

# Early Downstream Bioprocess Development Training Course

25 – 29 October 2027
Istanbul

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## Overview

Early Downstream Bioprocess Development Training Course is a one-week intermediate course for downstream-development, purification, bioprocess, analytical, quality, and manufacturing-interface functions who leave with a Downstream Process Development Evidence Pack. Participants translate product and impurity attributes into a separation sequence, screen clarification, chromatography, membrane, and viral-clearance options, define scale-down studies, assess integration with upstream material, and prepare optimization and scale-up decisions. The course emphasizes evidence-led process selection rather than general biotechnology vocabulary. Agile Leaders Training Center presents early downstream bioprocess development.

## Who Should Attend

- Downstream-development functions responsible for purification routes and experimental plans
- Bioprocess-engineering functions responsible for unit-operation integration and scale translation
- Purification functions responsible for chromatography, filtration, recovery, and yield
- Analytical-development functions responsible for product, impurity, and process evidence
- Quality-development functions responsible for traceability, risk, and control rationale
- Manufacturing-interface functions responsible for technology transfer and scale-up readiness

The course assumes participants already work with biologic materials, laboratory studies, or bioprocess data, and it leaves out introductory molecular biology, routine production operation, equipment certification, and product-specific validation protocols.

## Departments and Industries

The course supports departments and industries that develop, transfer, or assure biologics purification processes.

- Biopharmaceutical, vaccine, recombinant-protein, and biosimilar development
- Process development, purification science, and bioprocess engineering
- Analytical development, formulation interfaces, and quality development
- Clinical and commercial manufacturing technology transfer
- Contract development and manufacturing organizations
- Life-science research, engineering services, and applied training laboratories

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## Learning Objectives

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

- Analyze product, impurity, and feedstream separation needs
- Build an early downstream process-development strategy
- Compare clarification, chromatography, and membrane options
- Apply scale-down, screening, and optimization study designs
- Evaluate viral-clearance, cleaning, and testing interfaces
- Prioritize integration, scale-up, and transfer-readiness actions

## Course Agenda

## Day 1: Define the Separation Challenge

- Target Product and Critical Impurity Profile
- Upstream Feedstream Variability and Handover Register
- Recovery, Purity, Yield, Throughput, and Quality Objectives
- Downstream Unit-Operation Sequence and Decision Map
- Development Risk, Assumption, and Evidence Register

## Day 2: Develop Harvest and Capture

- Cell Removal, Centrifugation, and Depth-Filtration Screen
- Flocculation, Precipitation, and Crystallization Decision Factors
- Primary Recovery Mass-Balance and Yield Calculation
- Capture Chromatography Mode and Resin-Screening Plan
- Feed Conditioning, Fouling, Capacity, and Cycle Assessment

## Day 3: Build Purification and Viral Control

- Ion-Exchange, Affinity, Hydrophobic, and Mixed-Mode Comparison
- Polishing Step Selectivity and Impurity-Clearance Matrix
- Ultrafiltration, Diafiltration, and Membrane-Selection Study
- Viral Inactivation and Viral-Filtration Interface Map
- Intermediate Hold, Pooling, Stability, and Compatibility Screen

## Day 4: Optimize and Prepare Scale-Up

- Scale-Down Model Purpose and Representativeness Criteria
- Factor Screening, Experimental Range, and Response Matrix
- Process Parameter, Performance, and Quality Relationship
- Cleaning, Reuse, Testing, and Lifecycle Considerations
- Scale-Up Basis, Equipment Fit, and Manufacturability Review

## Day 5: Integrate the Development Package

- Suggested Exercise: Define the Separation Strategy
- Suggested Exercise: Compare Capture and Polishing Options
- Suggested Exercise: Review Membrane and Viral-Control Interfaces
- Suggested Exercise: Build a Scale-Down and Optimization Plan
- Capstone Exercise: Complete the Downstream Process Development Evidence Pack

## Practical Exercises

The course uses suggested activities to turn product, impurity, unit-operation, and scale evidence into a coherent development route.

- Suggested activity: convert a feedstream description and quality target into a separation objective and unit-operation sequence.
- Suggested activity: compare clarification, capture, polishing, membrane, and viral-control options against yield, purity, capacity, and risk.
- Suggested activity: define scale-down acceptance criteria, experimental factors, responses, ranges, and evidence gaps.
- Suggested activity: assemble process rationale, mass balance, study results, risks, controls, scale-up basis, and transfer actions.

## FAQs

### Who suits early downstream bioprocess development training, and what does it assume?

Early downstream bioprocess development training suits downstream scientists, purification specialists, bioprocess engineers, analytical and quality developers, and manufacturing-interface teams. It assumes familiarity with biologic materials, laboratory studies, or bioprocess data.

### How does downstream process development differ from routine downstream manufacturing?

Process development selects and characterizes a purification route through experiments, models, and evidence. Routine manufacturing executes a defined process within approved instructions, controls, equipment, and operating ranges.

### How are chromatography modes selected for a biologic?

Selection considers product and impurity properties, binding mechanism, selectivity, capacity, recovery, buffer conditions, fouling, cleaning, cycle time, scalability, and how capture and polishing steps work together.

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## Why are scale-down models used in downstream development?

Scale-down models reproduce the important behavior of a larger operation with less material and time. They support screening, optimization, characterization, troubleshooting, and risk assessment when their representativeness is defined and verified.

## What belongs in a downstream process development evidence pack?

The pack contains product and impurity profiles, feedstream assumptions, separation rationale, unit-operation screens, mass balances, experimental plans and results, viral and cleaning interfaces, risks, scale-up basis, gaps, and transfer actions.

## Conclusion

Participants take back a Downstream Process Development Evidence Pack containing the separation basis, feedstream profile, recovery sequence, screening studies, chromatography and membrane choices, viral-control interfaces, scale-down models, optimization evidence, scale-up rationale, risks, and transfer actions. The pack connects laboratory decisions to a traceable purification strategy. It supports clearer development reviews and more disciplined preparation for manufacturing.