

# Software platforms for the healthcare industry

With Klaus Müller, 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.

00:00:19 Speaker 1

With all the regulatory requirements, we must never forget that we should also develop products and they should help patients, they should be safe.

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But the development should also take place in such a way that we quickly reach this result.

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And especially with software, it has a lot to do with processes.

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But it also has a lot to do with how well we can reuse code, because I sometimes have the impression that the different companies always reprogram the same functionalities.

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And how to reuse code well, i.e. software code, that's exactly what I want to talk about today.

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with Klaus Müller from Adessa and it's best to just introduce himself, because then you can assess where exactly his expertise lies and then we go deeper into the topic.

00:01:08 Speaker 1

Mr. Müller, perhaps very briefly, who are you?

00:01:10 Speaker 2

Yes, hello, thank you very much, Mr. Jona, for the invitation.

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I am very pleased.

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I always follow your podcast and we know each other personally, which is really very

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very nice thing for me.

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So from my side, Klaus Müller is my name.

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I'm 54 years old, I once studied computer science and business informatics in Karlsruhe and Mannheim and actually went here right after my studies and founded my own company and actually dealt with the topic of the, let's say, website and software in the pharmaceutical industry for almost 20 years.

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A lot of Big Pharma was therefore very much involved in these compliance guidelines and all these topics, everything that had to do with them.

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And then, all of a sudden,

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89 years ago, a customer came along and said, you, I would like to have a score calculator in the psoriasis area and I said, I think it's a medical device, but somehow I had only heard something about it very casually and the customer also said, somehow yes, I heard that once and then my career in the field of medical devices or software as a medical device began, so to speak, 8 years ago.

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In the end, we've had the

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started the topic as therapy-accompanying software.

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That's my expertise.

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We built up a QM system after 13 and 85 and I thought, great, I'm in the big pharma industry and they all want to have medical apps and software in the topic now.

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And nothing came of it yet, because the industry was a bit slower.

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And since then, I have actually been increasingly involved in the field of therapy-accompanying software in medium-sized companies for start-ups in innovative medium-sized companies.

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The pharmaceutical industry is also becoming more and more important.

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And these are the topics that I have been dealing with for several years and now since the end of last year at ADESUSE, where I am responsible for the area of Personal Health.

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So we try to involve the patient in therapy or in his, let's say, administration doesn't sound good, but in principle directly involved in the topic of health and prevention and well-being with all the topics that are then necessary to know both the patient and the regulations.

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Yes, and I think there is always a good team today, namely someone who has really gotten to know the matter from all perspectives from the development side and I will of course ask a few questions on the subject of regulation.

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But let's start with the main question first.

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What are such typical software functionalities that we use for medical devices, i.e. especially for medical devices?

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Healthcare sector over and over again and which are accordingly reprogrammed by the manufacturers over and over again from 0.

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Yes, the question comes up again and again and we have divided it like this, in the end not into a list that can pray down now, but quite interesting, it is actually divided into 3 rough topics.

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We have basic functionalities that are always

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used and rebuilt.

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These are topics such as data management, data storage, data protection and data security, interoperability, interfaces, integration, such topics, authorization issues, user authentication.

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So these are topics that I can actually use again and again regardless of the type of software or have to develop again and again.

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The second area,

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I call this medical context, especially the medical context in the German health care system, which comes up again and again.

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So that means, what does Gematik mean to me, do I have to have interfaces where I have to go, to what extent are keywords like EPA necessary, do I perhaps have to write data to the EHR at some point or not, to what extent are there guidelines that the DIGA V.

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prescribe to me or B.S.I.

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Guidelines or the topic of TIM, such as telematics infrastructure messengers, are so

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Areas up to the topic of billing of DiGAs, which also come back again and again.

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These are, so to speak, the second block, as I said, medical context, which is also very exciting for foreign companies to somehow get along in Germany.

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And the third area is really indication-related topics.

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That is, if you look at the digital health applications, which are very much in the psycho field, I always have the topic of diary, I always have the topic of interventions, it's always about making a change in life or behavior with mental issues, with nutrition, with different

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exercises that I have to do, which are always similar, are a different indication, but the basic principle is actually the same and that's why I like to divide it into these 3 big blocks or 3 big topics.

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So like a kind of pyramid, yes, at the bottom the crosscutting concerns, which every framework should bring with it somehow, no matter which domain, then the

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health-specific things, although we have just learned, I have just learned, these are of course also things that are specific to the respective country.

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So right now, when we talk about telematics infrastructure, despite all interoperability efforts, there are always German variants and billing is, I think, 1 of the most tragic examples of this.

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And then again the very specific, so be it psychiatry or radiology or

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I.V.D., which areas we have, where there is another step on top, so to speak.

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I guess the deeper we are on the one hand, the more standard frameworks have something to offer and the further up we get, so it will probably be a balancing act somehow, it will then perhaps become too rare that it is profitable.

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But before we maybe talk about what is profitable now, let's take another look at

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In what form can such reusable software be offered?

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Yes, that's a question, of course especially those who are now on the road for you as a development service provider, but maybe also some manufacturers of components or frameworks.

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So, what can you offer as a product and how?

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In principle, there are 3 topics again.

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So, the topic of component framework, what you said, I think we'll come back to that in a moment or I'll come back to it in a moment.

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Actually, it starts with the topic, I'll call it backend-as-a-service.

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So, there are now providers who really provide you with various components and topics as backend-as-a-service, some of which are also billed per use, which is not so uninteresting in the giga environment.

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These are systems of which there are still few.

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There are a few startups that are trying to get into this market right now.

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Because I have a large black box, of course, many people are still shy about it.

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It may be very, very nice for a startup to build something quickly, but especially in the industrial environment, especially when I have compliance guidelines, I often have the question of what is really behind it in that direction.

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I think we're a bit further along abroad, but in Germany there are a few systems, but it's definitely a very good system in principle as a service.

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as a service, so to speak.

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Then in the second area we have the topic of Dev Framework or Framework and Components they have called it.

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I'll call it from my not too technical point of view, it's more like the framework topic is more of, I'll say a techie topic, yes.

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The more technical they are with the contact persons, the more likely I am to come to this framework that I call, what framework do I have and what idea do I have and how do I develop all the topics on the one hand.

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And that a strongly learned system is, of course, so I know how it works.

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There are some that cost licenses, there are those that don't cost licenses and the third area again the topic of components.

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I would take that more solution-oriented, yes, that you just say: ,OK, what kind of kit can I put together

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Building?

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Yes, and what components are in it?

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And then I come back to these three topics that we just had before.

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Yes, are these basic components?

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Are these health or indication components in the area?

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To what extent is it the medical context and what component is there?

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or I say I buy three components and maybe develop the fourth together with you and if it's so good, you can continue to use it and such topics, so that's a very open system, I find in this component topic what we have there and I think these are the three main topics that are also on the market where I just have to think about when I want to use an application or if I have to develop a solution, I just go into this component framework or service topic, which also depends a bit on it, am I able to manage it myself, yes do I have my own developers or do I just want to buy a solution?

00:09:06 Speaker 1

So we have a 3 times 3 matrix, so then 9 fields matrix, where you don't have the content side on the one hand, so to speak, from cross-sectional functions to medical functions to indication-specific and on the other hand then have the stack of yes backend as a service to frameworks to the components and that's yes.

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Ultimately, decisions that affect both the providers, yes, where they want to place themselves in this matrix and, conversely, of course, the question that the manufacturers want to ask themselves, where do I want to put something together from existing offers, so to speak.

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I think we have to talk a bit about a few business aspects in a moment, but before we get away from that, maybe you can limit the solution space if necessary or a bit.

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If we now take a look at what do you have to pay attention to when you

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now as a customer, now as a manufacturer, buys such services, such frameworks or such components.

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So I think there should be things like regulatory requirements, sub pops up there with me, risk management, maybe also licensing business.

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Maybe we can go through these aspects individually.

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So what do you think would be the important points that we should look at from a regulatory point of view?

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Good, regulatory

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as the name suggests, yes, what regulations do I have to observe when I use such a component kit in any form?

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Yes, then let's take 3 things, I find it quite interesting, A.

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of course always the theme of M.

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or medical device issues, this is certainly not easy, especially with components.

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Yes, if I have this as part of my medical device, I may have to include it in my Q.

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M.

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system or can I only do the whole thing as a move, to what extent are the

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People who built it, to what extent, how do they understand it?

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That's also a topic, which is very, very exciting in this area.

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The main topic is data protection, yes, D.S.G.V.O., everything that has to do with the topic of data protection, with the topic of data that is particularly worthy of protection, patient data, everything I have there.

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I think that's also the main risk in the use of software today, that it's really clean, that I know what I'm talking about.

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then we also have the issue regulatory or I call it compliance-wise, especially when it comes to the company that does it.

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When I think about it, I have an American company, in which cloud solution am I possibly on the road, that's a very exciting topic.

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Many work with the big providers, but I'm not allowed to do that in Germany.

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Yes, if I have a medical device, I might be able to use A.W.S.

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or Google, do I want to build a DiGA at some point, may I do the whole thing, does it have to be a German hyperscaler in this area, how do I want to use the European

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markets, I might want to go to France, where I have different requirements, also in the data protection issue, although it is European, there are special regulations there again.

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So these are areas that should be considered and also to what extent the provider is involved in this topic, so to speak.

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I once had a nice example, we once worked with a low-level partner who specialized in e-commerce solutions.

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They were only about time to market counting 120%, quality was not so decisive.

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Yes, in our environment it's the other way around, it can take a week longer, but the quality has to be right and the regulation has to be right.

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I think these are topics that are very important, that everything is documented, that the testing is documented, that I also have appropriate test protocols for these construction kits, that I may be able to incorporate all the topics relatively easily into my documentation, into my technical documentation.

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These are all questions that should be clarified in advance and that you have to pay attention to overall.

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Risk management

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Hatten it was a big issue.

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I think that includes yes.

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That's the parenthesis of everything, actually, to see the whole.

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The topic of licenses is perhaps still very exciting.

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That comes up again and again with us.

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Do I have a licensing model?

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Model?

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Do I actually have a product that I buy?

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Do I have a product?

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Do I have product liability and such issues?

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In principle, do I only buy components that the supplier gives me?

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Yes, and then I'll just take over.

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Then the topic of open source is very exciting.

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Plus, what we always have in the startup space is the IP question.

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What if I in principle, to what extent does the modular system of components be included in the evalua-

tion of my company?

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that's what the investor asks me, how is it regulated, what happens when you're no longer there, how is it regulated, so also all these topics, in order to ultimately see the component as my own software or as a service in the evaluation of my own company or the company that uses it.

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Mhm, I'll summarize very briefly, so that was once the big stack of medical device law, I would perhaps make a very short addition, then the stack of data protection law, which we had with us,

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Of course, there is also the question of where this data is stored and how do the data protection requirements differ in different areas of law, as you have just said, even within Europe.

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And then the last block to keep in mind, licenses and I.P.

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and a bit related to that, the topic of risk management for the company.

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So not to be confused with risk management for patients, because that would be another medical device, legal question.

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If you want to shed light on this topic of medical devices again right now, please contradict if I have misunderstood.

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Yes, components and frameworks on the one hand, something of the Software as a Service on the other.

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Because in the first case, we have software that becomes part of a medical device, namely your own medical device, either as a sub or not as a sub.

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And in the other case, we are faced with questions as to whether it becomes part of the product.

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Is it an accessory of the product or is it simply software that somehow runs together with your own medical device and they have and that is ultimately also a question of the regulatory strategy that the companies would have to operate and the topic of risk management flows into it.

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Yes, so the more dangerous the product is, i.e. the higher the risks, the more you will probably tend to

have things under control yourself and that can perhaps be divided into 2 parts again.

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either of control, because it is part of one's own product.

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That would probably be easier with frameworks and components because they are full.

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Or because you have the operator of this enterprise software well under control, for example because he is certified himself, because you can audit him yourself, because there is a high level of transparency of what you do.

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Would you agree with that?

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Exactly, these are exactly the topics we have there.

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in the area.

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That's why the first question in all inquiries is always who will be the distributor of what they do, if it is a medical device.

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What I would perhaps add, which is always very strong in addition to the classic, legal regulations, so to speak, is the compliance issue within companies.

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That is, the own compliance that a company has in each case.

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You should always keep an eye on this, because sometimes there are very individual solutions that every company has.

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And we had always called it the legal look for fun.

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That means you were almost done with the project and then someone comes out of the corner from the back, so to speak, and has other compliance requirements that are written down somewhere, especially in the corporate environment.

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These are topics that should always be kept in mind when using such components and systems.

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This could then be an example of this, with a requirement that then appears again at meter 99 in the 100 meter run.

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Exactly, are 2 things, A.

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again and again the topic of I.P., which is suddenly in contracts, we want the unrestricted worldwide right valid for the next 240 years to be allowed to do everything, so that where you can then sometimes have a hard time with it.

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and a second topic is, for example, that there may be a policy with which I have to encrypt data.

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Mhm, yes, so that in some cases it is prescribed that data encryption or anonymization with software X.

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Y.

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has to be done, suddenly.

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But the overall concept may include a completely different software, so to speak.

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And these are things that sometimes, if they come too late, can either increase a project by a 0 or bring it to a complete end.

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Yes, so here, too, the issue of stakeholder requirements is decisive, but that's where it seems to be the most and

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In this case, we are now eating what you have just said, not only the usage requirements, but also regulatory requirements, market requirements, which we want to have taken into account here.

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Maybe also a thought of mine, because it pops up again and again with us, manufacturers of such solutions, be it Software-as-a-Service, be it components, be it frameworks, always have the topic that they try to put it on the market as a medical device, as an accessory.

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But if it is not clear in what context it will be used afterwards, everything that goes in the direction of risk

management and clinical evaluation will necessarily collapse.

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And you have to be aware of that.

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So you can't delegate that to them either.

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Yes, this is now also the appeal to the medical device manufacturers, so to speak.

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So they can do the basic work.

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Yes, they can, for example, meet the 62,304 requirements, but these providers certainly can't make a clinical assessment

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In the overall concept, it must in principle be, I am just saying, what you are saying, a medical device marketing concept, yes.

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So because even if I have my own medical device for every indication, so I can't just take the framework below just like that.

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So in principle I have to think about it in advance, even if the software is 95% the same, if there are different indications, I have different clinical topics, I actually have different products in the area and of course I have to do that in such a component or framework conception

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keep an eye on it.

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Mhm, great.

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Now maybe we'll take a look, because Adeso is tackling this topic.

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So I don't want to ask any secrets, but what do they offer anyway?

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Maybe I'll do that, the first question, and what can other providers learn from it?

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What are perhaps commercial considerations that should be made?

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What should you pay attention to as a manufacturer when choosing a provider like Adeso, for example?

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So, we have one, we call it the Adesso Health Stack, we basically have such a component kit on offer.

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Maybe I can tell you a little bit from the story.

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That's when I took it over, that's what I found quite interesting.

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The whole thing was actually called DiGA S.D.K.

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developed.

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When the big DiGA market came, they basically developed a DiGA or an app with a project in the field of depression and basically built a component kit out of it to see that I wanted to have various things that I needed already in it.

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As I said, we always have a diary, we always have an intervention, we have a small content management system that we need, we always have the issue of identity and access management.

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Interoperability is a very big issue to have HL7 FHIR standards.

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And since the DiGA market is developing, I'll say, a little slower for the manufacturers than we all wished for in this area, we have or I suddenly noticed that there is a great demand for these component topics in the area of really interoperability.

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So not how do I build a diary, but how can I ultimately have an interoperability framework in order to have different requirements from the giga sector as well as from the area of hospital funding or study topics, how can I build a study app very quickly.

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And that's why we developed this modular system of components in order to be able to cover exactly

these topics.

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If we are now back in this app market,

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Is it very exciting that the inquiries or what is actually a big topic is not the indication-specific thing at all, but precisely this context.

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Yes, I have to deal with the EPA now.

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How does that work?

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Or how can I generate the DIGA code?

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Do I have to call 120 health insurance companies now, such topics, so to speak?

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And that's where we have the strength at Adesso that we just come from this, let's say, from this health sector.

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, we are also familiar with the topic of how the health insurance works, how does the connection to the context work.

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We are very close to Gematik in these areas.

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So this domain knowledge is what we can keep up with, regardless of the fact that we are good at building software, and I think it's also important for all providers, in principle, to give their customers this context and to know in which market we are actually moving.

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Mhm.

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if I understand correctly, the offer is now mainly in the middle of these 3 layers, i.e. not into the indication-specific and possibly not all the way down into the completely domain-agnostic areas, but this middle central medical layer.

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And that, as I have just heard, actually in two respects, namely firstly in terms of software technology, i.e.

that these functionalities such as interoperability, connection to the telematics infrastructure and so on, that all this is given.

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But I also listened in a bit, also organizationally.

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Well, you talked about the fact that you also get in touch with the health insurance companies, so to speak, who want to replace it later.

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That is, did I understand that correctly?

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Adesu not only offers software, but also the services for it or the contacts that are necessary for it.

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Can you say something else?

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Exactly, on the one hand we offer the software and on the other hand we offer the advice and services that I need for it.

00:22:04 Speaker 2

That is, how can I get into the health insurance systems in principle or how can I say in the consulting approach, I'm now a company, maybe have 3 or 4 patient apps, how do I bring them, how do I consolidate them, me as I.

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00:22:16 Speaker 2

Leiter am responsible for the data and for the software, how do I bring this together in any form accordingly.

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Mhm, yes, we also offer the whole thing in the hosting concept,

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that we say, O.

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K., there are ways to operate the whole thing as a cloud solution, and we are deliberately not focusing on our own cloud offerings at the moment, but on the large magenta-colored providers, that we really say that there are 23 providers in Germany, and thank God there are a few more coming onto the market, so that we can really say that in the context of healthcare, you basically get the best of this environment from us, because we simply know the market from all directions, from the past.

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Finally, I focus on the patient in my team, that in such ideation and discovery phases we really approach the patient and make the application, let's say, patient ready.

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Mhm.

00:23:02 Speaker 1

If you summarize that now, you have almost reproduced what are the criteria that you should pay attention to when choosing providers, such as AD.

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I hope I can get them together.

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Repeat very briefly.

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So, one thing is of course the software competence, that's clear.

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In other words, simply being able to develop state-of-the-art software and, in our context, 62, 304 compliant software.

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The next thing is that the software meets the requirements that we have specifically in the healthcare sector and that can also be integrated into the future medical device offerings that are to be developed with it.

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Number 3 was

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the ability of the provider to also offer services that are necessary and that go beyond the purely technical.

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And have I forgotten anything else?

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That was actually the main point.

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In the end, it's about knowing the context of the healthcare system and being set up accordingly in terms of regulation.

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Yes, with certified QMS according to 13 485 and such topics that are included.

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There is certainly, we are not the only ones, of course,

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Of course, I have to say that we are the best, but there are some providers and of course you have to, you should see who suits me best.

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Yes, we are now a large house and certainly there are also smaller ones, where I can perhaps also say as a customer, maybe I can get along better with the smaller team, where I only have 3 people, but they are exactly in this core.

00:24:27 Speaker 2

I think you have to look at who you get along with best, that will be a very important topic in this area and then someone really knows the software, the regulation and the health issue.

00:24:40 Speaker 2

Topic, these are the 3 areas that must ultimately be available with the provider.

00:24:44 Speaker 1

Great, so we now have a very good overview of what medical device manufacturers can do, i.e. who are of course active in the software sector and who don't want to reprogram everything from scratch.

00:24:57 Speaker 1

So, we have now clarified, so to speak, functionality, so to speak, what you can buy.

00:25:04 Speaker 1

We thought about how to build this stack technologically.

00:25:07 Speaker 1

We have criteria for selection.

00:25:10 Speaker 1

corresponding service provider and software provider.

00:25:14 Speaker 1

So that means that everyone who writes any medical software is hopefully a little further ahead.

00:25:19 Speaker 1

And if you will allow me, Mr. Müller, I would also publish your contact details, because then people simply have the opportunity to contact them directly and then get to know each other and decide whether the next product will be developed with you.

00:25:33 Speaker 2

Of course, gladly.

00:25:34 Speaker 1

Thank you very much, Mr. Müller.

00:25:36 Speaker 2

Thank you.

00:25:37 Speaker 2

See you soon.

