Johner Institute

International Approval

With Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

Medical Device Insights.

00:00:08 Speaker 1

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

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Many manufacturers want to register their products internationally.

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Sometimes they are afraid that there may be problems, e.g.

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delays the approval or that it does not take place at all.

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What many people don‘t realize is that not being admitted is not even the worst case.

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I would now like to discuss with my colleague Luca Salvatore what can happen during international approval and how these difficulties can be avoided.

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Hello Luca, can you introduce yourself very briefly so that our listeners know who I am allowed to talk to here?

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Hello Christian, dear listeners.

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Yes, I‘m Luca Salvatore and I help our clients at the Jona Institute

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in the approvals of their medical devices outside Europe.

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What are these countries, in particular, in which companies are trying to register their products?

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So, of course, we are now talking mainly about companies that come out into the world from the German, Austrian and Swiss countries.

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What are the countries in the world where you ask for support the most?

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This is exactly what we asked our customers in our major survey on international approval in March.

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At the top of the list were the M.D.

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Sub-countries, i.e. this includes the U.S.A., Canada, Brazil, Japan and Australia.

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Yes, there is also a great demand for approval in China, Russia, the Euratic Union and we are also receiving more and more inquiries about Saudi Arabia.

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If you were to compare these countries with each other now, you can tell in which countries approval is the most difficult.

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You can say that, yes.

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So one of the most difficult, the most complex is certainly the approval in China, Russia, Japan is not so easy either.

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The problem here is that there is mainly product technology

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tests in the countries are required, even if the products have already been developed and tested according to international standards.

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Yes, that‘s the special feature of these countries.

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In other countries, the E.U.

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Declaration of Conformity, i.e. the C.E.

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labelling.

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Then you have a rather simple registration procedure ahead of you.

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You have now actually mentioned 2 things, 2 extremes.

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On the one hand, countries,

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those with which one can be treated with the C.

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Signs are already coming a long way, other countries where you have to repeat the tests again, the exams in part.

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Are there any other differences that you have to consider when it comes to registrations, i.e. where the registration is particularly different compared to the E.

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distinguishes it in particular.

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Yes, there are.

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First of all, one could assume that the requirements for approval are quite similar internationally.

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So in principle, it's always about proving safety, efficacy and clinical benefit.

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Similar to Europe, there are also international country-specific basic requirements, compliance with

which you can prove exactly that.

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What are the biggest differences?

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Internationally, there is often no conformity assessment that the manufacturer carries out independently, as is now the case in Europe.

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Possibly for higher-class products with the involvement of a notified body.

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This means that there is an approval, registration by an authority.

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That's a big difference at first.

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Then, as I have already mentioned, for China and Russia, there are country-specific requirements for type examinations in the country.

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In China, for example, standalone software products also require product testing by an NMPA-accredited laboratory.

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This does not exist in the EU.

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In this case, you typically also need a local representative internationally.

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This means that he then takes over the approval on behalf of the manufacturer.

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This can be your own branch, but often it is the local sales partner.

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In this case, the international authorities often require a so-called Home Country Approval.

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This would now be a CE declaration of conformity for manufacturers in Europe,

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this must then also be proven by submitting the declaration of conformity, certificate of the notified body.

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And in addition, the so-called free sales certificate is then also required.

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By the way, you can now get one in Germany from your responsible state authority.

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Here is perhaps a little tip.

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It is therefore very important that you rely on these free sales certificates

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specify the destination country and also all variants that are to be covered by the registration or covered by the certificate in the destination country.

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If there is an error on this certificate, this can lead to enormous delays in approval.

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Then it should be mentioned that there are different requirements for the QM system, for example in the USA or China.

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That is,

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Your Q.M.

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The system must also meet these additional requirements or differences from ISO 13 485 and they should then also be used for an official inspection, for example by the N.M.P.A.

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or the F.D.A.

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be prepared.

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Oh, that's a huge list that you've given us here.

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One thing has aroused my particular interest, namely product testing in software.

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Can you tell us something about that?

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Do you have to disclose your source code for this?

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Yes, so you don't have to disclose the source code, but the software has to be tested completely in the test laboratory now in China, which is then an accredited laboratory of the N.B.A.

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Of course, the problem here is always that a laboratory employee is not necessarily a product expert and yes, not a doctor either.

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And

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this often leads to problems with these local exams.

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Here is always our recommendation that a product expert is really on site at least during the installation and also during the initial induction training.

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Now you have already mentioned many differences, so I'm thinking of the topic Q right now.

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system, to the topic

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Examinations of what we have just been talking about to these local representatives that we need.

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What would you say, what are the biggest challenges that companies are facing, or what do you perhaps feel are the biggest challenges when they want to register their products in the world?

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We also asked our customers this in our survey in March.

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Yes, and the challenges are multi-layered.

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The biggest problem is with

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the lack of knowledge of the national regulatory requirements and thus also the differences to the requirements in Europe.

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The big problem is simply finding the information, especially if the regulatory requirements are only available in the respective national language.

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Yes, if you go to Asia, it will be really difficult.

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It is also often unclear whether the product qualifies as a medical device at all,

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whether you have selected the correct class and which is the right admission procedure.

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K., what are the questions you are asked most often in this context?

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Quasi, if you were to write an FAQ, what would come with it?

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These were exactly these questions.

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So my product is a medical device in country XY?

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Which admission procedure do I have to choose?

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What would be a suitable comparison product, a predicate device?

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How much does such an approval cost?

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What are the official fees and how long does it take?

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It is also often asked what the language requirements are in the countries.

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There are typically requirements for the instructions for use, but other documents that you need for approval also have to be translated, sometimes also certified and legalized.

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Now you have just mentioned 2 points that are certainly of particular interest to many.

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How long does it take and how much does it cost?

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Could you perhaps show us 23 countries as an example of what it takes and what costs are that the manufacturers have to prepare for?

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Yes, according to our perennial favorite U.S.A., I assume that it is a product of a medium risk class.

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So class 2, there is the current procedure at the F.D.A.

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still the so-called 510K process.

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You can expect a roughly 10,000 euros official fee.

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You still have to register there and pay an annual fee.

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This then amounts to 5,000 euros per year.

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Then you have to consider, of course, the composition of the submission, the communication with the authority.

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is a certain amount of effort.

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If we provide support here, then the costs amount to around 15,000 to 20,000 euros, depending on the complexity of the product.

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How long does it take then, such an approval process, when you're talking about the USA right now?

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The approval procedure, i.e. from submission to the authority, you can expect to, let's say, 4 to 6 months.

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in a yes rather with a simple product with a yes suitable predicate device.

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In the case of complex products, in the case of systems, depending on queries from the authorities, this can sometimes drag on and take over a year.

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Are there countries where it is particularly expensive or takes a particularly long time to get your approval?

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Yes, China is at the top again.

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such a class 2 approval needs at least 18 months, but is more in the direction of 2 years and even there the official fee alone is already around 30,000 euros.

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Wow, that will be well thought out,

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whether you want to do that at all.

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What would be the most important tips you give companies to get their approval through as smoothly as possible?

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This means that the costs do not explode, that the times actually remain the planned ones, so that you don't get into other difficulties.

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What would you recommend that companies should do in most cases or maybe even in all cases?

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Yes, manufacturers should

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really think about their target countries quite early in the product life cycle.

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On the one hand, the documentation can already be adapted accordingly so that it meets the requirements of the target countries.

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In the same way, the products can then be designed in such a way that they already meet international standards, local, deviating normative requirements.

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then you should also think about the order of admissions, i.e. in which countries you want to approach which admissions.

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Some countries, as I have already mentioned, rely on the CE marking, such as Australia.

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Otherwise, it is important to establish solid technical documentation.

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This is the basic prerequisite for a smooth admission.

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An international format is always recommended, such as the STAT or the newer format of IMDRF, IMDRF, the Table of Contents format.

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Do the documents have to be translated when you are talking about the table of content and the associated technical documentation, do we need them in the national languages or is English sufficient?

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Again, this varies from country to country.

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In some countries, the entire technical documentation has to be translated, in others only a fraction of it is sufficient.

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Now like the instructions for use, the labeling, other countries also accept a complete English submission.

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Yes, now I had just interrupted you, you were about to give tips.

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So if I may recap very briefly, you said to think about which countries you want to go to at an early stage.

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You said to create as complete a technical documentation as possible, which covers the requirements of all countries and also to think about the order in which market approval is then sought.

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Now, as I said, I had interrupted you.

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What else would you like to give our listeners?

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Yes, it is very important to have the translated submission file

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at best.

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Again, for example, China, where your local agent, the authorized representative, creates the file and then submits it to the authority.

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Errors can then become ingrained there, for example certain performance parameters, which have then been incorrectly translated.

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Nevertheless, the authority gets this Chinese filing file and if there are errors in it,

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you have approved a, yes, the wrong product, so to speak.

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This can then lead to trouble, later during an inspection and can then also mean that you need a change approval, i.e. a change of certificate.

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Even after admission, i.e. when you hold the certificate in your hands, you should really check it for correctness and completeness.

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They should also monitor their certificates.

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In many countries, these are only valid to a limited extent.

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Also another problem, design changes, yes, which you then make after the initial approval.

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Here, each country also has specific requirements.

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When is a design change notifiable?

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When is a re-registration necessary or a change registration?

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you need to find out about that, ideally, and then you get this information from your local agent.

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I had just said in the introduction that a non-approval, which sounds bad enough, is not the worst case.

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What can happen with the international approval of products?

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If you as a manufacturer don't have a

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local branch in the target country, then the local sales partners often take over the approval.

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On the one hand, this is tempting, because then typically no additional costs are charged.

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However, you also have to be aware that you will then provide this sales partner with the complete technical documentation.

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This means that he has access to all data, including those relating to the product.

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And we had seen cases where this data was really stolen, so to speak, i.e. theft of intellectual property, that products were then copied in the countries.

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And so it can happen that the company flies completely out of the market.

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Another problem in disputes with the sales partner is that he no longer releases certain documents that have been submitted, such as the certificate.

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And that you then have considerable problems and time delays with product changes and modification approvals.

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That can also lead to trouble with the authorities, right?

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Exactly, that can then also lead to trouble with the authorities.

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Yes, thank you very much, Ducat.

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That was quite a lot.

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so that our listeners have it all again.

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A super, super short summary.

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We had talked about which countries companies go to the most.

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You said that these are mainly the M.

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Subcountries, but also China and the Russian Federation.

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You have described in which countries it is also one of the most challenging.

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Here, too, China has taken a prominent place.

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We talked about the

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differences in approval, especially compared to the EU.

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Among other things, you also spoke about this product testing, which is still necessary, that there are different requirements for local people, for authorised representatives, that in other countries we do not have a declaration of conformity by the manufacturer, but a real approval.

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These were examples of points you mentioned.

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Then we moved on to the biggest challenges facing manufacturers

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You mentioned above all a lack of knowledge of the regulations, which you first have to find and then understand, which proves to be particularly difficult when they are formulated in the respective national language.

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Another point, before which they sometimes find this a challenge, was the question, is this a medical device at all and if so, in which class does it fall?

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And you also said that this qualification and classification 1 of the

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would be one of the most common questions you would be asked.

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Also the question about the predecessor product, about the Predicate Device and you also provided us with a few answers to the question of how long it takes and what it costs and how it differs in some countries.

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And finally, you helped us with a few tips, namely I would like to remind you very briefly to determine at an early stage which countries you want to go to, also in which order to create a solid technical documentation and then

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I also found the tip from you very exciting to have a back translation done to be sure that the right thing is really submitted.

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And at the end, you drew our attention to a very important point, namely the dependence on the dealers and the dangers that you run with them, namely the theft of intellectual property on the one hand and the high level of dependence that you always have with it on the other.

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Maybe Luca, one last thing

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Tip, maybe one last thing to watch out for or that is a typical difficulty.

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Yes, I have 2 more tips about the language problems, i.e. the wrong translations or incorrect translations

of the submission documents, we had already spoken.

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However, there are often misunderstandings with the local partner, whether it is the sales partner or an independent company that

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are often not sufficiently proficient in German or English.

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We also had a current example: a very complex product with many variants that should be grouped together as much as possible in order to save costs and thus get by with few certificates.

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The product, the complexity, was not properly understood and so only a fraction of the products were really registered.

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Then it is also the case that often

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the information for the submission file can only be requested in bite-sized chunks.

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This means that completely new requirements suddenly appear.

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You don‘t see an end at all.

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You should really choose a good registration partner.

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I think that‘s also a very important tip.

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Another problem with the technical documentation and the associated redundancies.

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What we often see is that manufacturers who then operate internationally then create several variants of their technical documentation on a country-specific basis.

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Then, for example, they have a purpose in five different variants or a requirement specification in five different variants, and of course they all have to be maintained.

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This means that if something elementary changes in the intended purpose, they all have to be followed.

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in some cases, however, these files are then also with the local representative and that is exactly what does not happen.

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That means they really do have a lot of document corpses.

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This means that there is almost no way around the fact that you really use a tool that manages this information centrally.

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Yes, maybe another tip from my side, first of all thank you very much, Luca, what I would recommend to our readers and our listeners.

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Luca has written a few articles on specific approval procedures for individual countries, for example Saudi Arabia, China, Brazil, some more.

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So my tip would be to read these articles, which we have also linked to you below in the podcast and if there are any questions, he and his team will be happy to help you.

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Feel free to take advantage of our free micro consulting.

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Yes, Luca, thank you very much again and see you soon.