

Downstream Processing Course & Workshop

- OVERVIEW:** Downstream Process (DSP) applications of biopharmaceutical separations, clarification and purification represent key, higher value-adding manufacturing steps. Through technological innovations, bioprocessing experts anticipate significant improvements in the productivity and efficiency of utilizing these downstream processes.
- DESCRIPTION:** The Downstream Process program will provide an insight and overview into the fundamentals of DSP for the biopharma product separations and purification operations, e.g., crossflow (CFF/TFF) filtration through final filling. Emphasis on traditional downstream processes, separation, clarification and purifications will provide an understanding of operational optimization on the overall process. Attention is given to emerging technologies of membrane adsorber (MA) chromatography and virus clearance technologies and applications. Primary focus is on high purity protein production, applicable smaller molecular purification and scaling up / down are covered topics along with regulatory and industry requirements.
- RATIONALE:** Attendees will learn the latest developments in Downstream Processing products and applications. 'How-to' apply these technologies on their projects and process operations will provide practical application.
- TARGET AUDIENCE:** Process Development Engineers and Scientists, Research and Development Personnel, Pilot-Plant Operations, Protein Purification Staff.
- PREREQUISITES:** An understanding of process development, improvements, and scaling will enhance the attendees learning experience. The program is designed as a refresher course for the experienced and those new to bioprocesses.
- OBJECTIVES:** At the completion of this workshop the participant will be able to:
- Define principle parameters governing downstream processes
 - Be able to make informed decisions in process optimization.
 - Design small scale to large scale optimization trials.
 - Identify relevant applications for membrane chromatography application.
 - Understand virus clearance studies to meet requirements.
 - Consider DS Single-Use disposables technologies in bioprocesses.
 - Understand regulatory requirements and industry qualification standards.
- KEY TOPICS:** Main lecture topics and workshop program;
- DS Separation and Purification Processes with practical applications.
 - Product separation / clarification and purification processes.
 - Use of CFF and membranes for DNA, HCP, viral protein removal.
 - Methods for performing viral clearance studies.
- DURATION:** Two Days

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Materials and Equipment:

- Classroom Instruction Area
- Laboratory Area
- A/V Equipment:
 - Computer Projector
 - Easel and markers
 - Laser Pointers
- Bench Scale CCF / TFF Device
- Membrane Adsorber Q membranes
- Cytochrome C
- Assorted Lab Glassware, e.g., beakers, Test Tubes, etc.
- Personal Protection Equipment
- Flow through UV Spectrophotometer and chart recorder