Johner Institute

The successful regulatory affairs executive

With Stefan Fischer, 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.

00:00:20 Speaker 1

We have already talked many times in the podcast about the huge tasks that regulatory affairs experts have

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which are the areas of tension in which they stand.

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And the question is, of course, how to meet these challenges, and that's why I've invited someone today who knows this exactly, namely Stefan Fischer from Hartmann, a large medical device manufacturer, but who's best to just introduce himself.

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Yes, very much.

00:00:52 Speaker 2

Thank you very much for the invitation.

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Stefan Fischer, my name, as I said, at Paul Hartmann.

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is now responsible for Global Regulatory Affairs.

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And I took a look in my C.

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V.

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actually in the industry for 34 years, always working on regulatory quality, environment-like topics and thus already done a lot in the whole environment of life science.

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Mhm.

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Yes, so if someone tells me, I've been in the

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in this industry, on the one hand I always think it's great, on the other hand I'm always afraid, oh God, when so much knowledge goes into retirement, it's going to be really hard.

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So I think we have to talk very briefly about the topic of human resources later, but now let's take a step back.

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So you're a top executive in a large company.

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What draws, if you were to look at it from a management point of view, what does a top executive draw

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or you could also ask, how do you notice, how does your management notice that you have done a great job?

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Yes, that's a good question and it certainly depends very much on the circumstances.

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So we, we're now a medium-sized, larger company with two and a half billion in sales and a very, very large portfolio.

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We don't just make medical products, we make pharmaceuticals, we make consumer goods, we make cosmetics and so on.

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And there, of course, there is always something moving.

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Former boss once said, keep me out of the press, then I'll be satisfied.

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I think there's a kernel of truth in it.

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So you often notice the absence of quality and not the presence of quality.

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So if recalls and various quality problems dominate the day-to-day business, then I wouldn't be satisfied and my boss certainly wouldn't either.

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But I believe that if everything runs smoothly and there is little regulatory emerged, then you can be satisfied.

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Mhm.

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From the point of view of the management, do you now have wishes, specifications, i.e. without revealing details among yourselves, for example in terms of admission periods, is that an issue for them or are you also measured by them?

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To be honest, we don't have any K.P.I.s now, because that would also be very, very difficult with a global portfolio.

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We have approvals in China, U.S.A., Russia, which of course have completely different durations, some and an insane number of projects in different regulations.

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A pharmaceutical approval is a different story than an I.V.D.R.

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for example.

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But of course we also coordinate closely with our sales and marketing colleagues.

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We go through the launch plans, we give an estimate

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and we are also measured by this and we have actually driven these targets and also simply budgets in the countries specifically, because of course we also have to budget the costs for the quarters, we know relatively precisely, in the big markets we meet our targets in the approval or not.

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And of course, the wish is always as fast as possible, that's clear, but you also have to look at how many attempts I need and what costs I cause.

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So

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better a month longer and done the first time than 23 rounds, which simply cost time and money.

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So there were now 3 even things, I think, that are in there.

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The first was adherence to deadlines, which is important.

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The second was that it was fast.

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So it has to go quickly according to plan and the costs should be kept under control.

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Not surprisingly, from her point of view, what are the things she is doing now

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among other things, as the greatest challenges.

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So on the one hand, we are currently looking very closely at the cost side, because we have completely different approaches in the different countries and regulations.

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So sometimes approval costs are part of the development, sometimes part of the country registration or the sales organization, whatever, you try to get a certain amount of transparency into that.

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and thus again a planning security for the budget.

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I think the other challenge is always cooperation.

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Well, we have an insane number of stakeholders, R.

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and D.

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Marketing sales, to name the most important ones, but also more and more purchasing, legal compliance, all those who also have to have a say in larger projects.

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And to find the vote here in the sensible way.

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even now a bit actually hindered by home office.

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I always say disabled because I think it's nicer in the office.

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I think there is the challenge of getting all this under one roof and getting everyone behind a project from the stakeholders.

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K., so you said that this communication referendum topic.

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In a subordinate clause, however, you also mentioned another challenge, namely you said that it is different in all markets.

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So that also means the

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regulatory diversity is an issue for you.

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Are the changes, i.e. the quantity and the change speeds, also topics for you?

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Yes, we have it with the M.

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D.

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R.

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very clearly noticed, these these significant changes, which played a very big role there with M.

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D.

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D.

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to M.

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D.

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R.

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I think everyone had to learn too, so they had to learn the

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that the representatives of the industry, but also the Notified Bodies and the authorities learn, which changes are relevant, what, what do I really have to report, approve, check in what form, in what level of detail, can I change from one supplier to another if it is the same material specification or not, or can I change a packaging of a sterile product, is it still in the worst case or not.

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So this topic is already very, very detailed today.

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in every approach and then again nationally, there are regulations that are more precise or not more precise in other countries, despite all the harmonization also in Europe.

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France and Italy sometimes behave a little differently than from the E.

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U.

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Desired.

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Mhm, which brings us back to this topic of diversity from a regulatory point of view, so that's a challenge and then what you just described, to understand what they want,

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which has now been mentioned as the example of MDR, the other side must first understand what it actually wants and that even with the same regulation afterwards, the interpretation changes over time or becomes more precise.

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OK, so it's also quite a lot of challenges.

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We talked about communication, we talked about costs.

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We talked about the amount of regulatory requirements, about the divergence of these requirements.

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how do you manage all this, how do you go about it and how maybe an ideal world will look like for you.

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I, I, I would say that there are 33 essential elements for the fact that one is of course the process landscape, also the technology behind it, so example regulation, how do I do it?

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to really grasp, evaluate, understand all relevant regulatory inputs, even simply the language hurdle in certain countries.

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How do I get the basis laid for it, so to speak, there is certainly K by now.

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I.

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and everything that goes with it, a big topic, which we also look at very intensively.

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The second point is simple, I need the best people.

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So I need

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People, people who enjoy what they do, who think outside the box, who not only work through the task that some software dictates and says, you have to tick a box here, but who, together with other partners and external parties, can also drive things forward in the team and work in a value-adding way.

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And the third point for me is also all this regulation and and

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political issues somewhere and to influence and perhaps also criticize them.

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We are very strongly represented at Medtech Europe and we try to influence it at the level and simply bring in the practical knowledge there, so that the regulators don't not decide in their ivory tower, but that experts actually have a say and say, this makes sense and that it may not make sense what you are doing right now.

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Now you have the whole regulator

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process, which I think is wonderful.

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So the statement is yes, we actually have to start at the beginning.

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We have to make sure through our initiatives, through our, through our commitment to the regulatory framework, that no nonsense is written at all, whether at the legal or normative level.

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Number 1, number 2, now this stuff is being written, hopefully in the best way.

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Then the next one is

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Task or where it differs, a good and a bad regulatory affair, I am able to notice all these changes, evaluate them and then implement them internally, so to speak.

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And that presupposes number 3 that we also have the people who can really do it and who understand it deeply.

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And you just said that they don't just tick boxes.

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Which brings us back to this topic of human resources.

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sounds.

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But I would like to interject a question beforehand.

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Where do you see this whole journey going?

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I think that was one of those insights from the last 2 years, where I also dealt very intensively with the digital topics and A.I.

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that there is such a kind of dichotomy.

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That's my personal opinion now.

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I think we will do a lot of daily work

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have to do in Regulatory and also in other functions, also in Quality and the like, simply to keep the systems alive, to keep my Q.

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M.

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S.

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to keep my certification alive, to write my reports, to write my C.

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R.s and everything that goes with it.

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I think that's an important part that you just have to cover and for that I have to have the right workforce and the right processes.

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And then there's just this part, I think, where

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and distinguish the good from the bad or the successful from the less successful, this point is that of implementation.

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What do I make of it?

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where, where do I create added value?

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Where can I get to market faster?

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Where do I bring certain claims into the product that a competitor can't?

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That's the trick with the right team and with the right ideas and creativity within the regulatory rules.

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and and for the patient and ultimately of course for the company.

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Mhm.

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Let me rephrase that so you're sure you've got it right.

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I have now heard or think I have heard 2 levels.

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One level is this, I'll call it bread and butter level now.

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Yes, it just has to work well.

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We have to make sure that all regulatory changes are made up of what you described earlier.

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We make sure that this is implemented.

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Here you can see,

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I hope I don't overinterpret that now, also a special value or benefit through digitization.

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So that's actually how you had initiated it.

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And then you said, but then we have a second level and that is the strategy level.

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So that we don't use the term you didn't use, but I'll bring you the document pushers anyway, but that you say, now we're the ones who look at what the market actually needs,

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Yes, you said that competition was also an issue for you right now, and we at Regulatory are in a position to ensure that or, if necessary, even to drive it forward, yes, because we have certain information.

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Did I reproduce you correctly?

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I don't want to overinterpret you.

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Does that fit?

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No, maybe to the first part, this bread-and-butter theme.

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I think cost sensitivity is very important here.

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So you really have to deal with automation

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maybe also with outsourcing or with whatever very brutal look, how to do it most efficiently.

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Mhm.

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Because that's a topic, I have to do that and it's all about how well, how quickly, how cost-effectively I do it.

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Mhm.

00:13:51 Speaker 2

With the second part, creativity, it's really the case to find the right people for it and to give them the freedom and to give them this environment and that something can be created here, because the

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the competitive pressure is gigantic, also of course geopolitically between the different regions it is beco-

ming more and more difficult to fight Europe against U.

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S.

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A.

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and so on.

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And I have to make sure that I put my time and brainpower in the right place.

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Mhm.

00:14:25 Speaker 1

Yes, now we really have to tackle this issue of personnel, now that we've teased it twice or almost a third time now.

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So, you already have important

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called things.

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Well, you said, they must have brainpower, was just a word, yes, they must be able to think it through and not only in checklists, checklist ticks was, I think, the term earlier.

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If you describe that again, i.e. which people do you want, what do they have to be able to do, what perhaps also character traits should they have, so that they would say, yes, we really want to have them.

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Mhm.

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Yes, I don't think that's my thing at all

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my secret, but this is common knowledge, diversity helps.

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So both professionally as well as about the age groups and and and everything you count in there.

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There are now more regulatory educational paths and training, but I'm not so much looking for candidates, I think, who now have some certificate or title, but rather broadly positioned.

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That is perhaps also a bit due to my,

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my C.

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V. that technology and economics somehow come together.

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I think that has always helped to cover several pages.

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In this respect, I always look at hobbies in addition to CV, so if someone doesn't write hobbies in CV, I always find it a bit strange.

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Then I'll ask right away.

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And so in my themes, I always mention the example,

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for example, I hired someone at the age of 67 who just wanted to do something and bring his experience to bear.

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And he's still with us and he now has his, I think, 72.

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Birthday or something like that in the meantime.

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Mhm.

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And of course it's an incredible enrichment for the younger colleagues who benefit from the experience.

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We have in the

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there are a lot of different cultures and backgrounds in the approval team and, of course, that also helps in the regions to respond to certain things in the markets.

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So it's always important to me to have people with the broadest possible view, with someone with an open mind, who have fun with it, because I think that's the most important thing when someone comes here to the company or

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then you go to your job and say, that's, I have to do that now or when is, when is the end of the day, that, that's a bad prerequisite.

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Mhm.

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Now you have even answered much more than I asked.

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Not only have you now said what you want from people, but you have also just revealed the secret of the teams.

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So at the team level, i.e. across people, this topic of diversity was important, also age, I found that a very exciting aspect.

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I hope, Mr. Fischer, that we still have you here in the team at 75, because we know that it is needed.

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And then you went into the individuals, so I have now heard, clever, ideally intrinsically motivated, broadly educated, were characteristics that you would like to see.

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If you could advertise this profession, what would you say to people who are considering it?

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Well, we actually always try to pick up young talents at the universities and so on.

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Yes, we are also a bit active there, do advertising.

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I think regulatory is a very interesting profession because it is so diverse.

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So especially in maybe a larger company, where you don't just have one or 2 products, but are very bro-

adly positioned, like Hartmann now,

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We just have something new every day.

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So if we think we have the M.D.R.

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just finished, then the Consumer Regulation comes and hits us and we have a new challenge again.

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I think that's a lot of fun.

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Also that the medical technology industry or life science industry is a relatively stable industry.

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So the one that won't disappear overnight, but it's something where you can plan longer and a certain development part in the company

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where should the journey go, do I want team responsibility, I want to become a specialist, you just have a lot of opportunities and I have the feeling that they appreciate the applicants we have and that can of course be sold very well if you also offer a reasonable culture.

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Yes, then everyone who appreciates the culture, who appreciates a variety of tasks, who wants to have a good company should apply

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and who also appreciate the fact that they are doing something meaningful, namely actually helping patients.

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The only question that remains is where they can apply to you or how?

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Feel free to hartmann.info on our website at any time or directly, so feel free to contact me via LinkedIn or anything else.

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Then we will also include your LinkedIn link in the show notes.

00:19:25 Speaker 1

Mr. Fischer, it was a wonderful interview, thank you very much for this interview.

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Insights from the perspective of a top medical device executive.

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Thank you very much.

00:19:36 Speaker 2

With pleasure.

00:19:36 Speaker 2

Thank you.