Cleanroom Technology and Environmental Monitoring Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

Cleanroom Technology and Environmental Monitoring Training Course is specifically engineered to minimize the introduction, generation, and retention of airborne particles, microbial contamination, and other pollutants. Essential for industries like pharmaceuticals, biotechnology, microelectronics, and aerospace, these specialized spaces utilize sophisticated technologies such as HEPA/ULPA filtration, laminar airflow patterns, and strict pressure cascades to achieve and maintain an ISO-classified level of air cleanliness. The integrity of critical manufacturing processes and product quality hinges on maintaining these stringent conditions, which can be compromised by a particle as minute as a human skin cell. Personnel are the single largest source of contamination, making proper cleanroom behavior, gowning procedures, and adherence to strict protocols an absolute necessity for successful, compliant operations.

Environmental Monitoring (EM) serves as the critical Quality Control (QC) guardian, providing real-time data and continuous assurance that the cleanroom environment remains within its qualified parameters. An effective EM program involves the systematic sampling and analysis of viable and non-viable contaminants in the air, on surfaces, and in personnel?ÇÖs gloves. Techniques like Particle Counting, Active Air Sampling, Contact Plating, and Surface Swabbing are meticulously employed. By establishing baseline data, setting alert and action limits, and performing trend analysis, EM allows organizations to proactively detect deviations, investigate excursions, and implement timely corrective actions. This rigorous surveillance is mandatory for regulatory compliance and is indispensable for ensuring product sterility, efficacy, and ultimately, patient safety and product yield.

Programme Curriculum

Cleanroom Technology and Environmental Monitoring Training Course

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Course Objectives

1. Interpret and apply the latest ISO 14644 standards and global Cleanroom Classification limits for air cleanliness.
2. Develop and implement a robust, risk-based Contamination Control Strategy (CCS) for aseptic processing environments.
3. Demonstrate expert-level proficiency in Aseptic Gowning Procedures and disciplined Cleanroom Conduct to minimize personnel-borne contamination.
4. Critically evaluate and verify Cleanroom HVAC Systems, Laminar Airflow, and Pressure Differential integrity during qualification.
5. Understand the complete Cleanroom Validation lifecycle, from design to performance qualification, including utilities.
6. Design, execute, and manage a compliant Environmental Monitoring Program for both viable and non-viable particles.
7. Utilize Real-Time Particle Monitoring and data management software for proactive risk mitigation and trend identification.
8. Conduct thorough Root Cause Analysis (RCA) and implement Corrective and Preventive Actions (CAPA) for EM excursions and deviations.
9. Formulate and validate effective, compliant Cleaning and Disinfection Programs using sporicidal agents and rotational protocols.
10. Prepare facilities and documentation for successful Regulatory Inspections and GMP Audits
11. Design statistically sound Environmental Sampling Plans and sample locations based on a formal Quality Risk Management (QRM) approach.

12. Establish a continuous Aseptic Technique Training and re-qualification program for all cleanroom operators.
13. Evaluate the role of advanced solutions like Isolators, RABS, and Rapid Microbial Methods (RMM) in modern manufacturing.

Target Audience

1. Cleanroom Operators/Technicians.
2. Quality Assurance (QA) & Quality Control (QC) Personnel.
3. Validation & Qualification Engineers
4. Microbiologists & Lab Analysts.
5. Facilities & Maintenance Engineers.
6. Production/Manufacturing Supervisors & Managers.
7. Regulatory Affairs Specialists.
8. Cleanroom Design & Construction Consultants.

Course Modules

Module 1: Cleanroom Fundamentals and Classifications

- Definition, purpose, and importance of a controlled environment
- Sources of contamination
- ISO 14644-1:2015 Cleanliness Classes and particle limits.
- EU GMP Annex 1 Grades for sterile drug manufacturing.
- Case Study: Analyzing a semiconductor manufacturing facility's shift from ISO 7 to ISO 5 and the associated particle-shedding risk reduction.

Module 2: Aseptic Gowning and Personnel Behavior

- Personnel as the primary source of microbial contamination.
- Step-by-step procedure for donning and doffing various levels of cleanroom garments.
- Rules of conduct, material transfer, and restricted movement within the critical zone.
- Managing hygiene, cosmetics, jewelry, and street clothes protocols.
- Case Study: Investigating a media-fill failure linked to improper gowning technique and subsequent re-training validation.

Module 3: Cleanroom Airflow and HVAC Systems

- Principles of Laminar Airflow and Turbulently Mixed Flow.
- Understanding Air Change Rates (ACH) and Pressure Cascades for contamination exclusion.
- Function and maintenance of HEPA and ULPA Filters
- Criticality of temperature and relative humidity (RH) control in cleanrooms.
- Case Study: Tracing a pressure differential alarm to a blocked return air vent and calculating the impact on air balance and classification integrity.

Module 4: Regulatory Frameworks and Standards

- Overview of Current Good Manufacturing Practices and global expectations.
- Deep dive into the requirements of EU GMP Annex 1
- FDA expectations for Aseptic Processing
- The role of the Quality Risk Management (QRM) process (ICH Q9) in compliance.

- Case Study: Comparing the regulatory response to a major microbial excursion under both FDA and EMA jurisdiction.

Module 5: Cleanroom Qualification and Validation

- Design, Installation, Operational, and Performance Qualification (DQ, IQ, OQ, PQ).
- Filter Integrity (DOP/PAO) Test, Airflow Velocity/Uniformity, and Recovery Test.
- Validation of cleanroom utilities
- Establishing "At-Rest" and "In-Operation" performance states.
- Case Study: Developing a validation master plan for a new Grade B compounding pharmacy cleanroom.

Module 6: Principles of Environmental Monitoring

- Defining Environmental Monitoring (EM) and its role in Sterility Assurance.
- Establishing Alert and Action Limits based on classification and historical data.
- Critical surfaces, personnel, air, and non-critical zones.
- Differences between Viable and Non-Viable monitoring.
- Case Study: Designing a risk-based sampling map for an ISO 5 Filling Line based on contamination risk assessment.

Module 7: Non-Viable Particle Monitoring

- Theory and operation of Optical Particle Counters (OPC) and sizing thresholds.
- Continuous and Periodic Particle Monitoring strategies.
- Data logging, alarm management, and regulatory reporting requirements.
- Equipment calibration, maintenance, and handling procedures.
- Case Study: Interpreting a sudden spike in 0.5??m particle counts and initiating a controlled sweep investigation.

Module 8: Viable Air Monitoring

- Techniques for Active Air Sampling and equipment
- Frequency and duration of air sampling in different cleanroom grades.
- Media selection (TSA/SDA) and incubation conditions.
- Colony-Forming Unit (CFU) enumeration and reporting.
- Case Study: Analyzing a high CFU count from an air sample taken near an operator and implementing immediate re-training.

Module 9: Viable Surface and Personnel Monitoring

- Methods for Surface Monitoring: Contact Plates/Rods and Swabbing.
- Specific focus on Glove Fingertip and Garment Sampling for personnel qualification.
- Establishing recovery rates and neutralization protocols for cleaning agents.
- Interpretation of results against defined acceptance criteria.
- Case Study: Reviewing the quarterly gowning qualification results for 20 operators and identifying a systemic failure in glove change procedures.

Module 10: Cleaning, Disinfection, and Sanitation

- Developing a rotational program for Disinfectants and Sporicidal Agents.
- Cleaning Process Validation.
- SOPs for cleaning tools, mopping techniques, and wipe usage

- Safe handling and preparation of cleaning chemicals.
- Case Study: Developing a three-month disinfection rotation schedule to prevent microbial resistance in a Grade C preparation area.

Module 11: Utilities and Water System Monitoring

- The criticality of Water for Injection and Purified Water
- Routine sampling and testing for water quality
- Clean Steam, Compressed Air, Nitrogen.
- Sampling techniques and validation for utility points of use.
- Case Study: Addressing a high bioburden result in a WFI loop and the subsequent sanitization and re-qualification plan.

Module 12: Deviation Management and CAPA

- Defining an Environmental Monitoring Excursion and initiation of investigation.
- Root Cause Analysis techniques for contamination events.
- Implementing effective Corrective and Preventive Actions and verification.
- The importance of Trend Analysis in predicting and preventing future deviations.
- Case Study: Conducting a formal RCA for a recurring Mould/Fungi isolation event in a gowning room and defining permanent corrective actions.

Module 13: Microbial Identification and Data Trending

- Importance of Microbial Identification to the genus and species level.
- Understanding the significance of different flora
- Statistical tools and Data Trending techniques
- Managing environmental monitoring data using Laboratory Information Management Systems
- Case Study: Using trending data to show a seasonal increase in spore-forming bacteria and adjusting the sporicidal cleaning frequency.

Module 14: Barrier Isolation Technology

- Introduction to Restricted Access Barrier Systems and Isolators.
- Benefits over traditional cleanrooms for sterility assurance.
- Operation, transfer protocols, and Vaporized Hydrogen Peroxide decontamination.
- Glove integrity testing and material transfer airlocks.
- Case Study: Comparing the EM program differences between a conventional Grade A/B line and an Isolator-based aseptic fill-finish process.

Module 15: Auditing and Continuous Improvement

- Preparing for internal, customer, and Regulatory Audits.
- Documentation review, cleanroom walkthroughs, and personnel questioning.
- Post-audit remediation and addressing 483s/deficiencies.
- Establishing a Continuous Improvement loop for the cleanroom and EM program.
- Case Study: Reviewing and responding to actual observations from a pharmaceutical facility's FDA audit and developing the final remediation plan.

Training Methodology

The training employs a blend of interactive, practical, and highly relevant learning techniques to ensure knowledge transfer and behavioral change:

1. Lectures & Case Studies
2. Hands-on Gowning Workshop
3. Demonstrations
4. Group Exercises & Discussions
5. Simulation & Role-Playing
6. Quizzes & Final Assessment.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call +254769199797

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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