Knowledge Beyond Measure.

Confident and Reliable Aseptic Environmental Monitoring for Vaccine Manufacturing

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With increased capacity, how should my Environmental Monitoring Program change?

Regulatory Considerations

Regulatory requirements do not change regardless of the scale of the operation. However, if scale up includes distribution to additional geographical regions, additional or different requirements may need to be met. In the United States (US) market, you must follow the Food and Drug Administration (FDA) Aseptic Processing Guide. Most other markets are guided by the harmonized Annex 1 of the European Union (EU), Pharmaceutical Inspection Co-operation Scheme (PIC/S), and World Health Organization (WHO) Good Manufacturing Practices (GMPs).

Scale Up Rapidly

To meet immediate vaccine demand, aseptic manufacturing capacity must increase quickly. This means environmental monitoring programs must adapt rapidly as well. Thoughtful planning can help.

Integrated monitoring systems where software and hardware are designed to work together, like TSI FMS Systems, can save months of engineering time. Integrated systems also require fewer vendors and simplified validation. Standardized connectivity (e.g. OPC UA) can ease environmental monitoring integration with other critical systems such as laboratory information management systems (LIMS) and prepare your facility for Pharma 4.0.

Partnering with experienced environmental monitoring equipment manufacturers, like TSI instruments for pharmaceutical manufacturing, is key. These suppliers must know their markets and the regulatory requirements for their products (e.g., ISO 21501-4; ISO 14698-1; 21 CFR Part 11). Locally-based systems integrators can help with system design and installation as well as provide service and calibration to simplify maintenance.

Scale Up Efficently

The global need for aseptic processing capacity is not going to subside, therefore your expanded environmental monitoring program should be future-proof. While we hope the worst of the pandemic will end soon, the need for new vaccines against COVID variants is inevitable—and an industry-wide shift towards biologics and advanced therapy medicinal products (ATMPs) is adding to aseptic processing demand. To meet this need, your environmental monitoring program should not slow your manufacturing process down—now or in the future. Automation can help streamline environmental monitoring programs.

Scaling up your production will not lead to a proportional scale up of production personnel, nor will it result in a scale up of quality control (QC) personnel. Therefore, like your production processes, your testing will also need to become more automated to keep pace and remain compliant.

Removing manual processing steps and automating more of your environmental monitoring program comes with the added benefits of improved data integrity and reduced risk to your process. Improved data integrity comes from removing opportunities for human error as well as the automatic storage of data to a secure database where it is always easily accessible. Risk is reduced because more data be obtained for better process understanding and the data is constantly assessed in real-time so personnel can immediately react to an adverse result. This results in improved quality and less downtime—two things that are extremely critical when it comes to meeting the demand for life-saving vaccines.

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