Hi, I'm Bruno Holthof, and you're listening to Health, Innovation and Entrepreneurship.

In our previous podcasts, we have listened to health entrepreneurs from Europe, Africa and Asia. And a key learning that was shared with our audience was to start thinking about regulation early on in your innovation journey. So, I'm very pleased to welcome Rita Hendrikusdottir as a guest today. Rita is the CEO and co-founder of Regmetrics, a spin-out from the University of Oxford. Rita and her co-founder Jeroen Bergman were developing a medical device and discovered like many other innovators that the regulations are a real struggle and often determine whether the technology reaches the market or not. So, she set out to bridge the knowledge gap between science and law.

Rita, welcome to the program. And you know, because we've been interacting with some of these health entrepreneurs, that they sharedwith us the learning, you have to start early. But why and how do you actually do that?

Thank you very much for having me on this podcast. I think it's really important that early stage innovators start on the regulatory journey really early. I mean, even as early as the ideation stage. Because if you have a clear strategy, you know what's coming, you know what is required of you according to the law, you know how to test your device, you know what type of materials to use. You know if you need to do a clinical trial or not. And I think all of this is a great starting point when looking into the strategy of developing that medical device, it will really save a lot of time and a lot of money if you know all of those regulatory requirements beforehand.

You mentioned materials, but is it also the same if you want to develop software, for example?

Oh, yes, definitely. When you're developing a software, it's really important that you have to have a clear plan. Everything needs to be tested. So, having a good strategy and plan how to develop your software is really, really important. Because if you have developed your software without any of those controls in place, it's really difficult to go back and redevelop everything. So yeah, software definitely really important. And I mean, there's different classes of regulation. And I think some of the innovators, they go with so-called lower class first, because it's easier, also less costly and faster.

What's your view on that?

I think, first of all, you should not just go with the lower classes, you have to classify your device according to your intended purpose. So, your intended purpose dictates the class of your device. But of course, you can take certain features out of your device. And then that makes it a lower classification, because the risk is not as high.

Maybe you can give the listeners a concrete example in, for example, diagnostics. I assume if you still have a health professional confirming the diagnosis, you could go with a lower classification, could you?

It depends how the device is designed and made and what the intended purpose is. You will have to be really clear that there's also no misuse of your device. So, you will have to put things in place so that the healthcare professionals don't think that you are actually making the diagnosis for them. So yes, you have to have a lot of things in place in order to make sure that people are not misled by your product.

That's quite insightful, Rita. Can you give some examples of unnecessary delays or failures in approval, because entrepreneurs started too late?

Yes, there was one university project that contacted us because they didn't look into the regulatory strategy before they got the grant for their medical device. They found out during the grant that they actually needed a biocompatibility testing that costed them 30,000. So, they were unable to go through to their clinical trial without this test. This really made them delay their project because they needed to find the 30,000. But if they were to know what was coming, if they knew the regulatory strategy, they could have added that money into their grant and then the project would have saved them a lot of time developing this product and testing it properly.

A great example, but it is clearly very complex and finding the right experts is not easy. So what's your advice? How do you get started? And maybe it's also a way to describe what RegMetrics does and how it helps entrepreneurs to navigate this complex field.

Yes, definitely. So it is really difficult to find the right expert. Often the experts are also experts in certain fields. So they're not experts in all medical devices. What I find is the best way is to make sure that you as a founder or a developer understand the regulation a little bit before you talk to them. Because if you understand how the classifications are built up, what are the clauses that you need to adhere to, you can have a much better conversation with your experts, but also you can find out if they are telling the truth, if they know a lot about the subject. So making sure that you both speak the same language. And this is what RegMetrics actually does. It's a software that takes you step by step through the regulation and the regulatory strategy. So at the moment, you can classify your device by simply going through a few yes and no questions. And I think one of the most important aspect of RegMetrics is that we have all the references in our tool. And I think this is also really important when you're talking to an expert. If they state like, oh, your class is 2A, ask them, where are the references? How do you come to this conclusion? Because when you are filing your documentation that you're responsible for, you cannot just say, John told me. You have to relate that information to the regulation, the official law documents. And this is what RegMetrics does. We give you all the references to empower you in understanding the regulatory strategy. Next to the classification, we also have the GSPR. It's the General Safety and Performance Requirements.

So you can go in and click on the clauses that might be useful for your device. And then we will also give you, knowing that information, the standards that might be useful for you. And even test houses in the UK that might be able to help you test your devices. So actually, going through RegMetrics will give you a lot of good information to be able to talk to an expert and understand if that expert is actually able to help you.

Yeah. And currently RegMetrics is focused on medical devices, diagnostics and software, but it's not yet available for drug development, I understand. And it's also focused on European regulation. So what are your plans in terms of expanding this to drug development and other parts of the world? And certainly the US is an important market.

Yes, we decided to focus on the EU. And the reason was because the EU was going through a significant change, going from the the old regulation to the MDR. And we thought it was important to help people with the European regulations. But of course, in the future, we hope to be their regulatory compliance software worldwide.

And is there a lot of difference between the FDA, the EMA and other regulatory agencies? Or if you cracked your strategy for one of them, can you apply it across the globe?

There are some differences, but I think in general, they are very similar. One big difference is the way that FDA classifies their device compared to the MDR. MDR is very much rule-based, whereas with the FDA, it's all about what the device is and they give them certain codes. So that's very different. However, I think the quality management systems and most of the testing is required for both. One thing to note is that some regulatory agencies would like you to test on people in their country. So you will often need to do an additional test for that specific country.

But yes, definitely looking into all regions in the world is very important and something that we aim to add to RegMetrics in the future.

That's great advice, Rita. In terms of actually managing these regulatory bodies, it's dealing with people that have to interpret these often very intricate legal documents. And whenever there's interpretation and humans involved, you need to think about how you manage those interactions. Any advice that you have on the dos or don't dos in terms of managing these regulatory agencies?

In terms of signing up for the Notifying Body, make sure that just about six months before you have finalised your product, get in contact with the Notifying Body to make sure that you are in the queue when the right time is there. I think the one advice I would give is make sure that you speak the same language.

Because yes, there's a lot of regulatory definitions out there. Make sure you understand them and also make sure that you have all the information from both the law documents, the regulations, but also the official guidance documents so that you can really back up your claim, back up your thinking and your paperwork. So, it is really important that you as a founder, you as a developer, you as an academic, you're also understand the regulation and don't just lean on an expert, but understand the language as well so that you can have a clear communication with the experts and the regulators.

Wonderful Rita. This was great to get your insight in a complex matter. And as we know, this is a real struggle for many entrepreneurs around the world. So, thank you for that. If you also like this podcast, don't forget to subscribe to this series. Next time we will talk to a social impact investor because besides meeting regulatory standards, securing funding is another key challenge for entrepreneurs.

So, stay tuned and thank you for joining Rita. Thank you very much.