The rapidmicrobiology podcast series

Episode: The Future of Pharma QC is Automation and Digitalization

Paul Carton (host):

Hello, and welcome to the Rapid Microbiology podcast, and I'm your host, Paul Carton. Today, we're talking about automation, digitalization, and the future of quality control. We are now embracing Industry 4.0 in the pharmaceutical sector, and it's clear that the future of pharma is automation. There's no disputing it. It's now possible to meet your microbiological testing requirements via robotics and artificial intelligence, leading the microbiologist to validate the results or refer them for further investigation. With this greater dependency on instrumentation software, ensuring that your quality control automation software provider is reliable and has the experience, competency, and expertise to transform your lab from end to end with automation and digitalization is crucial. And with me today is Anke Hossfeld, Marketing Director for Automation and Digitalization at Merck KGaA, Darmstadt, Germany. Hello, Anke, and welcome to the podcast.

Anke Hossfeld (guest):

Hi, Paul. Thanks a lot for the introduction, and thanks a lot for having me on this podcast. I'm really happy to be here. I just wanted to say why I'm so interested in automation because in my role with the strategic marketing team, I'm supporting all the ongoing projects in our biomonitoring business. I'm also looking ahead and working on the mid and long-term strategy for automation and digital because I'm quite sure that this is the future and that we can have the right solutions in place to meet our customers' needs. This is why I'm looking into this topic in automation and digitalization.

Host:

So, this would be a relatively new role in Merck's company?

Anke:

Yes. Even though many people are working already on this, it's also something unique, which we have designed to focus on these automation topics and ensure the proper support.

Host:

And everyone's talking about automation, instrumentation, robotics, and artificial intelligence. It's all over the news. And so, I guess I would ask how Merck is addressing this trend of automation and digitalization?

Anke:

At Merck, we clearly see the interest in automation and digitalization because it has some benefits. It can, for example, improve the reliability of your testing and the data integrity and overcome some resource issues because it's increasingly difficult to find skilled personnel.

Before this overall automation trend, we had already started to equip our portfolio according to these needs. So, for example, having barcodes on consumables and devices that can be easily integrated so that we are already equipped for this digital change. And now as we see automation moving forward and these full automation trends, we have now started partnering with some key pharmaceutical companies. We are developing the first solution for various applications, for example, bioburden or sterility environmental monitoring. And we are partnering with customers to understand their needs to come up with a first pilot solution, which we will test at the customer site.

Host:

Sorry to go off-topic, but do you think it's difficult to get skilled labor now?

Anke:

We see that overall, there is a trend that personnel you have who have the right skill set, that there's a quite huge competition around specifically in areas where you have more than one pharma company. So everyone is looking for the same and whatever the conditions you can offer, people will leave and it takes some time to train them. For example, a person who goes into the clean room to perform the environmental monitoring can take up to six to 12 months to train them. And if personnel leave, then it's very difficult to get them back.

Host:

You mentioned partnering with pharmaceutical companies. When a pharmaceutical plant intends to implement new technology such as automation and digitalization into its operations, there are two questions they would ask themselves: what problem will this solve, and what problems could it create? So, can you tell me first why pharma needs automation and what challenges they will face implementing these changes?

Anke:

I think that's an excellent question because everything has pros and cons. So you can call opportunities and challenges which you have to address. I believe there are advantages that automation and digitalization can bring. First of all, it's the performance of the QC test and improvement of reliability, as I already mentioned, because you are always performing the test in the same way. By doing this in an automated way, you are recording all the details, meaning all the materials, equipment used, and even some parameters of the test, so that you have full traceability at the end of the test. So you know which materials were used and which operators did the test, which will also speed up your investigation. If you have an out-of-specification and need to check, it's easy to have all this documentation on hand.

Host:

And what problems could it create, let's say?

Anke:

One constraint could be that you might not have sufficient space in the laboratory or clean room. Because thinking about automated solutions sometimes they can be complex and can be bigger. It might not be possible to do this, especially in some older production facilities or if you have QC labs in older buildings. So this is why I think it's very interesting if you are building new facilities to keep this automation topic in mind and checking, are the corridors wide enough? Do you have doors that can open automatically? So, you can already consider this when you think about automation.

Host:

Okay, so realistically, you're going to have to expand, you think, to go with the trend?

Anke:

Yes, exactly. I mean, it's not necessary. We see that also this automation and digitalization can work in a standard environment. It's just for some of them if you think about a robot which moves automatically into a clean room that in this case it's good to check if your environment is capable of doing it. Another topic which I think is very important is that you think about the security of supply. So, if you think of specific consumables that might be needed and have the right service in place, thinking about automation concepts and solutions might be a bit more complex. Having the right partner on hand is important to provide this service. Because what do you do if your bioburden system doesn't work? So you would like to have someone quite soon on site who can help you.

Host:

Okay. So perhaps if you can't install automation, digitalization must be implemented because of so many benefits, as you've suggested, security of supply and stuff. And just back to the labor force topic there at the moment, because I imagine many microbiologists are going through education at the moment and developing their careers. And so, as the future of quality control is automation, microbiologists will obviously need to upskill to meet these demands of AI and the machine-driven world. How can microbiologists prepare for Industry 4.0?

Anke:

What's very important to mention here as a first place is that I don't think qualified microbiologists will be eliminated when we have automation. There is always a fear that we will replace personnel, and that's definitely not the case. I think the advantage of automation is that you are replacing repetitive tasks with automation so that your skilled personnel can focus on higher-value tasks, reporting, and validation analysis. And for sure, with automation, you are completely right; there are some skills required for the implementation or validation of a complex machine that is not part of the current, let's say-

Host:

Curriculum?

Anke:

..skill set. But on the other hand, I don't think operators need it. I believe it is essential that they go out and check in their company, who are the people who can support. For example, go and identify who are the IT colleagues I need for it, or do you have a service organization in your company that would be able to take part in the service of this kind of equipment? I think it's good to start thinking about automation and digitalization to set your network within the company that can support you, at

least in the initial phase of the project, and can help you. So I don't think it's necessary for all operators to be fully involved in all the topics.

Host:

From what you're saying, IT will become a major part of pharmaceutical operations, even more so than they were.

Anke:

I think so because the overall trend is to connect different equipment and data, and that's what's already happening in the pharmaceutical industry. And with automation, it will even increase. So I think to know your partner in the company who is taking care of these IT topics and who can help you to integrate it, I think that's a good first step.

Host:

Pharmaceutical manufacturers require faster and easier process monitoring and contamination control and will seek instrumentation and tools that can provide comprehensive information to support critical release tests. What solutions does Merck provide for robust contamination control strategies?

Anke:

First, Merck has been operating in the market for decades and has already provided high-quality consumables that can be easily integrated. So, innovation is always one of our priorities. That's why, even before this overall automation trend, we had started to equip our consumables with things like unique IDs and barcode labels, which is very good preparation for this digital transformation we see right now.

I think environmental monitoring is an excellent example of this contamination control. So here I talk specifically about viable and particle counting in air. Automation can improve this contamination control because if you think of an autonomous environmental monitoring robot that goes into the clean room and can perform the test automatically, this requires fewer people in the clean room and already reduces the risk of contamination. So, if you have a robot going in, you have fewer people to train and fewer people to stay in this clean room. Using this kind of automation, you have all the documentation ready afterward, meaning you have all the data consolidated, which is very important if you have an audit.

But besides environmental monitoring, where we talk about the full automation process, it can be a much easier solution, like software. We have recently launched M-Trace software, and that's something which supports sterility testing. Here, it takes all the different steps of the sterility testing, and you have good documentation afterward of what has happened. So whenever you need to investigate it, you have all the different steps available and the documentation, which will help you have good contamination control in place.

Host:

If a plant wants to move forward with robots in clean rooms to sample, how can Merck help in these improvements?

Anke:

This kind of solution I mentioned is one of our pilot projects. Whenever pharmaceutical companies are interested in this kind of solution, we are more than open to discussing their needs and seeing if what we are developing is going in the right direction of what can help them. We are open to getting feedback on the needs and looking into even specific solutions.

Host:

So you're continuously talking with your partners at the moment, to your pharmaceutical partners, and developing pilot projects and testing them out and getting feedback and reports and building plans for the future basically on an ongoing basis.

Anke:

Exactly, because we have to consider we are here in a completely new field. It's highly innovative. We need to try and develop with our partners and customers to come up with a perfect solution at the end, but that will not come from one day to the other. We are closely collaborating with different parties to develop a pilot and improve for a standard solution.

Host:

Just touching on what you said there, every day is different. Nowadays, technology is moving so fast, and constantly new problems are arising. And so, just for example, we see paper replaced with digital records for a long time now for traceability testing and standard operating procedures. How advanced is Merck's software in assisting microbiologists in carrying out these tasks?

Anke:

You're completely right. I think digitalization is really key. When we move forward with our projects, we take digitalization into account in each of these projects because digitalization is the enabler also later on for automation. But we have also worked on ensuring that with all these automation projects and digital projects, we can connect to our customers' IT to ensure that the customer protocols are taken into account. We are also using all different consumables which can be scanned and have an ID. And so during the loading, for example, of automated equipment, we can check if everything loaded is correct because if it's not correct after it's scanned, it will be refused. So this really helps to assist the microbiologist in carrying out exactly the protocol he has to do and using the right materials.

Host:

It's keeping the microbiologist in check in case he steps away from the protocol, just reminding him this isn't allowed. The microbiologist could get distracted, or what happens?

Anke:

Exactly, It's documented. I think that it's also very important also due to data integrity purposes that you have this documented that there was a mistake made; it was tried to enter false materials. So, for sure, it'll not be taken into account, but it's documented. So, we are not removing anything from these digital tools we are using to capture everything. We are not removing any data, and that's very important to be compliant.

Host:

Regarding compliance with that M-Trace software that you mentioned earlier, how does it make it easier for data integrity purposes?

Anke:

It's a support to capture all the different steps. If we take the M-Trace example, as you mentioned, if a customer would like to perform sterility testing with a sterility pump, it is taken into account each step. Materials are loaded and scanned. If you enter the wrong consumables, where there's an error, it will notify you but will still be documented. It has a voice control. So even during the test, whenever there's something ready, the operator confirms that they have done this task. At the end of the test, you have everything documented and a full set of data that you can use for investigation.

Host:

And so for voice control, I assume that's very easy to set up for the software to recognize the operator speaking.

Anke:

Exactly. That's taken into account as well. Before you go into the isolator, you can set everything up on a mobile device; we have tablets. Then, during the operation, considering that the operator is with the hands in the isolator, it's easier than pressing some buttons to confirm; it's easier to use your voice. So, the operator has a headset and can confirm.

Host:

Okay. As long as the operator doesn't get frustrated and curse or something, and then-

Anke:

We haven't had this issue yet.

Host:

Okay, good. And so just on a general topic regarding supply security, it's a hot topic at the moment, and I guess that's come out of the pandemic. So, how can you ensure supply security?

Anke:

Yeah, I think that's a very important point. If we look at our current customers, I mean most of them are global. If they are looking for supply, they are sometimes even looking for harmonization of supply so that different sites can use same consumables. As I mentioned, we sometimes have very specific consumables for the solution we are currently developing because they need to be robotic-friendly to allow a good performance of the automation system. And for that reason, I think it's imperative to choose the right partner here because if you have consumables, you use and there's a little change in the consumable itself, that can cause failure in the automated system. If you consider a human hand, it is easy to adapt to any shape. If you have a round, square, higher, or wider bottle, it doesn't matter, but for a robotic system, it's difficult.

If you have these specific consumables, then it's also important that you have a good supplier of it. And that's what we are trying to do with our consumables, which we can supply. So not only the equipment but as we are a supplier of consumables already, we will also take care of these robotic-friendly consumables. We have specific activities in place to keep special stock and also to monitor any potential change that might have been done to the consumables to avoid that there will be any failure in the automated system.

Host:

So there's a lot of checks I suppose to be done on a consumable, whether it fits the hand or the robotic. Would that probably require you working with the manufacturers of the robots themselves?

Anke:

That's what we are doing quite closely. We are working with all the partners involved in the equipment component. We have very experienced partners on site. So we are going in as the application experts, ensuring everything is according to regulation. There's a significant difference if you automatize a workflow for any purpose or work within the highly regulated pharmaceutical environment. Here, we are working very closely with specialized partners, but we are always taking the view of a microbiological expert to ensure that we do this in a compliant way.

Host:

There's a mention now of Industry 5.0, which adds sustainability and environmental consciousness into the equation. Is Merck prepared for this? For example, how does Merck provide lifecycle management?

Anke:

That's a very good point because lifecycle analysis is part of our development project. We do not look only at the product itself but everything that comes before or after the life of the product. I already mentioned service and maintenance. That's one of the key topics for an automation system to ensure that there's no disruption in your manufacturing process. But, also, you mentioned sustainability. So here this is getting more and more important for us. We have our goals here, but we know customers are increasingly looking for this. And I think that's a good thing.

For this reason, we are trying to switch wherever it's possible and wherever it makes sense, from a single use to a reusable one. We are also checking the packaging material. We are trying to reduce disinfectant. That's something that doesn't have the attention it should have, that we use a lot of disinfectant to get consumables in, and with automation and double packaging concept with materials which can be recycled, that can be avoided. We are trying to develop under these aspects and taking the entire lifecycle into account.

Host:

Okay, great. Anke, thanks very much for joining me on the podcast today.

Anke:

Thank you, Paul. With pleasure.

Host:

You're obviously clued into the automation and digitalization trend. Companies will need someone as experienced as you to help them adopt these new technologies and make it a smooth transition. Thank you to our listeners. I'll catch you next time.

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