Cleanroom Design and Validation Training Course

Professional Development Training Course Outline

Category	General Training	**Duration**	10 Days
Base Fee	$3,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

Cleanroom facilities are critical environments in pharmaceutical manufacturing, biotechnology, semiconductor fabrication, medical device production, healthcare, aerospace, and advanced manufacturing industries. The increasing emphasis on GMP compliance, contamination control, cleanroom classification, ISO 14644 standards, HVAC optimization, environmental monitoring, risk-based validation, digital quality systems, sustainability, and Industry 4.0 integration has elevated the importance of robust cleanroom design and validation practices. Organizations worldwide are investing in high-performance cleanroom infrastructures to ensure product quality, regulatory compliance, operational efficiency, and patient safety.

Cleanroom Design and Validation Training Course provides participants with comprehensive knowledge of cleanroom engineering, contamination prevention, airflow management, cleanroom qualification, commissioning, validation protocols, particle control strategies, energy-efficient cleanroom operations, regulatory inspections, and lifecycle management. Participants will learn industry best practices for designing, validating, operating, and maintaining cleanroom facilities while ensuring compliance with global standards and regulatory expectations. Through practical exercises and real-world case studies, attendees will gain the skills necessary to optimize cleanroom performance and minimize contamination risks.

Programme Curriculum

Cleanroom Design and Validation Training Course

Introduction

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Course Objectives

By the end of this training course, participants will be able to:

1. Understand modern cleanroom design principles and facility planning strategies.
2. Apply ISO 14644 standards for cleanroom classification and compliance.
3. Design effective HVAC and airflow management systems for contamination control.
4. Implement advanced contamination control strategies in critical environments.
5. Develop comprehensive cleanroom validation master plans.
6. Conduct Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) activities.
7. Establish robust environmental monitoring programs.
8. Apply risk-based validation methodologies and quality risk management.
9. Optimize cleanroom operations using Industry 4.0 and smart monitoring technologies.
10. Ensure compliance with GMP, FDA, EU GMP, PIC/S, and WHO requirements.
11. Analyze airflow visualization and smoke study validation techniques.
12. Improve energy efficiency through sustainable cleanroom design practices.
13. Manage cleanroom lifecycle performance through continuous improvement and data analytics.

Target Audience

1. Cleanroom Design Engineers
2. Validation Engineers
3. Pharmaceutical Manufacturing Professionals
4. Biotechnology Facility Managers
5. Quality Assurance and Quality Control Personnel
6. HVAC Engineers and Facility Engineers
7. Regulatory Compliance and GMP Professionals
8. Medical Device Manufacturing Specialists

Course Modules

Module 1: Fundamentals of Cleanroom Technology

- Cleanroom concepts and terminology
- Sources of contamination
- Types of cleanroom facilities

- Regulatory requirements overview
- Cleanroom lifecycle management
- **Case Study:** Investigation of contamination incidents in pharmaceutical manufacturing.

Module 2: Cleanroom Standards and Regulatory Framework

- ISO 14644 series overview
- GMP requirements
- FDA and EU GMP expectations
- WHO cleanroom guidelines
- Compliance documentation
- **Case Study:** Regulatory inspection findings and corrective actions.

Module 3: Cleanroom Classification and Zoning

- Cleanroom classification criteria
- Particle concentration limits
- Zoning principles
- Material and personnel flow
- Cross-contamination prevention
- **Case Study:** Design of a multi-grade pharmaceutical cleanroom facility.

Module 4: Cleanroom Design Principles

- Facility layout development
- Architectural design considerations
- Material selection
- Personnel and equipment movement
- Expansion and flexibility planning
- **Case Study:** Design optimization for a sterile manufacturing facility.

Module 5: HVAC Systems for Cleanrooms

- HVAC design fundamentals
- Air filtration technologies
- Pressure cascade design
- Temperature and humidity control
- Energy-efficient HVAC systems
- **Case Study:** HVAC redesign to improve contamination control.

Module 6: Airflow Management and Visualization

- Unidirectional airflow systems
- Turbulent airflow systems
- Airflow pattern analysis
- Smoke studies
- Airflow performance verification
- **Case Study:** Root-cause analysis of airflow disturbances.

Module 7: Contamination Control Strategies

- Microbial contamination control

- Particle contamination management
- Cleaning and disinfection programs
- Personnel gowning systems
- Contamination risk assessment
- **Case Study:** Reducing microbial excursions in aseptic processing.

Module 8: Environmental Monitoring Systems

- Monitoring program design
- Particle monitoring methods
- Microbiological monitoring
- Trend analysis
- Alarm management systems
- **Case Study:** Environmental monitoring data trending and CAPA implementation.

Module 9: Cleanroom Commissioning and Qualification

- Commissioning planning
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Documentation requirements
- **Case Study:** Qualification of a newly commissioned biotechnology cleanroom.

Module 10: Validation Master Planning

- Validation strategy development
- Validation protocols
- Acceptance criteria establishment
- Deviation management
- Validation reporting
- **Case Study:** Development of a Validation Master Plan (VMP).

Module 11: Risk-Based Validation Approaches

- Quality Risk Management (QRM)
- Failure Mode and Effects Analysis (FMEA)
- Critical parameter identification
- Risk mitigation techniques
- Lifecycle validation concepts
- **Case Study:** Risk assessment for aseptic manufacturing operations.

Module 12: Cleanroom Operations and Maintenance

- Preventive maintenance programs
- Calibration management
- Utility system maintenance
- Performance monitoring
- Change control procedures
- **Case Study:** Cleanroom maintenance optimization program.

Module 13: Digitalization and Smart Cleanrooms

- Industry 4.0 technologies
- IoT-based environmental monitoring
- Digital validation systems
- Data integrity requirements
- Predictive maintenance applications
- **Case Study:** Smart cleanroom implementation in pharmaceutical production.

Module 14: Energy Efficiency and Sustainable Cleanrooms

- Sustainable design principles
- Energy consumption analysis
- Green HVAC technologies
- Carbon footprint reduction
- Operational sustainability initiatives
- **Case Study:** Energy optimization project achieving significant cost savings.

Module 15: Auditing, Compliance, and Continuous Improvement

- Internal audit methodologies
- Regulatory inspection readiness
- CAPA systems
- Continuous improvement frameworks
- Benchmarking best practices
- **Case Study:** Preparing a facility for a successful regulatory inspection.

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
07 Sep 2026	18 Sep 2026	Online	$2,000
07 Sep 2026	18 Sep 2026	Physical	$3,000
14 Sep 2026	25 Sep 2026	Online	$2,000
14 Sep 2026	25 Sep 2026	Physical	$3,000
21 Sep 2026	02 Oct 2026	Online	$2,000
21 Sep 2026	02 Oct 2026	Physical	$3,000
28 Sep 2026	09 Oct 2026	Online	$2,000
28 Sep 2026	09 Oct 2026	Physical	$3,000

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