Johner Institute

Faster time to market with digital production

With Dr. Thimo Keller, Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

Medical Device Insights.

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

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Lately, we've been talking a lot about digital transformation, both in the journal and on our websites, as well as here in the podcast.

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However, the focus here was on the digital transformation of regulatory processes, such as approval, such as post-market surveillance or, for example, the monitoring of regulations.

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Of course, a digital transformation has a broader scope, there are others

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Processes that should be looked at, that should be transformed, that should be automated.

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And one of those processes that we haven't talked about much is production.

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And for this reason, I have invited someone today who is about to introduce himself, who is quite familiar with this area of digitization of production.

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Could you introduce yourself very briefly, Timo.

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Yes, of course.

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So first of all, hi Christian, thank you very much for the invitation.

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I'm very happy to be here.

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My name is Timo Keller

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I studied mechanical engineering at the Technical University of Darmstadt, then did my doctorate immediately afterwards and then very quickly delved into the topic of „digitization of production".

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My speciality was a bit of digital assistance in production, i.e. the question of how can I effectively support manual work so that employees can work better, faster and with higher quality?

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And it was exactly on this topic that I then wrote at the beginning of 2022 with a

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Colleagues with Dr. Stockinger and what we are now offering are basically services to support manufacturing companies on the path to digitalization.

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Yes, and that's exactly what we need today and yes, we should before digitizing, we have also clarified that pretty well in the Fit for Future program.

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So digital transformation is not an end in itself, but we want to.

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do something better, where do you want to achieve your goal, for example solve problems.

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What kind of problems could be solved by digitizing production?

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Yes, first of all, you can perhaps say that the problems are very, very diverse and are always very individual.

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So it depends on the production process and there may already be a secret in our approach, which I will go into again later.

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But typical examples that we see again and again are efficiency losses,

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If assembly information is outdated or poorly represented, then you have to ask again, the colleague, the foreman, the foreman or whoever, and that costs time.

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A very big problem is actually always the topic of rework or rejects, i.e. quality as an umbrella term and here I can of course also avoid certain assembly errors or other errors by providing good information and thus also reduce rejects.

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Which, of course, is extremely important, especially for medical devices, i.e. for products on which the health of the patients depends.

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But now I just interrupted you, keep going.

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I think the example is also really very good for the next point I wanted to make, which is the amount of time you often have to document things.

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For example, to confirm test steps or to prove qualifications by signing.

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And these are all topics that can really be automated very well in terms of the flow of information.

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So, when the employee is registered, a check step has been carried out, then I can automatically confirm it digitally and no longer have to fill out paperwork and, of course, somehow file it and then further process, evaluate and the like.

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I can save myself all that.

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Mhm, so I'll summarize that very briefly, also what advantages you have already implicitly mentioned.

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Well, you once said that we are faster, for example because there is less rework.

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you said that we are also more efficient in the sense that there is not only less rework, but also less waste, I think I just heard.

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That was the higher quality of the products you talked about, the higher conformity and then again an

efficiency issue, namely less work in terms of all the documentation.

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Did I get that right?

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Exactly, I would say there are 3 main topics

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and there are many, many more that come up again and again and, as I said, are very different from production to production.

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Mhm, so we already know what are the problems that we can eliminate, we already know certain advantages that we can achieve.

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What are the typical production steps that you regularly help with?

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So I would have expected welding, maybe it's less of a step now, but what are typical steps that you take where you go?

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Yes, so the most typical are actually assembly activities, i.e. really manual activities.

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You can also generalize it a bit by saying that digital assistance always makes a lot of sense when the activity is relatively complex, i.e. demanding in its nature.

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And then there is a second dimension that influences this and that is the employee's experience with the task, which could also be written as competence regarding the work task.

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And that's where we usually look for use cases where the complexity is relatively high and the competence comparatively low.

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And this is exactly where I have the greatest value of digitization in the flow of information.

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Yes, you have already mentioned for which companies this is particularly suitable, namely all companies that produce that have relatively complex production steps with people who are not quite well trained.

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Exactly, exactly.

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There are also other cases where it can really make a lot of sense, but this is the predestined area that we usually always look for first when we come into a new company.

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That's where you usually start, because that's where you can leverage the greatest potential very quickly.

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K., you had already hinted at a bit of how you go about it.

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So the question I would have for you, what are such typical steps, they call you or it's not about you, but in general a company has somehow

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a need until the problem is solved.

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What are, what is the process model, we could perhaps also ask.

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Mhm, exactly, so we structured it strongly, we gathered a bit of our experience from our consulting work while we were still working at T.

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have researched and worked and yes.

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And the essence is so little that you can summarize the whole thing in 4 steps.

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The first very important step is to first make the potentials clear.

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In other words, we really quantified, we also look again in detail at what else we have regarding the topic, in order to then align the project with these quantified potentials.

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So I defined my main goals very early on, so to speak, then I can work towards them and make sure that I achieve them.

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That's still very abstract, if I may just dig into it again.

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So potentials, that's what a lot of people say now somehow hand on heart, how much, how many euros can you typically save with such a production facility?

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Also quite exciting, so it's more than you probably think.

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In our projects, we can observe that we can save about 7 to 20000€ per job per year and so we come relatively quickly, so

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so even then for smaller areas of work quickly 50 to 200,000 euros together, which I can save annually.

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That is, is it really profitable to invest there, because you have an extremely fast return on investment.

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Exactly, so there are numerous quick wins that you have.

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Of course, there are also structural improvements.

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So I have a continuous flow of information, I have a more modern working environment, which can also be a strategy against the shortage of skilled workers.

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I'm also gradually building up a treasure trove of data, no, I'm collecting data that I can then process further, possibly evaluate and use with an AI at some point, and that's how I actually create the foundation for sustainable production, if you will.

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But what you have just described again was part of the first step, namely really just calculating, you can really say, what is actually what we want to save, also in euro amounts.

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Yes, you have just pointed out other potentials, but that would be quasi, you should really be absolutely clear about that.

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Step 1 Step 2 and.

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The second step is then to really develop a detailed understanding of the process.

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So analyze the process, we use a self-developed method,

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the information flow analysis, which was created as TU Darmstadt and was then adapted by us again to our production use case and what we do there is that we understand and visualize the processes bot-tom-up, typically in a small workspace and then also regularly, i.e. actually daily in a three to four-day project once a day discuss with the management level, all the more

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to create a uniform understanding of the process, from which the improvements can then be addressed much better.

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Do you then also talk to people directly at the workplace?

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Exactly, that's a central element, that you're a bit in the bottom-up for me now.

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We really go into production, talk to the employees, look at the process, record figures and data here and sometimes and can really draw a comprehensive picture on the wall.

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And that

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is actually information that you usually don't have in top management.

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There's a very interesting statistic that top management knows about 4% of the problems and at the very bottom I have 100% of the problems in the process itself and we bring them up, we can discuss them and then work on them accordingly.

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K., that was step 2, so step 1, we make the potential clear to ourselves, so to speak.

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Step 2, we make the problems clear, i.e. what, what is not going optimally, we understand the process that is actually running.

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Step 3.

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Step 3 is then that we really work out the requirements in a structured way from the analysis and then use these requirements to select suitable solutions on the market and then present them to the company accordingly.

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So we usually have 2 to 3, maybe even 4 profiles of different solutions, which we can also evaluate with a percentage value.

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What does that mean, so you can give an example of the requirement.

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Example of requirements are basically everything I get out of the

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derives from the process.

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So we then really capture the individual functions that are required to achieve the individual implementations that we want to place in the process.

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And so the requirements are always very much oriented towards the application.

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So a requirement would be, for example: I would like to enter this information here at process step AB or I would like to save the information in an evaluable way or even I would like to make an evaluation on

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based on this collected information.

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So we can form as many overarching categories and then go as deep as necessary and this is then always checked with the respective solutions available on the market.

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So these are actually what we in the medical device world often refer to as user requirements, namely what a person must be able to enter, select or recognize in an interactive system.

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Exactly, that's exactly what is in it, in any case, maybe the topic of interfaces,

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i.e. with which system do I still have to communicate, interact, what requirements do I have here and

that's how it comes together.

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Again, very individual, but then it is precisely compared with our database and we can then very quickly identify really suitable systems, often talk to the solution provider again to really tie it down again and then be able to make a recommendation.

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So that was step 3: Collect requirements, compare requirements with possible solutions and then select the best solution.

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there it goes into the fourth step, which is then the implementation, as I understand you.

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So, what is being done in concrete terms?

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That's the typical project business, I might say.

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So, that's where the third party comes to the table.

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No, I then have companies producing us as a consulting company and then the system provider and then it's a matter of designing the system in a very concrete way for the use case and implementing it step by step.

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In other words, really put it into the productive area.

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Sometimes it is still a matter of modernising workplaces,

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i.e. order new tables, set up screens and then load the system accordingly, adapt it, use it.

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K., so I'll summarize.

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The first step was to make the goals clear, above all, of course, the potential, which always wants to leverage.

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Step 2 Understand what is really going on, i.e. the analysis phase.

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Third phase, collect requirements and implement them with

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compare existing solutions, then also select one and fourth phrase, implement everything, build it, get it up and running and probably also check it, you could perhaps also say.

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And finally, evaluate exactly what is then probably the Computerized Systems Validation in our medical device world, which is to be done here.

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Yes, these are things that we also do in large numbers.

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So that would be a special feature of the regulatory company, so to speak.

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Of course, you can't forget that.

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But what are the other typical mistakes where you say, so you should avoid them at all costs or they occur particularly easily and you have to be careful.

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Yes, what we observe very often is that you are often already working on a technical solution without having taken the preparatory steps.

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So that you really fall in love with a technology, maybe even implement a rather unsuitable solution, because you skipped the previous steps such as identifying and quantifying potentials or building up a deeper understanding of the process, maybe and so often a unsatisfactory solution comes out.

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It's also super important to involve the operational staff at an early stage.

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That's very much in the analysis,

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because these operational employees are of course the people who then have to work with the system.

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Here you have to ensure acceptance, here you have to or can collect suggestions for improvement at a very early stage, that should not be underestimated, because of course these are the people who know the process best and can thus best help shape it.

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So 2 things, no, one not coming from technology and the second talking to the people it affects.

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Great, maybe a question at the end, so

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are there any special features on your part, so to speak, where one would have to pay attention during validation?

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So this is different from other areas or how do you usually go about it?

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Yes, so what we usually do in the evaluation is that we take another look at the potentials that we defined at the beginning and check whether we meet them.

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Now, of course, the validation

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So, of course, the regulatory requirement could have been a goal.

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That's one of the potentials that can be achieved from my point of view, no, that we've already developed an understanding of the process all along the way.

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We can visualize the process and that can be an aid for regulation in our experience.

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Yes, that, that, that's very exciting what you say.

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You can actually see how the term validation is not used quite correctly in the regulatory world.

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Because what you just said is, we want to see if we have achieved the actual goals.

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Yes, this is actually also a computerized and process validation, what you are doing there.

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So, you just mentioned, for example, do we actually have the savings potential.

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For example, we have really achieved the desired increase in quality, we have reduced the rejects, as we just defined at the beginning, and the Computerized Systems Validation somehow has a narrower scope, because it looks, do the system what it should actually do.

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So we are on a bit of a different level in terms of validation and you can see that you need both and the regulators, they often have these

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economic aspects are not included at all, but of course they are extremely important for companies, otherwise they wouldn't have to tackle this digital transformation, the digitization of production.

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Yes, so we're convinced of that, no, I think it's also very synergetic.

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So I would like to confirm you now, again, no, that I think you can already deduce a lot from the validation of the process.

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So I've visualized the process now and can now also very nicely describe the critical points

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and thus perhaps already meet the corresponding regulatory requirements.

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Mhm, although critical of course has to be careful again how you define critical.

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Yes, we have in mind once critical on, I have, is it critical for increasing efficiency, for example, or is it critical afterwards ultimately more for effectiveness, because we now achieve the conformity of my products in particular and that's a bit 2

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But from a regulatory point of view, of course, the focus here is on the patient, the conformity of the products, and then we come back to this risk-based approach.

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So, it happens nicely how 2 worlds come together, namely the economic world and then coupled with the medical device regulation, will, how will people contact you, how does he usually proceed, what would be the tip for companies that are interested in it?

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To your question how to reach us, I think we will end up in the,

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have a link in the notes to the podcast where we will deposit another landing page where all interested parties can then get in touch.

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And what we can offer is that you can now perhaps carry out a free quick check with companies for a limited period of time and this quick check is free of charge for listeners of the podcast.

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So that would be the first point of contact and from there you would then perhaps talk about the potential project and that would always start with the quantification of the potentials.

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Do we already have one?

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How long does a project typically take?

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We are currently in the process of concluding a larger one with a sensor manufacturer, so perhaps not so far away from medical technology, relatively small-scale complex product.

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We were there for the first time in March of this year.

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So you can expect a good six months.

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So we are already in the process of implementation, the line is equipped with hardware, is already in test operation and will be used in the middle of the

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It will go live in mid-December at the latest.

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And so everyone knows how long something like this takes and you can probably still somehow bill what

it will cost in terms of costs.

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You can, the ROI really has to be achieved.

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As always, we link the contact details to this page, but also perhaps to the general website, to your e-mails.

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So anyone who is interested in digitizing their production is welcome to contact you when it comes to the topic of Commuterized System Validation, including us.

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All that remains for me to do is to thank you very much for the insights you gave us.

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I thank you too.

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Have a nice day.