Johner Institute

Usability in medical devices

With Dr. Nils Becker, Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

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

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We receive several 1000 inquiries every year via our microconsulting.

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Above all, of course, there are questions about the regulatory requirements,

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of medical devices, but also how to fulfill them elegantly.

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And that's why we decided to set up a series in which we want to answer these questions.

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And the first episode of this podcast series will deal with the topic of usability.

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And that's why I asked my colleague, Dr.

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Nils Becker so that he can give us tips on how we meet the regulatory requirements for medical devices, what difficulties arise again and again and

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he should just report from the sewing box, because as someone who does it full-time, I think he knows all the tricks and tricks.

00:01:04 Speaker 1

Hello Nils, if you could perhaps say 2 sentences to yourself very briefly, that our listeners also know who I am dealing with here and can assess what you are doing all day.

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Yes, hello Christian, I'm happy to do that.

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Yes, what have I learned?

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I studied biology in Würzburg and also wrote my doctoral thesis in a molecular neurobiological topic,

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That was exciting basic research, but I lacked a bit of application relevance and that's why I started a job at the in-vitro diagnostics manufacturer after my doctorate, where I came into contact with the regulatory world for the first time.

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So quality management and creation and maintenance of technical documentation, but also usability engineering was one of my tasks and I really had so much fun with it that I wanted to focus completely on this area and so 5 years ago,

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yes, so almost 5 years ago I ended up at the Jonah Institute in the Usability Team.

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I am now also in charge of this department, which I am really very happy about, because I get to deal with new, exciting medical devices or their user interfaces and their usability every day.

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Ah, that's cool, but the right man in the right place.

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Yes, I would say, no, now let's jump right in.

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What would you say, what are the difficulties that manufacturers are now facing the most in this area, in your field?

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fight, so what annoys them or what, with what, where do they often have a hard time, what are the questions that keep coming up with you?

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Mhm, yes, I would say that the biggest difficulty is actually that many manufacturers don't know exactly what they really have to do to meet the regulatory requirements for usability engineering and, of course, how they can do it as efficiently as possible.

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So, how and to what extent does the usability engineering process actually have to be applied?

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We have many manufacturers of existing products who have a usability file, but it hasn‘t been updated for years and doesn‘t really correspond to the state of the art.

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But even many start-ups that have to deal with the regulatory world for the first time simply don‘t know exactly how they really have to do what now.

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In other words, very specific questions that reach us from time to time, whether they are from large corporations or start-ups, for example, how exactly

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do I now have to characterize my intended users, how do I combine my higher-level risk analysis with the usability-related risk analysis, what are the hazard-redated-use scenarios anyway and how do I determine them, how often and with which methods do I have to evaluate formatively and what do I have to document and do I have to do summative usability evaluation and if so, with which method, with how many participants and in which countries?

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Yes, for God‘s sake, that‘s the whole process, isn‘t it?

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That‘s the complete process.

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So we really get questions from start to finish, which I can understand well, because many things are simply not clear from the regulations, how you really have to meet them.

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Yes, and yes, the questions I have just mentioned are actually often the things that notified bodies complain about.

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So often the users are too generically specified, there is then either only as a doctor or nurse in the usability file,

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But of course, it would also be important to mention what specialization the healthcare professional has, for example, what training, what previous experience he usually has or should have.

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Yes, yes, in between with the tips, step by step, so the first thing was now, so to speak, what challenges do we have at all, what difficulties do they have and that was really enough, almost over the entire life cycle and new products for old products at small manufacturers, at large manufacturers.

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Before we maybe get into it, because there, there was what summed it all up, it's a regulatory issue.

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So, how, how do I fulfill all this and maybe we'll take a quick look at it again.

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So, what regulatory requirements are there, what do the manufacturers have to meet in concrete terms and then we'll go into your tips again.

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That's right, you say you say it, so it's regulatory requirements that manufacturers have to meet.

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And in the E.U.

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this requirement comes from the M.D.R.

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or I.V.D.R.

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So manufacturers simply have to meet the basic safety and performance requirements from other 1.

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I have brought here a short quote from other 1 paragraph 5, which I would like to read out briefly to make that clear.

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So I quote: ‚In eliminating or reducing the risks of application errors, manufacturers must

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reduce as far as possible the risks arising from the ergonomic characteristics of the product and the environment in which the product is to be used, and take into account the technical knowledge, experience, education and training, the environment of use where appropriate, and the health and physical condition of the intended users.

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So here the MDR or IVDR says that the manufacturers must know their users, they must know their user environment and they must know possible hazard and hazard situations.

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in order to develop the perfect user interface for these conditions, which is then really secure and can also be used safely by the intended users in the intended context of use.

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Yes, and manufacturers prove that this requirement has been met by adhering to the harmonised standards or the standards that are considered to be the state of the art.

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For usability, this is IEC 62 366 dash 1.

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But also in the U.S.A.

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there are requirements for usability engineering from the F.D.A.

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and the F.D.A.

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has its own guidance document entitled ‚Applying Human Factors in Usability Engineering to Medical Devices'.

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The good news is, IC 62 366 deleted 1 and F.D.A.

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Guidance largely have the same requirements.

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But there are still a few special features.

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which I might mention briefly here.

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So, for example, the F.D.A. requires that at least 15 participants per user group should always be tested in the summative usability test and that the participants must be tested in the U.S.A.

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Living.

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Yes, so much for the regulatory framework of usability engineering in the E.U.

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and the U.S.A.

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So, I will summarize very briefly, we have the hard legal text, so to speak, in our case now Europe, the M.D.R.

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or I.V.D.R.

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and then we have the state of the art, which usually has to be applied, which is described in standards or in guidelines or guidance documents.

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If you are now very briefly named, perhaps the most important points, which are deleted in 162 366 1 or in an F.D.A.

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Guidance document in it.

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So of course we can't quote this thing in its entirety, but maybe the most important points that are in it, what is required of manufacturers.

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Mhm,

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So both regulations first require that you create the so-called Use Specifications.

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You can imagine it like an extended purpose, in which you really characterize your users and usage environment exactly, think about what the purpose actually is and what the general functional principle of the medical device is.

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Then comes the next step in the process.

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I always call this usability-related risk analysis,

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where you have to analyze which U.I.

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Characteristics really have a connection to security, what consequences could possible use errors have and what kind of use scenarios do I have and which of them are hazard-related.

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In principle, this has done the groundwork.

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So now you know who my users are, my user environment and what risks I have and can in principle go to the specification of the user interface.

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This is then the next step that the regulations

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demand that you really think about it, what requirements does my U.I.

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so that it is really safe for the intended context of use.

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Yes, then it's time for development, in the best case of initial prototypes and then simultaneous formative evaluation.

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So formative is called that because the formative evaluation should take place during development, with the aim of being able to shape the development through the results that are achieved.

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So in the best case, you start very early during the formative evaluation to get feedback from the actual users in order to be able to analyze strengths and weaknesses and to be able to improve your medical device or the user interface accordingly, to analyze possible risks in good time, but also to analyze things in time that may be completely unnecessary or that have not yet been implemented, are absolutely necessary.

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That was the formative part, the development part and finally comes the summative part.

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Summative means, insofar as it is ultimately to take place conclusively, only with the aim of providing objective proof that the intended users can safely use the product in the intended usage environment.

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The choice of method is usability testing, where you then invite the intended user, who will interact with the product during realistic tasks and observe it objectively,

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whether they are doing everything the way you imagined, or whether some unknown or unidentified news errors might occur that could potentially lead to harm to users, patients or third parties and would require new risk control measures, possibly even on the user interface.

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Wow, now you have named all the active data or the most important ones that now give us the norm and analogously also the guidance document

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Just mention from the, I found the term very nice, extended purpose to risk analysis, then the design and parallel.

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That's yes, sounded very iterative, i.e. testing, formative testing, design of the user interface until later to this final one.

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Yes, that, so to speak, as far as the demands, i.e. the standard, says what needs to be done.

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What tips would you have for our listeners on what to do now?

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so that they don't run into trouble now.

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For example, that they don't get into trouble again from the banal spot or get something rejected.

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What would be your recommendation, because you do it all day.

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So, what would be your important takeaways from your experiences?

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Yes, you say so.

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So, my main tip might be that manufacturers should take usability engineering really seriously.

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because if you don't do this, you simply risk a deviation audit, you may get products that completely miss the market and which, in the worst case, lead to damage to patients, users and third parties.

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But if the manufacturers really implement this process successfully, then they get the opposite of it.

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So, they get a usability file, with which they usually get through the audit without any problems.

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You get products that the market really needs and are therefore successful.

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And the most important thing, of course, is that they then also get safe products.

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How do you achieve this now?

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I've written down a few tips here.

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So of course you could go into much more detail, but what I would definitely like to say is that you simply provide sufficient resources for the usability engineering process.

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This means that every project team should have a usability specialist with knowledge of usability engineering from the medical device domain and you should plan enough time and budget.

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That really pays off.

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You should create a specific plan for each development project, for a user interface, and this should be aligned with the interfaces for development, risk management, product management and marketing.

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And the plan should set goals or sub-goals, sub-goals, timelines, roles and responsibilities, and budget.

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And you should also determine at which development points you want to evaluate the user interface with which methods and which goals.

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so that it is simply an orderly, efficient process where you really get the results you need to develop successful and safe products.

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In this context, it is very important that you obtain feedback from the intended users as early as possible before and during development, so that you can easily identify possible weaknesses in your design or simply usage requirements at an early stage and avoid expensive undesirable developments.

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And you should then evaluate at different points during development,

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with different development stages and prototypes.

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They should document the results of this evaluation and the findings should flow into development,

which can then be used to design improved user interface prototypes until the perfect user interface can be achieved in this iterative process in the best case.

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It sounds more like, do what is in the norm and then everything is fine, because what you just described, these are yes, you said, so take it seriously,

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provide the resources, plan it properly and also do what you have planned, including this early formative evaluation.

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So it is the, so you could say that the main problem is that those who have problems in the audit afterwards or are there in the approval process have not adhered to these basic requirements of the standard.

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That's actually what we're observing.

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I don't want to insinuate any bad intentions at all, but

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But I do have the feeling that perhaps the usability engineering process is treated somewhat stepmotherly for historical reasons, because many manufacturers believe, believe, we know our users very well anyway, we know our user environment very well anyway.

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We also know that our user interface is secure.

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But if you then actually carry out formative and summative usability evaluation with the manufacturers, where

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where in principle the manufacturers get to see how the application really works in reality, this leads to surprises every now and then.

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So once again my appeal, manufacturers should really take this seriously, because the notified bodies in particular are increasingly looking at it.

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Face the brutal fact.

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Yes, maybe, if we could do a little deep dive on 2 now, namely maybe once, what would you particularly

recommend to startups and what would you recommend to manufacturers of products

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products that have been on the market for a long time.

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Maybe you have some kind of tip for us.

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Yes, so the C.

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62 366 dash 1 knows the concept of the so-called User Interface of Unknown Provenance, i.e. Oop.

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In other words, anyone who has placed medical devices on the market before 2015 can in principle create a leaner usability engineering process or a leaner usability file, where they ultimately only have to

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You have to evaluate the post-market data, of course especially with regard to usability, where you have to evaluate your risk analysis again in order to ultimately draw the conclusion that your medical device is really safe.

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At least in terms of the data you have at your disposal.

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However, as I said, this is only possible for products that were placed on the market before 2015.

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Now there are certainly some products that have been placed on the market after that.

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I would simply advise you to look at your usability file regularly, especially with all changes, new insights, new developments and check whether it is still up to date and update it accordingly.

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Yes, with startups, they will now develop new medical products,

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they certainly can't do this Appendix C.

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of the standard.

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I would refer again to my tips from earlier, that you simply think about what I want to achieve in advan-

ce, what goals should my user interface ultimately achieve, how should it be designed and make the appropriate plan there?

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Maybe a tip if you have very tight budgets now.

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If you have very tight budgets,

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I can perhaps say that formative evaluation is always a must.

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So there are no strict regulatory requirements now, at least the standards do not specify to what extent and how often they have to evaluate iteratively.

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But it's worth it to simply analyze these strengths and weaknesses and it helps to do this on a smaller scale.

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So it doesn't always have to be the big usability test with 15 participants per user group,

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with formative usability evaluation, but you can also do it iteratively on a smaller scale, for example, that you first evaluate an early prototype with only 3 users, develop the prototype further, develop it further and then evaluate it again with 3 users at the next development time, so that in total you might come to a relatively high number with 15 participants, but you can draw much more insights from it than if you can do a one-time usability evaluation with 15 participants.

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Then they have more of their resources.

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Yes, yes, I think 1 is also said, if you save money in the wrong corner, then it will be all the more expensive afterwards, because you just then, what I delay the registration and the costs continue to run and you just don't earn.

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Or even worse, if the products are not safe afterwards, then it will be, it can be relatively expensive.

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Yes, while we're talking about money and support, external support, what are the things where your team can help particularly well?

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What do you have in your portfolio, in your quiver and

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in order to be able to help the companies, be it the small ones, but also the larger ones.

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So, if you don't have quite the big budget, we offer help for self-help.

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I can only warmly recommend our Audit Garant with video training on usability engineering.

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The Audit Garant also includes our usability templates, which contain many practical examples and tips that make it easier to document.

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Otherwise, manufacturers can simply visit our blog, where we have many free articles on the topic of usability engineering, or download our free whitepaper from our website, where they also get an overview of the regulatory requirements for the usability engineering process and other tips.

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But beyond that, of course, we also like to be active ourselves and help with the creation of the usability file, for example, either we create it ourselves or together with the manufacturers

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or we guide the manufacturers accordingly.

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However, we also carry out formative and summative evaluations for manufacturers ourselves.

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We do this in our usability laboratories in Frankfurt directly at the main train station.

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We also have a nice observation room where the manufacturers can then be on site and see the results directly and live.

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and U.S.A.

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also works, because that can sometimes be quite helpful, because as you said earlier, the Americans like to use the U.S.

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Residence with you.

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So your team can also help there and avoid redundant usability checks, because that will simply be double the cost.

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Yes, Nils, thank you very much.

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We're packing the tips you've just given us, so in addition to the free technical articles, to the guide you just mentioned, we're adding the show notes and so all that's left for me to do is to say thank you very much.

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Christian, thank you too.