Johner Institute

The three dimensions of traceability

With Beat Keller, Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

Medical Device Insights.

00:00:08 Speaker 1

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

00:00:19 Speaker 2

Our medical device manufacturers are all still in the process of the MDR or IVDR conversion and we have already come relatively far there.

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Yes, that was one of those reasons that some people recently heard a presentation by Bert Keller on the topic of traceability and I thought it might interest a wider audience and that's why I asked Bert if he would come back to the podcast today and that we could exchange ideas about this topic of traceability.

00:00:45 Speaker 2

Bert, but I don't think everyone remembers you, you've been on the podcast before, if you say another 23 sentences to yourself, then I think that would be quite good.

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With pleasure, thank you very much for allowing me to be here, Christian.

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My name is Bea Keller, I am responsible for Regulatory Affairs and Quality Management at I.M.T.

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Firma I.M.T.

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we develop medical devices from startups to large multinational corporations.

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And of course, Tracer Bild is always a topic for me, what colleagues or our customers come up with.

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Excellent, that is, you

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If you practice it and therefore it is ideal, you can also report on it.

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Let's start again in a basic way, what is traceability, because it's not really that simple what is behind this term.

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Do you want to give a short introduction now, Bert?

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Very gladly, the M.

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D.

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R., when I look it up, I find the traceability 17 times, also the 13 for 85 has a lot of traceabilities in it,

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but it was defined by M.

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D.

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R.

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Unfortunately not.

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There is a definition in Reason 9000 that says that it is always about where material comes from, where it goes and with us in medical devices it is just about, on the one hand, where does my material come from, that I install in a medical device, where does the material or the medical device go, but beyond that, traceability also has

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for measurement results, traceability of requirements, risk control measures.

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So we have a lot of different and different traceabilities that we have to take into account.

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Yes, so that goes beyond the ISO 9000 that you just quoted.

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In other words, the one that it defined as the possibility of tracking the development, use or location of an object.

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Yes, that was more or less the one thing you reported about the

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components, the supplied components up to afterwards for use.

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So you could have done this whole life cycle for a long time and then you said that there is a second component, namely the traceability of requirements for implementation and proof of implementation, i.e. for the tests.

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Yes, and what you've already mentioned are the regulatory requirements.

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You've already mentioned some of them, if you might just get in on the action now,

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what do these individual regulations say now?

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You mentioned the MDR, the 13 585, I think the 62 304, you already said that briefly.

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If you could briefly shed light on what the legislator or the standards require of us.

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Mhm, so if we start with the legislator, then we have, for example, in the MDR Article 10 that we have to recall the device where we have a problem.

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if we have to recall this or that device or several specific devices, then we also have to know where the device has gone, what it has in the device, as one traceability requirements.

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If we then go a few lines further in the M.

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R.

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Article 17 then includes the reprocessing of equipment.

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Again, we have traceability in there, we need to know

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which device have we ever had, how often has it been with me and so there are quite a few in the M.

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D.

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R.

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Since we mentioned, there is the 13 for 85, which requires us to implement and test the requirements that can be input to output trace.

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In the 13 for 85 we also have what I said earlier, with the recall in it, where it says that we

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have to know where the devices have gone, with a small addition with additional requirements for the implantable devices.

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Then we have 62 304 with the proof, where did the software requirement come from, where did I implement it, where did I test it, or then also the 14 971 with the risk control measures, where I also have to prove again that I have implemented the risk control measure somewhere and have also tested it.

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Mhm, so we then have in the M.D.R.I.V.D.R.

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a great deal of emphasis is placed on the traceability of the product and its components throughout the entire phase.

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In the 13 for 85 we definitely have both aspects in it and yes, it also requires its own procedures.

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62 304, it is then mainly a matter of determining the requirements of which are usually from the system.

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and then also to be able to trace how they have been implemented and tested and 1471 similar.

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So that means that we have had some words, I believe it, you once mentioned it, horizontal and vertical traceability that we have to take into account.

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Yes, so we have to have it, now there is the question that many are asking, how do we ensure it?

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Yes, we have to look at the different aspects one by one when we look at the

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Faceability of requirements, design input to output.

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We need a matrix somehow.

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Most of the time, we do this in table form, where you show which user requirement, for example, has been implemented in which functional requirement.

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There it is broken down, I can understand all that nicely in such a table and then also the corresponding tests.

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On the one hand, you can do this by hand,

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with an Excel spreadsheet.

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On the other hand, there are also corresponding tools that support this.

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Which is certainly also suitable, because you didn't say explicitly, but it's not like we always have a 1 to 1 assignment.

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Yes, for example from User Requirement to yes Component Requirement, for example, are often N.

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to M.

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requirements, the same in the test.

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I think at the latest then it becomes clear when you look at N.

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to M.

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connections in different dimensions, that then the market leader Excel is perhaps a bit overwhelmed to be able to map something like that.

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I'm always amazed at how many people can still do it.

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Yes, yes, what you just said, even with these assignments, in my opinion helps now especially with these, yes, tracking of the requirement, where they come from, how they were implemented and how they were then really tested.

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What would you do to improve the traceability you have in the M.

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D.

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R.

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nor have you spoken?

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So the origin of components, the use of the products afterwards in the market, in order to ensure traceability or traceability, I think means character-wise in order to be able to ensure this.

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Yes, so on the one hand there is certainly E.

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R.

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P.

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Solutions that help me a lot where I want to be in my E.

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R.

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P.

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system can demonstrate how the

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When did the material come in?

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Where did I install it?

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I sent it there.

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Other manufacturers use classic tables, where I add the corresponding lots and serial numbers of the components to a series, a serial number of a device.

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The Excel list variant is certainly suitable if I have a product that is produced with very small quantities.

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If I have 1000000 quantities, then I will certainly have to find a more automated solution with

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is an M.R.P.

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system or something similar.

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Yes, then it will also be a prerequisite, yes, for this traceability is then also through the identification of the individual components, yes, be it via some serial number or via some barcodes, or it becomes more difficult when it is no longer components, but perhaps rather materials that are supplied.

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Then we are only in this area of badges, but without identification of these components, traceability is possible.

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do not succeed.

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And if you go out to the back now, so the product is now manufactured, traceability to the market, to the

user, what would be your thought, how to proceed, it's very important that I, as a manufacturer, know where I have sold my devices.

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The F.D.A.

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the U.D.I. has been demanding for a long time, now we have this in the M.D.R.

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that we have a U.U.D.I.

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need.

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Other countries are also working on it and the advantage with the U.D.I.

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is,

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I can scan them relatively easily if I send my device to an importer in another country.

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He, in turn, can simply scan it when he sends it to a distributor and so on, until at some point it is in a clinic, sold by a customer or implanted.

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And because of this possibility that I can always simply scan it anywhere, I always know where I sent it, what I received, when it went on

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and this source of error that I don't write something down nicely because I now have such beautiful handwriting or because I simply mistype something.

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Of course, I don't have them anymore with the machine-readable barcodes or dot matrices.

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Yes, you just said that I would simply agree in any case when it comes to this technical recording of these U.D.I.s.

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In terms of the procedures, it is perhaps a bit more complex, because that means that I have to carry out my entire

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chain, yes, via dealers or intermediaries and also obliges them to document exactly these U.D.I.s in each case.

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Because, if there is a tear in this chain, then we have lost the product and then exactly the original purpose of the M.D.R., namely the possibility of a recall, is then greatly weakened.

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Yes, what else should you know in the context of the whole traceability?

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Do we need anything else on the subject of U.D.I.

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Or is that enough for us?

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The most important things about Julia have said, on the one hand on the net is human-readable, I think we haven't talked about it yet, on the other hand it has to be machine-readable.

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In the case of human-readability, it is especially important when we end up somewhere with the end customer.

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The distributor, the reporter, he certainly has a device with which he can scan the device, the barcode.

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The end user at home, who now

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has to find out whether his clinical thermometer is affected by the recall or not, he will certainly continue to need the human-readable version.

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Mhm, yes, absolutely, always don't forget the human-readable version.

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We had also talked about this topic of measuring devices and traceability, which may be another construction site now, but maybe it still fits in.

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What are your thoughts, what do we have to take into account when it comes to measuring devices?

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So, it really works

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with the measuring devices, it's about the fact that if I measure something, for example a length and I measure 13 centimeters, I'll send it to you at the institute and you also measure, then that should be about 13 centimeters again, simply plus minus the measurement uncertainty.

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But that's the goal.

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In the past, it wasn't quite so secure with the cubits and then they hung a norm cubit on the wall of the town hall.

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and so the whole village knew that a cubit was too long.

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In the neighboring village it didn't work again, it didn't work anymore and the principle is actually the same today.

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I have to make sure that my 13 centimeters are the same as the 13 centimeters in Constance at the John Institute or at the F.D.A.

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in Washington or wherever the other person sits and does that with the traceability to the national normal.

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That means I can

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for example, my caliper in a laboratory, which in turn also calibrates its normal one, until we finally do it, now it's no longer the golden meter in Paris, that's solved a little differently today, technically, but that until we are on a common unit at the end, this S.I.

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units and in the end the same measurement result comes out worldwide.

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Mhm,

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Yes, boo, let me summarize very briefly before we come to the end.

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Well, you have now actually, if you take it exactly, even described this traceability to us in 3 dimensions.

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Namely, the dimension, the tracking of the product from its components to the application afterwards with the great goal of ensuring that defective products can be recalled quickly.

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The second dimension you pointed out was the traceability of the requirement.

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So, where does it come from?

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How are they and where have they been implemented and how have they been tested?

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That was another form of traceability, but it was also required.

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And the third was the return of measuring equipment to this standard that we have, which are supposed to ensure that we really measure the right thing afterwards, which is also a prerequisite for the others.

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And with that, we have now touched on a lot of regulatory requirements.

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Yes, I had already described that, M.D.R.

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The 13 for 85 has a separate chapter on traceability.

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There's a separate chapter on identification, as we've seen, which is a prerequisite.

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There is a separate chapter on these measuring devices.

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Well, that was a lot now that we got in.

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For all those who want to support you, Bernd, I would guess your company will be happy to help.

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We are very happy to help.

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We have also helped customers to use the Excel variants

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for example, to replace the requirements up to the tests with a tool, where the whole thing can be regenerated at any time with the help of a tool.

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So don't adjust something small somewhere, my whole Excel collapses.

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We have a lot of experience and appropriate tools in use to automate this.

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Yes, so contact Beat Keller or us if you need support.

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perhaps want to learn more, for example in the auditgarant.

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You've come to the right place.

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To help you find this, I have linked Beat's address to you below in the show notes, as well as further information, including a technical article that we have on this topic.

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Yes, and that's the end of it, Beat, thank you very much.

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Thank you so much for letting me be here.

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Yes, and then until the next podcast.

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Bye.

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Bye.