Biofluorescent Particle Counting (BFPC) — Hot Topic at Global Conferences

What I learned at 2022 Global Pharmaceutical Conferences — Leading to 2023

The impact of, and consideration for, the update to Annex 1 was very apparent at two major pharma industry conferences at the end of 2022. The PDA Microbiology Conference with the following Rapid Microbial Methods Workshop in October and the ISPE Pharma 4.0 and Annex 1 Conference in December had sold out attendance. With Annex 1 now encouraging the adoption of alternative monitoring methods to expedite detection and reduce risk to product, it is no surprise that there was a common topic that got a lot of attention — biofluorescent particle counting (BFPC).

PDA Microbiology Conference / Rapid Microbiological Methods Workshop

While there were no presentations specific to BFPC during the conference, it was mentioned during a number of sessions — including one on the update to TR#13 and the panel discussion with regulators.

Over and above the mentions of BFPC in the sessions, there was a noticeable increase in the level of interest in the BioTrak® Real-Time Viable Particle Counter, a biofluorescent particle counter, at the TSI exhibit booth. We repeatedly heard from microbiologists from across the industry, from startups to big pharma, comment that Annex 1 was driving them to consider using BFPC for their environmental monitoring. They believed they would now have to justify not using BFPC technology if they continued to use traditional methods.

Once the conference closed and the workshop began, the use of BFPC took center stage. Unlike previous years, when BFPC would be grouped with other interesting technologies at these events, this time around it was by far the most talked about method. Highlights of the workshop included:

- The Modern Microbial Methods (M3) working group reviewed the work being done by the group to advance acceptance of BFPC use.
- Novo Nordisk's Caroline Dreyer, Aseptic Specialist, presented a case study on implementing the BioTrak® Real-Time Viable Particle Counter on a filling line.
- A panel session featured a role-playing exercise on a company considering replacing active air sampling and settle plates with BFPC for real-time monitoring.

ISPE Pharma 4.0 and Annex 1 Conference

Featuring a broader range of topics than the PDA events, the ISPE Conference still had a considerable amount of materials focused on BFPC. During sessions with panel regulators, while not specifically mentioning BFPC, they repeatedly stated that companies must consider implementing modern technologies and some of the “new” methods being discussed may be a good alternative for monitoring gloveless isolators. The possibility for this could be seen during Groninger’s presentation on the Robocell —a gloveless fully automated filling line that they have developed in cooperation with Skan. The presentation featured how the filling line was designed specifically to accommodate the implementation of BioTrak Real-Time Viable Particle Counters, because they believe this will be a customer requirement.

I was fortunate to have the opportunity to present as well. I provided an overview of how BFPC meets the requirements of Annex 1, and, when paired with OPC UA, it is the best monitoring solution to achieve Pharma 4.0. I also reviewed the work we are doing in the M3 working group.

While all presentations during the conference were extremely positive in using BFPC, the highpoint came in the session following my talk. Novo Nordisk’s Henrik Louw, Strategy Specialist, gave a very similar presentation to that of Caroline Dreyer’s at the earlier PDA Conference. However, when he got to the slide discussing the interactions they have had with the regulatory agencies, he announced he had some new information that was not on the slide. He announced that a meeting with the FDA had just concluded and they had accepted their use of the BioTrak Viable Particle Counter to monitor their filling isolator.

2023 Outlook

One of the major roadblocks in using BFPC instruments has been the fear that it will not be accepted by regulators. With the release of the new Annex 1, and emphasized during these events, that roadblock is coming down. A pharma industry that is traditionally slow to adopt new technologies now has precedence with the announcement that an application of the BioTrak Real-Time Viable Particle Counter for use in monitoring a filling line has been accepted This will rapidly open up a number of opportunities in 2023 to expand use of this technology.

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