Transcript of the rapidmicrobiology podcast episode\_How to Handle Environmental Monitoring in Isolators

**Paul (Podcast Host):**

Hello and welcome to the Rapid Microbiology Podcast, and I'm your host, Paul Carton. Today, our topic of discussion is the role of environmental monitoring, but this time in isolators, which has the appearance of being quite challenging. My guest today is Adele Gisselmann, who is the Global Product Manager for Environmental Monitoring at Merck KGaA, Darmstadt, Germany. And Adele is no stranger to our podcast series.

**Paul:**

Hello, Adele. It's great to have you again.

**Adele Gisselmann (Guest):** Hello and Good morning. Thank you.

**Paul:**

Adele, as an introduction, can you please remind us what are the main differences between manufacturing in an isolator and a classical clean room?

**Adele:**

By definition, an isolator means that the production line is 100% isolated. This means there is no personnel inside the area. When any manipulation is needed for environment monitoring, it is only done from outside of the isolator via thick gloves made of neoprene. This can be challenging. Something that is very specific to the isolator as well as opposed to cleanrooms is that decontamination is done usually by vaporized hydrogen peroxide (VHP). Then, of course there is less space in an isolator, and you need to handle the material transfer very differently than in a clean room.

**Paul:**

To clarify, when you say manipulation, you mean the opening and closing of media and swabbing etc.?

**Adele:**

Yes, exactly.

**Paul:**

What are the differences between the environmental monitoring work done in an isolator and in a clean room?

**Adele:**

Generally speaking, you will need to perform the same tests you would as in a cleanroom to ensure that the environment is perfectly monitored. I would say that the design of the products should be adjusted to overcome the challenges of the differences that I mentioned before.

**Paul:**

Okay, when you say design of the products, can you be more specific? For example, how would you manipulate environmental monitoring samples with these thick gloves?

**Adele:**

If you are asking about the media, then you can have both plates and swabs. The general handling of our ICR plates is not difficult, even with our lockable plates. For our ICR swabs, they are easy to manipulate even with the thick gloves because it's all-in-one solution. There are only few steps needed to manipulate the product, and so the packaging of both ICR swabs and ICR plates is easy to remove.

**Paul:**

What about microbial air sampling? How do you handle the instrument with the thick gloves?

**Adele:**

We have a dedicated line of products for air sampling, which is called the Iso line of the MAS-100 family. It is designed to separate the sample location from the control unit. So, all you have to do inside the insulator is to open the lid, which is easy, and insert a plate. The control is done from outside of the isolator with the MAS-100 Iso control unit using the isolator HMI panel. This can be done outside with standard gloves.

**Paul:**

Okay. You mentioned vaporized hydrogen peroxide decontamination. Can you tell me, what impact has this broad-spectrum antimicrobial have on environmental monitoring?

**Adele:**

There are different aspects. First of all, as VHP is used for the decontamination, it might inhibit the cross-promoting properties of the media. A key requirement is that the media is protected from VHP during the decontamination, and for this, we tested that our packaging is fully impermeable to VHP.

Another aspect is that you want to make sure that every part of the isolator has been decontaminated. So, when you bring something into the isolator, you want to ensure that it can be decontaminated too, and that it won't bring cross-contamination risk.

When it comes to active air monitoring, you would need to put the sampling part of the instrument inside the isolator, and this is why we offer a unique solution with our MAS-100 isoline that enables you to perform an active decontamination of all air duct and parts. We do this with a unique double valve system.

**Paul:**

Okay. The packaging is impermeable and the isolator itself can be decontaminated while in the isolator, is that right? Is there anything else?

**Adele:**

Yes. Exactly. There is another aspect. It is that VHP can leave residues on the surfaces and the air in the isolator, and this is why neutralization of the residues should be taken into account. For surface monitoring, we need to ensure that even low possible residues of VHP will not affect the growth properties of the cultured media.

This is why we supplemented all our ICR media with Pyruvate. Pyruvate is a neutralizer against VHP, and all our ICR plates can neutralize up to 100 ppm of hydrogen peroxide. We have tested with such high level of hydrogen peroxide, because with active air monitoring, you can accumulate more residues on the plate. For swabs, we have tested 50 ppm, which is already higher than the maximum expected level of hydrogen peroxide on surfaces.

**Paul:**

In the beginning, you said there was less space and that material transfer is performed differently than in a clean room. Why would this be a concern for environmental monitoring?

**Adele:**

Yes, when you are running a production campaign, for example, it can be for several days or even weeks. You perform your decontamination cycles before the run, but you do not perform additional decontamination during the production and so you would usually need to store all material you need for environmental monitoring during those weeks inside the isolator. This requires a lot of space inside the isolator, which most of the time you don't have.

With the IsoBags, we offer a product that enables you to store all the plates outside of the isolator, and to connect it to the isolator when you need it. For this, we use a rapid transfer system, which you are able to connect and disconnect, easily and safely. This can be done multiple times so that you just need to take the volume of the required plates out of the bag, and we have several options for this: We provide the bags loaded with either contact plates or settle plates.

**Paul:**

Okay. What about the environmental plates or swabs when the environmental monitoring is done, how do you take them away for testing or incubation?

**Adele:**

In order to avoid any cross-contamination on the plates after the sampling, it's useful to transfer them within sterile bags. You will do the same in the isolator. For the swabs, we have a solution as well: Our ICR swabs are safely closed, so you don't need to put them again in bags, but they should be transported upright. So for this, you can use our swab rack and take them out of the isolator.

**Paul:**

Okay, is there any guidance from Annex 1 on how to perform environmental monitoring in isolators?

**Adele:**

It's not specific. The regulation is the same as for a Grade A cleanroom, and the new draft from 2020 of the Annex 1 mentions isolators as one possibility to achieve cleanroom Grade A conditions. But practically, you need to adapt to the configuration of the isolator.

**Paul**:

Okay, that's great. Thanks, Adele for describing to our listeners how easy environmental monitoring in isolators can actually be, and thank you to the listener for making the time.

**Adele:**

Thank you.

***End.***