REX DYNAMICS

EMPOWERING CONTROLLED ENVIRONMENTS

The Science Behind Cleanroom Particle Counting

Part 2 of 3

Monitoring using ISO 14644-2 vs EU-GMP Annex 1

Differences Between Monitoring Cleanroom Particle Concentration Using ISO 14644-2 and GMP Annex 1

Monitoring the cleanliness of a cleanroom is critical to ensure compliance with required standards and avoid contamination. Two major guidelines for cleanroom particle concentration monitoring are ISO 14644-2 and GMP Annex 1. While both serve the purpose of maintaining cleanroom conditions, they differ significantly in their scope, application, and requirements.

This document explores the differences between these two standards and their approach to monitoring cleanroom environments.

Overview of Standards

ISO 14644-2

ISO 14644-2 is part of the ISO 14644 series, designed to establish requirements for monitoring and verifying the ongoing performance of cleanrooms. This standard is applicable to industries such as aerospace, electronics, and healthcare, with a primary focus on ensuring particle levels remain within acceptable limits over time.

GMP Annex 1

GMP Annex 1, a European regulatory guideline, is tailored to pharmaceutical and biotechnological cleanrooms where sterility and product safety are paramount. The monitoring guidelines within Annex 1 emphasize compliance with Good Manufacturing Practices (GMP), requiring continuous control of both particles and microorganisms in cleanroom environments.

Key Differences Between ISO 14644-2 and GMP Annex 1

Aspect	ISO 14644-2	GMP Annex 1
Scope	Applicable across various industries such as electronics, aerospace, and healthcare.	Specific to pharmaceutical and biotechnological cleanrooms.
Monitoring Objectives	Focuses on ensuring cleanroom particle concentrations meet specified ISO Class limits.	Focuses on maintaining both particle and microbial control to ensure sterility of pharmaceutical products.
Monitoring Frequency	Determined based on risk assessment and cleanroom classification.	Requires continuous or frequent monitoring, particularly in Grade A areas, with detailed guidance.
Particle Sizes Monitored	Particles ranging from ≥0.1 µm to ≥5.0 µm, depending on the ISO Class.	Primarily considers particles ≥0.5 µm and ≥5.0 µm.
Microbial Monitoring	Excludes microbial monitoring; only airborne particles are considered.	Includes microbial monitoring alongside particle concentration, with limits for airborne contamination.
Action and Alert Limits	Focuses on alert and action limits for airborne particle concentrations only.	Specifies alert and action limits for both particles and microorganisms to ensure product sterility.
Continuous Monitoring	Not explicitly required; monitoring can be periodic based on risk assessment.	Continuous monitoring is mandatory for critical areas (e.g., Grade A).
Data Interpretation	Emphasizes statistical methods to analyze trends over time.	Requires real-time monitoring data and immediate response to deviations.
Environmental States	Monitoring can be conducted in as-built, at-rest, or operational states.	Emphasizes monitoring in both at-rest and operational states, particularly for Grade A and B.

Conclusion

ISO 14644-2 and GMP Annex 1 offer different approaches to cleanroom monitoring based on their intended applications. ISO 14644-2 provides a general framework for particle concentration monitoring across various industries, focusing on maintaining ISO Class levels. GMP Annex 1, on the other hand, imposes stricter requirements tailored to pharmaceutical production, emphasizing sterility, microbial control, and real-time monitoring.

Organizations must choose the appropriate standard based on their industry needs and regulatory requirements. Pharmaceutical manufacturers must follow GMP Annex 1 for compliance, while industries with less stringent contamination control needs may rely on ISO 14644-2.

This article is written by REX Dynamics. We empower controlled environments when it comes to consultation, design, installation, validation & servicing of environmental monitoring solutions. For further information please visit our webpage www.rexdynamics.se or contact us at info@rexdynamics.se