# Establishing Biopharma Manufacturing Capacity in Emerging Markets Training Course

Professional Development Training Course Outline

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|---|---|---|---|
| **Category** | Biotechnology and Pharmaceutical Development | **Duration** | 10 Days |
| **Base Fee** | $4,000 USD | **Delivery Mode** | Online / On-site Hybrid |

## Course Introduction

This course is a critical guide for leaders navigating the complexities of establishing globally compliant, cost-effective biomanufacturing facilities in Emerging Markets (EMs). The global health crisis has highlighted the urgent need for supply chain resilience and localized production of essential biologics and biosimilars. This intensive program integrates Quality by Design (QbD) principles with practical strategies for resource-constrained environments, covering the entire bioprocess lifecycle from facility design and technology transfer to managing a compliant Quality Management System (QMS) and cold chain logistics. Participants will gain the specialized knowledge required for de-risking capital investment, navigating local regulatory hurdles, and building a highly-skilled bioprocess workforce to ensure a reliable supply of life-saving medicines and drive Universal Health Coverage (UHC).

Establishing Biopharma Manufacturing Capacity in Emerging Markets Training Course directly addresses the strategic imperative for distributed manufacturing models and process intensification, leveraging modern solutions like Single-Use Systems (SUS) and digitalization to accelerate time-to-market. By focusing on practical case studies from African, Latin American, and Asian emerging markets, this course empowers participants to master the project economics and operational best practices necessary for sustainable success. Graduating with a robust framework for cGMP compliance and a deep understanding of bio-economy development, attendees will be positioned as key drivers in transforming their region's capacity for advanced therapy medicinal products (ATMPs) and securing medicines accessibility for millions.

## Programme Curriculum

**Establishing Biopharma Manufacturing Capacity in Emerging Markets Training Course**

**Introduction**

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**Course Duration**

10 days

**Course Objectives**

1. Strategize and develop a Biomanufacturing Ecosystem tailored for resource-constrained environments.
2. Master the project economics and financing models for establishing a new facility.
3. Implement a robust, compliant Quality Management System aligned with global cGMP/ICH guidelines.
4. Navigate complex local regulatory hurdles and develop an effective market access strategy for biologics and biosimilars.
5. Design modular facilities and integrate Single-Use Systems (SUS) for flexibility and process intensification.
6. Optimize Upstream and Downstream Bioprocessing for high yield and cost-effective production.
7. Apply Quality by Design (QbD) and Quality Risk Management (QRM) to all phases of development and manufacturing.
8. Establish and validate a resilient cold chain and global supply chain transparency for temperature-sensitive products.
9. Develop a workforce training and upskilling program to address the skills gap analysis in emerging markets.
10. Evaluate and implement digital transformation strategies, including Industry 4.0 and data analytics.
11. Secure Technology Transfer agreements and manage intellectual property with local and international partners.
12. Design for Sustainability and waste management in facility operations to minimize environmental impact.
13. Conduct a comprehensive Feasibility Study and Risk Mitigation plan for investment justification

**Target Audience**

1. Biopharma Executives and Investors.
2. Project Managers/Engineers.

3. Process Development Scientists.
4. Quality Assurance (QA) and Regulatory Affairs (RA) Professionals.
5. Government Officials/Policymaker.
6. Supply Chain and Logistics Managers.
7. Engineers/Technical Staff
8. Consultants.

**Course Modules**

**1. Global Biopharma Market Dynamics & Strategy**

- Global Health needs and the drive for Universal Health Coverage
- Analysis of Market Opportunities and key macroeconomic indicators in EMs.
- Comparing Biologics and Biosimilars and their production complexity.
- Case Study: Assessing the market entry strategy for a biosimilar monoclonal antibody (mAb) in the ASEAN region.
- The strategic imperative of localized production for national health security.

**2. Biologics Manufacturing Fundamentals**

- Overview of the Bioprocess Lifecycle
- Key unit operations in Upstream and Downstream processing.
- Differences between manufacturing mAbs, Vaccines, and ATMPs.
- Case Study: Comparing the production process of a traditional chemical drug to an insulin biologic.
- Introduction to cell culture, microbial fermentation, and basic bioprocess control.

**3. Regulatory Strategy & Compliance (cGMP)**

- Understanding ICH guidelines and global regulatory bodies
- Navigating local regulatory hurdles and registration requirements for market access.
- Developing a robust Regulatory Submission Plan and dossier preparation.
- Case Study: Navigating the regulatory approval process for a domestically produced vaccine in a Latin American country.
- Preparing for and successfully managing facility cGMP audits and inspections.

**4. Quality by Design (QbD) & Risk Management (QRM)**

- Principles of QbD and its application to Critical Quality Attributes
- Implementing Quality Risk Management (QRM) techniques.
- Establishing a compliant Quality Management System (QMS) structure and documentation.
- Case Study: Using Failure Mode and Effects Analysis to identify and mitigate risks in a new DSP purification train.
- Best practices for Good Documentation Practices (GDP) and batch record keeping.

**5. Biomanufacturing Facility Design & Utilities**

- Conceptual design, layout planning, and flow optimization.
- Design of Cleanrooms and classifying controlled environments
- Critical HVAC Systems design and qualification for sterility control.
- Case Study: Designing a modular biopharma facility in Africa to quickly scale production for a pandemic response.
- Sustainability in facility design and managing utility consumption in EMs.

**6. Upstream Processing (USP) Optimization**

- Cell line selection, development, and Master Cell Bank (MCB) management.
- Bioreactor technology.
- Media and feed optimization for enhanced product yield and viability.
- Case Study: Troubleshooting a bioreactor run to improve cell viability and product titer in a fed-batch process.
- Implementing Process Control strategies and in-line monitoring (PAT).

**7. Downstream Processing (DSP) & Purification**

- Techniques for harvest, clarification, and primary solid-liquid separation.
- Principles of Chromatography and Filtration for impurity removal.
- Strategies for effective Viral Inactivation and clearance validation.
- Case Study: Developing a cost-effective, high-throughput purification train for a vaccine product using membrane chromatography.
- Formulation of the drug substance and sterile drug product handling.

**8. Process Intensification & Next-Gen Manufacturing**

- Benefits and limitations of Single-Use Systems (SUS) integration.
- Continuous manufacturing and traditional Batch Processes.
- Strategies for Process Intensification.
- Case Study: Implementing a single-use bioreactor suite to reduce changeover time and contamination risk in a multi-product facility.
- Integrating automation and digitalization (Pharma 4.0) into operations.

**9. Supply Chain, Logistics, and Cold Chain**

- Sourcing and qualification of Raw Materials and critical consumables.
- Optimizing logistics for global and local distribution networks.
- Cold Chain Validation and real-time temperature monitoring for biologics.
- Case Study: Establishing a reliable and validated cold chain for a perishable biopharma product in a country with limited road and power infrastructure.
- Building Supply Chain Resilience and risk mitigation against disruptions.

**10. Financial Planning & Project Economics**

- Developing Feasibility Studies and comprehensive business cases.
- Detailed planning of Capital Expenditure (CAPEX) and Operational Expenditure
- Exploring diverse Financing Models and securing investment
- Case Study: Developing a financial model to justify a new facility investment based on projected local market demand and import substitution.
- Conducting Risk Analysis and financial sensitivity modeling.

**11. Technology Transfer & IP Management**

- Managing the entire Technology Transfer process lifecycle.
- Developing a robust Validation Master Plan (VMP).
- Addressing intellectual property (IP) and licensing considerations in EMs.
- Case Study: Successfully transferring a complex mAb manufacturing process from a Western CMO to a new facility in Southeast Asia.

- Strategies for building internal technical competency to receive and adapt foreign technology.

**11. Quality Control (QC) and Analytical Testing**

- Essential Analytical Testing methods for biopharmaceuticals
- Validation of analytical assays and bioassays for QC release.
- Microbiology and environmental monitoring programs for cleanroom operations.
- Case Study: Investigating an Out-of-Specification (OOS) result in a final product test and implementing a corrective and preventive action (CAPA) plan.
- Setting up Release Testing protocols and managing long-term Stability Studies.

**13. Workforce Development & Talent Retention**

- Conducting a Skills Gap Analysis for local talent pools.
- Designing effective Training and Upskilling Programs for bioprocess technicians and engineers.
- Strategies for Recruitment and Retention of skilled personnel in competitive markets.
- Case Study: Creating a partnership with a local university or technical college to build a sustainable pipeline of bioprocess engineers and scientists.
- Fostering a Culture of Quality and continuous improvement throughout the organization.

**14. Lean Manufacturing & Operational Excellence**

- Principles of Lean Manufacturing and waste reduction in bioprocessing.
- Implementing a Root Cause Analysis (RCA) and CAPA system for continuous improvement.
- Developing Key Performance Indicators for manufacturing efficiency and yield.
- Case Study: Applying Lean principles to reduce changeover time and contamination risk in a multi-product filling line.
- Strategies for enhancing operator safety and process security.

**15. The Future: Pharma 4.0 & Advanced Therapies**

- Introduction to Digital Manufacturing and Data Analytics in biopharma.
- The impact of Artificial Intelligence on process optimization and predictive maintenance.
- Manufacturing considerations for Cell and Gene Therapies (ATMPs).
- Case Study: Implementing a digital twin of a bioprocess to predict process deviations and optimize yields in real-time.
- The role of Distributed Manufacturing networks for regional supply.

**Training Methodology**

The course employs a highly interactive and blended learning approach, combining theoretical lectures with practical workshops, group exercises, and real-world case studies.

- Instructor-Led Sessions.
- Interactive Workshops.
- Case Studies and Debates
- Simulations/Virtual Plant Tours.
- Modular Learning.

**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 |

Ready to enroll or request a customized program? Book online or contact us:

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