

Modeling your own company into the abyss

With Prof. Dr. Christian Johner

Transcript

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There is very little chance that companies will succeed in adopting an enterprise-wide data model.

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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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Many companies such as IVD and medical device manufacturers have understood that

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that it's time to adapt, that it's time to undertake a digital transformation to stay competitive.

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And so it is not surprising that these companies, or some of these companies, have now started to think about company-wide data models and have set up corresponding projects.

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But so far I have not seen a case where I have thought, yes, this is a project that will be successful and will actually benefit the company.

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just harms.

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And I would like to report on the problems I have seen, which I have observed, as well as a few tips that I have seen that increase the probability that it will be a success afterwards.

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Yes, let's start with the things I've seen that I don't think are very helpful in achieving this goal.

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And the first problem does indeed have something to do with goals, namely that it is unclear at all what the

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goal to be achieved.

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Because a data model has no value per se, and even if this data model has been introduced, whatever that means, nothing has yet been achieved.

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This means that there is no measurable goal, a benefit that one wants to achieve through this introduction of this data model.

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And that is also important and this brings us to the second point in order to be able to model at all.

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Because the way we model depends on that goal.

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Modeling is a simplified,

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Mapping reality, in order to learn something from this model, from this simplification, or to achieve something with it.

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So, for example, if someone says, I want to optimize production, then there is probably no reason to model the usability engineering file or the activities associated with it.

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If, on the other hand, someone talks about an approval process that he or she has to optimize, then yes, then the part of the

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Agility Engineerings.

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And if you then also know in which countries, contexts, that this approval should then take place, then that also helps to decide, do you now have to model use scenarios, for example, do you have to model safety critical tasks or perhaps both.

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So the type of model is determined by the goal and by this context.

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If you don't have that, then you just analyze, model and probably suffer more of a

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Paralysis by analysis.

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The third thing I'm observing is that the task of developing an enterprise-wide data model is being shifted to cross-sectional functions.

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For example, a Chief Digital Officer.

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So first of all, it's a good thing when companies attach such importance to digitization that they implement such a function.

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However, these staff functions are lacking

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often also a little bit of assertiveness and resources.

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In other words, what has happened is that they set up projects and then get on the nerves of those who claim that we are the ones who actually bring the money into the company.

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And with that, they have now also created friction within their own company.

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What I also see as an issue is the amount of what you take on.

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So, if you think the whole thing

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To be able to model companies and their data.

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Well, at least he has my admiration, but I see that often the identical companies already fail to manage the master data uniformly in the company.

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In other words, uniform between headquarters and national companies, uniform between production and service, or between production and development or approval.

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Another topic is

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That even if they manage to do all this now, i.e. if they had achieved the art of developing a company-wide data model, then the question arises: Yes, so what?

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So, what's in it for us now?

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You have to implement this model afterwards and for that you will most likely need software and you should have thought about it in good time.

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Do we have this software at all and.

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the software we have is able to adapt it accordingly.

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In other words, to implement these models in there, to ensure interfaces between software systems and then to bring the data through the processes according to this model.

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And that's something you think about at the beginning and not at the end.

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And even if that had succeeded, the company must be aware that this modeling is not a one-time thing.

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This is an ongoing issue.

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This means that we need an organizational unit, a function within the company that continuously and endlessly keeps this model up to date.

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For example, if the context changes, if any master data changes, if regulatory requirements change, if technologies change.

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And of course, that also means never-ending effort and associated resources.

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Having said all this, I don't want to give the impression that I advise against modeling data.

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I think that would be quite implausible from my mouth, because I like to do it very much and because we also develop software ourselves.

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That's why I'd rather give tips that might help to actually achieve the goals.

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And that's the first tip I'd like to give here, you'll find it first

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the problem that is worth solving, that is, that justifies all these efforts and resources.

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If, for example, a company says we want to reduce the approval period from years to a few months, then it is indeed a problem worth solving.

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Because every month in which products cannot be marketed, hundreds of thousands, sometimes millions, slip through the cracks of this company.

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So then you have really found something that is worth actually solving.

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The second tip would be to make sure what this landscape looks like afterwards.

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So, this applies to the software landscape, it affects the process landscape, but it also affects the organization.

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Of course, you don't know the details at the beginning of this project, but we should already have an idea of how the company should be structured later on, if everything has worked out, in order to achieve the previously defined goals or problems

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Because if you do it too late and then discover too late that we can't introduce or adapt the software at all, we can't change the processes that are necessary for this, then you would simply have recognized showstoppers far too late.

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Third tip would be to slice down the project, preferably in such a way that you can successfully complete this first sub-project in 3 months.

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At Fit for Future, this is how it is done, we have minimized it according to various dimensions, sliced it down.

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So they were dimensions like processes.

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So, for example, we first started in the approval process before further processes were added.

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We first concentrated on a product, which is now a product, now also a good dimension in this context, on a market.

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We thought about a level of detail and were able to do so in a quarter-year.

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we have now called it sprint, certainly not the best term, but to actually achieve a result in such a quarter-year sprint that actually has a benefit.

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As you can see, now the thoughts of agile transformation are also coming into play here and then it would of course be quite good if you actually achieved quick wins in these 3 months.

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With Fit for Future, for example, suddenly the companies saw, ah, I don't have to enter a Use Specification anymore, because this data, it had long since been recorded elsewhere.

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Or they realized that I can no longer release documents in the wrong order.

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So, it is no longer possible, for example, to release the intended purpose after the clinical evaluation.

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Or they have recognized that there is no longer any work at all in biocompatibility to record the materials and components, because this has long been done with the system architecture.

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Well, those were such inspiring quick wins and it would be good if you could do them after every sprint, at the latest after every sprint, for example after this sub-project, this

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quarterly, which can actually achieve.

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The next prerequisite, which I also think is mandatory, is that you actually have a project.

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A project not only has a clear goal and somehow also a clear schedule, i.e. an end.

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A project also needs resources.

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So people need money that is made available, and of course a management commitment is part of it.

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And it also requires a commitment from all people who are involved in or affected by it.

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And these are things that should have been clarified beforehand, because otherwise you will have such subversive torpedoes afterwards, which will ultimately not make the project a success.

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Maybe the tip that is almost the most important to me.

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I said earlier that modeling depends on the goal and in this specific context of regulatory processes or if regulatory goals are to be achieved, then it is.

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A top-down modeling that needs to be done.

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This means that we have to start with the regulatory requirements and these regulatory requirements, if you want to have them fulfilled automatically, then we need algorithms.

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This means that we have to derive the algorithms and the algorithms result in the inputs, i.e. the data that are necessary for the algorithms to be able to test.

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And if we know the inputs, this data, then we know what the data model looks like.

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So, this is not arbitrary, but a top-down approach in which we arrive at the appropriate data model.

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And perhaps it is also noticeable what is another prerequisite that goes hand in hand with it.

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They need top experts, now in this case top regulatory experts.

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By the way, also a statement that the F.D.A.

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They told me that they only took regulatory people with them in the modelling, for example in the e-store context.

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And no longer I.T.

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Experts, because only the regulatory people were able to model and describe this in such a granular way.

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That means they have given the regulatory people I.T.

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knowledge because the approach that I.T.

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Teaching people regulatory knowledge was not successful.

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Yes, these are a few tips that I hope will be useful to you when you are thinking about your digital transformation and, if necessary, modeling

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or a company-wide data model.

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It is very important that now is not the time for academic finger exercises.

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Almost all the companies we are currently supporting have completely different concerns, they have to ensure their competitiveness and that should be taken care of and perhaps not completely forgotten the patients.

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So, if we always have this goal, namely this competitiveness and the patients, in the back of our minds and then break them down, what does it mean now,

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competitiveness.

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I said earlier, for example, faster approval period.

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And if you perhaps give you the tips that I have just given you or that I have just given you, I think there is a very good chance that it will be a success.

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If not, or if you have any questions, if you are not quite sure, just get in touch.

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We can certainly help.

