EXPERT VIEW

Microbial air monitoring in aseptic fill/finish isolators faces changes

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Environmental monitoring solutions, such as active viable air sampling in aseptic fill/finish isolators, have to support processes performed in the containment. They must comply with guidelines and regulations, provide maximum protection for the product, operators and the environment, plus be durable and fail-safe in routine production. This requires clever design and high-quality manufacturing of components and materials. Additionally, air samplers must allow for easy integration and communication with the IT environment of a facility.

Robotic processing and gloveless isolators

Multiple drivers support minimal human interaction within aseptic processes: Avoiding introduction of contamination, lack of qualified personnel, more reliable automation and robotisation, availability of robot-operated containers or the need to handle highly potent substances. Robotising active microbial air sampling based on the compendial method of growing colony forming units on nutrient plates is not yet state of the art – but this is soon to change. Several market-leading isolator manufacturers have approached my company to help them automate this process. Some have published their solutions in conferences, others will launch products shortly.

I invite anyone with robotising plans to contact us. As market leader with own lean development and manufacturing capabilities, we are the ideal partner to support your project.

Real-time biocontamination control in containments

Statements from regulatory agencies are clear: for aseptic fill/finish operations the proven method of active air sampling will continue. However, for certain applications it will be complemented with real-time biomonitoring, eg, based on laser-induced fluorescence technology. Its instantly available data will allow for informed batch release decisions, if a product must be administered to patients before the result of the growth-based method is available.

Adoption of real-time methods is encouraged by the agencies and the upcoming Good Manufacturing Practice (GMP) Annex 1, but has not yet been widely implemented in routine. Recognising the customer need for fully validated real-time solutions, we will soon publish first results of our partnership with an innovator in this field.

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