CONCEPT

# Bioprocess Engineering: Bioreactor Selection, Scale-Up and Downstream Purification

23 – 27 August 2027
Amsterdam - Zuidas business district hotel



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## Introduction:

Bioprocess engineering decisions on biologics lines are often made late: bioreactors are bought on vendor brochures, scale-up repeats the bench recipe until oxygen transfer fails, and harvest and purification trains are sized after titres change. The result is lost batches, idle suites and slow technology transfer. This Core Concept course gives engineers, MSAT, production and QA staff the upstream, bioreactor and downstream methods needed to select, scale and run a biomanufacturing process. Participants build a Bioreactor Selection and Scale-Up Plan for a product or process from their own site.

## Course Objectives:

- Map a biologic product from cell bank and seed train through production bioreactor, harvest, purification and fill, naming the critical process parameters at each stage
- Select a bioreactor design and operating mode, batch, fed-batch or perfusion, for a given cell line, titre target and campaign plan
- Compare single-use and stainless steel bioreactor trains on oxygen transfer, scale ceiling, cleaning and sterilisation effort, extractables and leachables and changeover time
- Calculate scale-up criteria such as kLa, power per unit volume, impeller tip speed and mixing time to move a process from pilot to production scale
- Specify harvest, chromatography and filtration steps and link them to upstream titre and impurity load
- Set up process analytical technology monitoring, contamination controls and a technology transfer package that sustain batch consistency after scale-up

## Target Audience:

- Bioprocess and process development engineers responsible for upstream and downstream process design
- Manufacturing science and technology staff responsible for scale-up, process transfer and campaign support
- Production supervisors and operators responsible for running cell culture suites and purification trains
- Quality assurance staff responsible for batch record review, deviation handling and contamination control in biologics areas
- Engineering and facility staff responsible for bioreactor, utility and single-use system installation
- Technical project staff responsible for new product introduction and contract manufacturing interfaces

## Course Outline:

### Day 1: Biologics and the Bioprocess Flow

- Biologic Product Families: Recombinant Proteins, Monoclonal Antibodies, Vaccines and Viral Vectors
- Bioprocess Flow Map From Working Cell Bank and Seed Train to Drug Substance
- Microbial Fermentation Versus Mammalian Cell Culture Process Requirements
- Critical Process Parameters and Critical Quality Attributes Linkage Table
- Current-State Assessment Checklist for a Biomanufacturing Line

### Day 2: Upstream Cell Culture, Media and Bioreactor Types

- Culture Medium Formulation, Chemically Defined Media and Feed Strategy Design
- Batch, Fed-Batch and Perfusion Operating Modes With Chemostat Principles
- Stirred Tank, Airlift, Bubble Column and Rocking-Motion Bioreactor Designs
- Bioreactor Control Loops: Temperature, pH, Dissolved Oxygen, Gas Flow, Agitation and Foam
- Single-Use Bag Bioreactors Versus Stainless Steel Vessels: Selection Matrix

### Day 3: Bioreactor Scale-Up and Downstream Purification

- Oxygen Transfer Coefficient kLa Estimation and Oxygen Uptake Rate Balance
- Power per Unit Volume, Impeller Tip Speed and Mixing Time as Scale-Up Criteria
- Harvest and Clarification: Centrifugation, Depth Filtration and Cell Disruption
- Chromatography Train Design: Capture, Intermediate Purification and Polishing Steps
- Tangential Flow Filtration, Viral Filtration and Sterile Filtration Sizing

### Day 4: Process Monitoring, Contamination Control and Advanced Formats

- Process Analytical Technology: In-Line Raman, Near Infrared and Biosensor Probes
- Multivariate Data Analysis and Design of Experiments for Bioprocess Data
- Good Manufacturing Practice, Aseptic Connections and Cleanroom Grade Basics at Overview
- Continuous Bioprocessing and Integrated Perfusion-to-Chromatography Lines at Overview
- Cell and Gene Therapy and Viral Vector Manufacturing Operations at Overview

### Day 5: Scale-Up Modelling Build and Technology Transfer

- Modelling Build: Pilot-to-Production kLa and Power per Volume Scale-Up Workbook
- Modelling Build: Single-Use Versus Stainless Steel Cost of Goods and Capacity Comparison
- Technology Transfer Package: Process Description, Parameter Ranges and Engineering Runs
- Case: Oxygen Limitation and Foaming at Production Scale Root Cause Review
- Bioreactor Selection and Scale-Up Plan Presentation and Peer Challenge

## Skills You Will Gain:

- Bioprocess Flow Mapping
- Bioreactor Operating Mode Selection
- Oxygen Transfer Calculation
- Scale-Up Criteria Analysis
- Purification Train Sizing
- Bioprocess Data Interpretation
- Contamination Risk Control
- Technology Transfer Planning

## Why Attend This Course:

- Return with a Bioreactor Selection and Scale-Up Plan built on a product or process from your own site
- Challenge vendor claims on single-use and stainless steel equipment with your own kLa, capacity and cost figures
- Anticipate oxygen, mixing and harvest problems before an engineering run rather than after a failed batch
- Compare bioprocess practice with peers from innovator, biosimilar, vaccine and contract manufacturing organisations

## Conclusion:

A biologics process only scales when cell culture, bioreactor physics and purification capacity are planned together. The week moves from the bioprocess flow and critical parameters, through media, feeding, operating modes and bioreactor designs, to kLa, power per volume and mixing-based scale-up and the harvest, chromatography and filtration train. It then covers process analytical technology, contamination control, continuous processing and viral vector operations, and closes with modelling builds, a technology transfer package and a Bioreactor Selection and Scale-Up Plan for each participant.