Advanced Sterile Filtration and Integrity Testing 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 biopharmaceutical landscape demands zero-defect manufacturing, placing Sterility Assurance at the apex of Current Good Manufacturing Practice. This is particularly critical for Aseptic Processing, where terminal sterilization is not feasible for sensitive biologics and Advanced Therapy Medicinal Products. Sterile Filtration using sterilizing grade filters is the last defense against microbial contamination, directly safeguarding patient safety and product quality. However, filtration processes are complex, involving intricate interactions between fluid, filter media, and process parameters. A single failure in filter integrity can lead to costly batch recalls and significant regulatory non-compliance. Advanced Sterile Filtration and Integrity Testing Training Course is designed to move beyond basic concepts, focusing on Quality by Design (QbD) principles, automated integrity testing, and navigating the complexities of modern bioprocessing environments, ensuring personnel are audit-ready and proficient in all aspects of this critical unit operation.

Filter Integrity Testing (FIT) is a mandatory regulatory requirement to verify the performance of a sterilizing filter, both pre- and post-use. The industry is rapidly trending towards Pre-Use/Post-Sterilization Integrity Testing to mitigate risks associated with thermal or mechanical stress from Steam-In-Place (SIP) or autoclaving cycles. This course provides a deep dive into the underlying physical principles of the Bubble Point, Diffusive Flow, and Pressure Hold tests, including the specialized Water Intrusion Test for hydrophobic membranes. Learners will master automated integrity test systems to reduce human error and ensure objective, operator-independent readouts. With new global regulatory frameworks, such as the revised EU GMP Annex 1, mandating enhanced Contamination Control Strategies, this training is indispensable for ensuring global regulatory compliance, maximizing process robustness, and achieving a high state of operational excellence in sterile manufacturing.

Programme Curriculum

Advanced Sterile Filtration and Integrity Testing Training Course

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Course Objectives

1. Master the physical principles and correct application of all major Filter Integrity Tests.
2. Implement and defend the regulatory necessity of Pre-Use/Post-Sterilization Integrity Testing in complex bioprocesses.
3. Design and validate Contamination Control Strategies that integrate sterile filtration as a primary control barrier per EU GMP Annex 1 requirements.
4. Select the optimal sterilizing grade filter and membrane chemistry based on API/Biologic compatibility and fluid characteristics.
5. Perform advanced filter sizing and capacity calculations to ensure economic efficiency and prevent premature fouling.
6. Develop robust microbial challenge testing protocols for process-specific filter validation
7. Analyze and interpret data from Automated Integrity Test Systems to troubleshoot common and complex filter failures.
8. Understand the impact of extractables and leachables from filter materials and establish risk mitigation strategies.
9. Integrate sterile filtration processes into a broader Quality Risk Management framework using tools like FMEA.
10. Optimize and validate Sterilization-In-Place (SIP) and Autoclave cycles to prevent filter damage and ensure membrane integrity.

11. Prepare, execute, and defend the sterile filtration and integrity testing sections during FDA and EMA regulatory audits.
12. Implement the principles of Quality by Design to establish Critical Process Parameters and Critical Quality Attributes (CQA) for filtration.
13. Apply digital validation and Industry 4.0 concepts, such as real-time monitoring, to the filtration unit operation.

Target Audience

1. Validation Engineers.
2. Quality Assurance (QA) & Quality Control (QC) Specialists.
3. Manufacturing & Aseptic Operators/Supervisors.
4. Process Development Scientists.
5. Regulatory Affairs Personnel
6. Engineering & Maintenance Staff.
7. Technical Services/Subject Matter Experts.
8. Bioprocess & Clean Utilities Engineers.

Course Modules

Module 1: Foundational Principles of Sterilizing Filtration

- Sterility Assurance in Aseptic Processing and Terminal Sterilization.
- Mechanism of Microbial Retention.
- Filter Media Selection.
- Impact of fluid properties on filtration performance.
- Case Study: Analysis of a batch failure due to incorrect filter media selection leading to excessive protein adsorption and loss of API.

Module 2: The Regulatory Landscape of Sterile Filtration

- Review of EU GMP Annex 1 and its mandate on Contamination Control Strategy
- FDA Guidance on Aseptic Processing and the role of Filter Integrity Testing.
- Global regulatory expectations for sterilizing grade filters.
- Batch Records, Change Control, and filter Certificate of Quality.
- Case Study: Review of an FDA Warning Letter citing deficiencies in filter identification and documentation control for sterile-filtered drug product.

Module 3: Pre-Filtration and Depth Filtration Strategies

- Theory and application of Depth Filters for Bioburden Reduction and particle removal.
- Strategies for handling high-particulate or high-bioburden feed streams
- Optimizing the Filter Train for maximum economic capacity.
- Techniques for sequential or graded pore size filtration to prevent premature fouling.
- Case Study: Optimization project demonstrating 5x increase in final filter life by correctly implementing a multi-stage depth filtration system.

Module 4: Advanced Filter Sizing and Throughput

- Quantitative methods for determining required filter surface area and cartridge length.
- Practical calculation of flux rates and throughput based on pre-validation data.
- Impact of differential pressure and temperature on the filtration rate and efficiency.

- The concept of Critical Process Parameters in filtration.
- Case Study: Modeling exercise where process scale-up fails due to linear scale-up of filter area without accounting for pressure drop limitations.

Module 5: Principles of Automated Integrity Testing

- The relationship between pore size, test fluid, and measured parameters.
- Detailed review of the Bubble Point Test and its inherent limitations and advantages.
- In-depth physics of the Diffusive Flow Test and its sensitivity.
- Practical use and correlation of the Pressure Hold Test for process efficiency.
- Case Study: Troubleshooting a transient "false failure" during a Bubble Point Test traced back to temperature fluctuations in the gas supply or housing.

Module 6: Practical Mastery of Automated Test Equipment

- Calibration and preventative maintenance of Automated Integrity Test Systems.
- Setting correct test parameters for different filter types.
- Advanced operation modes: multi-test protocols and sequencing.
- Ensuring Data Integrity within the AIT software.
- Case Study: Demonstration of a complete AIT validation, including successful execution of challenging a filter at the Pass/Fail limit with standardized methodology.

Module 7: Pre-Use Post-Sterilization Integrity Testing (PUPSIT)

- The regulatory justification and high-risk scenarios that mandate PUPSIT
- Developing a compliant, auditable PUPSIT protocol that addresses pre-wetting and post-sterilization cooling.
- Mitigating the risk of false-positive results during PUPSIT due to temperature gradients or residual steam condensate.
- Designing and operating filtration systems to enable downstream sterile connections for PUPSIT.
- Case Study: Review of a large-scale product recall caused by a filter flaw undetectable by post-use testing but identifiable by a mandatory PUPSIT.

Module 8: Integrity Testing of Hydrophobic Filters

- Specific application of hydrophobic membranes for gas venting and solvent filtration.
- Theory and execution of the Water Intrusion Test and its correlation to standard FIT methods.
- Understanding the challenge of wettability and its impact on test results.
- Validation of gas filtration systems, including pre-use pressure decay testing.
- Case Study: Analyzing a bioreactor contamination event traced to a failed PTFE vent filter where standard Bubble Point was incorrectly used.

Module 9: Validation of the Sterilizing Filtration Process

- Development of a comprehensive Process Validation plan for the filtration step.
- Executing the Bacterial Challenge Test using B. diminuta or process-relevant organisms.
- Determining the maximum acceptable differential pressure for a validated filter.
- Establishing Hold Time Studies for the pre-filtered and final filtered bulk solutions.
- Case Study: Detailed review of a successful three-lot validation report, including acceptance criteria and excursion handling.

Module 10: Extractables & Leachables (E&L) from Filters

- Regulatory requirements and guidelines for assessing E&L from filter components
- Risk-based approach to E&L testing.
- Designing an E&L study
- The difference between Extractables and Leachables studies.
- Case Study: Discussion of a product degradation issue caused by a leachable compound from a new filter housing material that affected the API's stability.

Module 11: Steam-In-Place (SIP) and Autoclave Impact on Filter Integrity

- Understanding the thermal and mechanical stresses imposed by SIP and Autoclave on the filter membrane and housing.
- Best practices for filter protection during sterilization, including correct installation and venting.
- Validation of the SIP cycle to ensure both sterility and filter integrity are maintained.
- Troubleshooting filter damage post-sterilization.
- Case Study: Protocol for a SIP cycle validation that establishes the maximum allowable ?öP and temperature hold time to prevent filter compromise.

Module 12: Troubleshooting Filter Integrity Failures

- Systematic investigation of a Post-Use Filter Integrity Test failure
- Root cause analysis techniques.
- Common root causes.
- The impact of product wetting/drying on post-use test results and necessary corrective action.
- Case Study: Simulated RCA of a failed Diffusive Flow Test leading to a confirmed root cause: incomplete wetting of the filter membrane.

Module 13: Single-Use Systems (SUS) and Sterile Filtration

- Design and qualification of pre-sterilized, single-use filter assemblies
- Integration of single-use filters into fully automated, closed Bioprocessing trains.
- Challenges of integrity testing single-use filters and assembly?ÇÖs post-gamma irradiation.
- The role of sterile connectors and their impact on the overall sterility of the filter train.
- Case Study: Evaluation of vendor qualification data for a single-use filter system, assessing its compatibility and integrity after two years of storage.

Module 14: Quality Risk Management (QRM) for Filtration

- Applying Failure Mode and Effects Analysis to the entire sterile filtration process.
- Developing a risk priority number score for potential filtration failure modes.
- Establishing robust Critical Quality Attributes and Critical Process Parameters.
- Risk mitigation strategies, including implementing redundant filtration or continuous monitoring.
- Case Study: Walk-through of a QRM document for a parenteral drug, identifying high-risk steps and corresponding control measures.

Module 15: Future Trends and Advanced Technologies

- Introduction to 0.1 ??m filtration for enhanced Mycoplasma and viral retention in ATMPs.
- Predictive Maintenance and Industry 4.0 integration
- Continuous monitoring of filtration performance and real-time data analytics.
- New regulatory focus on Bioburden Control and in-situ sensor technology.

- Case Study: Discussion on the implementation of a digital system for continuous monitoring of?öP and automatically logging AIT results, minimizing transcription errors.

Training Methodology

The course employs a blended **experiential learning** approach:

- Interactive Classroom Sessions.
- Hands-on Laboratory Practice.
- Process Simulations.
- Troubleshooting Workshops
- Audit Defense Role-Playing.

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

Start Date	End Date	Location	Price
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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