Pharmaceutical Process Engineering 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

Pharmaceutical Process Engineering is a critical discipline that integrates engineering principles with pharmaceutical manufacturing to ensure safe, scalable, compliant, and cost-effective drug production. With increasing global demand for GMP-compliant manufacturing, continuous processing, process validation, and quality by design (QbD), professionals must be equipped with advanced technical and regulatory expertise. Pharmaceutical Process Engineering Training Course is designed to bridge the gap between theoretical engineering knowledge and real-world pharmaceutical production systems, enabling participants to master modern pharma manufacturing technologies, process optimization, and regulatory compliance frameworks.

The course delivers a comprehensive understanding of API manufacturing, formulation engineering, bioprocessing, process scale-up, validation protocols, and advanced automation systems used in pharmaceutical plants. It emphasizes hands-on learning, industry case applications, and data-driven decision-making aligned with Industry 4.0, smart manufacturing, PAT (Process Analytical Technology), and lean pharmaceutical operations. Participants will gain the ability to design, troubleshoot, and optimize pharmaceutical processes while ensuring adherence to global quality and safety standards.

Programme Curriculum

Pharmaceutical Process Engineering Training Course

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5 days

Course Objectives

1. Master Pharmaceutical Process Engineering principles and industrial applications
2. Understand GMP, cGMP, FDA, EMA regulatory compliance systems
3. Apply Quality by Design (QbD) in drug manufacturing processes
4. Learn API manufacturing and formulation development techniques
5. Implement Process Analytical Technology (PAT) in real-time monitoring
6. Optimize pharmaceutical plant design and layout engineering
7. Develop expertise in process scale-up and tech transfer strategies
8. Improve biopharmaceutical production and bioprocess engineering workflows
9. Strengthen validation protocols: IQ, OQ, PQ in pharma systems
10. Utilize Lean Manufacturing and Six Sigma in pharma production
11. Enhance process automation and Industry 4.0 integration
12. Control contamination, sterility assurance, and aseptic processing systems
13. Achieve cost optimization and operational excellence in pharma plants

Target Audience

1. Pharmaceutical Engineers
2. Chemical Engineers in Pharma Industry
3. QA/QC Professionals
4. Production and Manufacturing Managers
5. Biotechnology Professionals
6. Regulatory Affairs Specialists
7. Fresh Graduates in Pharmacy / Chemical Engineering
8. R&D Scientists and Process Development Experts

Course Modules

Module 1: Fundamentals of Pharmaceutical Process Engineering

- Basics of unit operations in pharma
- Drug development lifecycle overview
- Material and energy balance in pharma processes
- Pharmaceutical raw materials classification
- Introduction to GMP systems

- **Case Study:** Failure analysis in tablet production batch inconsistency

Module 2: API Manufacturing & Chemical Process Design

- Active Pharmaceutical Ingredient (API) synthesis
- Reactor design and optimization
- Catalysis and reaction engineering
- Solvent selection and recovery
- Process safety in API plants
- **Case Study:** Optimization of paracetamol API synthesis yield improvement

Module 3: Pharmaceutical Formulation Engineering

- Solid, liquid, and semi-solid formulations
- Tablet compression and capsule filling processes
- Excipient functionality and selection
- Stability and compatibility studies
- Controlled release formulation design
- **Case Study:** Extended-release tablet formulation failure investigation

Module 4: Bioprocess Engineering & Biopharmaceuticals

- Fermentation technology and bioreactors
- Cell culture systems
- Downstream processing techniques
- Protein purification methods
- Biosimilars production process
- **Case Study:** Monoclonal antibody production scale-up challenge

Module 5: Process Validation & Quality Assurance

- IQ, OQ, PQ validation lifecycle
- Cleaning validation strategies
- Process validation protocols
- Deviations and CAPA management
- GMP documentation systems
- **Case Study:** Regulatory audit failure due to incomplete validation records

Module 6: Process Scale-Up & Technology Transfer

- Lab to plant scale-up strategies
- Pilot plant operations
- Tech transfer documentation
- Risk assessment tools
- Process reproducibility control
- **Case Study:** Scale-up failure in antibiotic production batch transition

Module 7: Automation, PAT & Industry 4.0 in Pharma

- Process Analytical Technology (PAT) tools
- SCADA and DCS systems in pharma
- Real-time process monitoring

- AI and data analytics in manufacturing
- Smart factory integration
- **Case Study:** AI-based predictive failure prevention in tablet coating process

Module 8: Lean Manufacturing & Continuous Improvement

- Lean Six Sigma in pharmaceutical production
- Waste reduction strategies
- Process optimization tools
- Energy efficiency in pharma plants
- Continuous manufacturing systems
- **Case Study:** Cost reduction in sterile injectable manufacturing line

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
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:

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