

Cleanroom Regulations Readiness Checklist

A Practical Guide for QC Lab Managers

Use this checklist to assess how well your cleanroom program aligns with regulatory expectations and to identify opportunities for clarification, standardization or risk reduction.

This resource is intended for education and internal review, not as a formal audit tool.

1. Cleanroom Purpose and Risk Understanding

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You can clearly articulate why cleanroom controls are required for your process (e.g., sterile drug manufacturing, aseptic processing, critical QC testing)

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You understand personnel as the primary contamination source and account for this in procedures and monitoring strategies

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Cleanroom controls align with a documented quality risk management (QRM) approach

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Historical contamination events or near misses inform current controls and training

2. Cleanroom Classification Fundamentals

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Cleanroom classification is performed according to the latest release of ISO 14644-1

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Cleanroom grades align with applicable EU GMP Annex 1 or regional regulatory expectations

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Classification activities are treated as a snapshot in time, not ongoing performance monitoring

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Sampling locations for classification are fixed, justified and documented

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Classification testing conditions (e.g., at rest state) are clearly defined and consistently applied

3. Routine Environmental Monitoring Program

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Routine monitoring is clearly distinguished from classification in procedures and training

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Sampling frequencies reflect risk level (e.g., daily in critical zones, less frequent in lower risk areas)

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Sampling locations prioritize process risk points (filling zones, operator interventions, equipment interfaces)

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Data is used for trending over time, not just limit checks

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Alert and action limits are defined, justified and periodically reviewed

4. Particle Counting Methods and Reliability

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Particle counting is used as a surrogate indicator for microbial contamination risk

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Particle counters are appropriate for the cleanroom class and particle size ranges monitored

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Air particle counting instruments are calibrated and verified in line with ISO 21501-4

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Differences between instruments are minimized through standardized methods and maintenance

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Instrument performance and calibration records are readily available for audits

5. Data Integrity and Documentation

- ☐ Environmental monitoring data is accurate, traceable and reviewable
- ☐ Electronic records and workflows support data integrity principles
- ☐ Manual steps that introduce transcription errors or rework are identified and controlled
- ☐ Audit trails support accountability and review
- ☐ Data retention practices align with internal policies and regulatory expectations (e.g., 21 CFR Part 11 where applicable)

6. Trend Review and Continuous Improvement

- ☐ Routine monitoring data is reviewed on a defined schedule
- ☐ Trends are evaluated even when results remain within limits
- ☐ Excursions trigger root cause analysis and documented follow-up
- ☐ Corrective and preventive actions are based on evidence, not assumptions
- ☐ Continuous improvement is demonstrated and inspection-ready

7. Internal Alignment and Governance

- ☐ Quality, operations and QC teams share a consistent understanding of cleanroom expectations
- ☐ IT and cybersecurity teams are involved when monitoring systems generate or store digital data
- ☐ Cleanroom procedures are accessible, current and understood by all relevant personnel
- ☐ Training materials reflect both regulatory requirements and site-specific risks
- ☐ Roles and responsibilities for monitoring, review and escalation are clearly defined

8. Final Reflection

- ☐ You can confidently explain the difference between cleanroom classification and routine monitoring
- ☐ Your program emphasizes control, consistency and risk awareness, not just pass/fail results
- ☐ Monitoring data supports decision making, not just compliance
- ☐ Your cleanroom strategy is inspection-ready and improvement-driven

Want to go deeper?

This checklist is a starting point, but if you'd like to learn more about compliance-ready air particle counting solutions for your cleanroom, visit becl.co/cleanroom-checklist