Sterile Product Manufacturing and Aseptic Processing 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

Sterile product manufacturing and aseptic processing are critical components in the pharmaceutical and biotechnology industries, where maintaining the highest standards of product quality and safety is paramount. This training course offers in-depth insights into the complex processes involved in the sterilization and aseptic preparation of pharmaceutical products, including biologics, vaccines, and injectable drugs. It covers the fundamental principles, regulatory frameworks, and best practices for ensuring product sterility, meeting FDA, EMA, and WHO guidelines, and mastering cutting-edge aseptic techniques. Sterile Product Manufacturing and Aseptic Processing Training Course is designed to equip professionals with the essential skills to manage aseptic processes and comply with strict industry standards to avoid contamination and ensure the integrity of sterile drugs.

The Sterile Product Manufacturing and Aseptic Processing Training course emphasizes practical knowledge and hands-on training, ensuring participants are well-versed in industry practices. Through real-life case studies, participants will explore common challenges faced in aseptic processing, such as contamination risks, equipment validation, and environmental monitoring. By the end of the course, trainees will gain proficiency in designing, implementing, and auditing sterile manufacturing processes, fostering a deeper understanding of Good Manufacturing Practices (GMP), validation protocols, and quality control. This training will empower professionals to make critical decisions, maintain compliance with evolving regulatory requirements, and ensure the continuous production of safe, effective, and sterile pharmaceutical products.

Programme Curriculum

Sterile Product Manufacturing and Aseptic Processing Training Course

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Course Duration

10 days

Course Objectives

1. Understand sterile product manufacturing fundamentals and key principles.
2. Learn critical aseptic processing techniques in pharmaceutical production.
3. Master Good Manufacturing Practices (GMP) for sterile product environments.
4. Identify key regulatory guidelines for aseptic processing and sterile product production (FDA, EMA, WHO).
5. Gain expertise in sterilization methods such as autoclaving, filtration, and radiation.
6. Implement effective cleanroom design and classification to ensure aseptic conditions.
7. Perform thorough risk assessment in sterile manufacturing processes.
8. Explore environmental monitoring techniques to prevent contamination during production.
9. Understand the validation process for aseptic processing and sterile product manufacturing.
10. Learn about quality control practices to ensure product sterility and integrity.
11. Gain proficiency in process automation in sterile manufacturing environments.
12. Learn how to effectively manage aseptic operations and ensure product consistency.
13. Examine real-world case studies related to aseptic processing failures and successes.

Target Audience

1. Pharmaceutical Manufacturers
2. Biotech Professionals
3. Regulatory Affairs Specialists
4. Quality Assurance and Control Managers
5. Production Supervisors and Managers
6. Microbiologists and Sterility Experts
7. Engineers in Aseptic Manufacturing Systems

8. Health and Safety Compliance Officers

Course Modules

Module 1: Introduction to Sterile Product Manufacturing

- Key concepts and definitions
- Importance of sterility in pharmaceutical products
- Regulatory and industry standards
- Case study: Overview of sterilization and aseptic processing
- Introduction to contamination risks

Module 2: Good Manufacturing Practices (GMP)

- Key GMP principles for sterile environments
- GMP compliance in aseptic processing
- Documentation and quality control
- Case study: Validation protocols in GMP
- The role of training in GMP compliance

Module 3: Sterilization Methods

- Types of sterilization techniques
- Autoclaving and its benefits
- Filtration as a sterilization method
- Radiation sterilization: Pros and cons
- Case study: Selecting the right sterilization method

Module 4: Cleanroom Design and Classification

- Cleanroom classifications (ISO 14644)
- Designing cleanrooms for aseptic processing
- Airflow and pressure considerations
- HEPA filtration and its importance
- Case study: Risk management in cleanroom design

Module 5: Environmental Monitoring

- Monitoring airborne particulates and microbial contamination
- Surface monitoring techniques
- Frequency of monitoring in sterile environments
- Case study: Contamination outbreaks
- Corrective actions for environmental failures

Module 6: Aseptic Processing Techniques

- Defining aseptic processing
- Common aseptic filling methods
- Critical controls in aseptic operations
- Case study: Aseptic processing failure
- Best practices for aseptic processing

Module 7: Sterility Testing and Quality Control

- Types of sterility tests
- Visual inspection of sterile products
- Microbiological testing methods
- Case study: Process for handling out-of-specification results
- Documentation and record-keeping for testing

Module 8: Process Validation and Documentation

- Importance of validation in sterile manufacturing
- Steps in process validation
- Case study on validation failures
- Regulatory expectations for validation
- Best practices in validation documentation

Module 9: Risk Assessment in Sterile Product Manufacturing

- Understanding risk in sterile environments
- Risk assessment methodologies
- Developing risk mitigation strategies
- FMEA (Failure Modes and Effects Analysis)
- Case study: Using risk assessment tools in validation

Module 10: Process Automation in Aseptic Manufacturing

- Benefits of process automation in sterile environments
- Automation of critical control points
- Case study on automated aseptic filling
- Validation of automated systems
- Regulatory guidelines for automation

Module 11: Contamination Control

- Identifying contamination sources
- Methods to control contamination risks
- Employee hygiene and gowning protocols
- Sterile product handling best practices
- Case study: Contamination incident response

Module 12: Regulatory Compliance

- Overview of FDA, EMA, and WHO guidelines
- Regulatory inspections and audits
- Common regulatory pitfalls in aseptic processing
- Preparing for a regulatory audit
- Case study: Navigating changes in global regulatory requirements

Module 13: Quality Assurance in Sterile Product Manufacturing

- Key elements of a quality assurance system
- Role of QA in sterile manufacturing
- Monitoring product quality throughout the process
- Case study: Creating a quality culture within organizations

- Training employees for quality assurance roles

Module 14: Troubleshooting and Problem Solving

- Identifying root causes of failures
- Solving common issues in aseptic processing
- Corrective and preventive actions (CAPA)
- Documentation and reporting of issues
- Case study: Solving an aseptic processing failure

Module 15: Future Trends in Sterile Manufacturing

- Emerging technologies in aseptic processing
- The role of AI and machine learning in sterile manufacturing
- Trends in regulatory changes
- Sustainable practices in sterile product manufacturing
- Innovations in sterilization technologies

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
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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