Johner Institute

Webinar on the FDA

With Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

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

00:00:17 Speaker 2

The approval of medical devices in the USA is not getting any easier.

00:00:21 Speaker 2

Many of you have probably heard of the 5 10 K.

00:00:23 Speaker 2

Procedure already heard or should I rather say of the 5 10 K.

00:00:27 Speaker 2

Procedure.

00:00:28 Speaker 2

Some

00:00:29 Speaker 2

You know the PMA Approvals or the Denovo process, but do you also know the IDE and the HDE?

00:00:37 Speaker 2

Have you heard of the programs, such as the Breakthrough Program, the Safer Technology Program, or the Presearch Program?

00:00:44 Speaker 2

It's not so easy to keep track of everything.

00:00:47 Speaker 2

And that's exactly why we've planned a free one-hour webinar on exactly this topic.

00:00:54 Speaker 2

And in this podcast

00:00:55 Speaker 2

I would like to briefly report on who this webinar is aimed at, what the goals of this webinar are and what topics we will cover or answer questions.

00:01:07 Speaker 2

Let's start with the target group.

00:01:08 Speaker 2

This webinar is intended for all persons who are obviously involved in the approval of products in the U.S.A.

00:01:14 Speaker 2

what to do.

00:01:15 Speaker 2

So these are in particular the regulatory affairs and the quality managers.

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But we also talk about business development

00:01:24 Speaker 2

people, i.e. managing directors or product managers, and in a certain way also project managers, because they have to know what such approval means in terms of time, costs, in order to be able to plan accordingly.

00:01:36 Speaker 2

The goal of this webinar is to give you an overview, i.e. to give you an overview of the regulatory requirements, but also to help you find out when your product counts as a medical device at all.

00:01:51 Speaker 2

That is, how it must be qualified

00:01:53 Speaker 2

And then also in which class it falls, i.e. the classification.

00:01:57 Speaker 2

We would like to give you an overview of the various approval procedures, so that you can choose the procedures or the procedure that is possible for your product and your product class, but which also helps you to achieve your goal of bringing this product to the U.S. as quickly and predictably as possible.

00:02:16 Speaker 2

market.

00:02:17 Speaker 2

As 1 of these

00:02:19 Speaker 2

Of course, we also provide the Five Ten K.

00:02:21 Speaker 2

or the Five Ten K.

00:02:22 Speaker 2

proceedings, also provide an outlook on further proceedings.

00:02:26 Speaker 2

We also want to report on such typical problems and help them avoid the ones that we always notice manufacturers suffer from, whether it's when preparing regulatory documents, submitting or communicating with the F.D.A.

00:02:41 Speaker 2

Yes, and we would also like to, or if I say that we are concerned above all with my colleague Lucas Salvatore,

00:02:47 Speaker 2

give you answers to your specific questions and you can submit these questions in advance.

00:02:53 Speaker 2

You can see where you can do this in the descriptions of this podcast below.

00:02:58 Speaker 2

Yes, I would say, have a first overview of what this webinar will be about.

00:03:04 Speaker 2

As I said, it will be an hour, will be on Thursday, 26.10.

00:03:09 Speaker 2

at 4:00 p.m., and then take exactly one hour.

00:03:14 Speaker 2

You can find more information on the website linked below.

00:03:19 Speaker 2

But for those who don't see it right now, that's www.jona-institut.de/pages/FDA-Webinar.

00:03:29 Speaker 2

I'll repeat it again very briefly: www.jona-institut.de/pages/FDA-Webinar.

00:03:38 Speaker 2

I am already looking forward to welcoming as many of you as possible to this webinar.

00:03:44 Speaker 2

That we can help you achieve your goals there, namely a fast and precise approval and also give you a few tips on the audit guarantor, because of course we can't discuss everything in a one-hour webinar.

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And that's why we have provided you with additional content in the Auditgarant, with which you can then really reliably create your approval documents and thus ultimately get your products onto the market just as reliably.

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I look forward to seeing you on

00:04:14 Speaker 2

Thursday, 26.10.

00:04:16 Speaker 2

at 4:00 p.m.

00:04:18 Speaker 2

See you then.