# Continuous Biopharmaceutical Manufacturing Training Course

22 – 26 March 2027
San Diego

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Training Center

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**Ref:** 1433_205762 **Date:** 22 – 26 March 2027 **Location:** San Diego **Fees:** 16000 Euro

## Overview

Continuous Biopharmaceutical Manufacturing Training Course is a one-week advanced course for manufacturing managers, process engineers, production scientists, quality professionals, validation staff, and technology-transfer teams who leave with a Continuous Biomanufacturing Implementation Dossier. Participants connect ICH Q13 concepts with integrated processing, process dynamics, material traceability, Process Analytical Technology, control strategy, validation, and lifecycle decisions for therapeutic-protein operations. Agile Leaders Training Center presents continuous biopharmaceutical manufacturing through process evidence, control design, and implementation practice.

## Who Should Attend

- Manufacturing functions responsible for continuous production strategy, capacity, and operating performance
- Process engineering functions responsible for integrated unit operations, dynamics, and control design
- Production science functions responsible for perfusion, downstream processing, sampling, and process evidence
- Quality and validation functions responsible for state of control, risk assessment, verification, and deviation decisions
- Technology-transfer functions responsible for process knowledge, scale translation, and site implementation

The course assumes participants already work with bioprocess development or manufacturing data and leaves out introductory biotechnology, equipment operation qualification, and product-specific regulatory advice.

## Departments and Industries

The course supports departments and industries that develop, operate, assess, or transfer continuous biopharmaceutical processes.

- Biopharmaceutical and therapeutic-protein manufacturing operations
- Biotechnology process development and production science teams
- Quality assurance, validation, and technical operations departments
- Engineering, automation, and manufacturing data functions
- Contract development, manufacturing, and technology-transfer organizations

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## Learning Objectives

By the end of this course, participants will be able to:

- Apply ICH Q13 concepts to therapeutic-protein process architecture
- Analyze process dynamics and residence-time distribution evidence
- Build material traceability, sampling, and diversion strategies
- Use Process Analytical Technology in monitoring and control design
- Evaluate validation, deviation, and lifecycle management choices
- Prioritize a continuous biomanufacturing implementation roadmap

## Course Agenda

### Day 1: Continuous Biomanufacturing Architecture

- ICH Q13 Integrated Manufacturing Scope Map
- Continuous Process Mode Selection Matrix
- Therapeutic-Protein Process Flow Architecture
- Connected Unit Operation Interface Register
- Batch Definition and Run-Time Decision Guide

### Day 2: Process Dynamics and Material Traceability

- Residence-Time Distribution Model Canvas
- Process Disturbance Propagation Map
- Material Traceability and Genealogy Method
- Sampling Frequency Risk Assessment
- Material Diversion Strategy Decision Tree

### Day 3: Monitoring and Control Strategy

- Critical Quality Attribute Linkage Map
- Process Analytical Technology Measurement Plan
- Closed-Loop Bioreactor Control Logic
- Continuous Downstream Control Strategy
- State-of-Control Monitoring Dashboard

### Day 4: Validation and Lifecycle Governance

- Continuous Process Verification Framework
- Long-Run Microbial Control Risk Register
- Resin and Membrane Lifetime Evidence Plan
- Deviation Detection and Response Workflow
- Lifecycle Change and Knowledge Management Plan

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## Day 5: Continuous Manufacturing Implementation Practice

- Exercise: Map an Integrated Therapeutic-Protein Process
- Exercise: Interpret Residence-Time Distribution Evidence
- Exercise: Design a Monitoring and Diversion Strategy
- Exercise: Review a Continuous Process Verification Case
- Capstone Exercise: Continuous Biomanufacturing Implementation Dossier

## Practical Exercises

The course uses suggested activities from therapeutic-protein, contract manufacturing, and biotechnology production settings.

- Suggested activity: connect perfusion, capture, purification, monitoring, hold, and diversion points in an integrated process map.
- Suggested activity: use residence-time evidence to trace a disturbance and define sampling and diversion decisions.
- Suggested activity: compare control options for upstream variability, downstream capacity, and quality-attribute signals.
- Suggested activity: assemble an implementation dossier containing architecture, evidence, controls, validation, and lifecycle actions.

## FAQs

### Who suits continuous biopharmaceutical manufacturing training, and what does it assume?

Continuous biopharmaceutical manufacturing training suits experienced manufacturing, engineering, science, quality, validation, and transfer functions. It assumes working knowledge of bioprocess operations and manufacturing evidence rather than foundation biotechnology.

### How does continuous biopharmaceutical manufacturing training differ from bioreactor scale-up training?

Continuous biopharmaceutical manufacturing training addresses connected upstream and downstream operations, dynamics, traceability, monitoring, diversion, validation, and lifecycle governance. Bioreactor scale-up training concentrates on translating reactor performance and culture conditions across scales.

### What does ICH Q13 mean for continuous biopharmaceutical manufacturing?

ICH Q13 provides scientific and regulatory considerations for developing, implementing, operating, and managing continuous manufacturing systems, including applications to therapeutic proteins and directly connected unit operations.

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## Why is residence-time distribution important in continuous bioprocessing?

Residence-time distribution helps teams relate material movement to disturbances, sampling, traceability, diversion, and batch boundaries. The model and its assumptions require evidence appropriate to the process design.

## How is a state of control maintained in continuous biopharmaceutical manufacturing?

A state of control is maintained through defined process limits, suitable measurements, data review, control actions, material-diversion logic, deviation response, and lifecycle verification that together show consistent process performance.

## Conclusion

The course integrates ICH Q13, process architecture, dynamics, traceability, analytical technology, control strategy, validation, and lifecycle governance. Participants take back a Continuous Biomanufacturing Implementation Dossier. The dossier aligns technical evidence, monitoring, diversion, validation, and change actions for disciplined implementation decisions.