Inspection Readiness: EM Program Documentation Package Checklist

Category	Documentation
1. Sampling plan	☐ Current, approved EM sampling plan ☐ Defined frequencies, locations, and sample types (viable air, surface, nonviable particulates) ☐ Rationale for site selection ☐ Classification of each room/area ☐ Revision history and change control documentation
2. Annual trending summary	☐ Comprehensive 12-month microbial and particulate trend analysis ☐ Graphs, visuals, and summarized data sets ☐ Identification of excursions, patterns, or seasonality ☐ Summary of corrective or preventive actions linked to trends ☐ Annual state-of-control conclusion
3. Logs and routine records	☐ Daily, weekly, and monthly EM logs ☐ Nonviable particle count logs (information obtained from biannual certification) ☐ Surface and air sampling logs ☐ Deviation logs ☐ Equipment calibration, maintenance, and certification records ☐ Chain-of-custody documentation for samples
4. Media and laboratory records	☐ Media lot numbers, certificates of analysis (COAs) ☐ Media growth promotion testing results ☐ Incubation logs and read-time records (applicable if performed in-house analysis) ☐ Laboratory identification reports ☐ Laboratory or vendor qualification documentation

Category	Documentation
5. CAPA documentation	☐ Full CAPA reports linked to EM excursions ☐ Root cause analyses ☐ Implemented corrective actions and timelines ☐ Preventive actions and program improvements ☐ Verification of effectiveness (VOE) documentation
6. Training and competency records	☐ Personnel training logs for EM procedures ☐ Aseptic technique and gloved fingertip and thumb testing records ☐ USP <797> personnel competency assessments ☐ Documentation of retraining after excursions or CAPAs ☐ Qualification records for staff performing EM tasks

Notes:

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Signature of pharmacy manager/designated person after document review Date