Single-Use Technology in Biopharma Manufacturing 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

Single-Use Technology (SUT) in biopharma manufacturing has revolutionized the way pharmaceutical and biotechnology industries approach production. As global demand for biologics, vaccines, and gene therapies increases, the adoption of Single-Use Systems (SUS) has become pivotal in ensuring efficiency, cost-effectiveness, and flexibility. This innovative technology streamlines processes, reduces contamination risks, and accelerates time-to-market. The integration of Single-Use Technology in the manufacturing process has led to scalable, customizable solutions that cater to both small-scale clinical trials and large-scale commercial production.

Single-Use Technology in Biopharma Manufacturing Training Course offers professionals in the pharmaceutical and biotechnology industries an in-depth understanding of the practical application, benefits, and challenges associated with SUT. Through this training, participants will gain expertise in process optimization, the latest advancements in single-use systems, and how to maintain product integrity and regulatory compliance. By mastering SUT, organizations can improve productivity, reduce operational costs, and enhance quality assurance, ultimately contributing to more efficient biopharma manufacturing processes.

Programme Curriculum

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Course Duration

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Course Objectives

1. Understand the fundamentals of Single-Use Technology in biopharma manufacturing and its significance.
2. Learn the advantages of SUT in improving flexibility and scalability in production systems.
3. Gain proficiency in SUT components such as disposable bioreactors, mixing systems, and filtration units.
4. Develop skills to optimize process design using single-use systems for upstream and downstream applications.
5. Analyze the regulatory guidelines and industry standards impacting single-use systems.
6. Explore cost-reduction strategies through the adoption of SUT and its economic impact.
7. Address contamination risks by understanding best practices in handling and using SUT.
8. Master the integration of single-use systems with existing manufacturing infrastructure.
9. Understand the role of SUT in biologics manufacturing for faster clinical and commercial production timelines.
10. Explore real-world case studies showcasing successful implementation of SUT in global biopharma operations.
11. Investigate innovations in single-use technology, including advances in materials and automation.
12. Build skills in troubleshooting and maintenance of SUT in biomanufacturing environments.
13. Examine sustainability practices in the usage of SUT for reducing waste and improving eco-efficiency.

Target Audience

1. Biopharma Manufacturing Engineers
2. Quality Assurance and Control Managers
3. Process Engineers in Biotech
4. Pharmaceutical R&D Scientists
5. Biotech Production Managers
6. Regulatory Compliance Professionals
7. Supply Chain and Logistics Experts
8. Industry Consultants and Trainers in Biomanufacturing

Course Modules

Module 1: Introduction to Single-Use Technology (SUT)

- Definition and History of SUT
- Benefits of Single-Use Systems in Biopharma
- Types of Single-Use Components
- Regulatory Overview
- Real-World Case Study: SUT Adoption in Clinical Manufacturing

Module 2: Key Components of SUT

- Disposable Bioreactors and Fermenters
- Single-Use Filtration Systems
- Mixing and Storage Systems
- Tubing and Bag Assemblies
- Case Study: Successful Integration of Disposable Bioreactors

Module 3: Process Design Optimization with SUT

- Process Flow with SUT Integration
- Designing for Flexibility and Scalability
- Enhancing Operational Efficiency
- Data-Driven Decision Making
- Case Study: Optimizing Bioreactor Design for Scale-Up

Module 4: Cost Analysis of SUT Adoption

- Capital and Operational Cost Comparison
- Cost Reduction in Manufacturing Processes
- ROI from Implementing SUT
- Handling Waste Reduction
- Case Study: Cost Savings in Commercial Biopharma Manufacturing

Module 5: Regulatory Landscape for SUT

- GMP and FDA Guidelines
- Regulatory Compliance in SUT Manufacturing
- Risk Management and Quality Control
- Certification and Standards
- Case Study: Navigating FDA Inspection for SUT Facilities

Module 6: Troubleshooting and Maintenance of SUT

- Common Issues with Single-Use Systems
- Preventive Maintenance Protocols
- Troublehooting Techniques
- Maintenance Best Practices
- Case Study: SUT System Failure and Recovery

Module 7: Single-Use Technology for Upstream Applications

- SUT in Cell Culture and Fermentation
- Enhancing Yield and Quality Control
- Integration with Other Technologies
- Material Considerations

- Case Study: Cell Culture Optimization with Disposable Bioreactors

Module 8: Single-Use Technology for Downstream Applications

- SUT in Filtration, Purification, and Chromatography
- Handling Protein Purification in Disposable Systems
- The Role of Single-Use Systems in Drug Purity
- Continuous vs. Batch Processing
- Case Study: Filtration System Efficiency in Vaccine Production

Module 9: SUT in Biologics and Vaccine Production

- Role of Single-Use Systems in Vaccine Manufacturing
- Scaling from Pilot to Commercial Production
- Managing Bioreactor Sizes
- Contamination Control Strategies
- Case Study: The Application of SUT in mRNA Vaccine Production

Module 10: Automation and Digital Integration in SUT

- Role of Automation in SUT Systems
- Data Collection and Real-Time Monitoring
- Enhancing Predictive Maintenance
- Industry 4.0 and the Future of Biopharma Manufacturing
- Case Study: Implementing Automation in Biotech Facilities

Module 11: Sustainability and Waste Management in SUT

- Environmental Impact of Single-Use Systems
- Reducing Plastic Waste in Biopharma
- Strategies for Recycling and Reuse
- Industry Trends in Sustainable Biomanufacturing
- Case Study: Reducing Carbon Footprint in Biopharma Manufacturing

Module 12: SUT Implementation Challenges

- Overcoming Resistance to Change
- Integration with Existing Infrastructure
- Training and Skill Development for Teams
- Managing Supply Chain Logistics
- Case Study: Transitioning to Single-Use Systems in an Established Facility

Module 13: Risk Management in SUT Adoption

- Identifying and Mitigating Risks in SUT Systems
- Managing Supply Chain and Vendor Risks
- Quality Assurance Protocols
- Contingency Planning
- Case Study: Risk Management in Global Biopharma Supply Chains

Module 14: Future Trends in Single-Use Technology

- Innovations in SUT Materials and Components

- AI and Machine Learning in Biopharma Manufacturing
- The Evolution of Hybrid Systems
- Trends in Personalized Medicine and SUT
- Case Study: The Future of SUT in Precision Medicine

Module 15: Final Project and Case Study Presentation

- Review and Synthesis of Learnings
- Presentation of Real-World Case Studies
- Group Discussion on Future Challenges and Opportunities
- Developing a SUT Strategy for a Hypothetical Biopharma Facility
- Course Conclusion and Certification

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
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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