

News from Denmark

With Dr. Ulrich Nitsche, Prof. Dr. Christian Johner

Audio File: [TÜV-DK.MP3](#)



Transcript

00:00:00 Speaker 1

We commit ourselves, we stand by our stated timelines.

00:00:04 Speaker 1

If there are delays on the part of the customer, then of course we cannot necessarily influence it, it is not in our hands.

00:00:11 Speaker 1

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

00:00:20 Speaker 2

Our regulatory system has slowly arrived in this new state of equilibrium.

00:00:26 Speaker 2

So, we know, for example, how this whole interaction with the notified bodies works.

00:00:32 Speaker 2

I also think that some of the very worst bottlenecks in this area have now slowly dissolved and I notice that there are still many topics, for example in the context of clinical evaluations, where you are still tuning what exactly the expectations are now.

00:00:51 Speaker 2

And what would be better suited than to invite someone who is both a doctor

00:00:56 Speaker 2

and at the notified body.

00:00:59 Speaker 2

And that's exactly what I succeeded.

00:01:01 Speaker 2

I have Doctor Nitzsche with me in the podcast today and he is responsible as a doctor at TÜV Süd, also for the context of clinical evaluations, of course.

00:01:12 Speaker 2

But Mr. Nitzsche, I think you can describe this a little more precisely and precisely, how I just did it, what you are doing and what falls within your area of responsibility.

00:01:21 Speaker 1

Exactly, yes, thank you very much for the invitation.

00:01:22 Speaker 1

Greetings from my side as well.

00:01:23 Speaker 1

Ulrich Nitzsche is my name, as you have already said.

00:01:25 Speaker 1

And

00:01:26 Speaker 1

The story with me is, I worked as a surgeon at the Klinikum Rechtsisell Munich for 10 years, so I am a specialist in visceral surgery and have always done a lot of research on the side.

00:01:37 Speaker 1

I also did a basic research course, a three-year one, and then at some point when I had my specialist, when I had my habilitation, where I thought to myself, how should it go on like this?

00:01:48 Speaker 1

What else appeals to me so much?

00:01:50 Speaker 1

Maybe also if you think outside the box a bit.

00:01:52 Speaker 1

And I ended up at TÜV Süd more or less by chance, it has to be said, as a clinical reviewer, i.e. as an internal clinician to review the clinical evaluation and I can't really imagine what it means at the beginning.

00:02:06 Speaker 1

But then I got into this topic very quickly and slipped into it, I had a lot of fun and due to the very strong build-up measures we had at the time, because of this massive M.

00:02:18 Speaker 1

D.

00:02:19 Speaker 1

R.

00:02:19 Speaker 1

Flood that you have already mentioned,

00:02:21 Speaker 1

we have expanded very quickly in that time.

00:02:24 Speaker 1

I've been with the company for a good 5 years now, and I'm currently called the Global Director of Clinical Center of Excellence.

00:02:30 Speaker 1

This means that I look after the internal clinicians, the 3040 internal clinicians, i.e. the mainly specialists, for all kinds of areas that we have at TÜV Süd for the evaluation of mainly high-risk products.

00:02:42 Speaker 2

Oh, that's exciting.

00:02:43 Speaker 2

What was new for you as a doctor, or perhaps I ask the question a little differently, has the

00:02:51 Speaker 2

Way of working scientifically in a clinical context is different from the way you always do a bit of science

and evaluate it in the context of clinical trials or clinical evaluations, more precisely.

00:03:05 Speaker 2

So, is there a difference or have you had to learn to think in a new way?

00:03:09 Speaker 1

Exactly, it's a very exciting question, the

00:03:12 Speaker 1

The decisive factor, perhaps because of the scientific background I already had, i.e. writing publications myself or working as a peer reviewer for scientific journals, was that it wasn't such a big change in principle.

00:03:25 Speaker 1

So it was the one where I already knew from my work before, that I enjoy familiarizing myself with certain topics, digging into them, trying to drill down, so to speak, to see if you see a possible problem somewhere.

00:03:36 Speaker 1

I don't think that was such a big change, that's more what I noticed, that some

00:03:41 Speaker 1

Clinicians who work as in-house clinicians at notified bodies may have a hard time if they don't already have these basics or previous scientific experience.

00:03:50 Speaker 1

What is of course especially exciting for you from a clinician's point of view is if you know how products are used in the O.P.

00:03:57 Speaker 1

.

00:03:57 Speaker 1

No one will ever look at the instruction manual, quite strikingly said, it is thrown away, the stuff is the products are used in the grossest extent off label, partly so that you have to

00:04:09 Speaker 1

can really bring this first-hand insight into the notified body, so to speak, I think that helps a lot.

00:04:15 Speaker 2

Ah, I think that's great and that's also good news.

00:04:17 Speaker 2

Yes, that means that there are not somehow 2 ways to work scientifically well, namely once in an academic context and once in the admission context, if I may call it that, but the same rules of the game apply and that is great news and that of course they bring exactly the contextual knowledge with them, that is of course of incredible value, because that is exactly what which is often missing or

00:04:39 Speaker 2

where I have what we have already experienced, these are called Clinical Experts in the manufacturers.

00:04:44 Speaker 2

But when they go into the clinical context, they change it rather than really know it from their daily work.

00:04:51 Speaker 2

That means they can help incredibly.

00:04:54 Speaker 2

Thank you for the insight you have given.

00:04:56 Speaker 2

Maybe one last question about yourself, do you have a certain class of products for which you feel particularly responsible, for which you have a special passion?

00:05:08 Speaker 1

So, if you now speak in classes, then of course it is the high-risk products, i.e. class 3 and implants, where the internal clinicians are very closely involved.

00:05:19 Speaker 1

But beyond that, we do the whole spectrum, especially as internal clinicians, all low-risk products, including those that come with Sampling Plan, we also look at them.

00:05:27 Speaker 1

So, if you do that, it's always the problem that you have in the regulatory world in M.D.A.

00:05:32 Speaker 1

and M.D.N.

00:05:33 Speaker 1

Codes and in speaks in risk classes and in the medical world.

00:05:36 Speaker 1

is spoken in medical areas or in medical specialist areas.

00:05:40 Speaker 1

So of course that means everything that goes in the direction of visceral surgery, emergency medicine, that's where I have my hobbyhorse, so to speak, where I am the experienced clinician, regardless of the class, I would say.

00:05:52 Speaker 2

O.

00:05:53 Speaker 2

K., yes, we'll come back to the topic of clinical evaluations in a moment.

00:05:57 Speaker 2

Today we wanted to make a very small trip to Denmark, where they have opened a new location of TÜV Süd.

00:06:06 Speaker 2

What were the thoughts you had, to which specific customer group would you like to address with it?

00:06:12 Speaker 2

Because it's a real effort to help build something new, a new notified body de facto.

00:06:19 Speaker 2

What were the rational ones, as you would probably call it, behind it?

00:06:23 Speaker 1

Exactly, a very exciting topic.

00:06:24 Speaker 1

For some time now, TÜV Süd in Denmark has been designated and plans to have the first M.

00:06:32 Speaker 1

D.

00:06:32 Speaker 1

R.

00:06:32 Speaker 1

certificate also released.

00:06:35 Speaker 1

Of course, it was a long journey, because building up a second mainstay, a second notified body, gave a variety of reasons and ideas behind it.

00:06:45 Speaker 1

On the one hand, that it gives you the opportunity to rebuild yourself from scratch, so to speak.

00:06:50 Speaker 1

M.

00:06:50 Speaker 1

To think about processes, to think through them, without any M.

00:06:55 Speaker 1

D.

00:06:55 Speaker 1

D.

00:06:55 Speaker 1

Preloads that are still somehow stuck in the system, so to speak.

00:06:59 Speaker 1

was also the idea that you have an agile structure with a relatively small, with a relatively small designated body, which could be very suitable for start-ups with new customers, for example, especially now at a time when TÜV Süd is not yet fully utilized, in order to get in touch with experts quickly, to be able to

plan appointments at short notice.

00:07:21 Speaker 1

in other words, where this whole ongoing business is not always floating in the background, so to speak, but where you can really respond to customers in a very concrete and detailed way, where it is also possible to foresee in the context of new developments or start-ups that a relatively large number of change notifications will come in even after certification, where you also have enough capacity, to work through this quickly at any time, to be in close contact with customers.

00:07:48 Speaker 1

In principle, nevertheless,

00:07:49 Speaker 1

both TÜV Süd, so it offers the same service, it is to a very large extent also the same experts behind it.

00:07:56 Speaker 1

So we see this as a global TÜV Süd company, no matter which TÜV Süd the customer goes to, he will get the same, hopefully very good service in the end.

00:08:07 Speaker 1

As I said, there may be individual differences, now also in the context of this structure of TÜV Süd Denmark with regard to intensive customer service.

00:08:16 Speaker 2

So you now have

00:08:17 Speaker 2

I also described which customers they particularly like to see there, namely if I understood them correctly, the young ones, the startups they mentioned, who are involved in development, who invent new things, who probably also need quick interaction in order to be able to write ahead.

00:08:35 Speaker 2

I know that you can't answer this globally, but can you sketch a bit about timelines that they might claim to want to achieve?

00:08:46 Speaker 1

In the same way, you can certainly sketch or determine.

00:08:49 Speaker 1

So, without going into too much detail, anyone who is very specifically interested can go to the TÜV Süd homepage.

00:08:56 Speaker 1

So, if you simply search the Internet for TÜV Süd M.

00:08:59 Speaker 1

D.

00:08:59 Speaker 1

R.

00:08:59 Speaker 1

Assessment timelines, then you can find the time scheme according to which we work.

00:09:04 Speaker 1

So, we guarantee and commit ourselves to certain timelines, which takes an evaluation in total.

00:09:11 Speaker 1

So that would be if you look at different evaluations

00:09:14 Speaker 1

rounds and add up, as it is just presented, something in the context of a few months, in the case of such dedicated services that we offer, i.e. those that have very fast turnaround times or even several months up to 9 months in the context of a base service, i.e. a regular evaluation service.

00:09:34 Speaker 1

So customers can choose freely, in the end which service model they book with TÜV Süd.

00:09:40 Speaker 1

The timeline and service model is, as I said, TÜV Süd is the same as TÜV Süd.

00:09:43 Speaker 1

So there is no difference between Denmark or Germany.

00:09:47 Speaker 1

In the end, it depends on the customer what his claim and his wish is, and of course it is never one hundred percent predictable that the certificate will be issued according to X.

00:09:59 Speaker 1

months.

00:10:00 Speaker 1

So we are quite committed, we stand by our specified timelines.

00:10:05 Speaker 1

If there is a delay on the part of the customer, then of course we can

00:10:09 Speaker 1

is not necessarily in our hands.

00:10:11 Speaker 2

Mhm, yes, then you should drill right into it.

00:10:14 Speaker 2

So, what can customers do to avoid delays?

00:10:18 Speaker 2

Well, you have already mentioned 1 to book the right service, because it obviously has an effect on the timeline.

00:10:26 Speaker 2

But beyond this, yes, I'll call it economic consideration, which probably plays a role here, what can they do procedurally?

00:10:36 Speaker 2

What can you prepare, what should you pay attention to so that the matter can then flow through on your side as smoothly as possible?

00:10:46 Speaker 1

Exactly, so there would be my first recommendation to medical device manufacturers, to customers, especially perhaps to areas that have not yet

00:10:58 Speaker 1

have a lot of experience in the field to seek contact with the notified body at an early stage.

00:11:02 Speaker 1

That was also in the beginning under the M.D.R.

00:11:05 Speaker 1

always a question of what may, can't, can't be done by a notified body, especially in this pre-application phase.

00:11:11 Speaker 1

The MDCG 2019 6 has recently been updated to revision 5, where Structure Dialogues are once again dealt with in a very concrete way.

00:11:20 Speaker 1

So I think that's a very elegant and very clever, a clever way for

00:11:28 Speaker 1

We are happy to offer manufacturers the opportunity to get in touch with the above-mentioned bodies at an early stage.

00:11:33 Speaker 1

At TÜV Süd, we also benefit from the fact that we have a relatively large internal pool of clinicians, of experts, which we can therefore obtain from.

00:11:43 Speaker 1

Hour 0 or already pre-application in contact with the corresponding manufacturers for discussions, in order to be able to continue or reflect this from time to time during the development phases.

00:11:59 Speaker 1

So that, I think, would be an important thing, that the manufacturers seek contact with the notified body at an early stage, also discuss intermediate steps and then, of course, the decisive question is always

00:12:12 Speaker 1

What is a notified body allowed to do?

00:12:15 Speaker 1

We are not allowed to advise, that's clear, I think.

00:12:17 Speaker 1

That means we can give assessments of the strategy, we can discuss ways of what can be an acceptable way to get a product on the market, especially when it comes to the questions of when is a clinical study necessary, when is a premarket study necessary, when is a P.M.C.F. necessary.

00:12:36 Speaker 1

Study required or when can a P.M.C.F.

00:12:38 Speaker 1

study.

00:12:40 Speaker 1

So the general regulatory issues, I think, are relevant points that can be discussed.

00:12:46 Speaker 1

Otherwise, what we are not allowed to do as a notified body, simply because it is prohibited by law, as I said, is advising or creating the concrete assessment, helping there or telling the customer exactly what he has to do, there will be consulting firms for that.

00:13:04 Speaker 1

So you have to make a clear distinction.

00:13:05 Speaker 2

Yes, we can help with that.

00:13:07 Speaker 2

So, I'll summarize very briefly.

00:13:08 Speaker 2

So, the first tip was to choose the right package.

00:13:11 Speaker 2

The second tip was to also seek out this structured dialogue and, especially then, to clarify regulatory strategies and clinical strategies with you at an early stage.

00:13:24 Speaker 2

Did I understand that correctly?

00:13:26 Speaker 1

Exactly, absolutely.

00:13:27 Speaker 1

So, we can see that the customers benefit a lot from it and are happy to discuss individual intermediate steps again and again, including the

00:13:34 Speaker 1

to make sure that you are on the right path can make sense.

00:13:37 Speaker 2

Mhm, what else would you have, since you are now the expert for clinical evaluations, what else would you give them, apart from clarifying the clinical strategy with you in order to get through as smoothly as possible with you afterwards, especially in the area of clinical evaluation?

00:13:55 Speaker 1

Mhm, so it's also an interesting topic, we can discuss it for hours and days, of course.

00:14:00 Speaker 1

What I can say from our experience is that individual points can be found again and again in the clinical evaluations that lead to a certain delay, to questions that we have to make.

00:14:16 Speaker 1

That would be very concrete, if you go into the clinical evaluation, for example the point, this goes a bit into storytelling, so as a buzzword, you often have the feeling that the manufacturer is actually not so

00:14:27 Speaker 1

it is very clear what he wants to get at or which direction he wants, but that he simply puts everything that is somehow possible and all data and all ways are packed into the clinical evaluation, so with the idea, then somehow the right thing will be there.

00:14:41 Speaker 1

So even if this is not a concrete M.

00:14:43 Speaker 1

D.

00:14:43 Speaker 1

R.

00:14:43 Speaker 1

requirement, then I can speak from my point of view, it makes perfect sense if it is clear from the technical assessment which regulatory route a manufacturer wants to take.

00:14:54 Speaker 1

So

00:14:55 Speaker 1

does it base its initial assessment on equivalence, does it have a legacy device, does the manufacturer reference MDC 2020 6 for legacy devices, or does it go for article 6110, i.e. for a performance-based evaluation without clinical data.

00:15:14 Speaker 1

So if the idea of the regulatory path through which the manufacturer wants to bring his product to market is clearly worked out, it helps a lot

00:15:24 Speaker 1

in order to understand and also to have points of attack, precisely where possible concrete problems could lie.

00:15:31 Speaker 1

So that's a very general thought regarding clinical evaluation, maybe in the sense that what a tip would be is if there are gaps, i.e. gaps in the clinical evidence or whatever, then in my opinion it's the worst idea to put it under the table.

00:15:53 Speaker 1

but then a way that normally leads to the goal much faster and is much less tedious would also be certain data, i.e. missing data, be it for indication groups for children, for example for certain disease spectrums, whatever,

00:16:17 Speaker 1

to describe this in concrete terms, to explain and to justify why one currently does not see such a relevant, such relevant gap in this case that it could not be enough for an initial certification and then within the framework of P.M.C.F.

00:16:34 Speaker 1

measures.

00:16:35 Speaker 1

So I could or would advocate that much more than that it is somehow veiled, ominously described, which usually only leads to increased inquiries.

00:16:46 Speaker 1

and then to an unnecessary delay, possibly.

00:16:49 Speaker 1

As a last point, if you talk about clinical evaluation, as I said, you could talk for days, but as a last point I could give one more thing.

00:16:58 Speaker 1

This is perhaps one of the great differences that von M.

00:17:02 Speaker 1

D.

00:17:02 Speaker 1

D.

00:17:02 Speaker 1

on M.

00:17:03 Speaker 1

D.

00:17:03 Speaker 1

R.

00:17:04 Speaker 1

also that we were able to communicate with M.

00:17:06 Speaker 1

D.

00:17:06 Speaker 1

R., where it is clearly defined what must be in the Clinical Aviation Plan and then also what must be proven in the Clinical Aviation Report.

00:17:13 Speaker 1

There will be a

00:17:15 Speaker 1

much greater focus is placed on the fact that in principle in the clinical evaluation plan, i.e. actually before the clinical evaluation itself is created, the manufacturer must define exactly what are the safety and performance parameters that the product wants to achieve, i.e. based on the state of the art.

00:17:35 Speaker 1

So in the end, what does my medical device have to be able to do, so that it can be considered state of the art and approved?

00:17:43 Speaker 1

And then he goes to the Clinical Aviation Report and then shows the data he has for these parameters in order to be able to prove these parameters and can thus conclude whether safety and performance thresholds have been reached or not.

00:17:59 Speaker 1

And present this very clearly, if possible with quantifiable data.

00:18:03 Speaker 1

They won't always be quantifiable endpoints, but the clearer you can show that, bleeding rate for some forklifts, for example.

00:18:12 Speaker 1

Below 3% based on state of the art and then in the C.E.R.

00:18:16 Speaker 1

there are 3 studies that show bleeding rate is below 3%.

00:18:19 Speaker 1

So this quantification, we need it as far as it is possible and that perhaps closes the circle again to the

first.

00:18:26 Speaker 1

So.

00:18:27 Speaker 1

there, even if, if there is a publication where the bleeding rate was 5%, it does not mean that the product cannot be approved under any circumstances, but if there is then a corresponding comprehensible justification, these were high-risk patients, were they elderly patients, were they patients with blood thinners or something, then in principle the data have to be discussed and that is perhaps the most demanding thing from an academic point of view.

00:18:50 Speaker 1

Often it's not just the results

00:18:53 Speaker 1

rump, but that you really do this deep dive into the clinical data.

00:18:59 Speaker 1

I think that's difficult for some, but that's what it is when manufacturers provide good and comprehensible justification.

00:19:06 Speaker 1

So then he is already very, very far and then this often saves multiple inquiries from the named body view.

00:19:15 Speaker 2

Wow, those were real insights.

00:19:17 Speaker 2

I will summarize very briefly again, these were ultimately 3 points, namely that was the topic of stringency, the

00:19:24 Speaker 2

transparency and traceability.

00:19:26 Speaker 2

I'll go through it again very briefly so that you are sure that I have understood.

00:19:29 Speaker 2

So the stringency was a clear route, as you sometimes call it, to have and also to pursue.

00:19:37 Speaker 2

So we also see that in our registration platform, you even have to click on it.

00:19:41 Speaker 2

So which route do you take now and that's when we notice how the discussions start.

00:19:46 Speaker 2

Yes, because

00:19:47 Speaker 2

the software says A.

00:19:48 Speaker 2

or B.

00:19:48 Speaker 2

or C.

00:19:49 Speaker 2

Yes, that means that it is suddenly relatively binary, then it is also forced, but it also creates exactly this clarity and depending on what you choose, it is then also other data that you have to provide.

00:19:59 Speaker 2

The second thing I thought I just heard was transparency.

00:20:04 Speaker 2

You said not to let anything fall under the table, that is, to have honesty and not to be guided by a fear that a,

00:20:14 Speaker 2

that a lack of data will inevitably cause the approval project to fail, but we always have the option, which of course needs to be weighed up, to provide data later.

00:20:22 Speaker 2

You have just entered the keyword P.M.C.F.

00:20:24 Speaker 2

and the third was traceability, i.e. the traceability between claims, medical claims, state of the art on the one hand and afterwards the evidence that you provide to ensure that you have actually reached the state of the art and these claims and that conditionally

00:20:43 Speaker 2

the ability to derive this conclusion scientifically from data, which of course requires a certain competence on the part of the manufacturer.

00:20:54 Speaker 2

So 3 mighty chunks that you just mentioned, which decide how well a clinical evaluation and ultimately the whole product will go through this process with you.

00:21:09 Speaker 2

Yes, they were real,

00:21:11 Speaker 2

valuable, valuable insights that you have given us here.

00:21:14 Speaker 2

If people want to contact you, have you already said, preferably via the website or have I heard?

00:21:20 Speaker 1

Exactly, so I think the easiest way would also be if you just try to google over the Internet, TÜV Süd M.

00:21:27 Speaker 1

D.

00:21:28 Speaker 1

R.

00:21:28 Speaker 1

or TÜV Süd Structure Dialogue, you are very quickly redirected to such a contact platform.

00:21:34 Speaker 1

The TÜV reacts within 24 hours at the latest, to any kind of request.

00:21:38 Speaker 1

So you can't be deterred,

00:21:40 Speaker 1

If there are a lot of crosses and queries in this initiation mask, the idea is that you will be forwarded to the right contact person internally as quickly as possible.

00:21:50 Speaker 1

But even if you put a cross wrong or if you just write in an unclear request, then we get in touch, then we ask, then it might take a day longer until you have found the right, the right place, so to speak.

00:22:02 Speaker 1

So that, I think, would be the easiest.

00:22:04 Speaker 1

Otherwise, Medical Device at [Tüvsued.com](https://www.tuvsued.com).

00:22:07 Speaker 1

is the e-mail address where you can reach TÜV Süd for any kind of inquiry regarding medical devices.

00:22:15 Speaker 1

Or I personally, Ulrich Nietzsche, can also be found, I think, if you search, you can also talk to or write to you and I will then also try to forward inquiries accordingly.

00:22:25 Speaker 2

Great, I'll summarize.

00:22:27 Speaker 2

So with you, Mr. Nietzsche, we had an expert from the field of clinics with us today, so not only an expert, but someone who could do the whole thing.

00:22:35 Speaker 2

Clinical Center of Excellence.

00:22:38 Speaker 2

They told us how they got into this area of the clinic at a notified body in the first place.

00:22:44 Speaker 2

They told us what the idea behind their new location in Denmark is and they gave us valuable tips to keep in mind if you can do well in clinical evaluations.

00:22:57 Speaker 2

They have said that they are not allowed to give advice.

00:22:59 Speaker 2

But that's why our clinicians are there to help.

00:23:03 Speaker 2

And I think we're always pretty well coordinated when it comes to that.

00:23:06 Speaker 2

Mr. Nitzsche, thank you very much for this wonderful interview.

00:23:10 Speaker 1

I was happy.

00:23:11 Speaker 1

Thank you very much.