

# Annex 1 Readiness Checklist

*15 Critical Benchmarks for Sterile Manufacturing Compliance*

## **1 - Contamination Control Strategy**

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- 1. The Contamination Control Strategy is current, site-specific, and approved
- 2. All Contamination risks are identified and risk-ranked
- 3. Control measures are mapped to each identified risk

## **2 – Cleanroom Design and Airflow**

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- 4. Airflow visualization studies (smoke) are documented
- 5. Grade A unidirectional airflow is verified over critical zones
- 6. Pressure differentials between classified zones are monitored

## **3 – Environmental Monitoring**

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- 7. EM program covers viable and non-viable particulates
- 8. Continuous particle monitoring is in place for Grade A
- 9. Excursion investigations follow a documented procedure

## 4 – Personnel and Training

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- 10. Aseptic technique qualification is current for all operators
- 11. Personnel monitoring data is trended and reviewed

## 5 – Process and Equipment

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- 12. Sterilization processes are validated and re-validated on schedule
- 13. Equipment and facility qualification is complete and current

## 6 – Quality System

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- 14. Batch record review captures all Annex-1 parameters
- 15. Annex 1 gap assessment has been completed and actions tracked