Johner Institute

Regulatory Science - Why We Need This Science

With Prof. Dr. Martin Haimerl , Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

Medical Device Insights.

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

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In a few months, the MDR is to finally come into force.

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And just before that, the discussions are starting again.

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whether this is the right regulation, whether the content is sufficiently understandable and specific, whether it does more harm than good.

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Ultimately, you think again about whether this makes sense overall.

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And that brings us to the topic that should take care of exactly that, namely the topic of regulatory science.

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In today's episode of our podcast I have Professor Heimerl with me and

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I would like to talk to him exactly about this topic of Regulatory Science.

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Hello Mr. Heimerl, you are very welcome.

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Could you introduce yourself very briefly so that our listeners know how to classify you correctly?

00:01:03 Speaker 2

Hello Mr. Johne, first of all, thank you very much for the invitation and the welcome here at this point.

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My name is Martin Heimerl, I am a professor of medical technology at the university campus in Tuttlingen of Furtwangen University.

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I'm also responsible for regulatory affairs there, I'm a computer scientist by training, so I know these areas, so to speak, I worked for a relatively long time, for 13 years in industry at the company Brainlab, in the field of medical navigation systems, I also had a lot to do with regulatory issues and then I moved to Furtwangen University in 2016 and took over the professorship there and also did scientific research on the side. Director of the Innovation and Research Center

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in Tuttlingen, these are my roles here in this direction, so to speak.

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And this topic of regulatory science is a very important topic for me to address precisely these points that you have already addressed here.

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Let's start quite properly, as you probably learn in the lecture, with the clean definition.

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What would you say, what is regulatory science, what are the typical questions that are being discussed?

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That's a very good question, actually also to get you started, just to understand what's actually behind it.

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And you have the topic M.

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D.

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R.

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M.

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Of course, it was actually a big development that was driven forward and of course there is also the question of whether you are going the right way, as you have also called it, and I believe that this is exactly when regulatory science comes into play.

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Why all this?

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how do we do that and if you think about how it came about, then on the one hand, of course, you have the political demands that are in the room, on the other hand, we have the corporate interests and what is perhaps missing a bit is this neutral view of all these issues, how we control regulatory processes, how we develop regulatory strategies, and I believe that these are already key points that point in the direction of regulatory science.

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Of course, science has a scientific approach somewhere, so somewhere there is also a gain in knowledge, as we

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function and effect of such regulatory systems, as we can then of course also design them as the next step.

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For example, how we can now set up new regulatory systems somewhere, how we can optimize them, how we can open up new approaches.

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I think now, what for example the M.

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yes, to say that in certain areas it is now not only a matter of proactively taking all the steps before approval, so to speak, but also of allowing certain things that are then done reactively.

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So such a point,

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where regulatory science also takes up new things, where new approaches are taken, so to speak, whe-

re innovation also comes in, so to speak, and of course has to be monitored again and again.

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And I think M.

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has a few clues in there, F.

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is currently in the process of taking in a lot of approaches and in the whole topic around Covid-19 we have also seen that it is very often important not to be completely static, so to speak, but to keep incorporating new assessments.

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and Regulatory Science is, of course, also the starting point, so to speak, to evaluate and validate them quite systematically and, so to speak, to pave the right paths in this direction.

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Maybe that's a bit of an all-round swing that comes in there and maybe you can then go into the individual tasks that play a role here.

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So it's a science, yes it's sometimes even called the regulatory science with the ultimate goal of politics or the legislators in

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to provide the information, evidence data, on the basis of which they can later make good and effective regulations.

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And that's exactly what you want at M.

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now questioned again.

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Has this really been achieved and on what basis has this been done?

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Maybe a distinction in the context between Regulatory Science and Regulatory Affairs.

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I think we should keep that separate again.

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So the

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Regulatory science, as we have just said, has as its objective scientific information, to provide support for regulators.

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That is not the job of regulatory affairs or regulatory affairs managers at all.

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These are the ones who are more likely to be able to take care of the implementation of this afterwards.

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So they have to live with the results of what has been thought up in laws and regulations and guidelines.

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and then have to make sure that it is followed.

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So, they are not discussing the meaningfulness now, even if that may be happening right now, but that is not the main task.

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You need to make sure that they are followed.

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You may also need to monitor it.

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Yes, that means we have regulatory affairs with the manufacturers, but certainly the notified bodies also

belong in this regulatory affairs apparatus and perhaps sometimes also take care of how we can implement it properly.

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If you think about it now, also how do the two play together.

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So in the end, as just mentioned, they are the regulatory affairs managers who have to implement this.

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Yes, what regulatory science and the resulting legislation have come up with.

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But conversely, I think it should also be the case that regulatory affairs are the ones who should report back.

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the scientists, the regulatory scientists, if we want to call them that, what exactly are the questions that arise, what are they having a hard time with, where do they need very concrete support on how they can implement things.

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So, if, for example, we may come back to this later, a manufacturer can determine the safety, efficacy, for example, of a medical device that is based on A.I.

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must be implemented,

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then a question can go back to Regulatory Science and consider, O.

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K., how can we design something like this exactly, how can we present the subsidies in an even more differentiated way.

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In other words, regulatory science as the ones who provide input to be able to design laws in a targeted manner afterwards, regulatory affairs as those who implement them afterwards, also in many markets.

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Maybe that would be such a demarcation.

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Then perhaps we will now also come to the question,

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who does regulatory science anyway?

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Well, I think you have addressed a very important point about how this interacts, and of course it is the case that I can only do regulatory science if I also process the corresponding empirical values.

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Especially in such an area, which is becoming much more data-driven, I need exactly this feedback, as you mentioned.

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Without that, it doesn't really work, because it's about processing these experiences and then steering the whole thing in the right direction, always carrying out this comparison with reality.

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and who does regulatory science, that's a good question.

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I don't think that's really anchored at the moment.

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If you look at the actors who are involved in such a development of the M.D.R.

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on the one hand, it was very strongly politically driven, on the other hand, of course, you have the companies and they rightly said, of course, not only the companies themselves, but also the notified bodies that are involved here.

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Of course, these are the main players that are in it.

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From the research side, if you think about it, there is actually not that much

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I think it is currently available.

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Universities, if you look at it, typically don't focus so much on regulatory science, regulatory affairs and all these topics around it.

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Why?

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Simply because most of the professors at the universities do not come from this practical environment, but have rather chosen the academic path.

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And I believe that it is precisely these regulatory issues that need this practical relevance.

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and without that, it doesn't work in teaching, i.e. that you also train people further in this direction, so to speak, but also in this research aspect.

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And I think we also have a bit of a difficulty in this, that universities naturally determine first and foremost what research is.

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And if you were to apply for a research project for regulatory science, so to speak, then it would probably not work at all, because it is not so much recognized as research, although really important questions, they have the A.I., the A.I.

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Topic, Validation of A.I.

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systems,

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this is also often done in university units that are neither so much into the practical relevance of medical application, nor know all these regulatory issues, and that, I think, is simply a shortcoming that is in it and where, for example, universities of applied sciences, such as Furtwangen University of Applied Sciences, are now located, just like the HTWG in Constance, where you are also involved, I think those are the units that take more of this practical relevance into it,

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I also have to say, from my personal experience, this is not a restriction at all or somewhere badmouthing the universities in this direction, I myself also came from university, then went into industry and at the beginning, to be honest, I couldn't do much with these regulatory issues.

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I really needed this practical experience, so to speak, in order to be able to delve into it, in order to really be able to tackle and take up these problems properly, and I think that's a very important element

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in order to make progress in this direction, so that you really have this practical understanding at this point.

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And maybe again this interaction of regulatory science, regulatory affairs, to go into that, that's of course a lengthy process, because when I look at how long it took to create such a M.

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It started somewhere in 2007, 2008, I think, that the first discussions took place, now we are in 2021 and there is still not everything defined that you need at this point,

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that's over 10 years in that direction and that's of course there the M.

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also a bit of a monster that tries to regulate a relatively large amount, which of course also makes sense, but it takes a bit of this dynamic out of us and I think it becomes apparent that we simply need other models in the direction of regulatory science, to let these experiences flow in again and again in order to make such systems more dynamic, so to speak, to be able to react to it again and again and to be able to develop it again and again, so to speak, and perhaps again

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Let's look across the pond towards the USA.

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At the moment, they are very much involved in the fact that the FDA, which has been relatively static and relatively strict for many years, opens up and says: „OK, they deliberately want to bring in this feedback.

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They actually want such a regulatory system, so to speak."

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as a system that always gets input from the companies, which also has to question itself again and again, so to speak, and I think we need that here as well with many topics that are currently topical, in the direction of K.

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I., in the direction of additive manufacturing and similar topics, which ultimately need much more this feedback, this dynamic, and where we simply have to take new steps via regulatory science, so to speak.

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So I think it's a complex interaction, to make it short, the players, as I said,

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must, I think, also develop at this point.

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As I said, on the one hand, companies include notified bodies, and on the other hand, I think politics needs this third player who is involved, who also brings the scientific perspective into it.

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And I think that if we maybe take up the topic of Covid-19 again, then you will have seen how important it is, just here

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simply having neutral ground that can steer certain things again and again, so to speak, and can evaluate them in an independent way, so to speak, is, I think, a very important topic for the future, especially in these areas.

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Yes, I think we have absolute agreement that there is still a lot of desert here in Europe as far as the topic of regulatory science is concerned, and I think we both agree absolutely that the F.D.A.

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progresses there.

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So it really does this regulatory science on a large scale and

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is also teaming up with some universities, they have formed a CERSI network, where Stanford and the University of California, among others, are involved, which, by the way, just had a conference on this topic last weekend, Regulatory Science and who said exactly what they have just confirmed again.

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Here, systematic research is being carried out into how we need to create regulation, how

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Here, systematic research is being carried out into how we can also implement existing regulations in practice and how we can redesign existing approval procedures.

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And you have already mentioned the important ideas, namely the idea of interactivity and the other also the idea of modularization, so to speak, as a counterpoint to the monster, as you have called it, the M.

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So that means that since

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we must, and we should definitely get more involved in Europe, so as not to fall behind, but perhaps we will come back to it later.

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I would also like to briefly take up the point they had with Covid 19, that you might even see it as a prime example and take a look specifically at what worked so well, so how was it possible to get an approved vaccine within nine months?

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available.

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Of course, there are a few pharma peculiarities that play a role now.

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It also plays a role in the fact that it was a pandemic, which is something bad at first, but in this case something good again.

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We had enough potential study participants.

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Yes, please don't want that to sound cynical.

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But that was one thing that is now specific to the pandemic.

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But we have seen a few other things that I think we can transfer quite well to the medical device sector.

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You have already mentioned one point, and that was the

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scientific support that the authorities have systematically and all the time obtained.

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And that, in turn, presupposes that there is this scientific support.

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And this explicitly does not only mean scientific support, so to speak, in the biological or clinical.

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We also need more support now, for example with regard to the economy.

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What does that mean?

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What does this mean for companies?

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What does this mean for availability?

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It is useful, as with medical devices and vaccines, we can look at it more or less in the same way.

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It's no use if we have a perfectly safe and effective vaccine, but no one can produce it because, for example, regulatory hurdles or other things stand in the way.

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Yes, that means that there is sometimes a conflict of goals between safety and availability or efficacy and availability of medical devices.

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of vaccines.

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So I think a systematic success factor was this existence of research, which made it possible to advise the authorities in a targeted manner and then to come to decisions quickly.

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Number 1.

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Number 2.

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I think it was equally important to

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To change processes in turn, for example to do what they have called rolling review of these studies.

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So we've made it of one.

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sequential approach into a parallelized and interactive and iterative approach.

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So that's completely missing in our approval models or procedures.

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But in order not to simply blindly implement something like this and cause chaos again, we need evidence again, i.e. the results of systematic research, and we also need the political will to do so.

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And if we are with political will, then of course it also has something to do with the fact that we have the will and thus also the regulations with which we regulate more efficiently in the first place.

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Secondly, to optimise internal processes in the authorities.

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This will not happen without political will.

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And thirdly, to create the constellation of how cross-organizational processes can be improved, for example between authorities and manufacturers.

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or between authorities and authorities or between authorities and notified bodies.

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That is, the starting points for an improvement of a system, as we have now seen in Covid in a positive example, are 2 important factors, so to speak, that are decisive, the political will and the existence of systematic research that also gives the input for the will and for regulation.

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So I think that's why it's so important and that's why it's so relevant for our location, so that we're really able to get the right products in the right quality, by quality I mean safety, performance and in the right number and at the right cost.

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And there we have conflicting goals, and in the end, politicians have to decide on them.

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That also has something to do with ethics.

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only these decisions, they must not be taken out of the custom at some point, smoke, always gut, gut and always made, but there is simply a need for a scientific basis, you need evidence, otherwise it will just be a question of opinion or wild guessing.

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Yes, so that was my short one, so to speak, I don't know whether, whether you should call it a fringe, but perhaps a plea that we should get more involved there and, above all, in Europe.

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Because

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although we also support the F.D.A.

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Director again, and this was just the case last weekend, he now sees regulation not only as something that the F.D.A.

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ensure that we have the right products, safe products in the U.S.

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market and of course they only have a U.S.

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Blick, but he explicitly says that we will fall behind, especially in the field of digital health.

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He has already described China as the Leading Nation for Digital Health and he says there,

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This is also part of the task of an authority, to form a counterweight to this and to design it according to regulations in such a way that innovation is also enabled and further promoted.

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And that's why I think it's absolutely important that we get more involved so that this doesn't happen to us and so that we are not so overwhelmed and surprised by these negative consequences that an MDR now brings.

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Well, Spectaris' estimate, for example, is that around 9 to 10% of the sales of medical device manufacturers are now needed for these regulatory adjustments.

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With the 100 billion euros that the medical device market in Europe has, we are talking about 10 billion euros that we have simply spent now, but without having this evidence as to whether we are doing more good or more harm.

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So, I think these are the reasons why we should do this research.

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That was a brief explanation of what is now the relevance of this topic and also a reason why we should get more involved in Europe.

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Yes, let's get to the current topics that are currently on the minds of regulatory science.

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What would you see as important research potential research priorities, Mr. Heimer?

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Perhaps, before I get to the point, I would like to say again in 23 comments about what you have said and I agree with you one hundred percent in that direction.

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I want to put another 1 on top, so to speak.

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First point, if you look at it, for example from the pharmaceutical industry in the.

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In the last century, there were simply a lot of pharmaceutical companies on the move in Germany, Switzerland and Europe as a whole.

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If you look at the point at which they then switched to America, it was exactly the time when it was very much about this clinical research, about the generation of data.

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where, so to speak, the Americans are much more open in this direction and the Chinese are perhaps even more involved in this direction through their state system.

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And I think that's a point where you have to be careful that this strong European and, above all, strong German medical technology industry doesn't simply lose touch.

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So I think that's a very crucial point and the second point that comes in here, this dynamization that you mentioned, also of the approval processes, is also a very important factor.

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You also have to see that basically these approval systems are statically oriented,

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That means I have the approval once, no matter how the circumstances change.

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We have seen through this pandemic that of course a lot depends on the circumstances.

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If I have a vaccine now, then I may have to be able to take a few more risks in relation to the benefits I have in each case, because if I can simply achieve restrictions on the spread of the vaccine, so to speak, then I naturally have a positive risk-benefit ratio from the overall spectrum, from the overall context.

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while in other situations I may not have that, so to speak.

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So I think you also need regulatory science in this direction, where we are perhaps already involved in a few topics, as far as this regulatory structure, the regulatory strategies, so to speak, is concerned, what should definitely be taken up in such a field and what should also be specifically examined from the research side, how something like this works.

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I believe this OVID pandemic, even if it was primarily the pharmaceutical sector,

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has pointed out many of these points, which are important here and if we look at M.

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, even with surgical instruments, so to speak, and the like, when the effort becomes so great, there is simply a danger to this profitability and then you also have to include an overall view somewhere and it must also be permissible somewhere, so to speak, and I think it must also be moderated somewhere by the neutral side, as you also said.

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There are many topics that come in this direction, and you have addressed ethical issues, you have addressed responsibility, perhaps on the subject of responsibility, if we talk about the current

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already come.

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We have already mentioned additive manufacturing, K.

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I., I think we can still go into both topics.

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I'll start with the other topic, that we haven't had quite as much focus now, but I think that the topic of interoperability is also a very important one.

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If we have different medical devices that act together, we don't really have a consistent regulation so far on how to deal with them, also in the sense of responsibility, obligation, if something goes wrong, so to speak, how the whole thing interacts.

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And I think we just have everywhere these days

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interacting systems and the fact that there is no clear regulatory approach to them, for example, is an issue that makes the whole thing difficult.

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You can perhaps take a look at it, interoperability works a little better in other areas, technically it is not a problem at all, it is actually the regulatory question, the question of responsibility that is behind it.

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In the automotive sector, a lot has been done, because all kinds of devices want to connect here, so to speak, some of which are not even available now.

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are so very technical, but come from the consumer sector, any jukeboxes that you want to connect and so on, you have done it relatively well.

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In the automotive sector, however, you have the advantage that the area that is safety-critical is encapsulated quite well, because a central manufacturer typically has its hand over it.

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In the medical technology sector, there are a lot of small manufacturers working together, a lot of small instruments, so you have a completely different scenario and to hand it over completely to the operator, so to speak, is of course also difficult.

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So I think there are a lot of questions involved,

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how to deal with such issues from a regulatory point of view.

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Briefly address a second topic, additive manufacturing of medical devices is of course also a typical topic, if you look at what the MDR has done, especially in the direction of individualized implants, for example.

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In this area, it has been said that it is still seen as a custom-made product, that is, so to speak, the point of view that such individualized implants have in the field of MDR.

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I have to say,

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Basically, the MDR is not entirely consistent in this respect.

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Everywhere else, it very strictly demands proof, clinical proof of how this is to be implemented.

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Here you say „OK", in the end the doctor has to decide, so to speak, how the whole thing works.

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Actually, we have a situation here.

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where basically this overall manufacturing process needs to be validated as a whole and approved as a whole.

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Actually, it is no longer the individual implant of the medical device that is behind it, so to speak, but the overall process of how it is manufactured.

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And that's where we get into topics that you have to work out more over time how such overall processes have to be validated.

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And of course, we have a lot of requirements in different areas, in the 13485 and so on, that go in the direction of process validation and

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Thinking quite consistently to the end, it actually also concerns this question of how we can systematically validate such an overall process, which is also partly automated, as we might do when we go in the direction of AI, so to speak.

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even if they are always evolving, how to keep repeating such validations, so to speak.

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And I think I'll stop at these 2 topics and I think in the direction of K.

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I.

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You can say a few more things about this, because I think we have a somewhat similar question, or such a deeper question, that we actually have to work out such automatisms for validation step by step, if we want to make such systems learn again and again, even if we have, so to speak, these experiences that we have here, this data that we have here,

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Always want to feed in a system and have a developing process, so to speak, that does that.

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And perhaps one last word: If you relate this to this overall regulatory system, we naturally have these requirements right there.

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Data keeps coming in, the process has to renew itself.

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it must nevertheless remain valid.

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Are questions that I think can be answered in this topic A.I.

00:25:59 Speaker 2

because they are also very data-driven and I think it will be interesting to see what they are also heading towards A.I.

00:26:07 Speaker 1

Still be able to report.

00:26:08 Speaker 1

I like to do it very much, but until they take up or reinforce thoughts again.

00:26:13 Speaker 1

What you have just beautifully described is that we need a view that is beyond the individual product itself.

00:26:23 Speaker 1

Yes, you have now spoken about the topic of interoperability, but even in the field of additive manufacturing, it is not just about this object, whether it is physical or not physical, but we need thinking in systems and the article on systems actually has a bit else in the background.

00:26:43 Speaker 1

Yes, the article on the systems and treatment units.

00:26:46 Speaker 1

Ultimately, we already have a regulatory gap in the

00:26:50 Speaker 1

Systems that consist of several products and where the question of overall overall responsibility is simply not properly regulated.

00:26:59 Speaker 1

And this I.

00:27:01 Speaker 1

T.

00:27:01 Speaker 1

Products, if I may call them now, are of course predestined and that, as you just said, also leads us into the topic of machine learning, where we want to be able to answer many questions well.

00:27:14 Speaker 1

So, for example,

00:27:16 Speaker 1

how much can we prove by testing these algorithms at all?

00:27:21 Speaker 1

So, what is enough?

00:27:22 Speaker 1

We have questions, when does which regulation apply at all?

00:27:26 Speaker 1

But because we have such topics with these machine learning libraries, for example, that they fall under ,ne 62 304, i.e. parts of this library and other parts of this library would rather be examined under ,ner 13 485.

00:27:41 Speaker 1

We also had in another podcast

00:27:44 Speaker 1

I had talked about how we deal with pre-trained models, i.e. this pre-trained model, what about this transfer learning?

00:27:52 Speaker 1

Well, we have a lot of unregulated things, so to speak, where there are no uniform best practices yet.

00:27:59 Speaker 1

I'm currently involved in a research project that deals with the gender gap.

00:28:04 Speaker 1

So, how much are men ultimately used, abused or whatever as, let's say, as a prototype of the human being,

00:28:13 Speaker 1

because data from male patients in particular are included.

00:28:17 Speaker 1

How much do you then examine the specifics of your own genders and, above all, what effect does it have afterwards really in the sense of damage with probabilities and degrees of severity, i.e. risks.

00:28:29 Speaker 1

So here we are still moving relatively early in the process of cognition, so to speak, also the questions of what we or as a notified body are allowed to do or do we even have to demand,

00:28:39 Speaker 1

For example, as far as this transparency or the explainability of these models is concerned, we have very exciting, also ethical questions that are still open.

00:28:50 Speaker 1

The, this is now a point, he is now not alone on A.I.

00:28:53 Speaker 1

and M.L.

00:28:53 Speaker 1

but then again of particular relevance.

00:28:57 Speaker 1

In risk management, we always examine the benefits and risks, so to speak, and do not take into account specific, patient-specific preferences.

00:29:07 Speaker 1

Yes, it's almost all going to be under one, a large sum is made underneath, then looks under differ or predominantly, the benefit now the risks.

00:29:16 Speaker 1

But we don't go into the fact that these preferences are completely different from the patient, also from their situations.

00:29:23 Speaker 1

And I think there is also a need for research, for example, at the U.C.S.F.

00:29:29 Speaker 1

a lot of work is done there.

00:29:30 Speaker 1

So I think Regulatory Science is not running out of questions at all.

00:29:36 Speaker 1

I

00:29:37 Speaker 1

Yes, and with that I would perhaps briefly summarize again, what were the points we talked about?

00:29:41 Speaker 1

Yes, I first worked with Professor Heimann or he clarified, what is regulatory science anyway, what are typical questions?

00:29:49 Speaker 1

I differentiated it a bit from Regulatory Affairs, but also showed how the two interact with each other.

00:29:56 Speaker 1

We talked about who does regulatory science.

00:29:59 Speaker 1

In Europe, we almost have to say that if you don't do it, then we would have a plea to really do that.

00:30:06 Speaker 1

we had shed light on why this is so important and also got a few suggestions from the current vaccine development and made a plea for us in Europe to get more involved in this area and, at the end, we also pointed out a few exciting questions that we as scientists should investigate here.

00:30:27 Speaker 1

We talked about additive manufacturing, machine learning, ethical aspects.

00:30:32 Speaker 1

Mr. Heimer, I would say that we have

00:30:35 Speaker 1

a good overview or at least I hope created.

00:30:38 Speaker 1

Of course, we will also link articles and our contact details here in the show notes below and you can be sure that you will hear a lot more from both of us, Mr. Heimann and me, on this topic.

00:30:51 Speaker 1

So, we are both involved.

00:30:53 Speaker 1

Heimann, thank you very much for joining us.

00:30:56 Speaker 2

Many thanks to you, too, Mr. Jonas.

00:30:58 Speaker 2

I think it should be a serve, simply this appeal, to push this topic more strongly, that it is taken up, that it also comes into consciousness a bit, I think it's an important topic, it's simply a personal concern for me, as you may have noticed, that something is developing here.

00:31:13 Speaker 2

As I said, U.

00:31:14 Speaker 2

S.

00:31:15 Speaker 2

A.

00:31:16 Speaker 2

There's a little bit going on and in Europe, I think, you really need it to make it sustainable and that's a very crucial point, I think.

00:31:21 Speaker 2

And if we could have made a little contribution to it,

00:31:24 Speaker 2

Faith, then we are on the right track.

00:31:25 Speaker 2

And then again many thanks to Mr. Jona for setting it up like that.

Audio file

2021-05.mp3

Transcript

00:00:05 Speaker 1

Medical Device Insights.

00:00:08 Speaker 1

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

00:00:17 Speaker 1

In a few months, the MDR is to finally come into force.

00:00:22 Speaker 1

And just before that, the discussions are starting again.

00:00:25 Speaker 1

whether this is the right regulation, whether the content is sufficiently understandable and specific, whether it does more harm than good.

00:00:33 Speaker 1

Ultimately, you think again about whether this makes sense overall.

00:00:37 Speaker 1

And that brings us to the topic that should take care of exactly that, namely the topic of regulatory science.

00:00:44 Speaker 1

In today's episode of our podcast I have Professor Heimerl with me and

00:00:51 Speaker 1

I would like to talk to him exactly about this topic of Regulatory Science.

00:00:55 Speaker 1

Hello Mr. Heimerl, you are very welcome.

00:00:58 Speaker 1

Could you introduce yourself very briefly so that our listeners know how to classify you correctly?

00:01:03 Speaker 2

Hello Mr. Johne, first of all, thank you very much for the invitation and the welcome here at this point.

00:01:07 Speaker 2

My name is Martin Heimerl, I am a professor of medical technology at the university campus in Tuttlingen of Furtwangen University.

00:01:14 Speaker 2

I'm also responsible for regulatory affairs there, I'm a computer scientist by training, so I know these areas, so to speak, I worked for a relatively long time, for 13 years in industry at the company Brainlab, in the field of medical navigation systems, I also had a lot to do with regulatory issues and then I moved to Furtwangen University in 2016 and took over the professorship there and also did scientific research on the side. Director of the Innovation and Research Center

00:01:43 Speaker 2

in Tuttlingen, these are my roles here in this direction, so to speak.

00:01:46 Speaker 2

And this topic of regulatory science is a very important topic for me to address precisely these points that you have already addressed here.

00:01:53 Speaker 1

Let's start quite properly, as you probably learn in the lecture, with the clean definition.

00:02:00 Speaker 1

What would you say, what is regulatory science, what are the typical questions that are being discussed?

00:02:06 Speaker 2

That's a very good question, actually also to get you started, just to understand what's actually behind it.

00:02:11 Speaker 2

And you have the topic M.

00:02:13 Speaker 2

D.

00:02:13 Speaker 2

R.

00:02:13 Speaker 2

M.

00:02:14 Speaker 2

D.

00:02:14 Speaker 2

R.

00:02:15 Speaker 2

Of course, it was actually a big development that was driven forward and of course there is also the question of whether you are going the right way, as you have also called it, and I believe that this is exactly when regulatory science comes into play.

00:02:28 Speaker 2

Why all this?

00:02:29 Speaker 2

how do we do that and if you think about how it came about, then on the one hand, of course, you have the political demands that are in the room, on the other hand, we have the corporate interests and what is perhaps missing a bit is this neutral view of all these issues, how we control regulatory processes, how we develop regulatory strategies, and I believe that these are already key points that point in the direction of regulatory science.

00:02:52 Speaker 2

Of course, science has a scientific approach somewhere, so somewhere there is also a gain in knowledge, as we

00:02:59 Speaker 2

function and effect of such regulatory systems, as we can then of course also design them as the next step.

00:03:06 Speaker 2

For example, how we can now set up new regulatory systems somewhere, how we can optimize them, how we can open up new approaches.

00:03:15 Speaker 2

I think now, what for example the M.

00:03:16 Speaker 2

D.

00:03:16 Speaker 2

R.

00:03:16 Speaker 2

yes, to say that in certain areas it is now not only a matter of proactively taking all the steps before approval, so to speak, but also of allowing certain things that are then done reactively.

00:03:28 Speaker 2

So such a point,

00:03:29 Speaker 2

where regulatory science also takes up new things, where new approaches are taken, so to speak, where innovation also comes in, so to speak, and of course has to be monitored again and again.

00:03:38 Speaker 2

And I think M.

00:03:39 Speaker 2

D.

00:03:39 Speaker 2

R.

00:03:39 Speaker 2

has a few clues in there, F.

00:03:41 Speaker 2

D.

00:03:41 Speaker 2

A.

00:03:42 Speaker 2

is currently in the process of taking in a lot of approaches and in the whole topic around Covid-19 we have also seen that it is very often important not to be completely static, so to speak, but to keep incorporating new assessments.

00:03:55 Speaker 2

and Regulatory Science is, of course, also the starting point, so to speak, to evaluate and validate them quite systematically and, so to speak, to pave the right paths in this direction.

00:04:06 Speaker 2

Maybe that's a bit of an all-round swing that comes in there and maybe you can then go into the individual tasks that play a role here.

00:04:14 Speaker 1

So it's a science, yes it's sometimes even called the regulatory science with the ultimate goal of politics or the legislators in

00:04:24 Speaker 1

to provide the information, evidence data, on the basis of which they can later make good and effective regulations.

00:04:32 Speaker 1

And that's exactly what you want at M.

00:04:34 Speaker 1

D.

00:04:34 Speaker 1

R.

00:04:35 Speaker 1

now questioned again.

00:04:36 Speaker 1

Has this really been achieved and on what basis has this been done?

00:04:40 Speaker 1

Maybe a distinction in the context between Regulatory Science and Regulatory Affairs.

00:04:46 Speaker 1

I think we should keep that separate again.

00:04:49 Speaker 1

So the

00:04:49 Speaker 1

Regulatory science, as we have just said, has as its objective scientific information, to provide support for regulators.

00:04:59 Speaker 1

That is not the job of regulatory affairs or regulatory affairs managers at all.

00:05:05 Speaker 1

These are the ones who are more likely to be able to take care of the implementation of this afterwards.

00:05:09 Speaker 1

So they have to live with the results of what has been thought up in laws and regulations and guidelines.

00:05:17 Speaker 1

and then have to make sure that it is followed.

00:05:20 Speaker 1

So, they are not discussing the meaningfulness now, even if that may be happening right now, but that is not the main task.

00:05:27 Speaker 1

You need to make sure that they are followed.

00:05:29 Speaker 1

You may also need to monitor it.

00:05:31 Speaker 1

Yes, that means we have regulatory affairs with the manufacturers, but certainly the notified bodies also belong in this regulatory affairs apparatus and perhaps sometimes also take care of how we can implement it properly.

00:05:45 Speaker 1

If you think about it now, also how do the two play together.

00:05:49 Speaker 1

So in the end, as just mentioned, they are the regulatory affairs managers who have to implement this.

00:05:56 Speaker 1

Yes, what regulatory science and the resulting legislation have come up with.

00:06:01 Speaker 1

But conversely, I think it should also be the case that regulatory affairs are the ones who should report back.

00:06:09 Speaker 1

the scientists, the regulatory scientists, if we want to call them that, what exactly are the questions that arise, what are they having a hard time with, where do they need very concrete support on how they can implement things.

00:06:24 Speaker 1

So, if, for example, we may come back to this later, a manufacturer can determine the safety, efficacy, for example, of a medical device that is based on A.I.

00:06:36 Speaker 1

must be implemented,

00:06:37 Speaker 1

then a question can go back to Regulatory Science and consider, O.

00:06:41 Speaker 1

K., how can we design something like this exactly, how can we present the subsidies in an even more differentiated way.

00:06:47 Speaker 1

In other words, regulatory science as the ones who provide input to be able to design laws in a targeted manner afterwards, regulatory affairs as those who implement them afterwards, also in many markets.

00:07:00 Speaker 1

Maybe that would be such a demarcation.

00:07:03 Speaker 1

Then perhaps we will now also come to the question,

00:07:07 Speaker 1

who does regulatory science anyway?

00:07:10 Speaker 2

Well, I think you have addressed a very important point about how this interacts, and of course it is the case that I can only do regulatory science if I also process the corresponding empirical values.

00:07:19 Speaker 2

Especially in such an area, which is becoming much more data-driven, I need exactly this feedback, as you mentioned.

00:07:25 Speaker 2

Without that, it doesn't really work, because it's about processing these experiences and then steering the whole thing in the right direction, always carrying out this comparison with reality.

00:07:35 Speaker 2

and who does regulatory science, that's a good question.

00:07:39 Speaker 2

I don't think that's really anchored at the moment.

00:07:41 Speaker 2

If you look at the actors who are involved in such a development of the M.D.R.

00:07:44 Speaker 2

on the one hand, it was very strongly politically driven, on the other hand, of course, you have the companies and they rightly said, of course, not only the companies themselves, but also the notified bodies that are involved here.

00:07:56 Speaker 2

Of course, these are the main players that are in it.

00:07:59 Speaker 2

From the research side, if you think about it, there is actually not that much

00:08:04 Speaker 2

I think it is currently available.

00:08:06 Speaker 2

Universities, if you look at it, typically don't focus so much on regulatory science, regulatory affairs and all these topics around it.

00:08:15 Speaker 2

Why?

00:08:16 Speaker 2

Simply because most of the professors at the universities do not come from this practical environment, but have rather chosen the academic path.

00:08:24 Speaker 2

And I believe that it is precisely these regulatory issues that need this practical relevance.

00:08:31 Speaker 2

and without that, it doesn't work in teaching, i.e. that you also train people further in this direction, so to speak, but also in this research aspect.

00:08:38 Speaker 2

And I think we also have a bit of a difficulty in this, that universities naturally determine first and foremost what research is.

00:08:45 Speaker 2

And if you were to apply for a research project for regulatory science, so to speak, then it would probably not work at all, because it is not so much recognized as research, although really important questions, they have the A.I., the A.I.

00:08:58 Speaker 2

Topic, Validation of A.I.

00:08:59 Speaker 2

systems,

00:09:00 Speaker 2

this is also often done in university units that are neither so much into the practical relevance of medical application, nor know all these regulatory issues, and that, I think, is simply a shortcoming that is in it and where, for example, universities of applied sciences, such as Furtwangen University of Applied Sciences, are now located, just like the HTWG in Constance, where you are also involved, I think those are the units that take more of this practical relevance into it,

00:09:27 Speaker 2

I also have to say, from my personal experience, this is not a restriction at all or somewhere badmout-

hing the universities in this direction, I myself also came from university, then went into industry and at the beginning, to be honest, I couldn't do much with these regulatory issues.

00:09:42 Speaker 2

I really needed this practical experience, so to speak, in order to be able to delve into it, in order to really be able to tackle and take up these problems properly, and I think that's a very important element

00:09:54 Speaker 2

in order to make progress in this direction, so that you really have this practical understanding at this point.

00:09:59 Speaker 2

And maybe again this interaction of regulatory science, regulatory affairs, to go into that, that's of course a lengthy process, because when I look at how long it took to create such a M.

00:10:10 Speaker 2

D.

00:10:10 Speaker 2

R.

00:10:10 Speaker 2

It started somewhere in 2007, 2008, I think, that the first discussions took place, now we are in 2021 and there is still not everything defined that you need at this point,

00:10:22 Speaker 2

that's over 10 years in that direction and that's of course there the M.

00:10:26 Speaker 2

D.

00:10:26 Speaker 2

R.

00:10:26 Speaker 2

also a bit of a monster that tries to regulate a relatively large amount, which of course also makes sense, but it takes a bit of this dynamic out of us and I think it becomes apparent that we simply need other models in the direction of regulatory science, to let these experiences flow in again and again in order to make such systems more dynamic, so to speak, to be able to react to it again and again and to be able to develop it again and again, so to speak, and perhaps again

00:10:51 Speaker 2

Let's look across the pond towards the USA.

00:10:55 Speaker 2

At the moment, they are very much involved in the fact that the FDA, which has been relatively static and relatively strict for many years, opens up and says: „OK, they deliberately want to bring in this feedback.

00:11:06 Speaker 2

They actually want such a regulatory system, so to speak."

00:11:09 Speaker 2

as a system that always gets input from the companies, which also has to question itself again and again, so to speak, and I think we need that here as well with many topics that are currently topical, in the direction of K.

00:11:20 Speaker 2

I., in the direction of additive manufacturing and similar topics, which ultimately need much more this feedback, this dynamic, and where we simply have to take new steps via regulatory science, so to speak.

00:11:32 Speaker 2

So I think it's a complex interaction, to make it short, the players, as I said,

00:11:37 Speaker 2

must, I think, also develop at this point.

00:11:39 Speaker 2

As I said, on the one hand, companies include notified bodies, and on the other hand, I think politics needs this third player who is involved, who also brings the scientific perspective into it.

00:11:50 Speaker 2

And I think that if we maybe take up the topic of Covid-19 again, then you will have seen how important it is, just here

00:11:56 Speaker 2

simply having neutral ground that can steer certain things again and again, so to speak, and can evaluate them in an independent way, so to speak, is, I think, a very important topic for the future, especially in these areas.

00:12:08 Speaker 1

Yes, I think we have absolute agreement that there is still a lot of desert here in Europe as far as the topic of regulatory science is concerned, and I think we both agree absolutely that the F.D.A.

00:12:20 Speaker 1

progresses there.

00:12:21 Speaker 1

So it really does this regulatory science on a large scale and

00:12:26 Speaker 1

is also teaming up with some universities, they have formed a CERSI network, where Stanford and the University of California, among others, are involved, which, by the way, just had a conference on this topic last weekend, Regulatory Science and who said exactly what they have just confirmed again.

00:12:48 Speaker 1

Here, systematic research is being carried out into how we need to create regulation, how

00:12:54 Speaker 1

Here, systematic research is being carried out into how we can also implement existing regulations in practice and how we can redesign existing approval procedures.

00:13:04 Speaker 1

And you have already mentioned the important ideas, namely the idea of interactivity and the other also the idea of modularization, so to speak, as a counterpoint to the monster, as you have called it, the M.

00:13:20 Speaker 1

D.

00:13:20 Speaker 1

R.

00:13:21 Speaker 1

So that means that since

00:13:22 Speaker 1

we must, and we should definitely get more involved in Europe, so as not to fall behind, but perhaps we will come back to it later.

00:13:33 Speaker 1

I would also like to briefly take up the point they had with Covid 19, that you might even see it as a prime example and take a look specifically at what worked so well, so how was it possible to get an approved vaccine within nine months?

00:13:52 Speaker 1

available.

00:13:53 Speaker 1

Of course, there are a few pharma peculiarities that play a role now.

00:13:56 Speaker 1

It also plays a role in the fact that it was a pandemic, which is something bad at first, but in this case something good again.

00:14:02 Speaker 1

We had enough potential study participants.

00:14:04 Speaker 1

Yes, please don't want that to sound cynical.

00:14:07 Speaker 1

But that was one thing that is now specific to the pandemic.

00:14:11 Speaker 1

But we have seen a few other things that I think we can transfer quite well to the medical device sector.

00:14:18 Speaker 1

You have already mentioned one point, and that was the

00:14:22 Speaker 1

scientific support that the authorities have systematically and all the time obtained.

00:14:29 Speaker 1

And that, in turn, presupposes that there is this scientific support.

00:14:35 Speaker 1

And this explicitly does not only mean scientific support, so to speak, in the biological or clinical.

00:14:43 Speaker 1

We also need more support now, for example with regard to the economy.

00:14:47 Speaker 1

What does that mean?

00:14:48 Speaker 1

What does this mean for companies?

00:14:50 Speaker 1

What does this mean for availability?

00:14:52 Speaker 1

It is useful, as with medical devices and vaccines, we can look at it more or less in the same way.

00:14:57 Speaker 1

It‘s no use if we have a perfectly safe and effective vaccine, but no one can produce it because, for example, regulatory hurdles or other things stand in the way.

00:15:08 Speaker 1

Yes, that means that there is sometimes a conflict of goals between safety and availability or efficacy and availability of medical devices.

00:15:16 Speaker 1

of vaccines.

00:15:17 Speaker 1

So I think a systematic success factor was this existence of research, which made it possible to advise the authorities in a targeted manner and then to come to decisions quickly.

00:15:31 Speaker 1

Number 1.

00:15:33 Speaker 1

Number 2.

00:15:35 Speaker 1

I think it was equally important to

00:15:38 Speaker 1

To change processes in turn, for example to do what they have called rolling review of these studies.

00:15:46 Speaker 1

So we've made it of one.

00:15:50 Speaker 1

sequential approach into a parallelized and interactive and iterative approach.

00:15:56 Speaker 1

So that's completely missing in our approval models or procedures.

00:16:02 Speaker 1

But in order not to simply blindly implement something like this and cause chaos again, we need evidence again, i.e. the results of systematic research, and we also need the political will to do so.

00:16:15 Speaker 1

And if we are with political will, then of course it also has something to do with the fact that we have the will and thus also the regulations with which we regulate more efficiently in the first place.

00:16:27 Speaker 1

Secondly, to optimise internal processes in the authorities.

00:16:31 Speaker 1

This will not happen without political will.

00:16:34 Speaker 1

And thirdly, to create the constellation of how cross-organizational processes can be improved, for example between authorities and manufacturers.

00:16:44 Speaker 1

or between authorities and authorities or between authorities and notified bodies.

00:16:49 Speaker 1

That is, the starting points for an improvement of a system, as we have now seen in Covid in a positive example, are 2 important factors, so to speak, that are decisive, the political will and the existence of systematic research that also gives the input for the will and for regulation.

00:17:12 Speaker 1

So I think that's why it's so important and that's why it's so relevant for our location, so that we're really able to get the right products in the right quality, by quality I mean safety, performance and in the right number and at the right cost.

00:17:32 Speaker 1

And there we have conflicting goals, and in the end, politicians have to decide on them.

00:17:38 Speaker 1

That also has something to do with ethics.

00:17:40 Speaker 1

only these decisions, they must not be taken out of the custom at some point, smoke, always gut, gut and always made, but there is simply a need for a scientific basis, you need evidence, otherwise it will just be a question of opinion or wild guessing.

00:17:55 Speaker 1

Yes, so that was my short one, so to speak, I don't know whether, whether you should call it a fringe, but perhaps a plea that we should get more involved there and, above all, in Europe.

00:18:05 Speaker 1

Because

00:18:07 Speaker 1

although we also support the F.D.A.

00:18:08 Speaker 1

Director again, and this was just the case last weekend, he now sees regulation not only as something that the F.D.A.

00:18:16 Speaker 1

ensure that we have the right products, safe products in the U.S.

00:18:20 Speaker 1

market and of course they only have a U.S.

00:18:23 Speaker 1

Blick, but he explicitly says that we will fall behind, especially in the field of digital health.

00:18:29 Speaker 1

He has already described China as the Leading Nation for Digital Health and he says there,

00:18:36 Speaker 1

This is also part of the task of an authority, to form a counterweight to this and to design it according to regulations in such a way that innovation is also enabled and further promoted.

00:18:48 Speaker 1

And that's why I think it's absolutely important that we get more involved so that this doesn't happen to

us and so that we are not so overwhelmed and surprised by these negative consequences that an MDR now brings.

00:19:03 Speaker 1

Well, Spectaris' estimate, for example, is that around 9 to 10% of the sales of medical device manufacturers are now needed for these regulatory adjustments.

00:19:16 Speaker 1

With the 100 billion euros that the medical device market in Europe has, we are talking about 10 billion euros that we have simply spent now, but without having this evidence as to whether we are doing more good or more harm.

00:19:33 Speaker 1

So, I think these are the reasons why we should do this research.

00:19:38 Speaker 1

That was a brief explanation of what is now the relevance of this topic and also a reason why we should get more involved in Europe.

00:19:46 Speaker 1

Yes, let's get to the current topics that are currently on the minds of regulatory science.

00:19:54 Speaker 1

What would you see as important research potential research priorities, Mr. Heimer?

00:20:01 Speaker 2

Perhaps, before I get to the point, I would like to say again in 23 comments about what you have said and I agree with you one hundred percent in that direction.

00:20:08 Speaker 2

I want to put another 1 on top, so to speak.

00:20:10 Speaker 2

First point, if you look at it, for example from the pharmaceutical industry in the.

00:20:17 Speaker 2

In the last century, there were simply a lot of pharmaceutical companies on the move in Germany, Switzerland and Europe as a whole.

00:20:24 Speaker 2

If you look at the point at which they then switched to America, it was exactly the time when it was very much about this clinical research, about the generation of data.

00:20:34 Speaker 2

where, so to speak, the Americans are much more open in this direction and the Chinese are perhaps even more involved in this direction through their state system.

00:20:41 Speaker 2

And I think that's a point where you have to be careful that this strong European and, above all, strong German medical technology industry doesn't simply lose touch.

00:20:49 Speaker 2

So I think that's a very crucial point and the second point that comes in here, this dynamization that you mentioned, also of the approval processes, is also a very important factor.

00:20:58 Speaker 2

You also have to see that basically these approval systems are statically oriented,

00:21:02 Speaker 2

That means I have the approval once, no matter how the circumstances change.

00:21:06 Speaker 2

We have seen through this pandemic that of course a lot depends on the circumstances.

00:21:10 Speaker 2

If I have a vaccine now, then I may have to be able to take a few more risks in relation to the benefits I have in each case, because if I can simply achieve restrictions on the spread of the vaccine, so to speak, then I naturally have a positive risk-benefit ratio from the overall spectrum, from the overall context.

00:21:28 Speaker 2

while in other situations I may not have that, so to speak.

00:21:31 Speaker 2

So I think you also need regulatory science in this direction, where we are perhaps already involved in a few topics, as far as this regulatory structure, the regulatory strategies, so to speak, is concerned, what should definitely be taken up in such a field and what should also be specifically examined from the research side, how something like this works.

00:21:48 Speaker 2

I believe this OVID pandemic, even if it was primarily the pharmaceutical sector,

00:21:52 Speaker 2

has pointed out many of these points, which are important here and if we look at M.

00:21:56 Speaker 2

D.

00:21:56 Speaker 2

R.

00:21:56 Speaker 2

, even with surgical instruments, so to speak, and the like, when the effort becomes so great, there is simply a danger to this profitability and then you also have to include an overall view somewhere and it

must also be permissible somewhere, so to speak, and I think it must also be moderated somewhere by the neutral side, as you also said.

00:22:14 Speaker 2

There are many topics that come in this direction, and you have addressed ethical issues, you have addressed responsibility, perhaps on the subject of responsibility, if we talk about the current

00:22:22 Speaker 2

already come.

00:22:23 Speaker 2

We have already mentioned additive manufacturing, K.

00:22:24 Speaker 2

I., I think we can still go into both topics.

00:22:27 Speaker 2

I'll start with the other topic, that we haven't had quite as much focus now, but I think that the topic of interoperability is also a very important one.

00:22:35 Speaker 2

If we have different medical devices that act together, we don't really have a consistent regulation so far on how to deal with them, also in the sense of responsibility, obligation, if something goes wrong, so to speak, how the whole thing interacts.

00:22:48 Speaker 2

And I think we just have everywhere these days

00:22:51 Speaker 2

interacting systems and the fact that there is no clear regulatory approach to them, for example, is an issue that makes the whole thing difficult.

00:22:58 Speaker 2

You can perhaps take a look at it, interoperability works a little better in other areas, technically it is not a problem at all, it is actually the regulatory question, the question of responsibility that is behind it.

00:23:08 Speaker 2

In the automotive sector, a lot has been done, because all kinds of devices want to connect here, so to speak, some of which are not even available now.

00:23:16 Speaker 2

are so very technical, but come from the consumer sector, any jukeboxes that you want to connect and so on, you have done it relatively well.

00:23:23 Speaker 2

In the automotive sector, however, you have the advantage that the area that is safety-critical is encapsulated quite well, because a central manufacturer typically has its hand over it.

00:23:34 Speaker 2

In the medical technology sector, there are a lot of small manufacturers working together, a lot of small instruments, so you have a completely different scenario and to hand it over completely to the operator, so to speak, is of course also difficult.

00:23:44 Speaker 2

So I think there are a lot of questions involved,

00:23:46 Speaker 2

how to deal with such issues from a regulatory point of view.

00:23:50 Speaker 2

Briefly address a second topic, additive manufacturing of medical devices is of course also a typical topic, if you look at what the MDR has done, especially in the direction of individualized implants, for example.

00:24:03 Speaker 2

In this area, it has been said that it is still seen as a custom-made product, that is, so to speak, the point of view that such individualized implants have in the field of MDR.

00:24:13 Speaker 2

I have to say,

00:24:14 Speaker 2

Basically, the MDR is not entirely consistent in this respect.

00:24:16 Speaker 2

Everywhere else, it very strictly demands proof, clinical proof of how this is to be implemented.

00:24:21 Speaker 2

Here you say „OK“, in the end the doctor has to decide, so to speak, how the whole thing works.

00:24:25 Speaker 2

Actually, we have a situation here.

00:24:28 Speaker 2

where basically this overall manufacturing process needs to be validated as a whole and approved as a whole.

00:24:34 Speaker 2

Actually, it is no longer the individual implant of the medical device that is behind it, so to speak, but the overall process of how it is manufactured.

00:24:42 Speaker 2

And that‘s where we get into topics that you have to work out more over time how such overall processes have to be validated.

00:24:50 Speaker 2

And of course, we have a lot of requirements in different areas, in the 13485 and so on, that go in the direction of process validation and

00:24:58 Speaker 2

Thinking quite consistently to the end, it actually also concerns this question of how we can systematically validate such an overall process, which is also partly automated, as we might do when we go in the direction of AI, so to speak.

00:25:12 Speaker 2

even if they are always evolving, how to keep repeating such validations, so to speak.

00:25:16 Speaker 2

And I think I'll stop at these 2 topics and I think in the direction of K.

00:25:20 Speaker 2

I.

00:25:21 Speaker 2

You can say a few more things about this, because I think we have a somewhat similar question, or such a deeper question, that we actually have to work out such automatisms for validation step by step, if we want to make such systems learn again and again, even if we have, so to speak, these experiences that we have here, this data that we have here,

00:25:38 Speaker 2

Always want to feed in a system and have a developing process, so to speak, that does that.

00:25:44 Speaker 2

And perhaps one last word: If you relate this to this overall regulatory system, we naturally have these requirements right there.

00:25:51 Speaker 2

Data keeps coming in, the process has to renew itself.

00:25:54 Speaker 2

it must nevertheless remain valid.

00:25:56 Speaker 2

Are questions that I think can be answered in this topic A.I.

00:25:59 Speaker 2

because they are also very data-driven and I think it will be interesting to see what they are also heading towards A.I.

00:26:07 Speaker 1

Still be able to report.

00:26:08 Speaker 1

I like to do it very much, but until they take up or reinforce thoughts again.

00:26:13 Speaker 1

What you have just beautifully described is that we need a view that is beyond the individual product itself.

00:26:23 Speaker 1

Yes, you have now spoken about the topic of interoperability, but even in the field of additive manufacturing, it is not just about this object, whether it is physical or not physical, but we need thinking in systems and the article on systems actually has a bit else in the background.

00:26:43 Speaker 1

Yes, the article on the systems and treatment units.

00:26:46 Speaker 1

Ultimately, we already have a regulatory gap in the

00:26:50 Speaker 1

Systems that consist of several products and where the question of overall overall responsibility is simply not properly regulated.

00:26:59 Speaker 1

And this I.

00:27:01 Speaker 1

T.

00:27:01 Speaker 1

Products, if I may call them now, are of course predestined and that, as you just said, also leads us into the topic of machine learning, where we want to be able to answer many questions well.

00:27:14 Speaker 1

So, for example,

00:27:16 Speaker 1

how much can we prove by testing these algorithms at all?

00:27:21 Speaker 1

So, what is enough?

00:27:22 Speaker 1

We have questions, when does which regulation apply at all?

00:27:26 Speaker 1

But because we have such topics with these machine learning libraries, for example, that they fall under

‚ne 62 304, i.e. parts of this library and other parts of this library would rather be examined under ‚ner 13 485.

00:27:41 Speaker 1

We also had in another podcast

00:27:44 Speaker 1

I had talked about how we deal with pre-trained models, i.e. this pre-trained model, what about this transfer learning?

00:27:52 Speaker 1

Well, we have a lot of unregulated things, so to speak, where there are no uniform best practices yet.

00:27:59 Speaker 1

I'm currently involved in a research project that deals with the gender gap.

00:28:04 Speaker 1

So, how much are men ultimately used, abused or whatever as, let's say, as a prototype of the human being,

00:28:13 Speaker 1

because data from male patients in particular are included.

00:28:17 Speaker 1

How much do you then examine the specifics of your own genders and, above all, what effect does it have afterwards really in the sense of damage with probabilities and degrees of severity, i.e. risks.

00:28:29 Speaker 1

So here we are still moving relatively early in the process of cognition, so to speak, also the questions of what we or as a notified body are allowed to do or do we even have to demand,

00:28:39 Speaker 1

For example, as far as this transparency or the explainability of these models is concerned, we have very exciting, also ethical questions that are still open.

00:28:50 Speaker 1

The, this is now a point, he is now not alone on A.I.

00:28:53 Speaker 1

and M.L.

00:28:53 Speaker 1

but then again of particular relevance.

00:28:57 Speaker 1

In risk management, we always examine the benefits and risks, so to speak, and do not take into account specific, patient-specific preferences.

00:29:07 Speaker 1

Yes, it's almost all going to be under one, a large sum is made underneath, then looks under differ or predominantly, the benefit now the risks.

00:29:16 Speaker 1

But we don't go into the fact that these preferences are completely different from the patient, also from their situations.

00:29:23 Speaker 1

And I think there is also a need for research, for example, at the U.C.S.F.

00:29:29 Speaker 1

a lot of work is done there.

00:29:30 Speaker 1

So I think Regulatory Science is not running out of questions at all.

00:29:36 Speaker 1

I

00:29:37 Speaker 1

Yes, and with that I would perhaps briefly summarize again, what were the points we talked about?

00:29:41 Speaker 1

Yes, I first worked with Professor Heimann or he clarified, what is regulatory science anyway, what are typical questions?

00:29:49 Speaker 1

I differentiated it a bit from Regulatory Affairs, but also showed how the two interact with each other.

00:29:56 Speaker 1

We talked about who does regulatory science.

00:29:59 Speaker 1

In Europe, we almost have to say that if you don't do it, then we would have a plea to really do that.

00:30:06 Speaker 1

we had shed light on why this is so important and also got a few suggestions from the current vaccine development and made a plea for us in Europe to get more involved in this area and, at the end, we also pointed out a few exciting questions that we as scientists should investigate here.

00:30:27 Speaker 1

We talked about additive manufacturing, machine learning, ethical aspects.

00:30:32 Speaker 1

Mr. Heimer, I would say that we have

00:30:35 Speaker 1

a good overview or at least I hope created.

00:30:38 Speaker 1

Of course, we will also link articles and our contact details here in the show notes below and you can be sure that you will hear a lot more from both of us, Mr. Heimann and me, on this topic.

00:30:51 Speaker 1

So, we are both involved.

00:30:53 Speaker 1

Heimann, thank you very much for joining us.

00:30:56 Speaker 2

Many thanks to you, too, Mr. Jonas.

00:30:58 Speaker 2

I think it should be a serve, simply this appeal, to push this topic more strongly, that it is taken up, that it also comes into consciousness a bit, I think it's an important topic, it's simply a personal concern for me, as you may have noticed, that something is developing here.

00:31:13 Speaker 2

As I said, U.

00:31:14 Speaker 2

S.

00:31:15 Speaker 2

A.

00:31:16 Speaker 2

There's a little bit going on and in Europe, I think, you really need it to make it sustainable and that's a very crucial point, I think.

00:31:21 Speaker 2

And if we could have made a little contribution to it,

00:31:24 Speaker 2

Faith, then we are on the right track.

00:31:25 Speaker 2

And then again many thanks to Mr. Jona for setting it up like that.