Advanced Strategies for Viral Clearance and Safety 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

Viral safety is a critical quality attribute and a fundamental regulatory requirement in the biopharmaceutical industry, underpinning the development and manufacturing of all biologics, from Monoclonal Antibodies to the rapidly expanding field of Advanced Therapy Medicinal Products. The industry is continuously evolving toward continuous bioprocessing and intensified manufacturing, which introduce new challenges to established viral clearance (VC) paradigms. This advanced course moves beyond basic compliance to focus on risk-based approaches, process robustness, and the seamless integration of both prevention and clearance steps throughout the entire bioproduction lifecycle. Participants will master the design and execution of next-generation viral safety protocols, ensuring a comprehensive viral safety strategy that meets the stringent expectations of global regulatory bodies like the FDA, EMA, and ICH Q5A.

Advanced Strategies for Viral Clearance and Safety Training Course is designed to empower process development scientists, quality assurance professionals, and regulatory affairs specialists to implement proactive risk mitigation and leverage cutting-edge analytical technologies. The curriculum deeply explores complex topics such as applying Next-Generation Sequencing (NGS) for adventitious agent testing, validating orthogonal viral removal/inactivation steps, and managing the unique viral safety challenges posed by Cell and Gene Therapies (CGT). Upon completion, attendees will be equipped to lead their organizations in achieving a zero-risk viral profile, thereby accelerating time-to-market for novel therapeutics, ensuring product integrity, and maintaining cGMP compliance in a highly competitive and regulated global marketplace.

Programme Curriculum

Advanced Strategies for Viral Clearance and Safety Training Course

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Course Objectives

1. Interpret and apply the latest global guidelines for Viral Safety Evaluation.
2. Design and implement a risk-based contamination control strategy using tools like FMEA
3. Evaluate and demonstrate the process robustness of existing and new viral clearance steps under worst-case conditions.
4. Select and optimize orthogonal viral inactivation and removal techniques to maximize the total Log Reduction Value (LRV).
5. Qualify and validate representative scale-down models of manufacturing unit operations for use in viral spiking studies.
6. Address and mitigate the specific viral safety challenges inherent in integrated continuous bioprocessing (ICB).
7. Critically evaluate the utility and regulatory acceptance of Next-Generation Sequencing (NGS) for adventitious virus detection.
8. Develop tailored viral safety programs for emerging modalities like Cell & Gene Therapy (CGT) and Viral Vectors.
9. Establish a robust program for raw material sourcing, testing, and control to prevent adventitious agent introduction.
10. Integrate advanced aseptic techniques and facility design principles to minimize contamination risk.
11. Accurately calculate, report, and interpret Log Reduction Factors and their associated Confidence Intervals (CI).
12. Formulate a detailed, compliant Viral Contamination Incident Response Plan and perform effective root cause analysis.
13. Prepare the complete Viral Clearance Documentation Package required for IND/BLA/MAA submissions.

Target Audience

1. Bioprocess Development Scientists/Engineers.
2. Quality Assurance (QA)/Quality Control (QC) Specialists.
3. Regulatory Affairs Professionals
4. Manufacturing/Operations Managers.
5. R&D Scientists.
6. Internal/External Auditors.
7. Raw Material/Supply Chain Experts.
8. Biotechnology Consultants.

Course Modules

1. Global Regulatory Landscape & Foundational Principles

- In-depth analysis of ICH Q5A (R2) requirements.
- Classification and characteristics of key model viruses
- The three pillars of viral safety.
- Defining the scope for Adventitious Agents and Endogenous Viruses.
- Case Study: Analysis of a historical viral contamination event and its impact on regulatory evolution.

2. Risk Assessment and Contamination Control Strategy (CCS)

- Systematic identification of viral risks across the bioproduction lifecycle
- Application of FMEA for proactive viral risk scoring and prioritization.
- Control of high-risk sources.
- Designing facility segregation and Containment Strategies
- Case Study: Developing a Viral Safety Master Plan for a new multi-product facility using a quantitative ICH Q9 risk approach.

3. Principles of Viral Inactivation Methods

- Detailed mechanism and kinetics of Low pH Inactivation
- Optimization of Solvent/Detergent (S/D) treatment for enveloped viruses.
- Alternative inactivation methods.
- Impact of process parameters (CPP) on inactivation effectiveness and Product Stability.
- Case Study: Optimizing low pH hold time and temperature to balance LRV and protein aggregation for an Fc-fusion protein.

4. Advanced Viral Filtration Strategies

- Comparative analysis of different **nanofiltration** membranes
- Mitigating **filter fouling** through effective **pre-filtration** and process design.
- Validation of **filter integrity testing** methods
- Strategies for **Filter Sizing and Scaling** from lab to commercial manufacturing.
- **Case Study:** A comprehensive **filter train optimization** to achieve $ > 4.0\ log_ {10} $ reduction while maximizing throughput and minimizing cost-of-goods.

5. Viral Clearance by Chromatography

- Mechanisms of viral removal/inactivation during Affinity Chromatography
- The role of Ion-Exchange Chromatography (IEX) in clearing both enveloped and non-enveloped viruses.

- Utilizing Membrane Chromatography for high-flow viral removal.
- Testing the impact of resin aging/reuse on sustained viral clearance capacity.
- Case Study: Demonstrating the LRV contribution of a non-dedicated Polishing Chromatography step in a 3-column purification process.

6. Scale-Down Model (SDM) Qualification

- Defining and justifying Critical Process Parameters for the SDM.
- Establishing equivalence criteria between the SDM and the full-scale process.
- Practical guide to executing the SDM Qualification Report.
- Addressing matrix effects and ensuring representative spike material behavior.
- Case Study: Qualification of a small-scale low pH hold step and a nanofiltration step for a continuous manufacturing train.

7. Design and Execution of Viral Spiking Studies

- Selection of the appropriate Spike Viruses based on process and product risk.
- Best practices for preparation, handling, and spiking of High-Titer Virus Stocks.
- Statistical principles for determining the required spike-to-harvest ratio.
- Post-spike sampling strategies and cytotoxicity/interference testing.
- Case Study: Designing a worst-case condition spiking study for a flow-through IEX column with reduced resin bed height.

8. Calculation and Interpretation of Log Reduction Values (LRV)

- Detailed methodology for calculating the Log Reduction Factor (LRF).
- Statistical analysis to determine the 95% Confidence Interval (CI) for LRV.
- Handling results from below the limit of detection (LOD).
- Regulatory expectations for total Cumulative LRV across orthogonal steps.
- Case Study: Performing statistical analysis on mock viral clearance data to ensure the reported LRV is scientifically justified and robust.

9. Next-Generation Sequencing (NGS) for Viral Safety

- The transition from traditional in vitro/in vivo assays to NGS for testing.
- Methodology: Untargeted/Deep Sequencing for comprehensive agent detection.
- Validation and regulatory acceptance of NGS for release testing and cell bank characterization.
- Data interpretation, bioinformatics, and handling Sequence Hits of Unknown Significance
- Case Study: Utilizing NGS to investigate an unknown adventitious agent detected in a production lot, leading to successful root cause identification.

10. Viral Safety for Advanced Therapy Medicinal Products (ATMPs)

- Unique viral risks in Cell Therapy
- Specific challenges for Gene Therapy Viral Vectors
- Donor and source material screening
- Tailoring clearance steps for non-chromatographic/non-filterable products
- Case Study: Developing a bespoke risk assessment and mitigation plan for an AAV-based gene therapy product.

11. Continuous Bioprocessing (ICB) and Viral Safety

- **Addressing the impact of process fluctuations on viral clearance performance.**
- Strategies for implementing continuous/automated Viral Inactivation (CVI) units.
- Managing filter clogging/replacement in a continuous filtration setup.
- Designing integrated viral spiking studies for linked unit operations.
- Case Study: Modeling the risk of a virus break-through during an integrated, continuous mAb capture and viral inactivation process.

12. Quality by Design and Process Validation

- Applying QbD principles to define the Design Space for viral clearance steps.
- Establishing Critical Quality Attributes (CQAs) and CPPs related to viral safety.
- Developing the Validation Master Plan and final Process Validation Report.
- Strategies for post-approval Change Management and Impact Assessment on viral clearance.
- Case Study: Using Design of Experiments (DoE) to define the parameter space for an efficient low pH viral inactivation step.

13. Audits, Inspections, and Deviations

- Preparation for and navigation of FDA/EMA inspections focused on viral safety.
- Effective documentation and presentation of the Viral Clearance Study Report.
- Framework for investigating and resolving a Viral Safety Deviation or Contamination Incident.
- Developing a training program for manufacturing personnel on aseptic and viral risk control.
- Case Study: Responding to a mock FDA 483 observation concerning the qualification and reuse of chromatography resin in a VC step.

14. Alternative & Next-Gen Viral Removal Techniques

- Exploration of Aptamer-based Chromatography for selective virus capture.
- Application of Hydrophobic Interaction Chromatography as an orthogonal step.
- Utilizing Tangential Flow Filtration (TFF) for large-scale removal/concentration.
- In-line PAT for real-time monitoring of clearance step performance.
- Case Study: Implementing a novel nanopore-based TFF system to clear a large-sized target virus from a non-mAb therapeutic protein.

15. The Viral Clearance Submission Dossier

- Structuring the Viral Safety Section of a BLA/MAA.
- Requirements for Certificate of Analysis (CofA) and Raw Material Dossiers.
- The importance of SOPs and Batch Records in demonstrating compliance.
- Lifecycle management: Planning for Re-validation and Bridging Studies.
- Case Study: Reviewing and critiquing a successful Viral Clearance Dossier submitted for an Investigational New Drug

Training Methodology

The course employs a blended, high-engagement methodology designed for seasoned biopharma professionals:

- Interactive Lectures.
- Practical Workshops.
- In-Depth Case Studies.
- Simulated Inspection.

- Q&A/Consultation.

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

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Physical	$12,000

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