# Digital Transformation with Polarion

With Sven Wittorf , Prof. Dr. Christian Johner

## Transcript

00:00:05 Speaker 1

Medical Device Insights is a podcast from the Johner Institute for medical device manufacturers, authorities and notified bodies.

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Many companies have embarked on a journey to digitally transform themselves so that they have faster approval times, less

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have to do unnecessary hard work, for example, be able to check files automatically and thus simply become a modern department that also attracts young employees.

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And one of these tasks in digital transformation is, of course, to configure, establish and also integrate systems.

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And one of these possible systems, these are the products that will be presented on the Polarion

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platform and Methotre is one of those companies that offers such services and products as well.

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And that's why I've invited Sven Wittdorf today, whom many of you already know, but who may still introduce himself very briefly.

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Yes, thank you very much, dear Christian.

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Yes, many people know me in the context of the Johner Institute, as someone who does seminars, as someone who is also active in research.

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I've been at the institute for almost 20 years, so when the institute was still

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was small and then Christian, we both spun off 15 years ago, already had a company, back then we didn't call it digitization, but that's exactly what we did.

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So we looked at what, what kind of information is there, how processes still have to be set up with a focus on software development at that time, what artifacts have to be created and maintained so that they can be managed with tools other than Word and Excel, if you can call that a tool.

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so we looked for and found a basic tool.

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That was the Polarion tool, which we have been supporting for about 14 years, has now been taken over by Siemens and has just spun off the company Medsoto, which I have now been able to accompany or develop as managing director for many years.

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And we are now focused on being a service provider around the topic of Polarion A.L.M.

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on the road and with a very, very big foot also in medical technology.

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Yes, maybe let's go straight in.

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So, what are your Polarion customers sitting for?

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typically a.

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So, I think we can limit it here to the medical device context.

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So, for which processes, for which artifacts do they manage in polaria?

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So, Polaria is first of all a curse and a blessing, very generic tool and comes from the A.L.M. family.

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Tools.

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So, A.L.M.

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stands for Application Lifecycle Management.

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These are tools that originally came from software development and have set themselves the goal of supporting the entire life cycle of the application, i.e. a software product, both in terms of documentation and organization.

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so the focus is on requirements, tests against them, all the traceability in between, traceability on different levels, when you talk about stakeholders, system, software requirements and also the topic of collaboration, i.e. task management with some planning boards and so on.

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Exactly, it comes from the software, but I always say that it is actually a requirement, it doesn't matter whether it is against software or against hardware.

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This means that our customers use it to

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to maintain documentation in development, to maintain it without redundancy and to get the entire development under control, including the release and review processes, which can also be documented in the tool, even collaborated with assignments with electronic signatures.

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In other words, development documentation, focus, requirements, tests, but also because it provides flexibility, things like risk management, usability.

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So if you develop pure software and

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Where you don't have all these laboratory 6060 1 things, you have 80 to 90% of the file, you can create from polars.

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Excellent, our listeners and fellow readers in the journal know how important it is that we have the data at the right granularity in order to be able to unleash algorithms on this data afterwards, which in turn automate tasks such as checking technical documentation or other documents.

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Yes, even later, in order to then

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if necessary, to be able to extract registration documents, if I may call it that, as long as this is still done on a document-based basis.

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So now my question, can Polarion be adapted at all so that you have this granularity?

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For example, that you can go down to the language level of a user, for example, when determining a purpose.

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Yes, so the smallest unit of all ALM tools is basically called Work Item or Issue, i.e. G.

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Ronet, das Issue,

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what DevOps calls the work item, which is ultimately information that has any number of attributes that a type also has.

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That is, different types can have different attributes.

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So a test has different attributes than a requirement, than a design item and they can be related to each other.

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And on the level I have to look at what I have to do, what do I have to be identifiable on my own.

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That‘s just an item and it can also be a purpose.

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This can also be a purpose item itself and it has any amount of attributes, which I can also

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So I define my set of information that I need and I can put it in relation to each other.

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Then we are on the subject of traceability and I have a workflow.

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That means I can also map the whole status, something like reviews, releases, again with conditions.

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That is, I can only do you, I don't just have a database, the granular A.

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is the way I want it to be, but I also have the relationship of the data to each other and that's where it starts to get exciting for analyses.

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That means that in the end there can be a database

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or a function that would be equivalent to a database.

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What has to be done, does it have to be programmed or is it about configuration?

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So, it's a pure configuration.

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You can say that it's actually a database with a web interface, where I build the granularity or the data model or build templates for data models.

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That's exactly what we did.

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So for requirements from a 62 304 and the 14 971 we have ready-made templates, which I then use in appropriate projects

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and that is but inherent functionality of this tool.

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That means I don't have anything there that I have to dig deep into the program, I name it.

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So we don't have to prohibit anything, that's the cut functionality, so to speak.

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That's what it's all about.

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But what is also said for a curse and a blessing at the same time, because I can also depict very, very, very, very different processes.

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So we ourselves at Mesuto also use it for example in the knowledge base or in our internal feedback process.

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system is based on the same system where customers also manage their requirements and sometimes also us.

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yes or similar processes in themselves.

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The good news that is now emerging from this is that these data models, which we have derived over years, decades, from regulatory requirements, from algorithms that are supposed to check them, transfer the data, these data models we can obviously map in Polarion quite normally, without having to bend anything.

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On the contrary, we use Polarion to a certain extent, as it is thought.

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You called it a database with a web interface.

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Now that the data is in there, we naturally want to be careful not to create data silos, because 1 of the essential elements of a good digital transformation is that we support the processes end-to-end.

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So in this case maybe even before development, when it comes to things like that, maybe like determining the purpose, through development to the notified body, authority, later also further into the area of post-varget surveillance.

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That means we have to

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so that we don‘t create data goals and can map the processes end-to-end that data need to reach.

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This is usually done via A.P.I.S, something like this is also possible in Polarion and if so, is it more of a pull that you pull the data or a push that you can direct the data out, for example into a digital approval platform like the one we have?

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So really, I can get to all the data, the data itself is actually stored as plain text, as a Subversion repository,

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That's always the original data soup I have, so to speak, where I also get the whole versioning for free.

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But I can actually get to it via various APIs.

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So, I can use a native API to extend the tool myself.

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I get it via a webservice API, I get it via a rest.

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A.P.I.

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on it.

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There's an O.S.L.C.

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interface, which is very exciting for collaboration with other tools that also include O.S.L.C.

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Also O.S.L.C.

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stands for Open Standard for Lifecycle Collaboration.

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This is precisely intended so that such tools talk to each other and we ourselves also use it to connect something to customers via standard interfaces, i.e. to integrate this into the landscape, but also ourselves.

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We did a translation, for example, connected in Deeple, because customers just needed requirements or even just tickets

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or we have built a very deep connection in Azure DevOps, up to test executions, test results and then synchronize it when there was nothing and because the requirement was simply there on the customer

side.

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It doesn't work any other way.

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So, the answer is, if I read it correctly, we have the possibility to access this data via both pull and push.

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This means that we can design the processes end-to-end and then determine on a case-by-case basis, so to speak,

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who is the leading system, if I may call it that, i.e. where the source of truth lies.

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For example, in Polars, Source of Truth, which is then forwarded via an approval system to the notified body.

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Or you could also say the other way around, the polar is more or less the server or the storage from which its other system pulls.

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Is that correct?

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Yes, that's exactly a very important point you say, that there is always a leading system

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Even if you can synchronize bidirectionally, you can't say that some do it there, others do it there.

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We have had very, very bad experiences with that.

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So ideally is an introductory system and that synchronizes unidirectionally, even at any point in time.

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For example, in the workflow, that's something we like to do, when you release something in the Polaron, then you take the data and push it there, for example now in the approval platform and then the intended purpose is released and all the atomic purpose information then moves

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without me actually really noticing it myself, as a user, at the moment when I say I'm releasing it, the data packet then moves accordingly to the next place, where it may then be approved by Regulatory in the context of approval.

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Exactly, and where algorithms can then run over it, which just encroach, yes, maybe now not only the purpose within the purpose, but also between other data, which may even come from other systems, let the algorithms run over it, let Confident check and then exactly the

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To be able to achieve advantages that you want.

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So real-time compliance, some also call it compliance on the fly, that will achieve that and this complete automation.

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And then maybe even in the next step, if I now do in my collaboration in Polarium, that exactly these collaboration items are created, please look at it again, there is still something missing, please do that and I will do that in my sprint board or planning board and then also have my, my,  I'll say, Regulatory Burndown Chart, if I have that in these tools.

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Great, so we've learned now that we can use the

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Mapping the data structure in the way we need it in order to achieve all the automation.

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We have learned that we can exchange the data bidirectionally, whereby, as you said, we should always determine a leading system.

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But we have complete freedom here, so the question now arises, if you have just bought a Polarum or are thinking about doing so, how do you usually go about it and yes, what are those that might be,

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Things not to do or tips to recommend.

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You have 15 years of experience in this area now.

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So you shouldn't do 1, but of course it's also fun for us, buy a Polarion and only then think about what you want to do with it.

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I think that's one of the most important things to do, that you really understand it as well as an introductory project.

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So that you don't think I'll buy a tool and then the project is over, but I buy a tool and then the whole transformation starts in the first place.

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and you have to see where you have the biggest stomach ache.

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So you shouldn't bend the tool.

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I said Polar can do a lot, but you should first use it where it is really strong.

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Administration, requirements also in different variants across different releases up to test management.

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That's actually where you, where you achieve success very quickly, if I have my traceability under control and no longer have to do it in Excel.

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But you also have to be aware that it is a project that has an influence on core processes,

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that this also requires the resources and also a little, I would say, the commitment in new German from everyone, i.e. from those who made the decision and they then have to see success.

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That means that on the one hand you have to have the big plan, where is my digitization going and that goes far beyond Polarion, but also which one, what part Polarion has and how do I leverage the greatest potential within the shortest possible time or how do I heal the biggest stomach ache.

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That, I think, is what you had previously done in the

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Clarity must be and must have and is exactly the discussion that we always start with.

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So we don't show, look, this is the tool that can do all this, but we say, where does it hurt you.

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That's our way of introducing it.

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At the end, I would perhaps describe very briefly what such a typical project looks like, which we usually tackle together when someone has polachias.

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You have said something very important, the first step will always be to explain this

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attractive picture of the future very clearly.

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So, what will that be like?

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So, how much automation do we want to have, for which processes, in which markets, for which markets should it work, for which products?

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And the target image usually gives quite a lot of energy.

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But that doesn't mean that we're starting with the big bang here, but we usually do it in sprints between a month, a maximum of 3 months

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And in these sprints, we would then carry out this digital transformation piece by piece, so that we can always evaluate the benefits directly after each individual step.

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So not after a year and a half or 2 years or maybe even longer, you know whether it worked out and whether it really helps now, but we strive to always know that immediately after every single sprint, and also to be able to readjust.

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And an example of the first sprint would be that you decide on a part, maybe a part of the technical documentation, for a process, for example an approval process, for a product class, maybe this digitization starts.

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So it usually starts with an as-is assessment.

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So where is the data stored?

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Sometimes you find out that it may even be missing or that they are saved and then saved with a comparison of the target image for this detailed subpart.

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And then we're going, so to speak, during the beginning of this month

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to make this transformation.

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That means that then you have really recorded this part digitally, for example the technical documentation, and thus almost all the mistakes that can be made are already thrown out.

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Yes, because everything that is missing data now will not happen anymore, because the data model does not allow that.

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There can be no contradictions because data only occurs once.

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Certain errors in data are excluded because it can be excluded simply by type safety or by value ranges.

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This means that at the end of the first sprint you have

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a digital and fully compliant part of its technical documentation and then comes the next sprint.

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Then you might take a different file, you spoke of a risk management file or usability file.

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This means that they could be too substantive sprints.

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It may be that other processes are added in sprints, for example a post-market surveillance process that is integrated.

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It could be that we serve other markets in a sprint, for example the documents for the F.D.A.

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or for other regulatory authorities and

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Now to the topic of today's podcast and not sure, one of the Sprinters will deal with connecting systems, such as Polarion's.

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Yes, and if you are also interested in such a digital transformation and, above all, want to have the benefits of digital transformation, as I said earlier, i.e. approval later at the push of a button and not just after

years away from document transfer stations, where any

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Word documents are copied and formatted for the different markets.

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If you want to get rid of all that, then this is the means to go this way.

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And Sven Wittdorf and Imezoto and both of us from the John Institute help with them.

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Just get in touch, you will find our contacts in the show notes.

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Sven, thank you very much for joining us.

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Thanks to you, greetings to you.