Advanced Aseptic Transfer and Gowning Techniques 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

In the highly regulated fields of **pharmaceuticals**, **biotechnology**, and **sterile compounding**, maintaining **aseptic conditions** is non-negotiable for product **quality**, **patient safety**, and regulatory **compliance**. **Aseptic processing** is the bedrock of sterile manufacturing, and the most frequent source of contamination is human intervention. This advanced course moves beyond basic principles to deep-dive into the complex nuances of **sterile material transfer** and **advanced cleanroom gowning**. Participants will master the **critical control points** and procedural subtleties necessary to minimize **microbial contamination** risk, ensuring operations meet or exceed global standards like **FDA** cGMP and **EU GMP Annex 1**. Advanced Aseptic Transfer and Gowning Techniques Training Course is essential for professionals seeking to elevate their skills in **contamination control** and demonstrate **regulatory mastery**.

The focus of this intensive program is to transform theoretical knowledge into **practical, repeatable, and verifiable** techniques. We will employ **hands-on simulations** and **real-world case studies** to address common **human error** pitfalls in **Grade A/B areas**. Key topics include **no-touch techniques (NTT)**, **advanced material segregation**, **bio-decontamination processes**, and specialized **gowning qualification** protocols. By the end of this course, participants will be **certified** in the industry's most **robust** and **validated** aseptic practices, directly contributing to enhanced **batch success rates** and a stronger **culture of quality** within their organizations.

Programme Curriculum

Advanced Aseptic Transfer and Gowning Techniques Training Course

Introduction

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Course Objectives

1. Validate and execute advanced cleanroom gowning protocols, specifically for Grade A/B environments, to minimize particulate generation.
2. Master sterile material transfer techniques, including VHP/gassing airlocks and double-bagging, ensuring first-pass yield integrity.
3. Identify and mitigate critical control points (CCPs) during aseptic interventions to prevent cross-contamination.
4. Apply No-Touch Technique (NTT) principles rigorously for all critical surface manipulations.
5. Interpret and comply with the latest regulatory expectations from EU GMP Annex 1 (2023) and FDA cGMP regarding Aseptic Process Simulation (APS) and gowning.
6. Perform gowning qualification and media fill preparation procedures with auditable precision.
7. Troubleshoot common human error scenarios in isolator and RABS environments.
8. Implement effective cleanroom behavior protocols to enhance environmental monitoring compliance.
9. Select and utilize appropriate disinfection agents and sporicides for various critical surfaces.
10. Develop and maintain Standard Operating Procedures (SOPs) for aseptic operations that are audit-ready.
11. Understand the importance of operator re-qualification and its impact on data integrity.
12. Analyze risk assessments related to aseptic practices using FMEA methodology.
13. Execute HEPA filter integrity checks and understand the impact on unidirectional airflow (UDAF).

Organizational Benefit

- Reduced Contamination and Batch Failure Rates.
- Enhanced Regulatory Compliance.
- Improved Quality Culture.
- Increased Operator Competency & Confidence.

Target Audience

1. Aseptic Processing Operators
2. Cleanroom Technicians
3. Quality Assurance (QA) Auditors/Specialists
4. Manufacturing Supervisors/Managers
5. Validation Engineers
6. Compounding Pharmacists/Technicians
7. Microbiology Laboratory Personnel
8. Training & Development Specialists

Course Modules

Module 1: Regulatory Landscape & Aseptic Principles Foundation

- Review of FDA cGMP and the latest EU GMP Annex 1 (2023) requirements for aseptic operations.
- Understanding the critical control points (CCPs).
- The science of Microbial Contamination Control and the Triangle of Contamination.
- Defining and maintaining Unidirectional Airflow (UDAF) and HEPA filter integrity.
- Case Study: Analysis of a major 483 observation due to systemic failures in aseptic protocols and contamination events.

Module 2: Advanced Gowning for Grade A/B

- Detailed gowning procedure for entry into Grade B areas, focusing on sequential steps and minimizing particulate burden.
- Specialized techniques for Grade A intervention and RABS/Isolator suit-up.
- Selection and proper use of specialized disposable apparel
- Protocol for re-gloving and glove disinfection during extended aseptic manipulations.
- Case Study: RCA of a media fill failure directly attributed to a breach in the operator's gowning integrity

Module 3: Gowning Qualification and Re-qualification

- Establishing a robust and auditable initial gowning qualification program.
- Criteria for routine re-qualification
- Gowning validation methodologies.
- Handling of out-of-specification (OOS) results during qualification testing.
- Case Study: Developing an SOP for automated gowning qualification testing and data tracking for regulatory review.

Module 4: Sterile Material Transfer Protocol

- Mastering the double-bagging and triple-bagging technique for materials entering Grade B zones.
- Procedures for the effective use of transfer hatches and dynamic pass-throughs.
- Techniques for transferring complex items, like vials and stoppers, without compromising sterility.
- Understanding and mitigating risks associated with material surface bioburden before transfer.
- Case Study: Analyzing a contamination event caused by improper material staging and ingress protocol through a pass-through chamber.

Module 5: Decontamination and Sterilisation Principles

- Selection and rotation of disinfectants and sporicides to prevent microbial resistance.
- Proper application and contact time for various critical surface cleaning agents.
- Protocols for Vaporized Hydrogen Peroxide (VHP) and other gassing decontamination methods.

- Cleaning procedures for RABS/Isolator interiors and exterior work surfaces.
- Case Study: Evaluating the effectiveness of a disinfectant rotation schedule following a documented environmental isolate, and modifying the cleaning process.

Module 6: Advanced Aseptic Interventions

- Application of the No-Touch Technique (NTT) for all critical manipulations and stopper placement.
- Proper body and hand positioning to maintain UDAF and prevent disruption to the critical zone.
- Techniques for handling forceps, tongs, and other tools in a sterile manner.
- Emergency and non-routine intervention protocols
- Case Study: Hands-on simulation of a complex vial filling machine jam intervention, emphasizing NTT.

Module 7: Aseptic Process Simulation (APS) / Media Fills

- The importance of APS in validating operator technique and the overall aseptic process.
- Designing a media fill protocol to accurately reflect routine manufacturing complexity
- Incubation, inspection, and OOS investigation procedures for media fill runs.
- Understanding the calculation of contamination rate and regulatory limits.
- Case Study: Detailed analysis of a multi-batch media fill failure and the subsequent root cause analysis (RCA) identifying specific operator error.

Module 8: Isolator and RABS Operation

- Operational differences between Restricted-Access Barrier Systems (RABS) and Isolators.
- Specialized techniques for working with glove ports and performing glove leak testing.
- Techniques for transferring materials into and out of the critical zone within RABS/Isolators.
- Maintaining positive pressure cascades and air balance in contained systems.
- Case Study: Troubleshooting a pressure differential alarm within an isolator and its impact on the Grade A environment.

Module 9: Aseptic Filling and Sealing Techniques

- Best practices for vial filling, ensuring accurate volume and preventing splashing.
- Proper technique for stopper placement and alignment before capping.
- Verification of vial crimping and seal integrity to prevent microbial ingress.
- Handling and segregation of rejects and in-process controls (IPCs).
- Case Study: Examining container closure integrity (CCI) testing failures and linking them back to poor aseptic handling during the sealing process.

Module 10: Water for Injection (WFI) and Steam Sterilisation

- Overview of WFI generation, storage, and distribution systems.
- Principles of autoclave operation and steam sterilization cycles
- Monitoring and documentation requirements for sterilization validation.
- Techniques for loading and unloading sterilized equipment and components.
- Case Study: Reviewing an OOS result from bioburden testing on WFI and tracing the source of contamination back to the distribution loop.

Module 11: Human Error and Cleanroom Behavior

- Identifying common human error types in aseptic processing
- Techniques for maintaining focus and minimizing fatigue during critical long-duration tasks.

- Principles of cleanroom etiquette and behavior
- The role of procedural adherence in preventing aseptic breaches.
- Case Study: Analyzing a series of minor deviations to establish a pattern of human error and implementing new controls.

Module 12: Environmental Monitoring (EM) and Response

- Setting up an effective EM program.
- Proper sampling techniques for critical surfaces and operator hands.
- Responding to and investigating action level excursions and alert limits.
- Documentation and trend analysis of microbial isolates for CAPA implementation.
- Case Study: Investigating a cluster of microbial hits and performing a root cause analysis linked to operator activity.

Module 13: Aseptic Documentation and Data Integrity

- Requirements for complete, accurate, and attributable batch record documentation.
- Adherence to ALCOA principles
- Protocols for managing deviations and implementing Corrective and Preventive Actions (CAPA).
- The role of electronic batch records (EBRs) in maintaining data integrity.
- Case Study: Mock audit review of a deficient batch record and the resulting regulatory impact on product release.

Module 14: Aseptic Transfer in Biologics Manufacturing

- Special considerations for handling live cultures and cell therapy products.
- Aseptic connection and disconnection techniques for single-use systems (SUS).
- Transfer of materials into and out of bioreactors and fermenters.
- Managing higher risk of viral contamination in biological products.
- Case Study: Review of a bioreactor contamination event and the specific aseptic controls required for seed train activities.

Module 15: Risk Management and Process Improvement

- Applying ICH Q9 (Quality Risk Management) principles to aseptic processes.
- Using Failure Mode and Effects Analysis (FMEA) to assess aseptic process risks.
- Developing a continuous process improvement plan based on CAPA trends.
- The connection between Process Analytical Technology (PAT) and aseptic control.
- Case Study: Performing an FMEA on a new aseptic filling line to proactively identify high-risk steps and implement controls before validation.

Training Methodology

This highly interactive and practical course employs a blended learning approach to ensure maximum knowledge retention and skill development:

- Interactive Lectures.
- Video Demonstrations.
- Hands-on, Practical Workshops.
- Group Exercises & Discussions.
- Case Studies & Root Cause Analysis (RCA).
- Skill Assessment & Certification.

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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