

How Air Sampling Integrates into RTMS



Authored by:

Jason Kelly, Application Director

2025 Refresh



Overview

The 2022 EU GMP Annex 1 update significantly emphasizes continuous microbial monitoring in Grade A and B environments, placing air sampling in the spotlight. Previously, sequential air sampling was the norm for aseptic manufacturing.

Now, continuous monitoring offers a real-time view of air quality, crucial for product safety and quality. This shift enables quicker detection of contamination risks, faster response times, and a more comprehensive understanding of the environment. The guidelines stress continuous viable air monitoring during critical processing in Grade A areas, including equipment assembly and operations.

This change requires manufacturers to update equipment and procedures, and train staff. However, it also presents an opportunity to enhance product quality and reduce contamination risks with the help of advanced air sampling systems designed for continuous monitoring. Annex 1 promotes a proactive approach to contamination control, ensuring safer manufacturing practices and higher quality sterile medicinal products.

Air Samplers

are Critical to Aseptic Processes

In the context of the EU GMP Annex 1, section 9, which focuses on environmental monitoring, air samplers play a crucial role in ensuring the sterility and quality of the manufacturing environment for sterile medicinal products. Air samplers are effective for several reasons:

1. Detection of Microbial Contamination: Air samplers are designed to capture and quantify microbial contaminants in the air. This is critical in sterile manufacturing environments where the presence of microbes can compromise the sterility of the product. By effectively sampling the air, these devices help in identifying and quantifying microbial contamination, which is essential for maintaining a controlled environment.

2. Continuous Monitoring: Some air samplers can operate continuously, providing real-time data on the quality of the air in the manufacturing environment. This continuous monitoring is crucial for detecting deviations in air quality promptly, allowing for immediate corrective actions to prevent contamination of the product.

3. Versatility and Coverage: Air samplers can be used in various areas within the manufacturing environment, including critical areas where sterile products are exposed and areas of lower classification that support the sterile core. This versatility ensures comprehensive monitoring of the entire manufacturing environment, not just the areas of highest risk.

4. Validation of Cleanroom Performance: The use of air samplers is integral to the validation and ongoing verification of cleanroom performance.

By regularly assessing the microbial load in the air, companies can verify that their cleanroom controls are effective, and that the environment remains within the specified limits for sterility.

5. Regulatory Compliance: The data collected from air samplers are vital for demonstrating compliance with regulatory standards and guidelines, including those specified in Annex 1. This data supports audit trails and can be used in regulatory inspections to prove that the manufacturing environment is controlled and monitored appropriately.

6. Risk Assessment and Control: Air sampling data is essential for environmental risk assessment, allowing for the identification of trends and potential sources of contamination. This information can be used to implement targeted control measures, improve cleanroom design, and optimize operational procedures to minimize the risk of contamination.

7. Supporting Aseptic Process Simulations (Media Fills): Air sampling results can also support the validation of aseptic processes, including media fill simulations, by providing evidence that the air quality during these simulations meets the required standards for sterility.

Portable & Remote

The Difference Between Air Samplers

Portable air samplers and remote air samplers are both used for environmental monitoring, particularly in cleanrooms and other controlled environments where maintaining air quality is critical. However, they serve different purposes and have distinct features. Here are the key differences between the two:

Portable Air Samplers

Mobility: Portable air samplers are designed to be easily moved and used in various locations within a manufacturing or laboratory setting. This mobility allows for flexible sampling strategies and the ability to monitor air quality in multiple areas with a single device.

Manual Operation: They typically require manual setup and operation, meaning an operator must physically place the sampler in the desired location and initiate the sampling process. This can be advantageous for targeted sampling based on specific needs or concerns.

Versatility: Portable samplers are versatile in their application, allowing for spot checks, validation activities, and troubleshooting specific areas within a cleanroom or controlled environment.

Battery Operated: Many portable air samplers are battery-powered, enhancing their mobility by eliminating the need for a constant power source.

Direct Supervision: The use of portable air samplers usually involves direct supervision by a technician or operator, ensuring immediate response to the sampling process and results.

Remote Air Samplers

Fixed Installation: Remote air samplers (also referred to as continuous) are installed in a fixed location, often in critical areas where continuous

monitoring is necessary. Once installed, they do not require physical movement for operation.

Automated Operation: These samplers can be programmed for automatic operation, allowing for continuous or scheduled sampling without the need for manual intervention, other than media swaps. This automation is crucial for long-term environmental monitoring and trend analysis.

Integration with Environmental Monitoring Systems: Remote air samplers are often integrated into broader environmental monitoring systems, allowing for centralized data collection and analysis. This integration can facilitate real-time alerts and comprehensive control over the cleanroom environment.

Power Supply Considerations: Since they are installed in fixed locations, remote air samplers are typically connected to a permanent power supply, eliminating concerns about battery life.

Minimal Operator Interaction: After installation and programming, remote air samplers require minimal direct interaction from operators, reducing the risk of human error and contamination.

Key Differences Summary

Mobility and Flexibility: Portable air samplers offer mobility and flexibility for spot checks and targeted sampling, whereas remote air samplers are fixed and designed for continuous, automated monitoring.

Operation: Portable samplers are manually operated and require operator presence, while remote samplers operate automatically and can be integrated into larger monitoring systems.

Application: Portable samplers are ideal for versatile, on-the-spot monitoring across various locations. In contrast, remote samplers are suited for continuous monitoring in critical areas, providing ongoing data for trend analysis and compliance.

Implementing Remote Air Samplers

into a Monitoring System

Implementing a remote air sampler into a continuous monitoring system involves several steps, from planning and selection to integration and operation. Here's a structured approach to effectively incorporate a remote air sampler into a continuous environmental monitoring system:

Needs Assessment and Planning

Identify Objectives: Determine what you aim to achieve with the continuous monitoring system, such as compliance with regulatory standards, ensuring product quality, or both.

Assess Environmental Requirements: Understand the specific environmental conditions and regulatory requirements for your industry and application, focusing on parameters like particle counts, microbial contamination, temperature, and humidity.

Define Monitoring Points: Based on a risk assessment, identify critical areas where continuous monitoring is essential. Consider areas with high risk of contamination or where sterile products are exposed.

Selection of Remote Air Sampler

Choose Appropriate Technology: Select a remote air sampler that meets your specific needs, considering factors such as sampling efficiency, flow rate, compatibility with the types of microorganisms of concern, and ease of integration with existing systems.

Evaluate Data Management Capabilities: Ensure the sampler can provide data in a format that is compatible with your continuous monitoring system. Look for features like real-time data transmission, automated alerts, and data logging.

System Design and Integration

Design the Monitoring System: Plan how the remote air sampler will integrate with other components of the continuous monitoring system, including sensors for temperature, humidity, and other relevant parameters.

Ensure Network Connectivity: Remote air samplers require network connectivity to transmit data. Ensure that your facility's network infrastructure can support secure and reliable data transmission from the samplers to the central monitoring system.

Software Integration: Integrate the remote air sampler with the central monitoring software, ensuring that data from the sampler can be collected, analyzed, and stored effectively.

Data Analysis and Reporting

Implement Data Analysis Tools: Utilize software tools that can analyze the data collected by the remote air sampler in real-time. These tools should help identify trends, detect anomalies, and trigger alerts based on predefined thresholds.

Develop Reporting Mechanisms: Create reports that summarize the environmental conditions monitored by the system. These reports should be designed to support decision-making, regulatory compliance, and continuous improvement processes.

Compliance and Regulatory Considerations

Ensure Regulatory Compliance: Make sure that the implementation of the remote air sampler and the continuous monitoring system complies with relevant regulations and guidelines, such as those from the FDA, EMA, or ISO standards related to cleanroom environments. Key documents to review would be ISO 14698 and EN17141.

Documentation: Maintain thorough documentation of the system implementation, including validation records, calibration certificates, maintenance logs, and training records. This documentation is crucial for regulatory inspections and audits.

Integration with Quality Management Systems

Link to Quality Systems: Integrate the continuous monitoring system with your organization's quality management system (QMS). This ensures that data and insights from the monitoring system can directly inform quality control, risk management, and corrective and preventive actions (CAPAs).

Feedback Loops: Establish feedback loops that allow for the continuous improvement of both the monitoring system and the manufacturing processes it oversees. Use data collected to refine processes, enhance product quality, and reduce the risk of contamination.

Scalability and Futureproofing

Plan for Scalability: Design the system with scalability in mind, allowing for the addition of more samplers or the expansion of monitoring capabilities as needs grow or change.

Stay Updated with Technology: Keep abreast of advancements in monitoring technologies and software analytics. Upgrading or expanding your system with new technologies can enhance its effectiveness and efficiency.

Continuous Learning and Improvement

Encourage Continuous Learning: Foster an organizational culture that values continuous learning and improvement. Use insights gained from the monitoring system to drive training and development opportunities for staff.

Engage with Industry Developments: Participate in industry forums, workshops, and conferences to stay informed about best practices and regulatory developments related to environmental monitoring.

Implementing a remote air sampler into a continuous monitoring system is a multifaceted process that extends beyond the technical setup. It encompasses regulatory compliance, data management, quality assurance, and continuous improvement. By addressing these aspects comprehensively, organizations can ensure that their monitoring systems not only meet current needs but are also poised to adapt to future challenges and opportunities in maintaining high-quality, compliant manufacturing environments in critical areas, providing ongoing data for trend analysis and compliance.

Choosing between a portable and remote air sampler depends on the specific monitoring needs, the criticality of the areas to be monitored, and the goals of the environmental monitoring program. Both types of samplers play crucial roles in ensuring the cleanliness and compliance of controlled environments.



Lighthouse Worldwide Solutions

is ready to help you.

At LWS we have dedicated subject matter experts and air sampling products that enable continuous monitoring. LWS was the first company in the cleanroom industry to develop real time monitoring systems feeding live data back to decision makers. We understand your process and we understand real time microbial monitoring. Our customers tell us continuously about how our monitoring systems improve their processes and the quality and safety of their products.

We developed the ActiveCountR to integrate with our particle monitoring systems. Designed to meet the industry need for continuous trouble-free operation and flexible running parameters, the ActiveCountR is the right choice to meet your viable sampling needs.

The ActiveCountR can be operated via the local start/stop button or remotely via a software interface.

Utilizing either a side mount or bottom mount 316L stainless steel impactor, the ActiveCountR offers superior sampling flexibility to meet all your viable sampling needs. The ActiveCountR now also comes with a 10L/min low flow sample head while still maintaining the all-important Biological and Physical Collection efficiencies as well as the d50 value to meet Industry standards.

The compact size provides true "plug and play" functionality in an easy-to-use package that quickly integrates into the LMS Pharma or LMS Express real-time monitoring systems from Lighthouse.

Whether you are sampling within a cleanroom or inside of a Biosafety Cabinet or Laminar Flow Bench, the ActiveCountR will meet your cGMP compliant monitoring needs.

Best in Class Real Time Monitoring Software

The LMS Pharma Monitoring System is designed to analyze and display data for all phases of pharmaceutical operations. Its advanced design provides sophisticated automated alarm, notification, viewing, reporting, and auditing capabilities to any pharmaceutical facility.

Simplified installation, configuration, and validation are key features. Designed explicitly for high-reliability and secure facility monitoring, LMS Pharma contains comprehensive security with a redundant data collection system and an intuitive, easy-to-use interface.

With LMS Pharma software you can easily access data when and where you want it. Whether you are at your desk or at any computer on your network, you can access all the data you need.



Conclusion

Transitioning to continuous microbial monitoring can indeed present challenges, but it becomes a smoother journey with the right partner. Lighthouse Worldwide Solutions (LWS) has extensive experience in this area, having installed hundreds of systems globally and established a substantial customer base within the Life Science industry.

LWS's proven track record of installing numerous continuous microbial monitoring systems worldwide translates to valuable insights and practical solutions for overcoming implementation hurdles. Their focus on the Life Science industry allows them to understand the unique needs and challenges of pharmaceutical manufacturing and related fields. LWS offers a range of environmental monitoring

solutions, including microbial samplers (or active air samplers) that are easy to integrate into real-time environmental monitoring systems. LWS's ActiveCount series of viable air samplers are high-performance and designed for cleanroom and aseptic environments. These samplers offer features like continuous and periodic sampling modes, programmable settings, and data logging. LWS emphasizes the importance of understanding air sampler technology and instrument specifications, recommending education on these technologies for successful implementation. LWS solutions can help manufacturers adhere to GMP standards and ensure the highest standards of cleanliness and safety in cleanroom environments.

Tel: 800.555.1212



golighthouse.com

©2025 Lighthouse Worldwide Solutions. Some rights reserved. Referenced products or services which are trademarked are owned by their respective trademark owners. No copyright infringement is intended, and is shared here only for educational purposes. Lighthouse Worldwide Solutions is based in White City, Oregon, USA with offices and service locations worldwide.