Advanced Viral Safety and Clearance in Bioprocessing Training Course

26 – 30 July 2027
Addis Ababa

AGILE LEADERS
Training Center

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Ref: 1405_224568 **Date:** 26 – 30 July 2027 **Location:** Addis Ababa **Fees:** 4500 Euro

Overview

Advanced Viral Safety and Clearance in Bioprocessing Training Course is a one-week course for biopharmaceutical manufacturing, quality, validation, process development, biosafety, and regulatory affairs functions who leave with a Viral Safety Strategy and Clearance Study Dossier. Participants connect adventitious-agent risk, cell substrates, raw materials, orthogonal clearance steps, scale-down models, spiking studies, reduction-factor interpretation, robustness, deviations, and lifecycle evidence. Agile Leaders Training Center presents viral safety evaluation as a cross-functional bioprocess governance discipline.

Who Should Attend

- Functions responsible for bioprocess design, characterization, and technical transfer
- Quality functions reviewing viral safety evidence and lifecycle controls
- Validation functions planning and governing clearance studies
- Manufacturing functions controlling raw materials and process parameters
- Biosafety and laboratory functions managing adventitious-agent risk and assays
- CMC and regulatory functions assembling and reviewing technical evidence

The course assumes participants already support biological-product development, manufacturing, quality, validation, or technical submissions and leaves out introductory virology, viral-vector production, and promises of regulatory acceptance.

Departments and Industries

The course supports departments and industries that design, execute, review, or govern viral safety controls.

- Biopharmaceutical and biotechnology manufacturing
- Contract development and manufacturing organizations
- Process development, MSAT, and manufacturing departments
- Quality assurance, quality control, and validation departments
- Biosafety, analytical development, and laboratory operations
- CMC, technical documentation, and regulatory affairs functions

Learning Objectives

By the end of this course, participants will be able to:

- Analyze viral contamination pathways across materials, substrates, and processing
- Build an orthogonal viral clearance strategy
- Evaluate model-virus and scale-down-model rationale
- Use spiking, sampling, assay, and reduction-factor evidence
- Diagnose robustness, deviation, and study-report weaknesses
- Prioritize lifecycle changes and cross-functional actions

Course Agenda

Day 1: Viral Safety Risk and Scope

- ICH Q5AR2 Scope and Applicability Map
- Viral Safety Triad Control Model
- Cell Substrate and Raw Material Risk Register
- Adventitious-Agent Pathway Analysis
- Product and Process Scope Decision Record

Day 2: Clearance Process Design

- Orthogonal Inactivation and Removal Matrix
- Low-pH Inactivation Parameter Map
- Virus Filtration Capability Assessment
- Chromatography Clearance Mechanism Review
- Clearance Step Independence Test

Day 3: Study Design and Scale-Down

- Model Virus Selection Rationale
- Scale-Down Model Qualification Protocol
- Virus Spiking and Sampling Plan
- Assay Suitability and Detection Strategy
- Worst-Case Parameter Study Matrix

Day 4: Evidence and Lifecycle Governance

- Log Reduction Factor Calculation Sheet
- Clearance Data Uncertainty Review
- Robustness and Step Contribution Analysis
- Deviation and Invalid-Run Decision Tree
- Process Change Impact Assessment

Day 5: Viral Clearance Practice

- Exercise: Build a Viral Risk Register
- Exercise: Qualify a Scale-Down Model
- Exercise: Interpret Reduction-Factor Evidence
- Exercise: Evaluate a Study Deviation Report
- Capstone Exercise: Viral Safety Strategy and Clearance Study Dossier

Practical Exercises

The course uses suggested activities from monoclonal-antibody, recombinant-protein, and contract-manufacturing settings.

- Suggested activity: map materials, substrates, process stages, contamination pathways, controls, owners, and evidence in a viral risk register.
- Suggested activity: assess model-virus selection, scale-down comparability, spiking controls, sampling points, and assay suitability for a proposed study.
- Suggested activity: calculate and interpret reduction factors while documenting uncertainty, robustness, limitations, and step independence.
- Suggested activity: assemble risk, study-design, evidence-review, deviation, change-impact, and governance artifacts in the capstone dossier.

FAQs

Who suits advanced viral safety and clearance in bioprocessing training, and what does it assume?

Advanced viral safety and clearance in bioprocessing training suits experienced development, MSAT, manufacturing, quality, validation, biosafety, laboratory, CMC, and regulatory personnel who already support biological-product processes or evidence.

How does viral safety and clearance training differ from introductory bioprocess safety training?

Viral safety and clearance training concentrates on risk strategy, orthogonal clearance, study models, spiking controls, reduction factors, robustness, deviations, and lifecycle evidence rather than general biological-safety awareness.

What is an orthogonal viral clearance strategy in bioprocessing?

An orthogonal viral clearance strategy combines process steps with different removal or inactivation mechanisms so that the overall evidence does not depend on one mechanism alone.

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Why are scale-down models used in viral clearance studies?

Scale-down models reproduce relevant full-scale process conditions at a manageable study scale, allowing controlled virus-spiking work while requiring documented comparability, limitations, and parameter rationale.

Does viral clearance evidence guarantee regulatory acceptance?

Viral clearance evidence does not guarantee acceptance; it supports a risk-based evaluation when study design, model suitability, controls, results, limitations, and lifecycle governance are scientifically justified.

Conclusion

The course connects viral risk, clearance-process design, study controls, evidence interpretation, deviations, and lifecycle governance. Participants take back a Viral Safety Strategy and Clearance Study Dossier containing risk, model, study, calculation, review, and change-control tools. The dossier helps teams coordinate decisions, test evidence quality, and document limitations without treating outcomes as predetermined.