

Advanced Bioprocess Economics and Cost Modeling 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

Advanced Bioprocess Economics and Cost Modeling Training Course is essential for professionals seeking to master the financial viability of complex biomanufacturing projects. The biopharmaceutical industry is rapidly evolving toward Integrated Continuous Bioprocessing and Novel Therapeutic Modalities, demanding a new generation of engineers and scientists who can link technical process parameters to robust economic outcomes. By focusing on advanced Techno-Economic Analysis, detailed Cost of Goods modeling, and Strategic Capital Expenditure planning, this training moves beyond basic finance to address the unique economic challenges of high-cost, high-risk bioproducts. Participants will gain data-driven decision-making skills using Digital Twin and Process Simulation tools, enabling them to de-risk Process Scale-Up and significantly enhance Return on Investment across the entire product lifecycle.

This program provides a practical, hands-on framework to evaluate bioprocess profitability and drive Sustainable Biomanufacturing. Key topics include comparative economics of Single-Use Technology vs. Stainless Steel, the financial impact of Quality by Design, and Risk Modeling for market volatility and supply chain disruptions. Mastery of these Advanced Bioprocess Economics principles is crucial for optimizing R&D Portfolio Management, justifying major facility investments, and achieving a competitive advantage in the global biopharma market. Graduates will be equipped to lead Cost-Optimization initiatives and guide their organizations toward economically sound, next-generation manufacturing solutions.

Programme Curriculum

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Course Objectives

1. Master Techno-Economic Analysis and its application in early-stage bioprocess design.
2. Develop Advanced COG models for both traditional biologics and Novel Therapeutic Modalities.
3. Evaluate Capital Expenditure and Operating Expenditure with high precision for biomanufacturing facilities.
4. Conduct comprehensive Sensitivity Analysis to de-risk investment in Process Scale-Up projects.
5. Perform comparative Single-Use Technology vs. Stainless Steel economic evaluations.
6. Integrate Quality by Design principles into economic models to quantify the ROI of quality.
7. Apply Net Present Value, Internal Rate of Return, and Discounted Cash Flow for project valuation.
8. Model the economics of Integrated Continuous Bioprocessing to quantify efficiency gains.
9. Utilize Process Simulation software to build and validate Digital Twin economic models.
10. Assess the financial impact of Supply Chain Volatility and Raw Material Risk Modeling.
11. Develop Strategic Pricing Models based on target COG, market access, and competitive landscape.
12. Quantify the economic trade-offs of High Titer processes versus throughput and purification cost.
13. Formulate R&D Portfolio Management strategies based on economic attractiveness and risk-adjusted valuation.

Target Audience

1. Biochemical/Bioprocess Engineers
2. Process Development Scientists and Managers
3. R&D Portfolio Managers and Project Leads
4. Manufacturing & Operations Directors
5. Biotech Finance & Business Development Analysts
6. Technology Transfer and Scale-Up Specialists
7. Quality by Design and Process Analytical Technology Team Members
8. Consultants specializing in biomanufacturing strategy

Course Modules

Module 1: Foundational Bioprocess Financial Principles

- Linking core bioprocess parameters to financial outputs.
- Understanding the time value of money.
- The anatomy of COG.
- Introduction to cost estimation heuristics and scaling factors
- Case Study: Modeling the COG for a first-generation mAb process to establish a baseline.

Module 2: Advanced COG Modeling and Cost Drivers

- Detailed breakdown of raw material costs, including media, resins, and critical consumables.
- Modeling labor costs based on automation level, cGMP requirements, and shift patterns.
- Calculating depreciation schedules for facilities and equipment.
- Quantifying the financial impact of batch failure, contamination, and high-risk operations.
- Case Study: Assessing the economic trade-off of using a more expensive, high-performance chromatography resin to reduce cycle time and buffer usage.

Module 3: Capital Expenditure Estimation

- Fixed Capital Investment for greenfield vs. brownfield biomanufacturing facilities.
- Detailed equipment costing: Bioreactors, purification trains, utilities, and WFI systems.
- Contingency planning and the financial modeling of project management costs.
- Utilizing CapEx benchmarks and applying power-law scaling for facility sizing.
- Case Study: Developing a CapEx estimate for a new multi-product cell culture facility based on desired production scale

Module 4: Techno-Economic Analysis for Process Selection

- Structuring a comprehensive TEA from process flowsheet to final economic metrics.
- Performing early-stage TEA to guide R&D toward economically favorable routes.
- Identifying and quantifying the primary TEA Bottlenecks in upstream and downstream processing.
- Sensitivity analysis
- Case Study: Comparing the TEA of a fed-batch vs. a high-density perfusion process for a biosimilar.

Module 5: Continuous Bioprocessing Economics

- Economic benefits of Integrated Continuous Bioprocessing for COG reduction.
- Modeling reduced facility footprint and lower CapEx for ICB platforms.
- Evaluating increased equipment utilization and reduced inventory costs in continuous mode.
- Financial modeling of intensified purification steps.
- Case Study: Quantifying the COG saving achieved by converting a batch mAb process to a fully continuous, end-to-end biomanufacturing line.

Module 6: Single-Use Technology (SUT) vs. Stainless Steel (SS) Comparison

- Deep-dive into SUT economics.
- Analyzing the OpEx impact of disposable consumable waste and supply chain risk.
- Modeling SUT flexibility for multi-product and clinical-scale manufacturing.
- Comparative CapEx modeling for SUT-heavy vs. traditional SS facility builds.

- Case Study: Performing an 8-year DCF analysis to determine the optimal platform for a new clinical CMO facility.

Module 7: Economics of Cell and Gene Therapies (CGT)

- Unique COG challenges in Autologous vs. Allogeneic CGTs.
- Modeling the high cost of viral vector production and lentivirus/AAV supply chain.
- Quantifying the economic impact of low batch yields and stringent quality control testing.
- Financial implications of decentralized/distributed manufacturing models for CGT.
- Case Study: Developing a COG model for a patient-specific CAR-T therapy, focusing on apheresis, cell expansion, and QC labor.

Module 8: Process Simulation and Digital Twin Integration

- Fundamentals of using commercial process simulation software
- Building dynamic Digital Twin models for real-time cost and performance prediction.
- Using simulation to perform scenario planning and rapid "what-if" economic analyses.
- Integrating simulation outputs with external financial modeling tools
- Case Study: Simulating a process failure scenario and calculating the immediate and long-term economic loss.

Module 9: Quality by Design (QbD) and Economic ROI

- Quantifying the upfront investment required for a full QbD implementation.
- Modeling the ROI of investing in Process Analytical Technology to reduce batch failures.
- Assessing the long-term economic benefits of reduced regulatory risk and faster approval cycles.
- Economic analysis of Critical Quality Attribute control limits and their process cost.
- Case Study: Calculating the net benefit of implementing a Soft Sensor in a bioreactor to improve yield and reduce unnecessary off-line testing costs.

Module 10: Financial Risk Modeling and Sensitivity Analysis

- Applying Monte Carlo Simulation to model cost uncertainty and project valuation.
- Modeling the impact of raw material price volatility
- Risk-adjusted NPV calculation for early-stage R&D bioprojects.
- Analyzing currency fluctuation and global supply chain risk on OpEx.
- Case Study: Performing a two-dimensional sensitivity analysis on titer and process yield to define the "break-even" process performance window.

Module 11: Supply Chain and Logistics Economics

- Modeling Cold Chain Logistics and its significant contribution to final COG for biologics.
- Optimizing inventory management costs for critical materials.
- Economic impact of vendor qualification, single-source dependency, and dual-sourcing strategy.
- Quantifying the financial loss from logistics failures.
- Case Study: Comparing the total logistics and inventory cost for a frozen drug substance versus a lyophilized final drug product.

Module 12: Project Valuation and Investment Strategy

- Advanced DCF modeling for biotech project valuation and licensing decisions.
- Structuring economic models for Outsourcing vs. In-House manufacturing decisions.

- Economic evaluation of facility expansion strategies
- Developing internal financial hurdles for project prioritization.
- Case Study: Valuing a new Phase 3 biopharmaceutical asset using rNPV to determine a go/no-go investment decision.

Module 13: Sustainability and Circular Economy in Bioprocessing

- Quantifying the economic cost of water usage, energy consumption, and effluent treatment.
- Life Cycle Assessment fundamentals and its link to long-term economic viability.
- Modeling the financial returns of Sustainable Manufacturing initiatives
- Analyzing regulatory incentives and carbon taxes on biomanufacturing OpEx.
- Case Study: Calculating the ROI of installing a high-efficiency WFI generation system compared to the OpEx of a standard utility system over 15 years.

Module 14: Economic Modeling for High-Titer and Downstream Trade-Offs

- Detailed modeling of the trade-off between upstream titer gains and increased downstream processing costs
- Economic sizing and cost allocation for chromatography and filtration unit operations.
- Analyzing the financial impact of platform vs. dedicated process development.
- Optimizing the number of purification steps for maximum economic return vs. purity.
- Case Study: Modeling a 50% titer increase and the subsequent required 2x increase in Protein A column size to find the point of diminishing economic return.

Module 15: Presenting and Defending Economic Models

- Techniques for creating clear, defensible economic reports for executive leadership.
- Translating technical data into financial language
- Strategies for effectively communicating Risk and Uncertainty in financial projections.
- Best practices in economic model documentation and version control.
- Case Study: Role-playing a presentation to a corporate investment committee, defending a \$150M CapEx request based on the course's developed TEA model.

Training Methodology

The course employs a highly **interactive, applied learning** methodology:

- Case Study-Driven Lectures.
- Hands-on Software Workshops.
- Team-Based Bioprocess Design Challenge.
- Expert Panel Q&A.

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
21 Sep 2026	02 Oct 2026	Physical	\$0

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