

Advanced Sustainability in Biomanufacturing 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 biomanufacturing industry, a cornerstone of global health and the bioeconomy, is at a critical inflection point. While it delivers life-saving therapeutics and sustainable materials, its traditional resource-intensive models pose significant environmental challenges, including high energy and water consumption, substantial waste streams, and a large carbon footprint. Advanced Sustainability in Biomanufacturing Training Course is designed to equip industry professionals with the cutting-edge knowledge and practical strategies required for the successful implementation of a Net Zero bioprocess roadmap. By focusing on principles of green chemistry, process intensification, and life cycle assessment, we transition the focus from mere compliance to the creation of a fundamentally resilient and circular biomanufacturing enterprise. Participants will learn to leverage digital transformation and Industry 4.0 technologies, such as smart sensors and AI-driven bioprocess optimization, to achieve unprecedented levels of efficiency and environmental performance.

Achieving Environmental, Social, and Governance (ESG) goals is no longer optional; it is a prerequisite for long-term commercial viability and attracting top talent. This training moves beyond theoretical sustainability, providing a deep dive into eco-design and sustainable supply chain management specifically within the complex regulatory landscape of the biotech and pharmaceutical sectors. We explore the financial imperative, demonstrating how reducing consumption of critical raw materials (CRMs), minimizing waste valorization, and adopting continuous manufacturing (CM) not only lowers operational expenditure but also enhances brand reputation and market competitiveness. Upon completion, participants will be strategic champions capable of leading their organizations in developing next-generation bioproducts while setting new industry benchmarks for biosustainability and ensuring a competitive edge in the rapidly evolving global market.

Programme Curriculum

Advanced Sustainability in Biomanufacturing Training Course

Introduction

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Course Duration

10 days

Course Objectives

Upon completion of this course, participants will be able to:

1. Lead the development of a comprehensive Net Zero Bioprocess Roadmap for their organization.
2. Integrate Life Cycle Assessment (LCA) methodologies across the entire bioproduction value chain.
3. Apply the principles of Green Chemistry and Green Engineering to optimize upstream and downstream bioprocesses.
4. Implement Process Intensification (PI) techniques, including Continuous Biomanufacturing (CM), to drastically reduce facility footprint and energy usage.
5. Evaluate the feasibility of alternative raw materials and cell-free biomanufacturing platforms for resource reduction.
6. Design Circular Economy strategies for waste valorization and solvent recycling in biopharma.
7. Utilize Smart Sensors and Process Analytical Technology (PAT) for real-time, AI-driven bioprocess optimization.
8. Conduct ESG performance reporting and ensure compliance with emerging international sustainable finance frameworks.
9. Develop robust, transparent, and sustainable supply chain metrics for critical raw materials.
10. Assess the impact of facility design by applying standards like LEED certification and ISO 14001 to biomanufacturing facilities.
11. Champion a culture of biosustainability and internalize sustainable practices across all operational levels.

12. Calculate and minimize the water-energy nexus impact within large-scale bioreactor operations.
13. Drive innovation in single-use technologies (SUT) disposal through advanced recycling and polymer breakdown solutions.

Target Audience

1. Bioprocess Engineers
2. Manufacturing & Operations Managers
3. R&D Scientists focused on Biologics and Industrial Biotechnology
4. Quality, Safety, Health, and Environment (QSHE) Leaders
5. Supply Chain and Procurement Professionals in Pharma/Biotech
6. Facility Design & Capital Project Engineers
7. Senior Management/Strategy Teams driving ESG and corporate sustainability.
8. Regulatory Affairs Specialists focused on environmental compliance.

Course Modules

Module 1: Foundations of Sustainable Biomanufacturing

- Biosustainability Principles and the Triple Bottom Line
- The current environmental impact of traditional batch bioproduction
- Case Study: The shift from fossil-fuel-based chemical synthesis to microbial bioproduction platforms.
- Sustainable Biologics Production
- Introduction to Global ESG Frameworks and their relevance to Biopharma.

Module 2: Advanced Life Cycle Assessment in Bioprocessing

- Life Cycle Impact Assessment (LCIA) Methodology.
- Defining System Boundaries.
- Case Study: Comparative LCA of a traditional mAb process versus a new continuous process
- Data collection, LCA software tools, and critical interpretation of results.
- Using LCA to prioritize hotspots for targeted process improvement.

Module 3: Green Chemistry and Engineering for Upstream

- Green Solvents and Reagent Selection.
- Optimizing media and feed components to minimize harmful chemical inputs
- Case Study: Implementing solvent-free or supercritical CO₂ extraction methods in place of traditional organic solvent use.
- Advanced control of cell culture to maximize yield and reduce the need for nutrient replacement.
- Designing bioreactors for energy efficiency.

Module 4: Process Intensification (PI) and Continuous Manufacturing (CM)

- Continuous Biomanufacturing and Perfusion Culture.
- Technical challenges and regulatory advantages of switching from batch to CM.
- Case Study: Adoption of end-to-end CM for monoclonal antibody production
- Detailed review of intensified downstream processing, including multi-column chromatography.
- Facility design implications: smaller footprint, reduced utilities, and mobile/modular facilities.

Module 5: Digitalization, PAT, and AI Optimization

- AI-Driven Bioprocess Optimization and Industry 4.0.
- Integrating Process Analytical Technology and smart sensors for real-time monitoring.
- Case Study: Using Digital Twins and Machine Learning to predict and prevent batch failures, saving resources.
- Advanced data analytics and predictive modeling for yield and purity improvements.
- Bioprocess Digital Transformation

Module 6: Sustainable Energy and Water Management

- Water-Energy Nexus Mitigation.
- Strategies for transitioning to Renewable Energy sources for manufacturing sites.
- Case Study: Retrofitting an existing biomanufacturing plant with highly efficient HVAC and utility systems for substantial energy reduction.
- Advanced water purification, recycling systems, and wastewater management.
- Minimizing water usage in Clean-in-Place and Steam-in-Place processes.

Module 7: The Circular Bioeconomy and Waste Valorization

- Waste Valorization and Byproduct Upcycling.
- Classification and management of solid, liquid, and hazardous bioprocessing waste.
- Case Study: Converting spent cell biomass or fermentation broth into value-added co-products
- Circular Biomanufacturing
- Designing products and processes with end-of-life recycling and reuse in mind

Module 8: Sustainable Supply Chain Management

- Critical Raw Materials Risk Assessment.
- Evaluating supplier ESG performance and enforcing ethical sourcing standards.
- Case Study: Auditing and improving the sustainability profile of single-use consumables suppliers
- Supply chain transparency using blockchain and digital tracking technologies.
- Reducing logistics carbon emissions through optimized distribution and transport modes.

Module 9: Bioproduct Eco-Design and Green Formulation

- Eco-Friendly Bioproduct Design.
- Selecting sustainable excipients and stabilizing agents for final formulations.
- Case Study: Developing alternative, biodegradable drug delivery systems and packaging materials.
- Impact of product stability and shelf-life on total environmental footprint.
- Applying Toxicity Assessments to minimize environmental release of pharmaceuticals

Module 10: Single-Use Technologies (SUT) and the Disposal Challenge

- Sustainable Single-Use Systems and Polymer Recycling.
- Analyzing the trade-offs between SUT and traditional stainless steel.
- Case Study: Collaboration programs for closed-loop SUT recycling and advanced polymer breakdown technologies.
- Strategies for standardizing SUT materials to enable easier recycling.
- Optimizing SUT design to reduce total plastic mass per batch.

Module 11: Facility Design and Green Building Standards

- LEED Certification for Biomanufacturing Facilities.

- Principles of Passive Design and maximizing natural lighting/ventilation.
- Case Study: Designing a net-zero energy or net-zero water biomanufacturing campus from the ground up.
- Integrating on-site renewable energy and rainwater harvesting solutions.
- Adherence to ISO 14001 for establishing an effective Environmental Management System

Module 12: Regulatory Compliance and Future Legislation

- Environmental Compliance and Reporting.
- Review of key global and regional environmental regulations affecting biotech
- Case Study: Navigating the regulatory landscape for introducing a recycled or circular raw material into a registered drug process.
- The role of voluntary standards and certifications
- Forecasting future legislative trends impacting carbon taxation and plastic waste.

Module 13: Next-Generation Sustainable Bioproduction Platforms

- Cell-Free Biomanufacturing and Synthetic Biology.
- Exploring non-traditional hosts for higher sustainability profiles.
- Case Study: The use of engineered microbes for industrial biotechnology applications like producing sustainable chemicals or biofuels
- Industrial Biotechnology Sustainability
- Developing processes that utilize low-cost, waste-derived feedstocks.

Module 14: Economic Modeling and Green Return on Investment (ROI)

- Total Cost of Ownership Analysis for Green Projects.
- Quantifying the financial benefits of reduced utility costs and waste fees.
- Case Study: Building a detailed financial model justifying the high upfront CapEx for a CM facility based on OpEx savings and faster time-to-market.
- Accessing Green Finance, subsidies, and tax incentives for sustainable investments.
- Pricing strategies and the willingness-to-pay premium for sustainable bioproducts.

Module 15: Change Management and Leadership

- Culture of Biosustainability Leadership.
- Developing internal communication strategies to promote sustainability goals and metrics.
- Case Study: Implementing an employee engagement and incentive program to drive site-level sustainable operational changes.
- Integrating sustainability KPIs into performance reviews and corporate strategy.
- Effective stakeholder engagement: investors, community, and non-profits.

Training Methodology

The course employs an Advanced, Blended Learning methodology designed for experienced professionals:

- Interactive Lectures.
- In-Depth Case Studies.
- Process Simulation Workshops.
- Group Project.
- Expert Guest Speakers.
- Q&A/Problem-Solving Sessions.

Register as a group from 3 participants for a Discount

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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 commencement 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

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