Johner Institute

A life dedicated to regulatory affairs

With Michael Herzog, Prof. Dr. Christian Johner

Transcript

00:00:00 Speaker 1

These are really important tips.

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I think every manufacturer should write them in the book, because these.

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

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So big issues that we have in our medical device ecosystem is the shortage of skilled workers.

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Especially when experienced colleagues retire and thus gain valuable knowledge

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is lost.

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In today's podcast episode, I would like to talk about this with an experienced warrior in the field of regulatory affairs, namely the head, the head of the lawyer of the Henkes company from Wulff.

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How can we also secure this knowledge for ourselves?

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Yes, you are very welcome, Mr. Herzog, to this podcast episode.

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You are an engineer.

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You have to ask yourself the question, how do you get into the R as an engineer.

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A.

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area?

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What interested you there?

00:01:00 Speaker 1

What inspired you about it?

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Yes, that was very, quite funny.

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In 1985, I had blindly applied to a large medical technology company in Tuttlingen and there was the task of obtaining a Q.

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M.

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Manual to be created according to 9001.

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That was the one that was also in the design at that time, at that time Q.

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M.

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was completely unknown at that time and or quality assurance was still called at that time.

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It is not quality management, but it is quality assurance.

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very cross-sectional functions, which means that they work together with all departments.

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We need to work together after development, sales, production and so on.

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And that interested me and said: Okay, I'll do it.

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And then I had my foot in the QM door or in the quality assurance door and then held other stations as a QM manager, mostly in medical technology.

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And then, or rather until before

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not too long ago R.

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A.

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Activities in Q.

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area and then with us in the company, then since the separation was pending, I then decided on the area R.

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A.

00:02:02 Speaker 3

, precisely because of the specific, the specific expertise and also in the interest, because there is generally in it, in the whole regulatory framework.

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In other words, you were the one who knew your way around best and who enjoyed it.

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Exactly.

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What made you happy?

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What was the interesting thing about this topic of regulations?

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Some say that's totally boring, who wants to deal with laws all day?

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Yes, that's, that's a very dynamic, very dynamic area, because if you just look at the M.D.R.

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then there is the M.D.R., there are implementing regulations, then there are guidelines, guidelines, F.D.A.

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it was exactly the same back then, because there, there were also a lot of guidance documents, because there and simply my norm changes maybe every 10 years.

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Rules, because they change in a, in a, so quite shorter period of time and in that respect it was interesting for me.

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So, you live the change, yes, not everyone is like that, that's what distinguishes you and I think you really have to have this willingness to change or at least a tolerance for change in this area, because I, we now monitor around seven and a half thousand regulations.

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Well, of course, there is really enough, which I actually

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changed from day to day.

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Now you've made the way to the top, which means you've obviously done the job pretty well.

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What do you think distinguishes a good leader?

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Or you could perhaps ask the question differently, when is your management particularly satisfied with you?

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So, which is very important for me, because there is my apart from the usual leadership qualities, because there are the soft skills,

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is simply the professional competence and professionalism with which you carry out this job.

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Especially in communication, internally with colleagues or externally with auditors and with customers.

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What is also important is that you don't forget or lose the lateral view, that you work your way into production topics, into development topics.

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I am still working on the area of compliance, which means that it is about materials, which is, as I said, just don't forget to look laterally.

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Let's look, sometimes look left and right.

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Simply so that you continue to have the connections on your screen.

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And okay, if they are completely satisfied, then the audit is successfully completed.

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The file review has been successfully completed and what is also very important is that these cost developments are partly coordinated with the sales department.

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These are corresponding business cases, they have to be resilient and if I then have the successful implementation

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or when the successful implementation has been completed and the operational planning works as planned.

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As I said, then at the end of the day everyone is satisfied.

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At this point, maybe some points that have always bothered me, then don't die in beauty.

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Courage to leave gaps.

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There are just things that you

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did not have to do 100%, but maybe only 80%, 80 20%, because the costs of course, I would have mentioned it briefly before, the costs are of course then or increase in part, when you see what an FDA inspection costs in the meantime or a 510k or 510k or

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China is looking at what costs there are with registration for product tests.

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Yes, of course, you have to make sure that you stay grounded here.

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Now they have answered 2 questions.

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Namely, the question of when are the superiors satisfied, when was the job a good one?

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There they had described, adherence to the plan.

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You had described, fast time to market indirectly.

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Yes, and of course they said, yes, regulatory compliance, i.e. audits and approvals, go through well.

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And they have explained to us what important prerequisites are.

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They have

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Ultimately, with this 8020, a pragmatism that is needed, seen as important, a deep professional competence, thus also an understanding.

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What legal requirements do we have here and also the ability to communicate internally and externally, with a professional understanding.

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You just said that, for example, you also have to be able to understand production, because otherwise you can‘t translate it.

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A legal requirement, what does that mean in concrete terms for products or materials.

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So a lot that you have already given us.

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This world is not an easy one.

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You have just described the amount of regulatory requirements.

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What other major challenges do you see?

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What are the big nuts that a Head of Regulatory has to crack?

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I would have touched on it briefly before, the professionalism.

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That means that of course you have to work for the recognition and respect in the company, which I don't call it a matter of course.

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Because for a long time it was the case that the lawyer and I now take my grand colleagues on board, the department, they don't bring anything, they just cost money.

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You just have to show that you have the right one for them, because if I don't have an approval,

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then I can't sell anything.

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And you have to have the understanding of the sales department and say, you're always there, because if I come to you and I want to buy something somewhere, then I'm not allowed to do that.

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And yes, you simply have to explain it and give professional reasons that indicate that it doesn't work for him.

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MDR has brought a lot of attention to this, because it is now on everyone's lips, not only in the company, but also in some cases

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into the private sphere, that people talk about it.

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That is, the requirements, medical devices or regulations.

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In the meantime, it has been brought into focus by the MDR.

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And what is also important, you must not let yourself be left behind.

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I said it before, I enjoy it when there is something new, that you can deal with something new.

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You just have to make sure that you don't let yourself be left behind by the many requirements,

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which are generated accordingly.

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O.

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K., that's interesting.

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So, you don't just see the amount and speed of change, all these regulatory requirements as an issue, but at least in the past also the recognition, the appreciation in the company, earning yourself and also being able to justify what your own role is.

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So, to a certain extent, it is also sales in the company that you have to manage as a regulatory manager.

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This coincides very well with the

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that I often hear, about his documents, marshalling yard or an obstructionist.

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And what you have just described, you also have to see yourself as an enabler and be able to communicate it accordingly.

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What I perhaps wanted to note was that these were the internal points, denominators, external, the biggest challenges is also part of one of the proposals that have been made to defuse the NDR a bit, is that notified bodies

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that there is simply a better coordination here.

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We are OEM manufacturers, which means that we deal with many industrial customers.

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Again, indirectly, of course, with many notified bodies or

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with many auditors and the divergence of requirements is therefore gigantic.

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There is no other way to put it.

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And what is also largely missing, from my point of view, is the practice-oriented training of the auditors, sometimes without industry experience.

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quoting only rules, only rules and sets the requirements, that can‘t be it.

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Denatis, something like that must not be.

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Denis, mhm, O.

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K., so on top of the quantity, she says now, there is the divergence to all these regulations and then on top of that there is a sometimes expandable understanding of what this actually means on the part of the examiners.

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K., I understand that.

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What would you like to happen,

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what have you perhaps done to bring us to a better world?

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So better now means, for example, that we get the products on the market faster, we have sensible regulatory requirements, we have sensible enforcement of these requirements.

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What do you think is necessary, who should do what?

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So what is already on the agenda somewhere, because what I have seen, because of it from the E.

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U., is simply because there is this global,

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this global consolidation of requirements.

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So as I said, MDSAP, the EU Commission is overcrowded and is about to check this at the moment or at least participate as an observer.

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I think that's very, very, very good, to simply deal with exuberant different requirements, as far as registration or registration is required.

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approval of medical devices in order to simply curb this.

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The other point is digitalization, clearly on everyone's lips.

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and here also a lot of dead information in PDF format.

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Of course, that's something that won't work for the future.

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We are sometimes talking about data models or single source of truth here, so that you can then anchor this information somewhere in the system and then access it from a wide variety of places without redundancies.

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But as I said, that's another

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probably a long way after that until everything works like this.

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How do you have to imagine that ideally?

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So, you mentioned 2 big things, namely, what does the legislator have to do?

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You mentioned the focus on consolidation.

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Perhaps a supplementary example, the FDA, which is trying to ally itself with Health Canada, with TJA, An

Visa, in order to at least bring the formats together.

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And then you addressed the topic of digitalization, which of course affects everyone.

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Especially by manufacturers, but we also need them on the other side, i.e. authorities and notified bodies, and they still see a long way to go.

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I fully share the assessment of the importance of this.

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We see, and I think this is good news, that a lot is happening there, that we are making rapid progress than on the manufacturer side and that notified bodies have also started to move.

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I'm glad to see that and I think we're pretty much alone in what the

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levers that we should use to be able to meet the challenge.

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You have now had a long professional life.

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What do you think is important that your successors should keep from your knowledge?

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So, what do you give them, do you include them in the book?

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What would you like to give them?

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Yes, I can follow up on what I just said, then that digitization should be pushed forward.

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Security is an extensive project, because all departments or all departments are then of course involved in it.

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But as I said, that's a very important point.

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What I also have to note, because the will to change is often not there.

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Keyword process silo thinking, that means the departments, because they just pay attention to themselves, or make sure that they adhere to their KPIs and

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and which may then be contradictory with other KPIs from other departments.

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A lot more simply has to happen here, because that these corporate goals or quality goals, as they are sometimes called, that they just come together and then you have a common goal and with digitization the thing is then accordingly

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and killer phrases like ‚We've always done it this way', that's of course completely out.

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These are really important tips.

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I think every manufacturer should include them in the book, because they are, I don't want to call them mistakes, but there are a few omissions that should not be made or that should be addressed in the future.

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And that's where I think both points, digitalization, process alignment, common alignment or process towards common goals.

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that's for sure, are the very, very important and big starting points.

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When you retire now, there is a bit of fear, because now the Duke takes all his knowledge with him.

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What else can you do or what can we look forward to so that the world can still benefit from the Duke's knowledge for decades?

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What are your plans?

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I hope the question is not too intimate now.

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No, definitely not.

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And as I said, I haven't thought about my retirement at all yet.

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I have not yet made an appointment regarding my exact resignation or resignation.

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how much pension I get.

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I put it all off because it's somehow completely unreal for me.

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But I definitely will, I am already active in various expert committees or expert groups or expert lists and hope that I can continue this work.

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after my professional activity and of course I would like to pass on my years of experience and expertise afterwards.

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Maybe as a consultant, there is one or the other Ms. Rodenau, who has any questions that can then be answered in terms of quality management or even the topic of regulatory affairs.

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That's exactly the answer I hoped they would give, because it ensures all the knowledge and

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if you will allow us, we would also leave your contact details in the show notes later.

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In other words, that all those who want to tap into their brains, who want to benefit from what they have built up over decades, that they know who they can turn to.

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I thank you from the bottom of my heart, Mr. Herzog, for this sweeping blow through, yes, starting the life of a regulatory affairs manager.

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How did he come to this?

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What are the major challenges we are facing right now?

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What would you recommend to successors that you do specifically?

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And until the good news, they are not gone yet.

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And thank you very much for all this.

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Professor Jonah also thank you very much.

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I had a lot of fun.