Johner Institute

What is ASCA, and who does it help?

With Mario Klessascheck, 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.

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1 of the most important goals of all our medical devices, regulations concerns patient safety.

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And play an important role in this whole construct

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the test houses, which are supposed to ensure or contribute to ensuring that no unsafe products are placed on the market as a result of their testing.

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Now, however, in this round robin test in the context of biocompatibility, for example, we have found that these results of the test houses are not all the same, to put it mildly.

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So the question arises, who actually tests the test houses?

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So, who ensures their quality?

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And that's exactly what I want to talk about today.

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Now not in the context of biocompatibility, but in the context of electrical safety and M.V.

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And who better to call in than Mario Gläserschek.

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Mario, welcome.

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For those who don't know you yet, maybe a short two-sentence introduction, so they know who you are.

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Hello, good afternoon.

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Exactly.

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My name is Mario Gresaschek.

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At the Jona Institute, I am responsible for the entire topic of safety of active medical devices, especially medical-electrical devices, but also I.V.D.

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devices and support manufacturers in this context with all these questions about the development of safe medical devices.

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And we then also accompany them during the exam.

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Yes, that means you are someone who also works a lot with the test laboratories.

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And yes, let's get straight into the exciting question.

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Who actually inspects the test houses?

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Who ensures their quality?

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Yes, exactly, in principle, test houses must also maintain a quality management system, just like manufacturers.

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In this case, however, this is ISO 17025, which is the pardon that medical device manufacturers know from ISO 13485.

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And in principle, a test house must first meet this quality management system and there are national

authorities that do this

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Test houses.

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In Germany, for example, that would be the D.A.K.K.S.

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or in U.S.A.

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these are so-called accreditation bodies, which then certify and also accredit the examiners.

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I then have to accredit the test house for certain standards, so it's not a blanket accreditation, but precisely for these test standards, where they then also offer the tests to the manufacturers, they have to create proof that they can do this in a suitable way.

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And in this context, you told me, there is now something like

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ASCA, tell us very briefly what this ASCA is and who it affects.

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So, ASCA definitely affects the test houses, the manufacturers and also the test centres.

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ASCA was founded with the background of the F.

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that test houses do not have the quality of the test reports of test houses or this also applies to the documents from the manufacturer, so that a reviewer at F.

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can check the documents without being asked.

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That is, these,

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these errors lead to long test times, to long test runs, which in turn also costs a lot of resources at the F.D.A.

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and you want to avoid that.

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And the actual I.C.

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ASCA's mission is to ensure that safe, effective and high-quality medical devices are available to patients without unnecessary delay.

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So the 2 points that the program concerns is actually improvement of safety and also improvement of efficiency in testing.

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O.K., what not yet

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is what ASCA actually means.

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Ah, exactly, the term ASCA is an abbreviation and means Accreditation Scheme for Conformity Assessment and this accreditation can be used by testing laboratories at the F.D.A.

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and that would mean that the F.D.A.

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checks the documents or the files that the manufacturer submits in a different way than it would do in the standard procedure.

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K., now we have to look at it piecemeal, so maybe from the point of view

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of test houses.

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So, what do they have to do to get this ASCA accreditation in the first place?

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And then the follow-up question will be, what does it look like from the manufacturer's point of view if they work together with an ASCA-accredited test house?

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But perhaps first the process from the point of view of the audit house.

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Exactly, i.e. the test house that wants to offer this test or procedure.

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has to register, so to speak, with the F.D.A.

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accredited.

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To this end, the F.D.A.

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An accreditation program has been set up, which in principle takes ISO 17 0 25, which is written rather generally for the test houses and there very specifically into these requirements for this Q.M.

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system, i.e. further activities that are to be carried out.

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So examples are, for example, in training, i.e. that the test house undertakes to maintain staff, that the requirements of the standard

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or even the basic concepts in which 60601 really understands essential performance characteristics in the area of basic security.

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It is also very important in this context that there is continuous training, not just a one-off training, all of that has to be proven.

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This can also be done through equipment, knowledge of verification, validation methods, and also through the management of the documentation of test plans.

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There, the F.D.A.

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very detailed requirements and activities for the test houses, which are then checked by these accreditation bodies.

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This means that these test houses are then also monitored.

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Who does that then?

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So, I suspect that it is not the F.D.A.

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powers.

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No, she does that through these Accreditation Buddies, who themselves register with the F.D.A.

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for now.

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We would then have to notify in Germany and they would then get the recognition, so to speak, that they can test these test houses.

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K., so now you have described what

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From the point of view of the test house, so in the end it is another accreditation in addition to the 1725.

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You described that the specific requirements are now being added in the context of electrical safety and EMC and you mentioned as an example: training, but also test equipment and test reports, which have to meet these special requirements.

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And if you do all that and then you have accredited yourself, then you have made it as a test house.

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if we now look at the matter from the manufacturer's point of view, i.e. under the assumption that he has chosen an ASCA accredited test house.

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Exactly, we first have to distinguish which procedures are approved for this ASCA program at the F.D.A.

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So at the moment these are all manufacturers who have a Five Ten K.

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or the Denovo process or the well-known Premarket Approval or even the Investigational Device Exemption procedure.

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And at the moment this applies to the areas, including active

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medical-electrical devices, i.e. everything included under the 60601, the I.V.D.

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devices, but only the basic standard, which deleted 61010 1 and the procedure under ISO 10993 also applies to biocompatibility.

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And test houses that now work under this scope or that have used this standard for the products, so to speak,

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before they apply for the test, they would also say to a test house that they would like to apply for the ASCA procedure or that this or that should be tested under this ASCA regime.

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The manufacturer would then sit down with the test house and determine the strategy, the test strategy quite intensively and would then build a test plan in particular.

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The test plan is

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not as is more well-known, i.e. not as today, only concerning basic safety, for example with IEC 60601 deleted 1, but also just the testing of the essential performance characteristics, which has so far been done more or less on the basis of the documentation, if there was no special standard for it, prescribes testing, one would then just define joint tests, define test setup.

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The tester may even need equipment from the manufacturer so that he can carry out certain tests.

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Mhm,

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So, you have now corrected me, which was very important, to the effect that it is not only a matter that concerns electrical safety and EMC, but also according to other standards such as.

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60601 family.

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You have now explicitly mentioned the 16010 for the IVD and the 10993 for the whole topic of biocompatibility.

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Furthermore, you said that the test plans that are now being created can be a bit broader on the scope than they usually are and you said in particular that the essential performance characteristics would also be checked here, explicitly again.

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what do manufacturers get out of it now?

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Now, of course, we can say, O.

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K., it probably costs even more if you add such an aggregated test house to ASCA, because they will probably want to see extra money for it.

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What would be the reason that a manufacturer chooses such an ASCA accredited test house?

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Yes, so the F.

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promises a shortening of the testing time.

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When a manufacturer submits a submission fire, there is this acceptance review at the beginning.

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And once the file is accepted so-called, then the noun review begins and in this cycle a close communication with the manufacturers begins, in which things are then asked back, further documents are requested and this loop is shortened in particular by the manufacturer compiling a so-called ASCA Summary

Report, Test Summary Report, which then answers all these questions, that inspectors or reviewers in particular have.

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So that means that the examiner no longer looks at 280 pages of 60 601 test report, but only at the summary test report.

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This should speed up the time considerably on the part of the F.D.A.

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There are a few initial estimates of the costs.

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So the additional effort for the test laboratories is estimated at about 47 hours.

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So that would be a working week with us in Germany.

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And I've already heard estimated additional costs from customers who work in the U.S.A.

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have participated in the pilot out of about 10000

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Dollar or then Euro, as the case may be.

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Yes, it can pay off very quickly.

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So, if you assume that a product comes to the market only 4 weeks faster, I think it's more than 10000€ then.

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So, what was always very important, what you added to the additional requirements in a certain way, is also the form of the documentation.

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Yes, for the time being you already need what you have taken with you about competencies, about certain test aspects, essential performance characteristics.

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And now again very clearly, in this ASCA program we also have a standardized documentation, which is then filed or tuned so that it can answer the questions of the F.D.A.

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particularly well and particularly quickly.

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Of course, this now raises the question if I don‘t go to the U.S.A.

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wants to go, is there any reason at all to deal with this topic ASCA?

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That‘s a good question, because at the moment it‘s still in the pilot phase and the pilot runs exclusively in the U.S.A.

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It is planned to roll out the pilot.

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We do not yet know in what period.

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Couldn‘t find any information on the website either.

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So first of all, it affects manufacturers who mainly want to sell their product in the USA.

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K., then let‘s assume we have a manufacturer who wants to go to the USA.

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What would be the things he should pay attention to now?

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So apart from the fact that he is now choosing such an ASCA accredited laboratory, what are the tips you would give them?

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What are the pitfalls that manufacturers should avoid at all costs?

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Yes, so a very important aspect is the documentation.

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This means that the auditor will have to go much deeper into the documentation to understand how the

entire security concept of the product is structured, what the performance criteria really are.

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The essential performance characteristics should not only have made an assertion, it has or has no essential performance characteristics, but they should just be derived.

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Limits must be set for the essential performance characteristics so that clear test criteria can be derived.

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It takes a more detailed product description than we usually see, down to the technology, so that you also understand the technology better, the advantages and disadvantages of a technology.

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It is even said that the test laboratories also write in the report whether a test had to be repeated on the product.

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So that means that if you have to constantly make improvements, it would appear in the test report.

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So in this respect, you should really only go to the test laboratory when you are sure that the product

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passes the test without further adjustment.

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These are things where more information is required, so that someone understands the product faster and more comprehensively.

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Mhm, so that means that what you should pay attention to is please have your product properly documented and this applies not only, no, probably to the system architecture, but also to the whole topic of risk management, because without that we would not be able to derive these limits, these acceptance criteria, at all.

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So that means 2 of your main tips are: Do a clean risk management and submit extensive documentation so that you don‘t see all these reiterations in this ASCA test report afterwards, which would then not be an advertising measure, in the direction of U.

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Any other tips?

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Yes, so of course I have already checked this for our documents, how we create it.

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In particular, the intended purpose, which also specifies the environmental conditions, that's where we are

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very precisely.

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So we don't just look at the purpose, the intended use statement, but also at all the people and roles and environmental conditions.

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That's an important thing and our risk analysis actually already covers these points.

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And in the area of system architecture, we have actually already included these points that want to be seen there.

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In addition, the ASCA, i.e. the F.D.A.

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in the case,

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further guidance documents are available, which once A.

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for the test houses, but also B.

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for the manufacturers, which then also contain suggestions for the templates, for example, how this ASCA Test Summary Report, which must be submitted, should then look like.

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Yes, you have already built a bridge to the last question, namely the question of how we can help.

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So what do you do, what does your team do,

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so that this whole process really goes from the application to the test house afterwards to the release from the F.

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E. that it runs smoothly smoothly.

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Yes, we would help the manufacturers to apply for this ASCA, the ASCA procedure and would of course help very much in the area of documentation to create the documentation in such a way that it can then be read by the inspector without further queries.

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Of course, questions arise, that always happens, so of course we also support you in answering the questions.

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So in particular, we are focusing strongly on what you have already mentioned, risk management, really looking at whether all aspects of the standard are also covered, above all that such blanket statements are then not included, how does the 60 601 have to be fulfilled as a risk mitigation, that will no longer be enough.

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The examiner now wants to understand what exactly is happening.

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And would we then document this accordingly in the architecture or safety concept and also check whether the documentation is complete and correct in the direction of functional safety?

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Yes, and above all, you help if you and your team determine that there are still gaps in it, that any risks are not recognized and sufficiently mitigated, you then also help to change the system architecture in such a way as to ensure functional safety.

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so that it is not a problem afterwards, because in the end it is not only a question of documentation, but it is a question of the product, which can then be found in the documentation.

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Yes, great, Mario, thank you very much.

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So all manufacturers of medical devices who want to go in the direction of U.S.A.

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want to develop and want to or have to involve a test house, we encourage you to take a look at this ASCA process, especially if you want this to be

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approval procedures work a bit faster.

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And if you need support, Mario Gläserscheck and his team are there for you.

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Mario Happ, thank you very much.

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Gladly, Christian.

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Thank you very much.