

Clean Air and Containment Review

ISSN 2042-3268
Issue 31 | July 2017

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Understanding ISO standards: ISO 14644-2:2015 cleanroom monitoring

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Standardising pharmaceutical builds using BIM

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Clean Air and Containment Review is a quarterly journal aimed at users, specifiers, designers, manufacturers, installers and testers of clean air and containment equipment. It publishes articles of topical, technical and historical interest, updates on standards and regulations, news, views and information on relevant events, especially training.

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An industry changing collaboration: Phillip Godden on the moment he discovered there was an alternative to Biological Indicators

Phillip Godden

Here are a few words about me, this new technology and the excitement it has generated for me and, I hope, you too, when you share the same moment I had a few years ago. The moment I discovered there was a revolutionary alternative to Biological Indicator decontamination validation.

Discovering a new science for decontamination validation

This all started in 2014. I was working with a provider of Hydrogen Peroxide decontamination technology and happened to be at Public Health England who had asked to hire the equipment to trial a new indicator.

To qualify my position, I'm an engineer but not hugely experienced in decontamination per se. I've enjoyed many years in the "clean air" sector and always had a technical interest. The one thing I had suffered from, and found to be a regular topic of conversation in the decontamination community, was the hassle and frustrations that Biological Indicators were causing, had always caused and would always cause – so I was naturally curious about something new.

I'm not going to go into the detail of issues with Biological Indicators because I think it's fair to say that if you are still reading here, you will I hope, have nodded your head and have your own issues and frustrations.

A new License agreement for Enzyme Indicators

So, a new indicator technology... I was curious and interested to learn more. It is also fair to say that I instantly picked up on the drive and passion at PHE that surrounded the technology. The next few weeks and months disappeared very quickly and we started to consider the potential of a license agreement. We reviewed the technology and the more I looked, the more excited and electrifying the reality became – they were a true, viable alternative to Biological Indicators. Here in front of me was an indicator that on every level outperformed the

current gold standard. We have lots of other information that proves these advances and I will leave a sales pitch to another day.

The fact is, I got it. I understood why the lead scientist at PHE had this excitement and passion every time we spoke about this new validation test. Okay, so it was better – but it was how this could change the decontamination society – that was what excited him and now me too. Sounds cliché but this technology makes everyone's life better – anyone who uses hydrogen peroxide as a decontamination tool – absolutely everyone benefits.

I welcome anyone to review, scrutinise and trial our Enzyme Indicators for themselves.

So, at the same time as reviewing the technology I started negotiating with PHE on the license deal and a development model that would ensure that the full potential of this new technology could be realised and delivered into the global community. The technology is focussed on H₂O₂ decontamination right now but we know it can be used for other gaseous agents as well. Again, months flew past very quickly and now I've been talking to PHE for over a year!

April 2015 came and we signed the deal with PHE. Protak Scientific became the global exclusive licensee for the commercialisation and development of thermostable Adenylate Kinase for verification of decontaminations within chambers and open volumes.

Moving forward with a Biological Indicator alternative

You would think that everything moves quickly from here but actually, no. From here we signed up to an 18-month research program. To create a product

that can be brought to market, with stability data, with different iterations of product and to do everything possible to launch a product that would meet with industry approval.

While the research and product development bubbled under the surface and repetitive manufacturing cycles, stability studies and the like developed, I started to very softly introduce the concept to people, and without exception people were positive! Possibly with an equal measure of conservative scepticism, but the repetitive message unanimously being, if we could use the technology it would be a massive step forwards!

Fast-forward to January 2017 – and we are live! We now have a fully usable, robust product – the Enzyme Indicator is here. I've started speaking to people in the medical and pharmaceutical industries that we know would gain immediate benefit. We are looking for the FDA and MHRA to approve the technology as a validation tool and we have interest...a lot of interest in the technology!

End users, resellers, isolator manufacturers, H₂O₂ decontamination equipment manufacturers, gassing cycle development consultants and even CEOs of very large corporations are interested. Everyone seems to have that same moment I had a few years ago where everything aligns and the realisation that the game has changed sets in.

What is the future? Well I hope we keep educating, showing the world and learning together. As I mentioned at the start, I'm not an expert. The world is full of people who have more experience and knowledge than I and I welcome anyone to review, scrutinise and trial our Enzyme Indicators for themselves.

The more people see the technology, understand it and help to deliver it to the world the better.

With any luck, in five years' time Enzyme Indicator technology will be the norm, the gold standard – replacing Biological Indicators completely.

I hope we will remove the run to fail mentality. I hope we will open new

frontiers in equipment and validation process monitoring. I hope we will make everyone's life just a little easier with new, better technology. I hope we save a heap of cash for big pharmaceutical companies and have a positive impact on society.

I know it's cliché but this is the most exciting thing I have ever done.

I'm enthusiastic and have found the enthusiasm is infectious – once someone has tried using an EI everything just clicks.

To close, if you have read to here then thank you again and if you are not already speaking to us then please get in touch – I would love to hear from you.



Phillip Godden
is CEO of Protak Scientific, www.protakscientific.com



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