



LARGE SCALE FREEZING OF BIOPHARMACEUTICALS

JEFFERSON INSTITUTE FOR BIOPROCESSING INDUSTRY BIOPROCESS TRAINING (IBioT) PROGRAM

August 12 - 14, 2019

October 28 - 30, 2019

Jefferson Institute for Bioprocessing

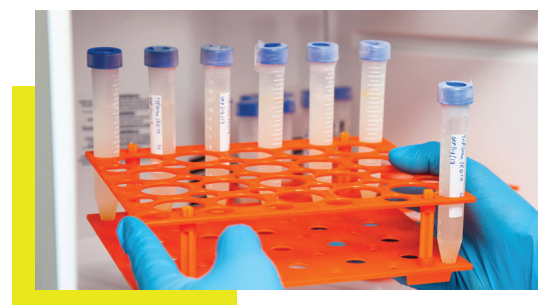
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One of the major supply chain challenges in biomanufacturing is the storage and transportation of large volumes of active (bio)pharmaceutical ingredients (Bio-API). While lyophilization may be used in early phase processes often freezing is the preferred option for late phase operation and commercial use. Freezing offers major advantages over other methods, and has widespread application despite proven difficulties in design and scale-up. Another often overlooked design challenge comes with the thawing of the frozen bulk Bio-API material prior to drug product formulation.

This 3-day course provides the scientific and engineering bases for the design and scale up of both passive and active freezing and thawing of bulk Bio-API materials in a biomanufacturing setting.

WHAT PARTICIPANTS WILL GAIN FROM ATTENDING THE COURSE

Participants attending the course will learn how to combine and use basic knowledge of heat transfer, scale-down, first principle modeling, DOE and QBD to design unit operations for freezing and thawing of bulk Bio-API in a biomanufacturing setting.



KEY LEARNING OUTCOMES

- Freezing of bulk Bio-API including proteins and monoclonal antibodies
- Cryo-concentration and its effect on product quality attributes
- Scale-down and scale-up models (10-20ml) for freezing on bulk bio-API
- Definition and characterization of commercial freezing as an scalable unit operation
- First-principle modeling of freeze-thaw operation
- Predicting freeze rate and freeze time in commercial scale operation
- Impact of time-temperature on stability of frozen Bio-API during storage
- Container-closure for freeze operation
- Monitoring freeze-thaw operation
- Impact of freeze operation and protein concentration on sub-visible particles
- DOE and QBD issues in Bio-API freeze-thaw operation

TARGET AUDIENCE

Scientists and engineers working in different functional areas in Bio-API and Drug Product (DP) including Bioprocess Design and Development (BD&D), Analytical and Biophysical Characterization, and Drug Product Formulation.

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

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