Advanced Cleanroom HVAC and Filtration Systems 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

The integrity of high-technology manufacturing and pharmaceutical production hinges critically on contamination control within controlled environments. Advanced Cleanroom HVAC and Filtration Systems Training Course dives deep into the complex world of Cleanroom HVAC and Filtration Systems, which are the lifeblood of maintaining ISO 14644 and cGMP compliance. As industries like Biotechnology, Semiconductors, and Aseptic Processing continue to evolve, the demand for experts proficient in energy-efficient design, smart cleanroom technology, and HVAC validation lifecycle is paramount. This specialized program moves beyond basic concepts to equip professionals with the cutting-edge knowledge required to design, operate, maintain, and certify these critical systems to the highest global standards.

Success in highly regulated sectors requires a mastery of air-handling units, pressure cascade control, and advanced HEPA/ULPA filtration techniques. This course emphasizes practical application through hands-on troubleshooting, Computational Fluid Dynamics (CFD) simulation principles, and comprehensive risk-based qualification protocols. Participants will gain actionable insights into sustainable cleanroom practices and integrating IoT for real-time environmental monitoring, ensuring both product quality and operational efficiency. By focusing on the latest regulatory updates and industry best practices, this training empowers attendees to become cleanroom subject matter experts (SMEs) capable of driving down contamination risks and optimizing system performance for a superior return on investment.

Programme Curriculum

Advanced Cleanroom HVAC and Filtration Systems Training Course

Introduction

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Course Objectives

Upon completion of this course, participants will be able to:

1. Master the principles of Airflow Dynamics and Pressure Cascade control for various cleanroom classifications.
2. Design and Optimize Energy-Efficient HVAC systems compliant with ISO 14644 and cGMP regulations.
3. Implement and Validate Advanced HEPA/ULPA Filtration Systems, including filter selection, installation, and integrity testing (PAO).
4. Perform and Document all phases of the HVAC Validation Lifecycle (DQ, IQ, OQ, PQ) using a risk-based approach.
5. Apply Computational Fluid Dynamics (CFD) principles to predict and visualize air change rates and unidirectional flow.
6. Develop robust Preventive Maintenance (PM) and Calibration strategies for critical cleanroom equipment.
7. Integrate Smart Cleanroom Technology and IoT for Continuous Environmental Monitoring (CEM) and data trending.
8. Analyze and Troubleshoot complex HVAC system malfunctions and deviations
9. Understand the specific HVAC requirements for Aseptic Processing, Biocontainment, and Isolator Technology.
10. Assess and mitigate cross-contamination risks in multi-product facilities via effective air handling.
11. Interpret regulatory guidelines regarding cleanroom certification and re-qualification.
12. Select and specify Sustainable HVAC components and refrigerants for future-proofing facilities.
13. Conduct Smoke Studies and other visualization tests to verify unidirectional airflow patterns and recovery time.

Target Audience

1. HVAC/Mechanical Engineers.

2. Validation & Qualification Specialists.
3. Facility Managers and Operations Personnel.
4. Quality Assurance (QA) and Quality Control (QC) professionals in GMP-regulated industries.
5. Process Engineers in Pharmaceutical, Biotechnology, Medical Device, and Semiconductor manufacturing.
6. Auditors and Regulatory Affairs.
7. Cleanroom Designers and Consultants.
8. EHS (Environmental, Health, and Safety) Personnel.

Course Modules

Module 1: Advanced Cleanroom Fundamentals and Standards

- In-depth ISO 14644 and EU GMP Annex 1 classification interpretation.
- Sources, transport, and control of viable and non-viable contamination.
- Defining and calculating Air Change Rates (ACR) and minimum requirements.
- Criticality assessment and determining cleanroom utility requirements.
- Case Study: Analysis of a product recall event traced to a misclassified cleanroom area and non-compliant ACR.

Module 2: Advanced HVAC System Design for Controlled Environments

- Detailed review of all-air vs. recirculating systems and their impact on cleanliness.
- Designing for pressure cascade control and calculating inter-room differential pressures.
- System component selection.
- Humidity and temperature control strategies in highly sensitive cleanrooms.
- Case Study: Comparing the design efficiency and complexity of unidirectional vs. non-unidirectional airflow systems for a Grade B/ISO 7 facility.

Module 3: HEPA and ULPA Filtration Systems

- Principles of filtration.
- Selection, specification, and proper handling of HEPA and ULPA filters.
- Filter housing design, sealing mechanisms, and installation best practices.
- In-situ integrity testing methods, including PAO aerosol challenge.
- Case Study: Troubleshooting and root cause analysis of a failed HEPA filter integrity test, tracing the leak to improper gasket seating.

Module 4: Airflow Dynamics and Visualization

- Understanding and measuring unidirectional flow and turbulences.
- Principles of Containment and Exhaust Air Treatment
- Performing and documenting Airflow Pattern Studies to verify design.
- Calculating and verifying Cleanroom Recovery Time post-event.
- Case Study: Using a Smoke Study to identify and correct a turbulence issue caused by personnel movement near a critical process area.

Module 5: HVAC Qualification - Design & Installation (DQ/IQ)

- Developing User Requirements Specifications (URS) focused on critical airflow parameters.
- Executing and documenting the Design Qualification (DQ) phase.
- Developing and executing a comprehensive Installation Qualification (IQ) protocol.

- Traceability Matrix and documenting system components, materials, and calibration.
- Case Study: Reviewing a DQ package for a new pharmaceutical cleanroom to ensure all critical design elements meet the EU GMP Annex 1 requirements.

Module 6: HVAC Qualification - Operational (OQ)

- Developing the Operational Qualification (OQ) test plan and acceptance criteria.
- Executing critical OQ tests.
- Verifying alarm states, interlocks, and control system functionality.
- Documenting OQ results and managing deviations and corrective actions (CAPA).
- Case Study: Conducting an OQ test scenario where an emergency power failure interlock is verified to maintain critical pressure for a specified period.

Module 7: HVAC Qualification - Performance (PQ)

- Defining the Performance Qualification (PQ) test strategy under dynamic conditions.
- PQ testing: particle counting, microbial monitoring, and environmental controls.
- Verification of sustained cleanroom performance over extended periods.
- Setting up the Re-qualification and Continuous Monitoring schedule.
- Case Study: Analyzing 6 months of PQ data to confirm consistent ISO Class 5 performance during peak production shifts, and identifying a seasonal variability trend.

Module 8: Advanced Environmental Monitoring (CEM & IoT)

- Implementing Continuous Environmental Monitoring (CEM) systems for non-viable particles.
- Integrating IoT sensors for real-time monitoring of temperature, humidity, and pressure.
- Data acquisition, trending analysis, and setting alert/action limits.
- System validation and compliance for the electronic data records
- Case Study: Developing an AI/ML-based predictive maintenance model using IoT data to forecast potential filter loading issues before they cause a pressure drop alarm.

Module 9: Aseptic Processing and Barrier Technology HVAC

- Specific HVAC design for Grade A/ISO 5 environments and RABS/Isolators.
- Unidirectional airflow principles for filling lines and critical zones.
- Vaporized Hydrogen Peroxide (VHP) decontamination cycle integration and air exchange.
- Maintaining sterility during Gowning Procedures and material transfer.
- Case Study: Evaluating the HVAC design changes required to convert a traditional Grade A cleanroom into an Isolator-based aseptic processing line.

Module 10: Energy-Efficient and Sustainable Cleanrooms

- Strategies for reducing fan energy using Demand Control Ventilation (DCV).
- Heat recovery systems and optimizing outside air intake and exhaust.
- Selecting low-GWP refrigerants and high-efficiency HVAC equipment.
- Lifecycle cost analysis and return on investment for sustainable design features.
- Case Study: Calculating the energy savings achieved by implementing a DCV system tied to real-time particle counters in a large-scale cleanroom facility.

Module 11: Cleanroom Troubleshooting and Root Cause Analysis (RCA)

- Systematic approach to diagnosing a pressure differential alarm or failure.

- RCA techniques for contamination events.
- Investigating High Particle Count (HPC) excursions and their HVAC correlation.
- Deviation management, corrective, and preventive actions (CAPA).
- Case Study: Performing an RCA on a recurring microbial contamination issue, tracing the root cause back to a poorly managed return air grille/filter bank.

Module 12: Documentation, Maintenance, and Change Control

- Establishing a compliant Standard Operating Procedure (SOP) system for HVAC operations.
- Developing an effective Preventive Maintenance and Calibration Program.
- Executing the Change Control process for HVAC system modifications.
- Maintaining the validated state after major changes.
- Case Study: Simulating the process of submitting and approving a Change Control request to upgrade fan motors for increased energy efficiency.

Module 13: Computational Fluid Dynamics (CFD) in Cleanrooms

- Introduction to CFD Simulation for airflow pattern and temperature modeling.
- Interpreting CFD results to optimize cleanroom layout and furniture placement.
- Using simulation to predict the impact of personnel movement on airflow.
- Validation and correlation of CFD models with actual smoke test data.
- Case Study: Analyzing a CFD model output to redesign a critical work zone's air supply diffuser locations to eliminate a high-risk stagnant air pocket.

Module 14: Cleanroom Architecture and Interaction

- Material selection for walls, ceilings, and floors to minimize particle shedding.
- Airlock and pass-through design for personnel and material flow control.
- Lighting, electrical, and utility penetrations design for cleanliness.
- Interface between cleanroom utilities and the HVAC system.
- Case Study: Designing a material airlock with dynamic pressure control to prevent cross-contamination between an ISO 8 warehouse and an ISO 7 staging area.

Module 15: Regulatory Audits and Future Trends

- Preparing for and successfully navigating FDA and EMA cleanroom inspections.
- Common HVAC-related audit findings and how to address them.
- Emerging trends: Modular Cleanrooms, Advanced Robotics, and AI in environmental control.
- Professional development and maintaining Cleanroom Subject Matter Expertise
- Case Study: Developing a strategy to respond to a major audit finding related to the lack of documented Differential Pressure calibration and alarm verification.

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.

- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

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
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

Start Date	End Date	Location	Price
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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