Advanced Tablet and Capsule Manufacturing Technology 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 pharmaceutical industry is undergoing a profound transformation, moving beyond traditional batch processing toward fully integrated, data-driven systems. This shift is powered by Continuous Manufacturing (CM), Quality by Design (QbD), and the strategic adoption of Industry 4.0 technologies. Mastery of these advanced methodologies is no longer optional; it is a critical necessity for maintaining global regulatory compliance and achieving operational excellence. Advanced Tablet and Capsule Manufacturing Technology Training Course is engineered to bridge the current skills gap by immersing participants in the next generation of Solid Oral Dosage (OSD) form production. We provide the expertise needed for successful digital transformation of pharmaceutical manufacturing lines.

This program goes deep into the most modern concepts, from Real-Time Release Testing (RTRT) and Process Analytical Technology (PAT) to the implementation of AI-driven robotics and Digital Twin modeling. Our focus is on practical, risk-based decision-making and process robustness, ensuring graduates can immediately design, optimize, and troubleshoot complex production flows for tablets and capsules. By mastering advanced formulation science and modern equipment qualification, you will be equipped to drive cost reduction, significantly accelerate time-to-market, and guarantee product quality consistency in a highly competitive and regulated environment.

Programme Curriculum

Advanced Tablet and Capsule Manufacturing Technology Training Course

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Course Objectives

1. Design and implement end-to-end continuous solid oral dosage (OSD) manufacturing lines.
2. Develop Design Spaces and Control Strategies for robust, high-quality tablet and capsule products.
3. Integrate and utilize advanced PAT tools for Real-Time Release Testing
4. Apply mechanistic modeling and simulation to predict process behavior and optimize product performance.
5. Evaluate and implement innovative methods like Hot-Melt Extrusion (HME) and continuous fluid-bed granulation.
6. Establish stringent data governance protocols for fully automated manufacturing systems.
7. Master precision coating and complex multi-particulate systems.
8. Conduct advanced Process Validation and Process Performance Qualification (PPQ) for continuous systems.
9. Navigate global regulatory expectations for novel manufacturing technologies
10. Execute seamless and truly scalable technology transfer from R&D to commercial CM lines
11. Perform comprehensive Quality Risk Management (QRM) for critical process parameters (CPPs) and critical quality attributes (CQAs).
12. Explore the use of Additive Manufacturing for tailored solid dosage forms.
13. Optimize the manufacturing flow for maximum supply chain responsiveness and lean principles integration.

Target Audience

1. Production and Manufacturing Managers.
2. Process Development Scientists/Engineers.
3. Quality Assurance (QA) and Quality Control (QC) Personnel.
4. Regulatory Affairs Specialists
5. R&D Formulation Scientists.
6. Validation Engineers.

7. Automation and IT Specialists.
8. Senior Technical/Operations Leadership.

Course Modules

Module 1: The Paradigm Shift: Batch to Continuous

- Comparison of traditional batch vs. modern continuous manufacturing economics.
- Regulatory drivers for CM (FDA Emerging Technology Initiative).
- Advantages: reduced risk, lower inventory, smaller footprint.
- Disadvantages: initial investment, complex control strategy.
- Case Study: Janssen's move to continuous processing for PREZISTA tablets and the subsequent facility footprint reduction.

Module 2: Quality by Design (QbD) in OSD

- Defining the Target Product Profile and Critical Quality Attributes
- Principles of Risk-Based Product Development
- Developing and mapping the Design Space using DoE methodology.
- Establishing a robust Control Strategy for Continuous Processes.
- Case Study: Pfizer's application of QbD to identify and control CPPs in a high-shear granulation process.

Module 3: Process Analytical Technology (PAT) Implementation

- Fundamentals of spectroscopic techniques.
- Strategies for in-line, at-line, and off-line PAT deployment.
- Calibration, maintenance, and data interpretation of PAT sensors.
- Integrating PAT data for Real-Time Release Testing
- Case Study: Application of NIR in-line monitoring for blend uniformity in a continuous mixer

Module 4: Advanced Granulation Technologies

- Principles and operation of Continuous Twin-Screw Wet Granulation.
- Fluidized Hot-Melt Granulation and its application in solubility enhancement.
- Dry Granulation and Roller Compaction optimization strategies.
- Process scale-up and the "Scale-up without scale-up" concept in CM.
- Case Study: Using a GEA ConsiGma continuous line to transition a moisture-sensitive API from batch to high-volume CM.

Module 5: Powder Mechanics and Material Science

- In-depth understanding of API and Excipient critical material attributes
- Measurement and impact of powder flow, cohesion, and compressibility.
- Advanced techniques for particle size and shape characterization.
- Selecting co-processed functional excipients for direct compression.
- Case Study: Resolving tablet capping issues by optimizing the particle size distribution and lubrication parameters of a powder blend.

Module 6: Tablet Compression and Tooling

- Advanced tablet press design, including high-speed and multi-layer presses.
- Troubleshooting common tablet defects

- Advanced tooling selection and maintenance.
- Compression physics.
- Case Study: Implementation of monitoring technology on a tablet press to automatically adjust fill weight based on in-die compression force.

Module 7: Hard and Soft Capsule Manufacturing

- Formulation strategies for hard-shell capsules
- Fundamentals of softgel encapsulation
- Automated and AI-driven robotic capsule filling technologies.
- Addressing content uniformity challenges for low-dose APIs in capsules.
- Case Study: Reformulation of an API from capsule to tablet using a common excipient blend to maintain consistent dissolution profiles

Module 8: Functional Tablet Coating Technology

- Principles of film coating and polymer selection.
- Advanced coating techniques for modified release
- Troubleshooting common coating defects
- Continuous tablet coating processes and parameter control.
- Case Study: Designing an enteric-coated tablet using QbD to ensure perfect dissolution at a specific intestinal pH.

Module 9: Advanced Drug Delivery Systems

- Designing and manufacturing multi-layer tablets and tablet-in-tablet systems.
- Mini-tablets and multi-particulate systems for dose flexibility and pediatric use.
- Fundamentals of Hot-Melt Extrusion for amorphous solid dispersions.
- Introduction to 3D Printing for personalized dosing.
- Case Study: Use of HME to improve the bioavailability of a poorly soluble drug by creating an amorphous dispersion.

Module 10: Process Modeling and Digital Twin

- Introduction to mechanistic modeling in pharmaceutical engineering.
- Concept and creation of a Digital Twin for the OSD manufacturing line.
- Using models to predict CQA variation based on CPP changes.
- Model-Predictive Control and its application in dynamic process adjustment.
- Case Study: Simulating a continuous drying process using a Digital Twin to optimize residence time and prevent over-drying without physical trials.

Module 11: Data Integrity and GMP in Pharma 4.0

- Principles of ALCOA+ and regulatory expectations for Data Integrity.
- 21 CFR Part 11 and EU Annex 11 compliance in automated systems.
- Implementing a robust Quality Management System for continuous operations.
- Digitalization of batch records and audit trails
- Case Study: Investigating a data integrity breach scenario and establishing a corrective Data Governance plan.

Module 12: Validation and Qualification of CM Systems

- Risk-Based Qualification of continuous equipment
- Advanced Process Validation (PV) for CM.
- Establishing and monitoring the Validated State
- Regulatory requirements for software validation and computer systems.
- Case Study: Process Performance Qualification of a new continuous direct compression line, demonstrating sustained control.

Module 13: Facility Design and Cleanroom Technologies

- Designing modular and flexible facilities for Continuous Manufacturing.
- HVAC and critical utility requirements for OSD cleanrooms.
- Containment strategies for high-potency APIs in solid dosage forms.
- Energy efficiency, sustainability, and Green Chemistry practices in manufacturing.
- Case Study: Designing a CM mini-plant to replace a large-scale batch facility, focusing on reduced footprint and utility consumption.

Module 14: Troubleshooting and Root Cause Analysis (RCA)

- Systematic approaches to Root Cause Analysis.
- Developing and implementing effective Corrective and Preventive Actions
- Managing deviations, OOS results, and product complaints in a CM environment.
- Utilizing PAT and Big Data for proactive anomaly detection.
- Case Study: Performing an RCA on unexpected dissolution failure in a finished tablet batch, tracing the cause back to a raw material CMA shift.

Module 15: Regulatory and Strategic Outlook

- Interpreting the latest ICH guidelines on lifecycle management.
- Strategies for regulatory submissions of CM products
- The future of pharmaceutical manufacturing.
- Economic modeling for justifying CM investment and ROI.
- Case Study: Preparing a comprehensive regulatory submission for a product manufactured using a novel continuous wet granulation technique.

Training Methodology

The course employs a high-engagement, blended learning approach to ensure practical mastery:

- Interactive Lectures.
- Virtual Simulation Workshops.
- Case Study Analysis
- Group Problem-Solving.
- Technical Demonstrations.

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

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