Biopharmaceutical Manufacturing Training Course

Professional Development Training Course Outline

Category	General Training	**Duration**	5 Days
Base Fee	$1,500 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

Biopharmaceutical Manufacturing Training Course is designed to equip learners with advanced knowledge of bioprocessing, GMP compliance, cell culture technology, upstream & downstream processing, and biologics production systems. As the global demand for monoclonal antibodies, recombinant proteins, vaccines, biosimilars, and cell & gene therapies continues to rise, the need for skilled professionals in regulated biomanufacturing environments has become critical. This course provides a deep dive into end-to-end biologics manufacturing workflows, ensuring participants understand both scientific principles and industrial-scale applications.

This training emphasizes real-world applications across biopharmaceutical production facilities, cleanroom operations, quality assurance systems, validation protocols, and regulatory compliance frameworks. Learners will gain hands-on insights into bioreactor operations, fermentation technologies, purification processes, quality control testing, and advanced analytics. The program is structured to build workforce readiness for high-demand roles in biotech manufacturing, pharmaceutical production, and biologics quality systems, ensuring alignment with global industry standards and emerging trends in biomanufacturing automation and digital bioprocessing.

Programme Curriculum

Biopharmaceutical Manufacturing Training Course

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Course Duration

5 days

Course Objectives

1. Master biopharmaceutical manufacturing lifecycle from cell line development to final product formulation
2. Understand GMP (Good Manufacturing Practices) and global regulatory frameworks (FDA, EMA, ICH)
3. Apply principles of upstream bioprocessing and cell culture optimization
4. Execute downstream purification techniques including chromatography and filtration
5. Analyze bioreactor design and scale-up strategies for industrial production
6. Implement Quality Assurance (QA) and Quality Control (QC) systems in biomanufacturing
7. Develop skills in cleanroom operations and aseptic processing techniques
8. Understand validation, qualification, and process optimization protocols
9. Gain expertise in biosafety, biosecurity, and contamination control systems
10. Interpret process analytical technology (PAT) and real-time monitoring tools
11. Integrate single-use technologies and disposable bioprocess systems
12. Explore advancements in biosimilars, monoclonal antibodies, and gene therapy production
13. Prepare for careers in digital biomanufacturing and Industry 4.0 pharmaceutical systems

Target Audience

1. Biotechnology graduates and postgraduates
2. Pharmaceutical manufacturing professionals
3. Bioprocess engineers and biochemical engineers
4. Quality assurance and quality control analysts
5. Clinical research and regulatory affairs professionals
6. Biomedical and life sciences researchers
7. Production supervisors in pharma/biotech industries
8. Professionals transitioning into **biopharmaceutical and vaccine manufacturing**

Course Modules

Module 1: Fundamentals of Biopharmaceutical Manufacturing

- Overview of biologics and biopharmaceutical products
- Evolution of biotech and pharma convergence
- Key manufacturing workflows and process flow diagrams
- Introduction to **GMP-compliant manufacturing systems**
- Case Study: Scaling monoclonal antibody production from lab to pilot plant

Module 2: Cell Line Development & Cell Culture Technology

- Mammalian, microbial, and insect cell systems
- Cell line engineering and optimization techniques
- Media development and fed-batch culture strategies
- Contamination control in cell culture environments
- Case Study: CHO cell line optimization for therapeutic protein yield

Module 3: Upstream Bioprocessing & Bioreactor Operations

- Bioreactor types
- Oxygen transfer and nutrient optimization
- Scale-up and scale-down models
- Process control parameters
- Case Study: Industrial-scale vaccine production using bioreactors

Module 4: Downstream Processing & Purification

- Harvesting and clarification techniques
- Chromatography
- Filtration and membrane technologies
- Protein purification strategies
- Case Study: Purification of recombinant insulin using multi-step chromatography

Module 5: GMP, QA & Regulatory Compliance

- GMP principles and documentation practices
- FDA, EMA, and ICH regulatory frameworks
- Audit preparation and inspection readiness
- Deviation management and CAPA systems
- Case Study: GMP audit failure analysis in a biotech facility

Module 6: Sterile Manufacturing & Cleanroom Technology

- Cleanroom classifications
- Aseptic processing and sterile handling techniques
- Environmental monitoring systems
- Contamination prevention strategies
- Case Study: Sterility breach investigation in injectable drug production

Module 7: Quality Control, Validation & PAT

- Analytical testing methods for biologics
- Process validation and equipment qualification
- Stability studies and batch release testing
- Process Analytical Technology (PAT) tools
- Case Study: Validation of biosimilar manufacturing process

Module 8: Advanced Biomanufacturing & Industry 4.0

- Single-use technologies and continuous manufacturing
- Automation and digital bioprocessing systems

- AI and data analytics in pharma manufacturing
- Emerging trends-gene therapy, CAR-T, biosimilars
- Case Study: Smart factory implementation in a modern biopharma plant

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

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	27 Nov 2026	Online	$1,000

Start Date	End Date	Location	Price
23 Nov 2026	27 Nov 2026	Physical	$1,500
23 Nov 2026	27 Nov 2026	Physical	$3,000
23 Nov 2026	27 Nov 2026	Physical	$3,000
23 Nov 2026	27 Nov 2026	Physical	$6,000
23 Nov 2026	27 Nov 2026	Physical	$4,500
23 Nov 2026	27 Nov 2026	Physical	$6,000
23 Nov 2026	27 Nov 2026	Physical	$6,000

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

Register Online Now

Email: info@fineskilltrainingcenter.com | Website: www.fineskilltrainingcenter.com