Advanced Validation of Aseptic Processes 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 landscape of sterile pharmaceutical and biopharmaceutical manufacturing is subject to increasingly stringent global regulatory scrutiny, making Advanced Validation of Aseptic Processes (AVAP) an indispensable function for Sterility Assurance and Patient Safety. This specialized course delves beyond fundamental cGMP requirements, focusing on the risk-based approach to designing, executing, and documenting Aseptic Process Simulations (Media Fills). Participants will master the latest EU GMP Annex 1 and FDA Guidance interpretations, utilizing advanced Contamination Control Strategy elements such as RABS and Isolator Technology to minimize the Human Factor the primary source of microbial contamination. The ultimate goal is to build a robust, Quality by Design (QbD)-aligned validation lifecycle that ensures Data Integrity and sustained Regulatory Compliance.

Advanced Validation of Aseptic Processes Training Course empowers quality and manufacturing professionals to lead comprehensive Aseptic Validation programs, transforming compliance from a reactive measure into a proactive Operational Excellence driver. By emphasizing Root Cause Analysis (RCA) for Media Fill Deviations and applying cutting-edge techniques like Process Analytical Technology (PAT), the course provides the strategic tools to significantly reduce Contamination Risk, prevent costly Product Recalls, and maintain a state of Inspection Readiness. A strong grasp of advanced validation principles directly translates into optimized process control, demonstrating Aseptic Capability and cementing an organization's commitment to the highest standard of sterile product quality.

Programme Curriculum

Advanced Validation of Aseptic Processes Training Course

Introduction

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Course Objectives

1. Master the Risk-Based Approach to Aseptic Process Validation (APV), aligning with the latest EU GMP Annex 1 guidelines.
2. Design and Execute scientifically sound Aseptic Process Simulations (Media Fills), including Worst-Case intervention modeling.
3. Evaluate and Validate Modern Contamination Control Strategies (CCS), focusing on RABS and Isolator Technology.
4. Implement a robust Environmental Monitoring (EM) program with an emphasis on Viable and Non-Viable Particle control and monitoring.
5. Perform comprehensive Root Cause Analysis (RCA) and implement effective CAPA for Media Fill Failures and Sterility Deviations.
6. Apply advanced Quality by Design (QbD) principles to the Aseptic Process Lifecycle management.
7. Develop and Validate Personnel Gowning and Aseptic Technique Qualification programs to mitigate the Human Factor.
8. Ensure Container Closure Integrity (CCI) validation and testing throughout the aseptic filling and finishing processes.
9. Interpret and Respond effectively to FDA 483 Observations and Warning Letters related to aseptic processing.
10. Validate critical support systems, including Sterilizing Filtration, Vaporized Hydrogen Peroxide (VHP), and Clean Utility systems.
11. Integrate Data Integrity principles into all stages of Aseptic Process Monitoring and documentation.
12. Leverage Process Analytical Technology (PAT) for real-time monitoring and control of critical aseptic process parameters.
13. Optimize Process Control and Sterility Assurance Level (SAL) determination through statistical methods.

Target Audience

1. Validation Engineers/Specialists in sterile drug manufacturing.
2. Quality Assurance (QA) and Quality Control (QC) Microbiology personnel.
3. Manufacturing/Operations Managers and Supervisors in Aseptic Production.
4. Regulatory Affairs Professionals dealing with sterile product submissions.
5. Process Development Scientists focusing on new sterile product introduction.
6. Qualified Persons (QPs) and Site Quality Heads.
7. Audit and Inspection Readiness Team Members.
8. Engineering and Maintenance staff responsible for Cleanroom and HVAC systems.

Course Modules

Module 1: Global Regulatory Trends in Aseptic Validation

- Latest interpretations of EU GMP Annex 1 and FDA Aseptic Processing Guidance.
- Key differences between US, EU, and PIC/S expectations on Sterility Assurance Level
- New requirements for Contamination Control Strategy and Process Monitoring.
- The shift towards Quality by Design in APV lifecycle management.
- Case Study: Analysis of a recent FDA Warning Letter citing repeat failures to update APV protocols based on new guidance.

Module 2: The Advanced Risk-Based Approach to APV

- Implementing a structured Quality Risk Management framework for APV.
- Conducting Failure Mode and Effects Analysis on the aseptic process steps.
- Identifying and prioritizing Critical Process Parameters and Critical Quality Attributes
- Using risk data to justify Media Fill frequency and batch size rationale.
- Case Study: Developing an FMEA for a high-speed vial filling line to determine the most challenging intervention points.

Module 3: Aseptic Process Simulation (Media Fill) Design

- Scientific justification and design of a robust Worst-Case Media Fill protocol.
- Determining appropriate batch sizes, incubation conditions, and acceptance criteria.
- Simulating all routine and non-routine Interventions, including maximum duration and personnel.
- Selection and qualification of the microbiological Growth Medium
- Case Study: A company's protocol failed to simulate lyophilizer loading under worst-case hold times; redesigning the simulation to incorporate this risk.

Module 4: Media Fill Execution and Documentation

- Best practices for on-the-floor execution and meticulous record-keeping.
- Procedures for Gowning Verification, Gloved Fingertip Sampling, and material transfer before the run.
- Controlling and documenting all planned and unplanned Interventions and their impact.
- Proper handling of Reject Units, line clearances, and environmental monitoring during the run.
- Case Study: Investigating a documentation deficiency where an unplanned intervention was performed but not accurately recorded in the media fill batch record.

Module 5: Media Fill Investigation and Root Cause Analysis (RCA)

- Comprehensive investigation of a Media Fill Failure or Deviation.

- Implementing a structured Root Cause Analysis methodology
- Differentiating between contamination sources: personnel, environment, or equipment.
- Developing effective and preventative Corrective and Preventive Actions
- Case Study: A contamination event tracing back to a poorly executed aseptic connection; defining CAPAs including enhanced training and equipment redesign.

Module 6: Advanced Contamination Control Strategies (CCS)

- The role of Isolators and Restricted Access Barrier Systems in contamination control.
- Validation of Bio-Decontamination Cycles
- Design and qualification of the Grade A/B Cleanroom environment, including HVAC and Airflow Studies.
- Integration of cleaning, disinfection, and sterilization procedures into the CCS.
- Case Study: Evaluating a RABS system upgrade and validating the new VHP cycle to meet non-routine decontamination requirements.

Module 7: Sterilizing Filtration Validation

- Comprehensive validation of Sterilizing Filters for liquid drug products.
- Microbial Challenge Testing and establishing LRV
- Integrity Testing and correlation with challenge data.
- Validating pre-use/post-use filter integrity testing for production.
- Case Study: A process where the drug product formulation negatively impacted filter integrity; revalidating with a product-specific hold time study.

Module 8: Personnel Qualification and Aseptic Technique

- Mitigating the Human Factor as the greatest risk source.
- Establishing an initial and periodic Gowning Qualification program with Gloved Fingertip Sampling.
- Designing Aseptic Technique Training utilizing mock-ups or VR simulations.
- Implementing Behavioral Audits and visual monitoring in the aseptic area.
- Case Study: Analyzing a series of positive fingertip samples leading to retraining and a change in the required gowning procedure and frequency.

Module 9: Clean Utility Systems Validation

- Validation of systems that directly contact sterile product/components.
- Qualification of Water-For-Injection and Pure Steam Generation and distribution systems.
- Establishing critical parameters, monitoring, and alert/action limits.
- Documentation requirements for System Lifecycle validation.
- Case Study: A recurring WFI excursion traced back to an inadequate rouging/passivation validation and monitoring program.

Module 10: Environmental Monitoring Program Optimization

- Designing an EM program for proactive Contamination Control.
- Strategy for sampling locations, frequency, and trending for viable and non-viable particulate data.
- Setting scientifically justified Alert and Action Limits for Grade A, B, C, and D areas.
- Microbial Identification and Trending Analysis for early warning signals.
- Case Study: Using historical EM data to adjust action limits and sampling points based on high-risk areas identified through heat mapping.

Module 11: Container Closure Integrity (CCI) Validation

- Ensuring the maintenance of Sterility until the point of use.
- Selecting and validating appropriate CCI Test Methods
- Establishing Acceptance Criteria and demonstrating container integrity across the product lifecycle
- Validation of the Sealing Process and Critical Capping Parameters.
- Case Study: Validating a new lyophilization cycle and demonstrating that the primary package integrity was not compromised by the freeze-drying process.

Module 12: Process Analytical Technology (PAT) and Advanced Monitoring

- Integrating real-time and in-line monitoring for enhanced Process Control.
- Applying PAT principles to aseptic fill/finish operations
- Validation of Automated Systems and software used for process control and monitoring.
- Utilizing advanced data analysis for continuous process verification.
- Case Study: Implementing a Real-Time Particle Monitoring system and validating its use as a primary control for critical interventions.

Module 13: Data Integrity and Documentation in APV

- Compliance with ALCOA+ principles in validation records.
- Validation of electronic systems, including Audit Trails and electronic signatures, for media fill data.
- Maintaining a comprehensive Validation Master Plan for APV activities.
- Managing Raw Data integrity and ensuring secure, accessible records.
- Case Study: Reviewing a validation package that failed an audit due to missing raw data and an incomplete audit trail on a critical sealing machine.

Module 14: Aseptic Processing for Advanced Therapies

- Unique validation challenges for Cell and Gene Therapies.
- Adapting Media Fill protocols for small batch, patient-specific, and open-process manufacturing.
- Validation of closed systems and rapid transfer devices.
- Specific regulatory expectations for Point-of-Care aseptic manipulations.
- Case Study: Designing a Mock Media Fill for a mobile cleanroom used for compounding ATMPs at a clinical site.

Module 15: Inspection Readiness and Regulatory Defense

- Preparing personnel and documentation for a regulatory inspection.
- Strategies for presenting the Contamination Control Strategy and APV data to inspectors.
- Practicing effective responses to common 483 Observations and investigator questions.
- Post-inspection activities, including CAPA planning and follow-up.
- Case Study: Simulating an inspector questioning the scientific rationale for a media fill's worst-case intervention selection and coaching the defense strategy.

Training Methodology

The course employs an Advanced Competency-Based Training model, blending theory with high-impact, practical application. The methodology includes:

- Interactive Lectures and Group Discussions on current regulatory trends and guidance documents.
- Hands-on Workshops for protocol design, Worst-Case scenario development, and Risk Assessment
- Case Studies.
- Mock Audit/Inspection Simulation

- Template and Checklist Utilization.

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
21 Sep 2026	02 Oct 2026	Online	$2,000
21 Sep 2026	02 Oct 2026	Physical	$3,000
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0

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