Sterile Process Engineering 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

Sterile Process Engineering is a critical discipline within the pharmaceutical, biotechnology, vaccine manufacturing, and healthcare industries, ensuring the production of contamination-free products that meet stringent regulatory requirements. With increasing global demand for biologics, cell and gene therapies, sterile injectables, and advanced pharmaceutical products, organizations are investing heavily in Aseptic Processing, Contamination Control Strategy (CCS), Cleanroom Engineering, Process Analytical Technology (PAT), Quality by Design (QbD), Digital Manufacturing, GMP Compliance, Risk-Based Validation, and Industry 4.0 technologies. Effective sterile process engineering minimizes product recalls, enhances patient safety, improves operational efficiency, and ensures regulatory compliance across the product lifecycle.

Sterile Process Engineering Training Course provides participants with advanced knowledge and practical skills in sterile manufacturing systems, aseptic process design, clean utility engineering, sterilization technologies, environmental monitoring, contamination prevention, process validation, digital quality systems, and regulatory inspection readiness. Through industry case studies, real-world applications, and hands-on exercises, participants will develop competencies required to design, operate, optimize, and maintain world-class sterile production facilities while ensuring compliance with global regulatory standards and operational excellence.

Programme Curriculum

Sterile Process Engineering Training Course

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Course Objectives

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

1. Understand modern Sterile Process Engineering principles and applications.
2. Design and optimize Aseptic Manufacturing Systems.
3. Implement advanced Contamination Control Strategies (CCS).
4. Apply Quality by Design (QbD) in sterile manufacturing.
5. Evaluate Cleanroom Design and HVAC Engineering requirements.
6. Manage Sterilization and Depyrogenation Technologies effectively.
7. Perform Risk-Based Process Validation and qualification activities.
8. Utilize Process Analytical Technology (PAT) for real-time monitoring.
9. Improve Environmental Monitoring Programs and data interpretation.
10. Integrate Digital Manufacturing and Industry 4.0 Solutions.
11. Ensure compliance with FDA, EMA, WHO, PIC/S, and GMP Regulations.
12. Conduct effective Root Cause Analysis and CAPA Management.
13. Enhance operational excellence through Continuous Process Verification (CPV).

Target Audience

1. Sterile Process Engineers
2. Pharmaceutical Manufacturing Engineers
3. Biotechnology Professionals
4. Validation and Qualification Engineers
5. Quality Assurance and Quality Control Personnel
6. Production Supervisors and Managers
7. Regulatory Compliance Specialists
8. Cleanroom and Facility Engineering Professionals

Course Modules

Module 1: Fundamentals of Sterile Process Engineering

- Principles of sterile manufacturing
- Sterility assurance concepts

- Product contamination mechanisms
- Regulatory expectations
- Process engineering fundamentals
- **Case Study:** Analysis of a sterile injectable manufacturing process failure.

Module 2: Aseptic Processing Technologies

- Aseptic process fundamentals
- Open and closed processing systems
- Barrier technologies
- Process flow optimization
- Critical process parameters
- **Case Study:** Optimization of aseptic filling operations.

Module 3: Cleanroom Design and Engineering

- Cleanroom classifications
- ISO 14644 requirements
- Facility layout design
- Airflow management
- Pressure cascade systems
- **Case Study:** Cleanroom redesign for contamination reduction.

Module 4: HVAC Systems for Sterile Facilities

- HVAC design principles
- HEPA and ULPA filtration
- Air change rate calculations
- Environmental control systems
- Energy-efficient HVAC solutions
- **Case Study:** Investigation of airflow-related contamination events.

Module 5: Contamination Control Strategy (CCS)

- Sources of contamination
- Microbial control programs
- Personnel contamination prevention
- Material transfer controls
- Integrated CCS development
- **Case Study:** CCS implementation in a biologics manufacturing plant.

Module 6: Sterilization Technologies

- Moist heat sterilization
- Dry heat sterilization
- Radiation sterilization
- Gas sterilization methods
- Sterilization cycle development
- **Case Study:** Validation of autoclave sterilization processes.

Module 7: Depyrogenation and Endotoxin Control

- Endotoxin fundamentals
- Depyrogenation mechanisms
- Validation requirements
- Monitoring methods
- Regulatory expectations
- **Case Study:** Endotoxin contamination investigation.

Module 8: Clean Utilities Engineering

- Water for Injection (WFI) systems
- Purified water systems
- Clean steam generation
- Utility distribution networks
- Utility qualification
- **Case Study:** Optimization of WFI distribution systems.

Module 9: Environmental Monitoring Programs

- Viable monitoring methods
- Non-viable particle monitoring
- Trend analysis
- Alert and action levels
- Data integrity requirements
- **Case Study:** Environmental monitoring trend investigation.

Module 10: Process Validation and Qualification

- Validation lifecycle approach
- Equipment qualification
- Process performance qualification
- Continuous verification
- Validation documentation
- **Case Study:** Sterile process validation project.

Module 11: Quality Risk Management

- ICH Q9 principles
- Risk assessment tools
- FMEA applications
- Hazard identification
- Risk mitigation planning
- **Case Study:** Risk assessment for aseptic filling lines.

Module 12: Regulatory Compliance and GMP

- FDA sterile manufacturing guidance
- EU GMP Annex 1 requirements
- WHO GMP standards
- Inspection readiness
- Compliance management systems
- **Case Study:** Regulatory inspection observations and remediation.

Module 13: Digitalization and Industry 4.0

- Smart manufacturing technologies
- Manufacturing Execution Systems (MES)
- Digital batch records
- Predictive analytics
- AI-enabled process monitoring
- **Case Study:** Digital transformation of sterile manufacturing operations.

Module 14: Deviation Investigation and CAPA

- Deviation management systems
- Root cause analysis methodologies
- CAPA development
- Effectiveness verification
- Continuous improvement
- **Case Study:** Investigation of repeated sterility test failures.

Module 15: Future Trends in Sterile Manufacturing

- Advanced aseptic technologies
- Robotics and automation
- Isolator advancements
- Continuous manufacturing
- Sustainable sterile production
- **Case Study:** Next-generation sterile manufacturing facility implementation.

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
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

Ready to enroll or request a customized program? Book online or contact us:

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