The Advanced Viral Vector Manufacturing for Gene Therapy 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 Advanced Viral Vector Manufacturing sector stands as the critical bottleneck and foremost opportunity in the trillion-dollar Cell and Gene Therapy (CGT) market. As breakthrough Advanced Therapy Medicinal Products (ATMPs) move from clinical trials to commercialization, the global demand for high-titer, high-purity viral vectors particularly Adeno-Associated Virus (AAV) and Lentivirus (LVV) has rapidly outstripped current manufacturing capacity. This course directly addresses the industry's most pressing challenges: achieving scalability from bench-scale to cGMP commercial manufacturing, implementing Process Intensification, and navigating the complex global regulatory landscape. Participants will transition from a foundational understanding to mastering next-generation bioprocessing technologies, including single-use systems, perfusion bioreactors, and advanced analytics for real-time Critical Quality Attribute (CQA) monitoring, positioning them as essential leaders in the future of precision medicine.

The Advanced Viral Vector Manufacturing for Gene Therapy Training Course is designed to bridge the gap between process development and commercial biomanufacturing. It moves beyond standard protocols to focus on Quality by Design (QbD) principles, process validation, and tech transfer best practices, which are vital for reducing the Cost of Goods (CoGs) and accelerating market access for life-saving therapies. Using contemporary industry case studies on overcoming downstream purification challenges and optimizing upstream yields in suspension culture platforms, attendees will acquire the practical, high-value skills needed to immediately impact their organization?ÇÖs productivity. Key topics include capsid engineering trends, the integration of Automation and Industry 4.0 technologies, and ensuring supply chain robustness in a strictly regulated, patient-focused environment, creating an invaluable investment in professional development.

Programme Curriculum

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Introduction

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10 days

Course Objectives

1. Master cGMP Viral Vector Scalability from pilot to Commercial Biomanufacturing.
2. Implement Process Intensification and Continuous Manufacturing strategies to enhance upstream yield and productivity.
3. Design and validate robust Downstream Purification workflows for superior vector purity and recovery.
4. Apply Quality by Design (QbD) principles to establish Critical Process Parameters (CPPs) and Critical Quality Attributes (CQAs).
5. Evaluate and integrate Single-Use Systems (SUS) and Perfusion Bioreactors to streamline facility operations and reduce turnaround.
6. Develop advanced Analytical Methods for precise vector characterization and quality control.
7. Analyze the role of Host Cell Line Engineering for maximizing transient and stable production.
8. Navigate the complex Global Regulatory Landscape for ATMP submission and approval.
9. Implement Automation and Data Analytics (PAT) to optimize process monitoring and facilitate troubleshooting.
10. Formulate stable Viral Vector Drug Product for enhanced shelf-life and effective Cold Chain Management.
11. Execute efficient Technology Transfer protocols between R&D, Process Development, and cGMP manufacturing sites.
12. Minimize Cost of Goods (CoGs) through process efficiency gains and optimized resource utilization.

13. Integrate Advanced Capsid Engineering and next-generation vector design concepts into manufacturing strategy.

Target Audience

1. Bioprocess Engineers
2. Manufacturing Scientists and Associates
3. Quality Assurance (QA) and Quality Control (QC) Specialists
4. Process Development and Analytical Development Scientists
5. R&D Scientists transitioning to Clinical Manufacturing
6. Facility Managers and Operational Excellence Leaders
7. Technology Transfer and Validation Specialists
8. Project Managers overseeing Cell and Gene Therapy (CGT) pipelines

Course Modules

Module 1: Foundational Principles and Market Trends

- Introduction to Viral Vectors and their role in Gene Therapy
- Vector biology, serotypes, pseudotyping, and therapeutic applications.
- Review of the Advanced Therapy Medicinal Products global market and pipeline.
- Scalability, CoGs, and Manufacturing bottlenecks.
- Case Study: The clinical and commercial success of an approved AAV-GT product

Module 2: Advanced Upstream Process Development

- Selection and engineering of Host Cell Lines
- Optimization of Cell Culture Media and feed strategies for high-titer production.
- Transfection and infection protocol optimization
- Principles of Perfusion Culture and Process Intensification for maximizing Upstream Yield.
- Case Study: Implementing a perfusion-based HEK293 system to achieve 5-fold increase in LVV productivity.

Module 3: Bioreactor Technology and Scale-Up

- Design and operation of Single-Use Bioreactors
- Bioreactor Scale-Up strategy and Geometric/Kinetic Similarity calculations.
- Advanced Bioreactor Monitoring and Process Analytical Technology integration.
- Aseptic connection techniques and closed-system processing in cGMP environments.
- Case Study: Troubleshooting a DO/pH excursion during AAV scale-up and its impact on product quality.

Module 4: Primary Recovery and Clarification

- Principles of Cell Harvest and Lysis methods for different vector types.
- Selection and optimization of Depth Filtration and Microfiltration steps.
- Management of Host Cell Proteins, Host Cell DNA, and impurities.
- Tangential Flow Filtration for initial volume reduction and concentration.
- Case Study: Designing a two-stage clarification train to minimize membrane fouling and maximize load volume.

Module 5: High-Resolution Downstream Purification (D-T-U)

- Theory and application of Affinity Chromatography for high selectivity.
- Optimization of Ion Exchange Chromatography for impurity removal and vector isolation.
- Advanced techniques in Hydrophobic Interaction Chromatography and mixed-mode resins.
- Non-Chromatographic purification alternatives and emerging technologies.
- Case Study: Comparing a three-step versus a two-step chromatography process to achieve >99% purity.

Module 6: Final Purification and Viral Clearance

- Advanced Ultrafiltration/Diafiltration for final concentration and buffer exchange.
- Implementation of Viral Inactivation and Viral Filtration steps
- Filter validation, integrity testing, and scale-down model qualification.
- Managing filter train economics and membrane capacity.
- Case Study: Executing a comprehensive Viral Clearance Study on a novel D-T-U platform.

Module 7: Analytical Method Development and QC

- Developing Critical Quality Attribute Centric Analytical Methods.
- High-Titer and Potency assays
- Purity and Impurity assays
- Safety and Identity testing
- Case Study: Validation of a novel HPLC-MALS method for accurate determination of Empty/Full AAV capsid ratio.

Module 8: Quality by Design (QbD) and Risk Management

- Introduction to the QbD framework
- Defining the Quality Target Product Profile and identifying CQAs.
- Conducting Risk Assessments in process development.
- Establishing Control Strategies and defining the Design Space.
- Case Study: Applying FMEA to mitigate the risk of contamination in an open-process step.

Module 9: cGMP Regulatory Frameworks and Compliance

- Understanding and adherence to Current Good Manufacturing Practices for ATMPs.
- Batch Records, Standard Operating Procedures, and Deviation Management.
- Regulatory expectations of global bodies for viral vector products.
- Preparation for and execution of successful Regulatory Inspections and audits.
- Case Study: Analyzing a major FDA Warning Letter related to facility design or documentation practices.

Module 10: Process Validation and Technology Transfer

- Principles and stages of Process Validation
- Developing and executing a robust Tech Transfer protocol from R&D to cGMP.
- Qualification of Analytical Methods and process scale-down models.
- Facility and equipment qualification
- Case Study: A detailed walkthrough of a successful, multi-site Tech Transfer for a lentiviral vector platform.

Module 11: Single-Use and Facility Design

- Economic and operational rationale for adopting Single-Use Technologies
- Designing a modular, scalable, and flexi-factory for multi-product manufacturing.

- Cleanroom classification, HVAC considerations, and environmental monitoring.
- Extractables and Leachables risk assessment for SUT components.
- Case Study: Designing the flow, material, and personnel movement of a new LVV cGMP suite.

Module 12: Automation, Data, and Industry 4.0

- Integration of Automation and robotics in high-throughput bioprocessing.
- Utilizing Data Analytics and Machine Learning for process modeling and prediction.
- Implementation of Process Analytical Technology for real-time control.
- Data integrity, electronic batch records, and 21 CFR Part 11 compliance.
- Case Study: Using a LIMS/MES system to automate process control and data capture in a large-scale run.

Module 13: Drug Product Formulation and Stability

- Principles of Viral Vector Formulation for long-term stability and optimal delivery.
- Selection of excipients, buffers, and cryopreservation agents.
- Conducting forced degradation and real-time Stability Studies
- Optimizing Fill/Finish operations and container/closure selection.
- Case Study: Optimizing an AAV formulation buffer to extend shelf life from 6 months to 2 years at? êÆ80?êÿC.

Module 14: Next-Generation Vector Technologies

- The science and manufacturing implications of Capsid Engineering and directed evolution.
- Production of designer vectors
- Comparison of Viral and Non-Viral Vectors
- In-vivo and Ex-vivo gene therapy manufacturing considerations.
- Case Study: Developing a manufacturing platform for a newly engineered, tissue-specific AAV capsid.

Module 15: Supply Chain and Operational Excellence

- Managing the complex Cold Chain Logistics for ATMPs
- Strategic relationship management with CDMOs and key raw material suppliers.
- Risk mitigation strategies for Single-Source Materials
- Implementing Lean Manufacturing and Six Sigma principles in bioprocessing.
- Case Study: Analyzing a Supply Chain disruption and developing a mitigation plan.

Training Methodology

The course employs an Accelerated Learning Model combining rigorous theoretical instruction with practical, real-world application.

- Interactive Lectures & Seminars.
- Deep-Dive Industry Case Studies.
- Hands-on Workshops/Simulations
- Group Problem-Solving & Debates.
- Virtual Facility Tours/Demonstrations.

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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