Johner Institute

The State of the Art

With Prof. Dr. Christian Johner

Transcript

00:00:06 Speaker 1

Medical Device Insights.

00:00:08 Speaker 1

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

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Everywhere, the MDR demands compliance with the state of the art.

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But what this state of the art is,

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It doesn't want to tell us.

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Rather, it confuses us with incorrect translations and inconsistent use of the term.

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In this edition of the ‚Medical Device Insights' podcast, we look at what the state of the art is, how it differs from the state of the art, and how you can also determine this state of the art.

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We have also invited a guest who does nothing else in the context of his research than to take care of this translation.

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I am Christian Johner, Director of the Johner Institute, and I would like to extend a warm welcome.

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The MDR, as I just said, demands that we determine the state of the art and then take it into account in a wide variety of places.

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For example, it is a matter of formulating the performance requirements for the products, which must meet this state of the art, even when it comes to determining the benefit-risk ratio.

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This means defining the risk acceptance criteria,

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Then it's time to determine standard technology.

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The same must be considered in software development, in the planning and execution of clinical evaluations, in the creation of clinical trial protocols and so on.

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In many, many places, the M.D.R.

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and the I.V.D.R.

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in the same way to determine and comply with this state of the art.

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Yes, what is the difficulty now?

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The first difficulty is that the M.D.R.

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and the I.V.D.R.

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do not define this term at all.

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Worse still, they use it in a completely inconsistent way, sometimes talking about the state of the art, sometimes about the state of the art, at other times about the generally accepted state of the art, and there is also the current state of the art.

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If you are finally confused and hope to get clarity from the original English edition, you will find that it does not fit exactly at all.

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So also the translations

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into German are at least inconsistent.

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There are also other problems, namely that the M.D.R.

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does not currently have harmonised standards, this state of the art has not really been defined and the notified bodies have not yet been able to agree to make a clear binding statement as to whether, for example, the latest standards should always be applied or perhaps only those standards that are intended for harmonisation at a later date.

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So, we have some problems finding out what this state of the art actually is.

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Fortunately, now comes some rescue, namely in the form of ISO 14971 in the 3rd grade.

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Edition.

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This 3.

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edition complements the definition of the state of the art and I quote it: ‚Includes the current and generally accepted good practice in technology and medicine.'

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Standard technology does not necessarily mean the most technically advanced solution.

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The standard technology described here is sometimes referred to as the generally accepted state of the art.

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End of quote.

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This is very, very helpful, because it allows us to say that standard technology and generally accepted standard technology are to be equated.

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This means that we don't need to distinguish between many of the things that the MDR has distinguished.

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And it is also important to note that the state of the art does not have to correspond to the very latest,

i.e. as she calls it, the most technically advanced solution.

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That simplifies a bit.

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I will talk to Professor Röhrig in a moment later about how they determine the state of the art in medical devices, but also in the healthcare system as a whole.

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Before we get to that, however, we should realize that the state of the art is not a

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The qualitative or even quantitative size of a medical device is, so to speak, a score.

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Rather, medical devices have many aspects regarding the state of the art.

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This applies above all to the usefulness of the product, the safety of the product and the performance of this product.

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And you can see that each of these 3 aspects can in turn consist of several partial aspects.

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There may not be just one benefit, but several benefits.

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There will probably not be just one performance parameter, but many, and there will also be various aspects in which the product needs to be safe.

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For example, it must be safe, perhaps against E.M.V.

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radiation, i.e. against an emission.

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It must be safe against dropping this product and so on.

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That is, when we compare products with each other.

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we have to weigh these different aspects against each other.

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One way to illustrate this is perhaps via a kind of raider chart and in the latest article in the Institut Journal or on our website you can also take a look at an example of this raider chart.

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But before I am about to interview Rainer Röhrig and ask him how you determine the state of the art and how it is also determined in the health care system, one last thought.

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It is not correct to believe that the very latest, i.e. in the direction of the state of science, is always the best.

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Because as we have just learned, the state of the art must be assessed in terms of usefulness, safety and performance.

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And often with these very latest products, the benefit may be high and perhaps also the performance, but often also at the expense of safety and since we manufacturers want the optimal level of benefit,

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Performance on the one hand and security on the other, it may be that these very latest products or the very latest technologies are not necessarily the best.

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And now it's time for us to interview Rainer Röhrig and hear for yourself.

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I now have Rainer Röhrig with me, who has a professorship at the University of Aachen.

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Rainer, could you introduce yourself very briefly so that our listeners know who I am allowed to talk to here.

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Yes, hello Christian, I am a professor of medical informatics at the R.W.T.H.

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Aachen and we also focus on translation here and also work on the board of the Translational Center, or rather the Center for Translational and Clinical Research at R.W.T.H.

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Aachen.

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Of course, this makes you the absolutely ideal contact person to discuss the topic

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state of the art.

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Listeners have already experienced that it is not so easy to define this state of the art at all.

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How would you determine the state of the art for a medical device?

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Do you even have an example of that?

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So, state of the art is actually easy to determine because it is what is available in the market.

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In other words, what I can buy today, or what is already installed in the devices today and is therefore available.

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Can you give an example of products that are now standard technology and perhaps take the opportunity to go into the next question of how this standard technology differs from the state of science?

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I think I'll start with the state of science.

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That's what we scientists, researchers and developers are working on, but it's not yet at the stage where I can really bring it to market.

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In software, for example, these are algorithms for knowledge-based systems, where I can show that they work, or devices, where I can show in animal experiments or in the laboratory or in a pilot project that it works for individual products that I get manufactured.

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where I can also prove that the effect or that the findings are scientifically proven.

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Then comes the difficult step, because then I still have to make sure that I can not only show this with an example, but that I can also get it across the board.

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I have to have manufacturing methods in order to be able to manufacture products safely.

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Yes, let's think of a vaccine.

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It would be nice if we now had a Corona vaccine that we could get produced in the laboratory once.

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But the big task will be to produce it billions of times so that we can really bring it out to the population, to humanity.

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And this step, how far do we get with our technology, is always to be considered when we talk about the state of the art and for this is often still more than just once an idea in a

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object or into a piece of software.

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To what does it regularly pass, this translation from the state of science then into technology?

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To put it simply, it's because you didn't think about how to get it there from the outset, because we scientists are often located in basic research and are initially only interested in gaining knowledge.

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To think afterwards, how do I really get that

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into the rollout, how do I get this into the market, how do I get it into distribution, needs a lot of things.

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One is of course the regulatory requirements, which everyone complains about, but there is much more.

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For example, if I have software that is knowledge-based or based on a knowledge-based system and is supposed to support doctors' decisions, then that doesn't help me if my algorithm is great.

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I also need data of appropriate quality on which this algorithm can work.

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I need an infrastructure that then supplies this system.

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The next thing I need to think about is maybe I need to adjust them everywhere in every hospital.

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The effort of installing a hospital information system is almost more complex than the license fees you pay due to the adaptation to the processes in each hospital, if you look at the lifetime.

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This means that you have to look from product class to product class,

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but the breadth of the market is the big challenge to really get it implemented afterwards.

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You just said that you are now working in exactly one area where this translation works.

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What are you doing or what are you preparing or what tips would you have for those who are sitting and working at this very junction to make this transfer work well?

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There is a broad team behind it, our translation management, and the first thing is that a researcher or scientist who has a good idea and perhaps already has the first successes in basic research, has perhaps already been able to prove a small effect, that he then makes a plan as early as possible.

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We call this a translation management plan, where we say, now we have to think about what are the necessary steps if you want to use it first-to-patient at some point.

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Or first human wants to go and how do you have to do that so that this can later lead to approval and then also to market success?

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And there are many areas that are needed.

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One thing, it covers the whole regulatory area, I don‘t need to explain to you that we carry owls to Athens.

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Then there is the business administration area, where we also cooperate with other structures here at the university that specialize in this.

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And then there is the area where I have to gradually develop the knowledge gained in order to get there.

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And with many things

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we also have to say, does something start where there is the realization that it is not a development and a realization alone that leads to the fact that it can be distributed afterwards, but that it often takes many developments, which then have to be orchestrated so that it becomes a reasonable product that can really arrive in the market.

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You have already talked about the Corona example and that should be a trigger for us, now not only about medical devices, but about

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more health care and medical care, perhaps a little more generally.

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Do you have an estimate of how long it typically takes for a new medical procedure, for example one that has been researched in science, to find its way into routine treatment?

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Normally it takes years, so I'll figure out right away why that is.

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Corona is now an extremely positive example, where we can see what science is capable of, also in terms of speed.

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We haven't even known Corona for a year and this year we have already made huge progress.

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we have begun to understand the disease.

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We understood that it is not a pure lung disease, as it was at the beginning, but that it is a disease of the vascular system and that a certain form of cells is damaged, and we were able to tailor the therapy to this.

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In the beginning, the intensive care mortality rate and especially the mortality of ventilated patients was well over 50%, which is now

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Over the course of the year, it has already fallen significantly, because we suddenly had three new therapy options that developed out of this understanding.

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One is the administration of remdesivir, this is a high-dose anticoagulation and this is the cortisone administration for all patients who need oxygen.

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And that shows how quickly knowledge prevails when there is still a huge amount of ignorance and there is a huge benefit and the risks of therapy are far behind it.

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Overall, however, medicine is at an extremely high level and a high level of quality, and every new procedure must prove that it is at least not worse than what has been the standard therapy so far.

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And in order to get there and to be able to prove this, we need studies and many drugs or medical devices that we bring to humans for the first time naturally also harbor dangers that could not have been recognized before.

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And that has to go through a long test procedure.

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And these clinical trials, which are going through one after the other, are they or are the main factor why it takes a long time to develop products in

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into medicine and to get new methods into it.

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But even if they are established there, if there are new guidelines, the knowledge must still be disseminated to all physicians.

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And here, too, we can only count on one to 2 years, one to 2 generations, i.e. 5 to 10 or 15 years, until the knowledge has really spread in medicine.

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By proving that they are at least as good as previous methods or alternatives.

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Returning to the state of the art, it seems sensible and even good to take this time.

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However, the duration from the guideline to implementation in really every private practice and every family doctor's practice,

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that's probably a point in time that one would like to shorten.

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Do you see a possibility of these, you now need 1015 years to get down to lower intervals.

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So my very big hope as a medical informatics specialist is, of course, to achieve this with knowledge-based systems.

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In other words, that we make knowledge available to doctors in a contextual way.

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I don't think computers have to make the decision that a doctor makes,

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But in the increasing dimension of knowledge that we need in order to be able to make individual therapy decisions based on the current state of science or technology, we have to manage the knowledge in such a way that it is presented to the doctor in the right situation at the right moment in the right form.

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And I believe that is the task of our discipline, to offer good solutions here in the next 5 to 10 years.

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And then there is the task of medical device manufacturers to take up precisely this knowledge and seduce it into effective, useful and safe products.

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Reinhard, thank you very much for these exciting insights.

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Yes, thank you very much for the interview.