



# INTRODUCTION TO BIOPHARMACEUTICAL PROCESS ENGINEERING

## JEFFERSON INSTITUTE FOR BIOPROCESSING INDUSTRY BIOPROCESS TRAINING (IBioT) PROGRAM

August 19 - 21

Jefferson Institute for Bioprocessing, Spring House Innovation Park

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The nature of the work performed by bioprocess scientists and engineers changes throughout process development, its optimization, characterization, transfer to manufacturing, and validation as drug candidates move from pre-clinical to early-phase and then late-phase clinical and commercial launch. A phase-appropriate process development strategy is reiterative in nature, starting with a simple process that is defined and executed to provide preclinical and phase I clinical material. If—and only if—supported by good clinical data, the process progresses through increasingly complex development, optimization, and characterization stages with the intent to produce consistent and reproducible material for late-phase clinical use and launch. A well-defined, characterized, and validated process will maximize productivity while critically and simultaneously meeting pre-defined critical quality attributes ensuring safety, efficacy, purity, and identity of the drug for its intended use. These considerations make biomanufacturing one of the most challenging aspects in the commercialization of biopharmaceuticals and biologics.

This 3-day course will increase the skills and knowledge of anyone working directly or indirectly in biopharmaceutical and process development. Participants will gain insight into the practical challenges of working in a highly regulated industry, especially in the launching of a new biomolecule beyond candidate selection. The course will introduce the participants to standard (good) industry practice, through specific examples and case studies based on industry experience, focusing not only on success, but critically on failures.



## PARTICIPANTS WILL LEARN

- Processes for commercial launch, from cell line development to scale up of API and DP
- The role of process development: Platform vs. non-platform processes
- First generation to next generation bioprocesses
- Batch vs. continuous bioprocessing
- Process flow diagram and process flowsheet
- Upstream, downstream, buffer exchange and concentration, storage and transportation operations
- Risk-based approach and Quality-by-Design (Q-b-D) concepts
- Phase appropriate process design and development: Practical applications
- Regulatory impact on process design and development
- The role of bioanalytical methods throughout all stages of process development
- Integration of cell culture processes with downstream product recovery and purification
- Quality control and assurance
- Tech transfer and validation

## TARGET AUDIENCE

This introductory course is intended to benefit anyone working directly on technical aspects of process development from early phase to late phase and manufacturing operations. This course will also provide a sound basis for those working in other functional areas within biomanufacturing, including scientific, regulatory, quality, business, marketing, and other support functions, who seek a detailed overview of biomanufacturing operations.

## LOCATION

The course will be held at the state-of-the-art Jefferson (University) Institute for Bioprocessing, a 25,000 sq. ft. fully flexible cGMP-like facility approximately 20 miles northwest of Philadelphia with close access to the Philadelphia International Airport, highways, hotels, and restaurants.

## FEE

The course fee is \$3,000 per attendee, and includes all lab equipment and supplies, handouts and materials. Breakfast, lunch, snacks and one course dinner are also included. If requested, the Jefferson Institute for Bioprocessing team can assist in securing convenient accommodations.

## ACCOMMODATIONS

### **Residence Inn by Marriott Philadelphia Montgomeryville**

1110 Bethlehem Pike  
North Wales, PA 19454  
267-468-0111

### **Hampton Inn & Suites Philadelphia Montgomeryville**

121 Garden Golf Blvd.  
North Wales, PA 19454  
215-412-8255

### **Courtyard by Marriott Philadelphia Montgomeryville**

544 Dekalb Pike  
North Wales, PA 19454  
215-699-7247

### **Candlewood Suites Philadelphia- Willow Grove**

250 Business Center Dr.  
Horsham, PA 19044  
888-614-3125

For further information contact:

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