



PRIMARY RECOVERY AND TANGENTIAL FLOW FILTRATION (TFF) OPERATION

JEFFERSON INSTITUTE FOR BIOPROCESSING INDUSTRY BIOPROCESS TRAINING (IBioT) PROGRAM

Jefferson Institute for Bioprocessing, Spring House Innovation Park

For dates and to register, [CLICK HERE!](#)

PART 1: PRIMARY RECOVERY IN BIOPHARMACEUTICAL PROCESSING (1½ DAY)

Major process improvements in upstream operations have been achieved over the past decade leading to high-cell density, high-titer, cell cultures. The high cell density combined with low cell viability on day of harvest can increase levels of process impurities including host cell proteins, DNA, RNA, lipids, and cell debris. These impurities can cause issues in primary recovery and downstream purification. For example, cells with low viability are more sensitive to shear forces prevailing in industrial centrifuges. If this happens, the resulting fines and colloids generated from shear breakage of the cells may remain in the supernatant causing fouling of the depth filters as well as the 0.2 µm membrane (bioburden) filter.

This 1.5 day training addresses primary recovery in the downstream processing of biopharmaceuticals including proteins and monoclonal antibodies. Topics covered will address the challenges associated with primary recovery of high cell density and low cell viability.

COURSE CONTENT

- Centrifugation, Microfiltration, Depth filtration, and Membrane filtration
- Process integration–Primary recovery platform design
- Scale-down and scale-up approaches
- Impact of cell culture bioreactor operation
- Flocculation and cell culture conditioning as an aid to primary recovery
- Precipitation and filtration of host cell proteins and Mabs

PART 2: TANGENTIAL FLOW FILTRATION (TFF) IN BIOMANUFACTURING (1½ DAY)

Tangential Flow Filtration is a major operation in downstream purification of monoclonal antibodies and proteins. Often it is the last operation in the API process and is performed prior to storage. The growing demand for biologics, in combination with an increase in drug product dose concentrations exceeding 200mg/mL, has made high protein concentration TFF operation the holy grail of bioprocessing. The impact of protein concentration on TFF operation and product quality is one of the most important aspects of tangential flow filtration. For example: the potential of product aggregation and generation of sub-visible particles, caused by several hours of pumping and excessive shearing of the protein solution during the TFF device, can have profound effects on critical product attributes since no further purification of the TFF material is possible.

This 1.5 day session will address the theory and practice of tangential flow filtration (TFF) including current methods and techniques for technology selection and process operation.

COURSE CONTENT

- Tangential Flow Filtration, mode and mechanism of operation
- Primary and secondary concentrations
- Diafiltration
- Process design, technology selection and process optimization platform design
- Scale-down and scale-up approaches
- High viscosity TFF operation–Challenges and opportunities
- Formation and mitigation of sub-visible particles in TFF operation

COURSE LEARNING GOALS

In each session, participants will:

- Identify and define operating and critical process parameters for each unit operation
- Identify techniques and apply methods for scale-up and scale-down of each unit operation
- Develop process screening and designing DoE studies for each operation to select and optimize process conditions
- Apply process knowledge and understanding to meet product and process quality attributes

WHO SHOULD ATTEND?

These courses are designed for professional bioprocess scientists and engineers who

- Wish to upskill and expand their process knowledge and capabilities in primary recovery and TFF operations as part of new responsibilities in process research & development, manufacturing science and technology, and manufacturing operation
- Have little prior knowledge of primary recovery and TFF operations functional areas, but need to learn more about operations as part of their roles in, for example, regulatory, quality, and procurement.

WHAT MATERIAL IS INCLUDED IN THE COURSE?

- Jefferson Institute for Bioprocessing certificate of attendance
- Hard and e-copy of course materials
- Case studies and workshop material

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 and snacks 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:

Lyn Kugel

Director of Corporate Engagement, Jefferson Institute for Bioprocessing
hlynda.kugel@jefferson.edu