The Medical Device File

With Prof. Dr. Christian Johner

Transcript

00:00:06 Speaker 1

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

00:00:16 Speaker 2

Congratulations, you've just heard the first words of the first episode of the Johner Institute's new podcast, Medical Device Insights.

00:00:26 Speaker 2

My name is Christian Johner and I would like to welcome you.

00:00:30 Speaker 2

In this 1.

00:00:30 Speaker 2

On the one hand, I would like to tell you what this podcast will be about in the future and on the other hand, I would like to discuss a very specific topic with you, the medical device file.

00:00:41 Speaker 2

This is a file that many confuse with technical documentation, but this is not exactly true.

00:00:47 Speaker 2

But first, let's talk about this podcast itself and how it came about.

00:00:51 Speaker 2

We came to this because we were simply asked to do so.

00:00:54 Speaker 2

We were specifically asked if we wouldn't do something like a podcast.

00:00:59 Speaker 2

At first we were a bit reluctant, but then we thought about our mission and that is to create exactly this knowledge for medical device manufacturers and to pass on this knowledge.

00:01:09 Speaker 2

And so it was clear that the answer had to be yes.

00:01:12 Speaker 2

We are podcast listeners ourselves and, for example, I now enjoy podcasts less on the way to work because I have a very short commute, but when doing sports or traveling.

00:01:22 Speaker 2

And so you can make very valuable times out of these times and that's exactly what

00:01:27 Speaker 2

we would like to guarantee you with this podcast as well.

00:01:30 Speaker 2

We want to help you as a medical device manufacturer to produce the best and the most correct and the safest products for the market and also to monitor them there.

00:01:43 Speaker 2

However, we would now like to address not only the manufacturers as a whole, but also the individual people and give help for their careers, for personal development, because after all, it is about people and not primarily about companies.

00:01:56 Speaker 2

We would like to keep your focus very narrow, namely on medical devices and their context.

00:02:02 Speaker 2

Of course, we will focus on regulatory requirements and approval, but we want to do more than just name regulations.

00:02:10 Speaker 2

Instead, we want to give very specific tips on admission.

00:02:13 Speaker 2

We would like to show in concrete terms how these regulations are implemented in practice.

00:02:18 Speaker 2

And that means we want to show and contribute to the better development of these products,

00:02:24 Speaker 2

to check, to operate risk management, to wind software, but also to understand the market in which these products are to be sold afterwards, to be applied.

00:02:35 Speaker 2

And this must also address the issue of health care as a whole.

00:02:39 Speaker 2

The focus is therefore on the world of medical devices.

00:02:43 Speaker 2

We would like to address the medical device manufacturers above all, but also their service providers, authorities and banal bodies.

00:02:51 Speaker 2

I will be the one who is the master of this show, but I will regularly consult interview partners.

00:02:57 Speaker 2

These can be the experts from your own institute.

00:03:01 Speaker 2

But we will also try to bring in external partners, interview partners, for example from research, politics or other manufacturers.

00:03:10 Speaker 2

So, if you have an exciting topic that you would like to talk about, please feel free to contact me.

00:03:16 Speaker 2

We plan this broadcast for about 5 to 15 minutes

00:03:20 Speaker 2

length and would like to offer it once a week.

00:03:24 Speaker 2

I think that's a good time and a good frequency, so that you can get information on the way to work and get the latest medical device insights.

00:03:35 Speaker 2

So we want to get to the point, pursue the clear goal of helping you as a manufacturer to manufacture the precise products and to get through audits and approvals with them without any problems.

00:03:48 Speaker 2

And this brings us to the second topic of the medical device file.

00:03:52 Speaker 2

This file does not equate many with the technical documentation quite correctly and that is not entirely true.

00:03:59 Speaker 2

And it is precisely these differences that we will now briefly talk about.

00:04:03 Speaker 2

The medical device file is an invention in a way of 13,485 in its very latest edition, the 2016 edition.

00:04:13 Speaker 2

And there in chapter 423 it is demanded,

00:04:16 Speaker 2

that manufacturers must prepare files per product type or at least per medical device group.

00:04:24 Speaker 2

What the difference between a type and a group is, we'll take a look at in a moment.

00:04:29 Speaker 2

The standard also specifies what this file must contain.

00:04:33 Speaker 2

This includes a description of the medical device.

00:04:36 Speaker 2

You have to describe, yes, how to use it, i.e. what the intended use and what the intended purpose are, also information on labeling and instructions for use.

00:04:46 Speaker 2

must be there.

00:04:47 Speaker 2

But other documents also belong there, such as specifications, i.e. specifications of the product, but also specifications of procedures.

00:04:57 Speaker 2

Specifically, they hope for a specification of the processes for production, packaging, storage and distribution.

00:05:05 Speaker 2

But other methods are also to be specified, namely specifically for measurement and monitoring.

00:05:12 Speaker 2

So you would have that in the manufacturing process, for example,

00:05:16 Speaker 2

that the quality of the products and the correct production are measured or monitored.

00:05:22 Speaker 2

And as applicable or appropriate as the standard writes, one should also describe the requirements for the installation or the procedures for maintenance.

00:05:33 Speaker 2

So that's a total of 6 points that the 13,485 gives us.

00:05:39 Speaker 2

However, it is important to know that the auditors do not usually oppose these

00:05:45 Speaker 2

6 points, but against the so-called Practical Guide.

00:05:49 Speaker 2

The Practical Guide is a document that has also been issued by ISO and that you can think of as a kind of instruction manual, in this case for 13485 2016.

00:06:01 Speaker 2

It is therefore comparable to ISO 24 971, which also specifies how ISO 14 971 should be used,

00:06:12 Speaker 2

or comparable to IEC 62 366 dash 2, which gives practice and implementation tips for the corresponding IEC 62 366 dash 1.

00:06:24 Speaker 2

Yes, and my tip would be that you get this Practical Guide from the ISO website, because our auditor always has this document under the table when he comes to us to audit us.

00:06:36 Speaker 2

This Practical Guide goes over the

00:06:39 Speaker 2

requirements that we now have in ISO 13485, at least as far as the level of detail and concreteness is concerned.

00:06:49 Speaker 2

For example, ISO 13485 says that the product must be specified.

00:06:57 Speaker 2

The Practical Guide goes on and says, yes, we also want to see the specification of the software or we want to see what materials are used in this product.

00:07:08 Speaker 2

So it's

00:07:09 Speaker 2

more granular, more concrete than the specifications in the standard itself.

00:07:14 Speaker 2

If you think it corresponds to the technical documentation according to MDR, you are not wrong, but it is not quite true.

00:07:23 Speaker 2

The MDR is much more granular in many places, but it also has requirements that go beyond that.

00:07:31 Speaker 2

An example would be the requirements for postmarket surveillance,

00:07:36 Speaker 2

it explicitly mentions only the MDR.

00:07:38 Speaker 2

This doesn't really appear in the Practical Guide either.

00:07:42 Speaker 2

Test results, i.e. not the procedures, but the results of these tests, will also be expected in the technical documentation according to MDR or IVDR, but not necessarily maintained as part of the medical device file according to 13 for 85.

00:08:00 Speaker 2

We have done the work and met the specifications of the

00:08:04 Speaker 2

ISO 13485 with those of the MDR to the technical documentation, i.e. in accordance with Annexes 2 and 3.

00:08:14 Speaker 2

And my tip would be that you take a look at this comparison in our technical article, which we have published on our website, we have even prepared it for you as an Excel list.

00:08:26 Speaker 2

download.

00:08:28 Speaker 2

If you look at this Excel list, you will even find a third

00:08:32 Speaker 2

document type or the third type of file, which is the files according to the FDA.

00:08:39 Speaker 2

Strictly speaking, you would even have to differentiate them into 3 acts, because the FDA knows both a Design History File and a Device Master Record as well as a Device History Record.

00:08:52 Speaker 2

So it even has 3 different file types.

00:08:55 Speaker 2

The medical device record corresponds most closely to the Device Master Record.

00:09:02 Speaker 2

but also contains some elements of the Design History File.

00:09:05 Speaker 2

Yes, so you know that, we have different types of files, but that doesn't mean that you have to create them all at the same time, but you will always go and reference them.

00:09:17 Speaker 2

So, you have existing documents and they have to form the superset of all these files, so to speak, and then in the medical device file you would then reference these documents in each case.

00:09:30 Speaker 2

Now ISO 13485 allows us to generate this medical device file not per medical device type, but per medical device group.

00:09:41 Speaker 2

And to understand what she means by that, let's take a very quick look at this definition of the medical device group.

00:09:48 Speaker 2

The standard defines it as a group of medical devices manufactured by or for the same organization and which have the same basic design and performance characteristics

00:09:59 Speaker 2

in connection with safety, intended use and mode of action.

00:10:07 Speaker 2

This may sound a bit familiar now and one or the other thinks, ah, that's exactly what the MDR wants to summarize with the basis UDI DI.

00:10:17 Speaker 2

And this thought is also correct, but the MDR and IVDR are a bit stricter when it comes to grouping products into groups, let's call it in general,

00:10:29 Speaker 2

.

00:10:30 Speaker 2

Both the medical device group according to ISO 13 485 and all medical devices on a common basis UDI-DI must have the same purpose.

00:10:43 Speaker 2

In both regulations, too, the design, which also speak of design, and the performance characteristics must be the same, whereby the 13 485 even reduces this to the characteristics in terms of safety.

00:10:59 Speaker 2

But what the MDR also demands, at least that's what it says in contrast to 13,485, is that these products must also be comparable in terms of manufacturing and production.

00:11:10 Speaker 2

Yes, that is, the requirements for equality are somewhat higher for the MDR and IVDR than for the 13 for

85. Nevertheless, I would say, as a good rule of thumb, everything that a common U.D.I.D.I.

00:11:24 Speaker 2

they can also be assigned to a medical device group with a clear conscience

00:11:28 Speaker 2

.

00:11:29 Speaker 2

My tip to you, the first one would be to take a look at the technical article and download this comparison list.

00:11:37 Speaker 2

Secondly, get the Practical Guide, because the auditors also use it, and then you might do a gap analysis to make sure that your medical device file, which may only be available as a reference document, which then refers to other documents, actually contains all the elements.

00:11:58 Speaker 2

if you've done that, I think you're in a pretty good position.

00:12:01 Speaker 2

If you still need help creating your documents or checking your documents for compliance, just let us know.

00:12:10 Speaker 2

Use our free micro consulting, ask your questions, then we can help you very quickly and very gladly.

00:12:17 Speaker 2

And that was our very first podcast.

00:12:19 Speaker 2

We looked at two topics, namely: What is this podcast itself?

00:12:23 Speaker 2

We said a weekly episode

00:12:27 Speaker 2

with new knowledge, with Medical Device Insights for medical device manufacturers, which should take between 5 and 15 minutes.

00:12:34 Speaker 2

And the second thing we looked at was the medical device file.

00:12:38 Speaker 2

We got to know what the 13 for 85 should contain, but we also saw that the Practical Guide gives us better guidance on what this file should include.

00:12:50 Speaker 2

However, this file is less extensive than what the M.D.R.

00:12:55 Speaker 2

as technical documentation, although it is not entirely correct to say that technical documentation is rather the superquantity.

00:13:04 Speaker 2

But there are also a few documents that are not so explicitly required by the MDR, but are part of the medical device file.

00:13:11 Speaker 2

I also pointed out the FDA with its 3 different file types and recommended that they download this comparison list, which we can download on our website

00:13:24 Speaker 2

free of charge and that you are doing a gap analysis to ensure that your central documents, i.e. both the technical documentation and your medical devices, are complete.

00:13:37 Speaker 2

And complete essentially means that they contain the respective links.

00:13:43 Speaker 2

Yes, and with that I thank you for listening and look forward to seeing you again next week.