.

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point of view, but also from A.I.

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Act: View out.

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What are these activities that you have started with it?

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How do you approach the whole project?

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Well, we started quite early, parts of the A.I.

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Regulation.

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So in principle, transparency and the whole thing with the bias and so on, we started quite early, we also got the corresponding standards, such as the standard, where in principle all the performance parameters are also set out, such as specificity, sensitivity.

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the DICORE or the A.U.C.

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Value, that in principle we are also held to the definitions of the standards in the end, so as not to create any definitions of our own, which will later become our undoing, but we have oriented ourselves very strongly towards the standards that the standards that were already defined by the E.E.

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The Commission ultimately falls under the A.I.

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Regulation, I say, even if they were still in draft status,

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we have already gained an insight there.

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At least that was the first step and the second step later, when the A.I.

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Regulation was then put into force, we of course first of all dealt with the fact that we first dealt intensively with the A.I.

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Regulation, also on Q.M.S.

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level the whole thing broken down, such as that you first have to use the Q.M.H.

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updates that we are aware of our role as A.I.

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Provider,

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that's also a requirement of 13485, that you are aware of your role and that you write it down in order to derive the regulatory requirements accordingly.

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Exactly, then what else did we do, we did a gap analysis, i.e. what is already fulfilled under the MDR in the end, what do we have to do under the A.I.

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regulation.

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Yes, besides, it wasn't a big deal either,

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What else did we do?

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Based on this, we then developed a quality policy, our quality policy expanded to include these 7 principles of A.I.

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Regulation.

00:06:01 Speaker 1

I can name them, maybe.

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That's just the way it is, yes, Human Oversight, Technical Robustness and Safety, Privacy and Data Governance, Transparency,

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and so on.

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These are the 7 principles that have been expressed throughout the A.I.

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regulation, like such a red thread.

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We have oriented ourselves and just derived a kind of quality policy from it and the corresponding standards that are under the A.I.

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Regulations are being planned for harmonization, which we have all procured.

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At the moment, they are all available.

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At that time, they were all still in draft status or not available at all.

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Exactly, we're going to take them on one after the other, so to speak.

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So, that's the rough plan we do in the company.

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Can you reveal how many procedural instructions you adapted and created?

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Well, of course I don't need any trade secrets now, but what was that to make it so that you can imagine it like that?

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What were perhaps examples of this?

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What were the quantity structures?

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Yes, so of course we tried to implement as much as possible into existing SOPs.

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We have a stock of about 20 SOPs, I would say, and we have tried to implement all these requirements in these SOPs, such as the classic SOP is data analysis, yes data analysis, which is a requirement from the ISO standard.

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And that's where we put all these things that I just mentioned, for example.

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But how do you calculate the A.U.C.

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Value, how do you calculate sensitivity and so on, things like that.

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Or like this, this whole topic with test set and validation set, what percentage of the total training data set we use for testing and for validation and so on.

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Well, we've already expanded that there.

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So, you don't need a new S.U.P.

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However, we have a new S.O.P.

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created, S.O.P.

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for A.I.

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Lifecycle.

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At first we wanted to implement this into the existing software lifecycle, but we found out that it was a bit bigger or a bit of an independent life and just have a new S.O.P.

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created.

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But this is also the only S.O.P. that we have created.

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And then wait, this goes on until yes, for example, S.O.P.

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We have updated Resource and Training Management, also with regard to article 4.

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A.I.

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Competence, we have expanded it, we have a new training I.D.

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yes, in our training matrix, for example the S.O.P.

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Purchasing, I also updated, just to, in case we also A.I.

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Buy solutions yourself, to name just a few.

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Yes.

00:08:44 Speaker 2

O.K., so that's pretty good news too.

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They essentially have existing S.O.P.s,

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00:08:51 Speaker 2

You have now explicitly mentioned the analysis of the training data.

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You talked about the purchasing S.O.P., probably also others such as model training or labeling, probably that and.

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Exactly, that's all in the, exactly, that's all in the S.O.P.A.I.

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Lifecycle.

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There we have the whole life cycle from the procurement of data, annotation of data and preprocessing, i.e. the preparation and then afterwards the training,

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And we have defined requirements for each of these steps in the S.O.P.

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and wait, I can perhaps give an example.

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We have created a checklist for this, for example data governance and data management, on how we manage our data.

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Where are they stored securely, that the test data is completely separated, for example, that it does not overlap with the training data, just a kind of quality control check.

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Yes, what you can show in a hurry, if someone asks, things like that.

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So for our listeners, there is also the A.I.

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Guidelines also of the notified bodies, which we helped to develop.

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Such aspects also come up and what you have just said is important.

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This then affects the entire life cycle of the A.I.

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products.

00:10:02 Speaker 2

That's why the guideline doesn't just have the topic of model development, for example, but it starts very early on from the intended purpose to the deriving requirements for the model and the

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Data until later on Post Market Surveillance.

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So that, there is everything.

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So that's good news and I think checklists are important.

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We have just talked about it in the specification document, which we have now also helped to develop.

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Now they have described what they have done, i.e. what the priorities were.

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Can they give the listeners an impression of the effort that this means for them?

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00:10:41 Speaker 2

Yes, because many are still faced with the question of what does this mean from us, what kind of budgets do we have to reserve, we don't have to work, prioritize in our company.

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And if we could have such an order of magnitude from you, it might help.

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Yes, exactly, i.e. the effort, which of course also depends heavily on the size of the company.

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So we are a small, agile team of around 10 people.

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And that also helped us to act quickly.

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Well, I personally now as Regulatory Affairs Manager have spent approximately, let's say, 2 hours a week to keep the A.I.

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regulation so successively bit by bit.

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I usually always have directly after some insights or webinars that I have attended, or podcasts or any LinkedIn posts.

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Yes, so somehow you are really well informed from all sides these days.

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I always acted quite quickly and implemented it immediately.

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Yes, for example these requirements such as Article 4.

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Yes, I have the right S.O.P.

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updated to this and I can now only give the tip here that the Q.M.

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system or that such a Q.M.

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system, which does not slow you down, but also grows with you and where you can also easily adapt and no longer have to somehow pass through 10 committees until it is approved.

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So we are actually quite well positioned there.

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Was unser A.I.

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team, there was already quite a lot of documentation behind it, it really has to be said.

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So especially because the field was relatively new, but it really helped a lot to pick up the employees really quickly.

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So, for example, I trained people in the A.I. very early on.

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regulation, what it means that we are obliged to comply with this, that certain requirements for transparency and fairness and all these things, that we simply have to disclose all of this.

00:12:34 Speaker 1

And that's what we did at the beginning, which was a lot of documentation.

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Yes, exactly, so the most important thing is really that you pick up all, actually all employees in the company.

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Yes, have you already arrived at the tips?

00:12:47 Speaker 2

Now there was just a short return to another question.

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Well, I understand now, you have probably worked on it for 2 years now, if I have understood correctly, at least 2 hours a week, but of course you also have expenses

00:13:00 Speaker 2

in the company, which now supports the A.I.

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Team, for example, did I understand you correctly?

00:13:07 Speaker 1

Just right, right, of course they also did a lot of work to finally write down this documentation effort of the models we developed.

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Yes, so all the statistics behind it, how is the distribution of the data, all the features, how are they distributed between male, female, age demographers, so this age curve.

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And yes, in the end all this statistic just behind it, yes, also the description of the overall models.

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So that was quite time-consuming.

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So there were, I'll say, 23 people sitting on it and of course documented it very intensively.

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Yes, and of course that was also possible.

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I'm not an A.I. by nature.

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Expert, although of course I'm interested in it.

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And of course, that is also very important, communication.

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So I have too.

00:13:55 Speaker 1

I'll say, not just one, but several internal audits were carried out, for example by taking this Team NB checklist, which they also helped to develop, and I turned it into a kind of internal audit and we are really successively for the design and development area.

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So we have now dealt with the questions.

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Of course, we didn't concentrate on the whole checklist, we concentrated on answering these questions and putting them down in terms of documentation.

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Yes, mhm, on the one hand you have all the M.

00:14:29 Speaker 2

D.

00:14:29 Speaker 2

R.

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requirements and then also implicitly those of A.

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I.

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Acts.

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I would guess that the way you did it is exemplary and the maximum

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efficiency.

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Of course, the size of the company suits you a bit.

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We have, we accompany corporations, they really talk about many, many people for years to help implement something like this.

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I emphasize that the listeners may not feel unduly pressured when they control the numbers.

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So that certainly depends on the size, but

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also how to proceed and you have already mentioned best practices, namely the early involvement of the team, building up internal competence at an early stage.

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What other tips and experiences would you like to share with other companies?

00:15:20 Speaker 1

Yes, so on the one hand, we as a small company, as a startup company, we also network with other startups and also exchange ideas in terms of

00:15:31 Speaker 1

What has been your experience with the regulatory requirements?

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We finally networked and what other tips can I give?

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Yes, so maybe go more philosophically so that you don't always have to be afraid of the A.I.

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Regulation.

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So I think the A.I.

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Regulation actually so in parts actually quite O.K.

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So at first it may be frightening because of the many requirements.

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I mean, they are at least quite.

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Well, it is structured in a similar way, ultimately to the MDR, the A.I.

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Regulation.

00:16:04 Speaker 1

Yes, she has no idea, 180 recitals.

00:16:06 Speaker 1

I don't think I know, 13 chapters where all the paragraphs are laid down and then just a few appendices.

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So, in the end, you can also look out if you look at the corresponding applicable parts of the standard.

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extracted from the AI regulation, then it actually works.

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Well, then it's actually quite manageable.

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Well, first of all, you don't always have to be so afraid of it.

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Well, I don't see it as a brake on innovation here, but rather as a benefit, because I mean, the AI regulation.

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This requires very basic things that everyone actually wants for themselves.

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Yes, of course, everyone does not want to be treated wrongly or be discriminated against in any way, if some A.I.

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tool is used, for example.

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And what also helps, of course, is to find out from your notified body what they ultimately demand.

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Yes, so what are the basic norms that you consider important at the beginning?

00:17:06 Speaker 1

I'll put it this way, our notified body is perhaps too small.

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Well, it is not based in Germany either.

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It does not provide us with such good information.

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But there are larger notified bodies that are much better positioned.

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Of course, they are already offering their customers or their manufacturers initial news.

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So here, please observe this and that standard.

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And because we just exchange ideas with others, I just get something like that more easily.

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And then I know, ah, OK, I have to follow certain standards now, because there are quite a few standards, right?

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And I can't implement all of them at once, I'll say, because that's a lot of work.

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For example, we do a kind of gap analysis for each standard.

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Yes, that is a lot of effort and it helps if the notified bodies simply give initial tips.

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So, hey, we attach importance to these 3 standards.

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Yes, you can pounce on it first, before you suddenly use some insignificant standard that may be relevant, but perhaps not primarily for the certification process.

00:18:06 Speaker 2

Mhm, I also have a little tip in addition to what you just said.

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I am currently in the process of implementing these very norms that you spoke of in the A.I.

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guide.

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That makes it a bit easier, because it's all sorted by life cycle phase and you don't have to buy and study all the standards.

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That just as a thought, you had hidden a few tips that I would like to make explicit again.

00:18:29 Speaker 2

You once gave the tip,

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look at this A.

00:18:34 Speaker 2

I.

00:18:34 Speaker 2

Act and filter out the parts that are relevant to you at all.

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That's only a fraction of this whole A.

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I.

00:18:42 Speaker 2

Act, there is a lot in it, which, for example, manufacturers, such as the big manufacturers, such as Open A.

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I.

00:18:48 Speaker 2

is more likely to affect this, these general-purpose models, as the regulation calls them.

00:18:54 Speaker 2

And for us medical device manufacturers, this chapter with high-risk products is particularly concerned.

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So that you first filter out what is relevant for me at all and then they had said something else before,

which I also think is very important.

00:19:08 Speaker 2

You said, do a gap analysis.

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So, that means that you don't somehow have 2 worlds, namely an M.D.R.

00:19:14 Speaker 2

World without A.I.

00:19:15 Speaker 2

Act world, but M.D.R.

00:19:17 Speaker 2

is what guides us, first with which we get very far and then you look at what you have to do as a delta.

00:19:24 Speaker 2

and then also the A.I.

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Regulation, the A.I.

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Act, implicitly to comply with.

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Now they have just opened up the topic in another direction, in the direction of notified bodies.

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So there was one of her tips, get in touch with them soon, clarify your expectations and the list of standards that you might see fulfilled in full was one of your recommendations.

00:19:45 Speaker 2

do you have any other tips or do you have any concrete experiences with notified bodies that you could share, anonymously or a bit convoluted, but I believe that you can simply learn from them.

00:19:56 Speaker 2

We are all still new to this topic and I think you already have it, are you further along like some others.

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Yes, so what I do, so you mean the experience with notified bodies in the end, right?

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Yes, well,

00:20:12 Speaker 1

When it comes to start-ups, it's always this difficulty, that of course the cost factor, yes that's something we see, for example, that's a bit unfair.

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The A.I.

00:20:23 Speaker 1

In the end, the Regulation actually took this into account.

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So she really said, OK, so start-ups and small companies, so please be careful with the costs.

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Of course, the valuation should not suffer from it, but nevertheless it is a factor that you simply have to take into account and.

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mean, we notified bodies, they are already announcing cost increases and I'll say, you're already through the M. anyway.

00:20:43 Speaker 1

D.

00:20:44 Speaker 1

R.

00:20:44 Speaker 1

You have to invest a lot for the C.

00:20:46 Speaker 1

E.

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certification and also for maintenance.

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Now comes the K.

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I.

00:20:50 Speaker 1

Regulation on top.

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So in principle, I think, as a tip for notified bodies or for regulators in general, that you simply take this into account in order to simply play a fair game on the market.

00:21:04 Speaker 1

And what I have also experienced is that the review process of the technical documentation, which turned out to be really unexpectedly time-consuming, especially due to the multiple review rounds and which were also very heavily burdened with questions about the A.I.

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in itself, i.e. less N.C., i.e. non-conformists who focus.

00:21:24 Speaker 1

Sure, we had some, but there were a lot of questions about the A.I.

00:21:28 Speaker 1

In itself and there you noticed, aha.

00:21:30 Speaker 1

Here someone really wants to learn, which is okay per se.

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Sure, I mean, where from, I mean, we started the process in 2024 and the more time passes, of course, the more competencies are built up at notified bodies.

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But wait, the earlier you start, of course, they want to learn.

00:21:47 Speaker 1

And what we have just established, while the first two rounds have also concentrated on perhaps essential aspects of content,

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the next rounds were just formal and that costs money.

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So every round costs, costs and yes, I would like to see notified bodies there perhaps with regard to structured dialogue, just because they are not all uniform.

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Some notified bodies offer this, which is very great.

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So we keep hearing from other notified bodies, our notified body is right, I'll say, used something like this sparingly.

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Or even now in terms of what I just mentioned, with the standards.

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Some notified bodies publish their expectations of the manufacturers, some do not.

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So, I think that notified bodies as a whole could also coordinate with each other and say: 'Here, this is our common consensus.' Yes, we expect that from the A.I.

00:22:37 Speaker 1

So, that's such a common denominator.

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I mean, we are all in Europe and somehow every notified body acts a little differently in this respect.

00:22:45 Speaker 1

Yes.

00:22:45 Speaker 1

And of course, they first have to build up their competence in terms of A.I.

00:22:49 Speaker 1

I mean, where is it supposed to come from?

00:22:51 Speaker 1

The K.

00:22:51 Speaker 1

All the hype didn't come until 2022, maybe 23 years have passed and in that time I wouldn't know that there are so many people who now have this competence, that they have at least 2 years of experience with the technology.

00:23:04 Speaker 2

So yes, mhm, you're a great diplomat.

00:23:07 Speaker 2

I'll put it a little less diplomatically and I won't put it in their mouths.

00:23:13 Speaker 2

But.

00:23:13 Speaker 2

these are also our observations.

00:23:15 Speaker 2

So the wishes they have, please don't train yourselves at our expense, because we have often seen that

auditors, tag file reviewers ask questions that ultimately only serve the training, their own and afterwards put that on the bill and that just works, that doesn't work.

00:23:31 Speaker 2

So we, so it's O.

00:23:33 Speaker 2

K., if they don't know something, but then they can't charge us for that, their own ignorance.

00:23:38 Speaker 2

So that would be a request and so everything else I think is also somehow.

00:23:42 Speaker 2

more than borderline.

00:23:44 Speaker 2

The second thing you said, please make sure that you coordinate with each other, and that is not just your request, but we have a European system and the way in which products are tested and certified must not depend on the notified body, because otherwise the entire system with notified bodies will tip us apart.

00:24:06 Speaker 2

So the desire for these comparisons should actually be a duty of these comparisons

00:24:11 Speaker 2

And the third thing you mentioned is efficiency, which can certainly be expanded, and also the focus on risks or on what is actually the purpose of our regulation and not to pour into formalities and then somehow kick things out of some way because formal requirements are supposedly not met.

00:24:34 Speaker 2

And so these are 3 wishes, which I would like to underline very much.

00:24:38 Speaker 2

So all notified bodies that are listening, please

00:24:40 Speaker 2

check whether this is the case for you or to what extent it is given.

00:24:45 Speaker 2

Because we need elegance, we need speed, we need efficiency, because otherwise we will simply crush small companies and start-ups, like yours now, under this regulatory burden and that simply cannot be.

00:24:59 Speaker 2

What else would you like to give our listeners or how do you look forward to the coming weeks and months?

00:25:05 Speaker 2

What's on your agenda?

00:25:07 Speaker 2

what could others learn from them, or from theirs, from their ideas and plans?

00:25:13 Speaker 1

Yes, perhaps one point or an important point is the topic of training, especially in connection with Article 4 of the A.I.

00:25:20 Speaker 1

Regulation.

00:25:21 Speaker 1

And here the responsibility lies not only with the A.I.

00:25:24 Speaker 1

providers, but also with the so-called deployers, i.e. those who use it professionally.

00:25:29 Speaker 1

In principle, in our case, this also applies to health facilities that use A.I.

00:25:33 Speaker 1

systems.

00:25:34 Speaker 1

Because in the end,

00:25:36 Speaker 1

there is hardly anyone left in the health care system who is not familiar with A.I.

00:25:39 Speaker 1

and there is always an algorithm in play somewhere.

00:25:42 Speaker 1

Yes, and for that you need training, that what the A.I.

00:25:46 Speaker 1

regulation, but wait, we don't just see this, this general A.I.

00:25:51 Speaker 1

Training with, yes, how do I use ChatGPT and what do I have to pay attention to, that's actually nice, actually falls more under the Data Protection Regulation, that you just don't put everything into such an A.I.

00:26:00 Speaker 1

Tool somehow smuggled in.

00:26:04 Speaker 1

but actually subject-specific topics.

00:26:07 Speaker 1

Yes, for ophthalmology, for example.

00:26:09 Speaker 1

So in principle it goes in the direction of product training or what in principle as a medical product consultant, which is in the direction of this M.

00:26:16 Speaker 1

P.

00:26:17 Speaker 1

D.

00:26:17 Speaker 1

G.

00:26:17 Speaker 1

is ultimately also required, so that our manufacturers, our users can ultimately be trained in this regard and we have it, so that's also an area that, for example.

00:26:28 Speaker 1

by medical associations in their seminar catalogue.

00:26:33 Speaker 1

They always have to educate themselves, and that's why we at Deep Eye are currently considering whether we should use an ophthalmologically oriented A.I.

00:26:41 Speaker 1

Offer training yourself via our website.

00:26:43 Speaker 1

Yes, so that's exactly our idea at the moment, which I might also be able to pass on to other manufacturers.

00:26:50 Speaker 2

Ah, I think that's wonderful, because there's a lot in it.

00:26:53 Speaker 2

So tell me,

00:26:54 Speaker 2

pay attention to competence, but now not only in your own company, but pay attention to the competence of your customers.

00:27:00 Speaker 2

This must be a very medically domain-specific competence.

00:27:05 Speaker 2

You haven't expressed it explicitly, but you could perhaps add, there may also be a special service, perhaps even a business model associated with sharing this for the customers.

00:27:17 Speaker 2

But of course we also need internal competence and that should be a competence that goes well beyond what is now somehow only the use of such tools.

00:27:27 Speaker 2

Instead, everyone must understand what is required by regulation and how to implement it.

00:27:31 Speaker 2

Well, it's not enough for us to get stuck on the level of understanding.

00:27:35 Speaker 2

We have to get to the skill level.

00:27:37 Speaker 2

By the way, this is exactly the reason why we have changed the course to the A.

00:27:40 Speaker 2

I.

00:27:41 Speaker 2

Act, where we then really lead companies to implementation in 7 sprints.

00:27:45 Speaker 2

You have to have done it, only then have you proven that you can actually do it.

00:27:51 Speaker 2

Yes, it was a wonderful interview.

00:27:54 Speaker 2

Thank you for the insights you have shared with us here, really first-hand from your professional practice.

00:28:00 Speaker 2

And if you will allow me, I would link your contact details so that all companies that may be in a similar situation, perhaps also the start-ups, can exchange ideas among like-minded people.

00:28:12 Speaker 1

Yes, thank you very much Mr. Jonah for the invitation and it was a lot of fun.

00:28:16 Speaker 2

Thank you.

