



STACK FAMILY
CENTER FOR BIOPHARMACEUTICAL
EDUCATION AND TRAINING

Industry Training Series

Title: Separation and Purification of Biological Products: Downstream

Date: November 9 - 12, 2021

Location: Stack Family Center for Biopharmaceutical Education and Training
NanoFab East, 257 Fuller Road, Albany NY 12203

**Why Attend
This Course:**

According to a number of industry studies, biopharmaceutical manufacturers have great difficulty hiring professionals for downstream work. This downstream training program in separation and purification can strengthen the skills of current employees as well as offer a knowledge pathway to others who could join your team.

This four-day course covers all aspects of protein product separation and accompanying purification strategies during downstream processing of both microbial and mammalian biologics, using advanced techniques and the latest equipment. Theoretical knowledge from lectures will be applied in the hands-on laboratory sessions.

**What Will You
Learn:**

- Cell disruption
- Centrifugation
- Filtration
- Chromatography
- Functional activity assays
- Protein characterization by UHPLC
- Quality aspects of the final product

**Who Should
Attend:**

- Scientists and engineers currently in downstream ops who wish to enhance their knowledge
- Staff who are new to downstream operations
- Biomanufacturing supervisors and managers who need to better understand the challenges and opportunities of downstream processing
- Personnel such as QA/QC and validation professionals who support downstream may not be knowledgeable about execution of the processes they support
- Vendors who supply the industry with equipment and components

*For more information, contact: Diana Bartlett, Corporate Engagement Leader:
518-694-7746 or Diana.Bartlett@acphs.edu*



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Schedule

Day 1
Tues, Nov 9

- AM Lecture*
- Novel and Prospective Downstream Processing Technologies
 - Cell disruption for intracellular biologics
 - Ultra and conventional centrifugation
- PM Lab*
- Cell disruption, cell lysis, conventional and ultracentrifugation

Day 2
Wed, Nov 10

- AM Lecture*
- Micro, Ultra and Diafiltration
 - Hollowfiber Filtration
- PM Lab*
- Ultra and Diafiltration
 - TFF Minimate setup and operation,
 - AKTA® Flux platform setup and operation,
 - FLU® spectrophotometry

Day 3
Thurs, Nov 11

- AM Lecture*
- Fast Performance Liquid Chromatography (FPLC)
 - Monoclonal Antibody Purification Strategies
 - Column Packing
- PM Lab*
- Sample preparation for AKTA Pure FPLC platform and data analysis

Day 4
Fri, Nov 12

- AM Lecture*
- Utilization of UHPLC for protein characterization and identification
 - QA/QC Principles in Downstream Processing
 - Fill & Finish
 - Protein Structures and Functions as Biologics
- PM Lab*
- Prepare samples for UHPLC setup, injection and analysis
 - SDS-PAGE gel to quantify protein size (ChemiDoc)

Instructors

Ron Bates, Ph.D., Immunovant
Payel Datta, Ph.D., ACPHS-CBET
Oumou Diallo M.S., ACPHS-CBET
Ehsan Mahdinia, Ph.D., ACPHS Assistant Professor
Kamal Rashid Ph.D., ACPHS-CBET
Julian Rosenberg Ph.D., ACPHS-CBET

Cost

Per Person \$3,400

Register

[cbet.acphs.edu/industry-training/
register-for-industry-training/](http://cbet.acphs.edu/industry-training/register-for-industry-training/)



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Instructor Bios

Ron Bates, Ph.D., Immunovant

Dr. Ronald Bates is the Vice President of CMC Process Development and Manufacturing at Immunovant (IMVT). At IMVT, Ron leads the development and manufacturing of novel biological moieties targeting immunotherapies. Prior to IMVT, he led the Manufacturing Science and Technology (MST) group at Bristol-Myers Squibb (BMS) in Syracuse, NY and was responsible for monitoring, validating, transferring, and improving late-stage and commercial manufacturing processes. Before BMS, Ron led the process development and MST group at Allergan (now part of AbbVie) focusing on developing and manufacturing wild-type and recombinant prokaryotic-based systems as well as developing novel technologies including automated, high throughput methods and disposable manufacturing processes. Ron started his career at Pfizer purifying small molecule moieties using chiral, normal phase, and reversed phase chromatography in traditional, flash, and multi-column continuous systems. He received his Ph.D. from the University of Maryland, Baltimore County in Biochemical Engineering under Doug Frey studying mathematical modeling of ion exchange chromatography and his B.S. in Chemical Engineering from Rensselaer Polytechnic Institute. Ron is also active in the biopharma industry sitting on conference planning, conference scientific, and journal editorial boards in addition to chairing and presenting at international conferences and authoring research articles and patents.

Payel Datta, Ph.D., ACPHS-CBET

Dr. Payel Datta is the Senior Scientist at the Stack Family Center for Biopharmaceutical Education, and Training (CBET). Dr. Datta has rich experience in course curriculum design, and teaching biology courses to both non-majors and biology majors. In addition, Dr. Datta has over ten years of research experience. These academic-industrial collaborative research projects focused on biomanufacturing of value-added chemicals; specifically, responsibilities included, (1) lead upstream process development and tech-transfer of recombinant strains expressing enzymes, polysaccharides, proteins, and small molecules, and (2) identify, develop, optimize, and implement in vitro, and cell-based assays for preclinical safety and efficacy studies. These projects are academic-industrial partnerships and required working collaboratively with interdisciplinary group of scientists from academia and industry. These projects resulted in numerous technical documents, scientific documents, and a patent. The work has led to rich experience in authoring and editing (1) technical documents (which include SOPs, batch records, documents as part of pre-IND and NDA applications), and (2) over 25 scientific documents (which include review articles, book chapter, peer-reviewed publications, and conference abstracts and presentations). Dr. Datta is highly motivated towards harnessing her experience and knowledge in workforce development and in biomanufacturing of biopharmaceutically important products.

Oumou Diallo M.S., ACPHS-CBET

Oumou Diallo, M.S., Bioprocess Operations Manager, CBET. Ms. Diallo has robust industry experience in cell culture from her career at Cytiva (formerly GE Healthcare). She has specific expertise in mammalian cell culture, monoclonal antibody production, protein purification, as well as quality control. She is trained in cGMP operations, including analytical method development, cell culture media optimization and growth investigations, and authorship of SOPs. Ms. Diallo earned her Master of Science in Biological Engineering from Utah State University.



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Ehsan Mahdinia, Ph.D., ACPHS-CBET

Dr. Mahdinia joined Team CBET in July 2020 as a founding faculty to help establish lab capacity in designing, procurement, installation and commissioning lab space and instruments. As a result, he holds excellent prowess in training professionals and students coming to CBET with hands-on and in-depth trainings. Dr. Mahdinia is an expert in fermentation technologies and an accomplished teacher. Since joining CBET at ACPHS from Penn State University, he has taught microbial fermentation, downstream processing of biopharmaceuticals and pharmaceutical microbiology courses from the PSM syllabus, with excellent feedback from students and trainees. Dr. Mahdinia earned a B.S. in Chemical Engineering and an M.S. in Biotechnology at Sharif University of Technology, Tehran, Iran. He earned his doctorate in Agricultural and Biological Engineering with a focus on bioprocessing engineering at Penn State University. His dissertation work explored vitamin K production from bacteria using biofilm reactors. Dr. Mahdinia is an author of 13 peer-reviewed publications and three book chapters in the fields of fermentation technologies and food safety engineering.

Kamal Rashid Ph.D., ACPHS-CBET

Dr. Kamal A. Rashid has over forty years of academic experience in research, teaching and workforce development programs for the bio-based industries. During his career he has developed, directed, and implemented biotechnology/biomanufacturing training programs at Worcester Polytechnic Institute, Utah State University, Penn State University and internationally. Presently, he is the founding director of The Stack Family Center for Biopharmaceutical Education and Training (CBET) at Albany College of Pharmacy and Health Sciences. Dr. Rashid received his undergraduate degree from University of Baghdad, Iraq with distinction and Ph.D. from the Pennsylvania State University with superior ranking. His major areas of research and educational interests are in bioprocessing and genetic toxicology. He is an expert in animal cell culture technology with over twenty-five years of teaching graduate level courses at the institutions that he served as a faculty member. He has received numerous awards including the international professor of the year award at Utah State University and faculty service award at Penn State University.

Julian Rosenberg Ph.D., ACPHS-CBET

Dr. Julian Rosenberg is the Associate Director of the Stack Family Center for Biopharmaceutical Education and Training at Albany College of Pharmacy and Health Sciences. He has more than 10 years of diverse experience in start-up and industry settings, where he focused on alleviating bottlenecks at the interface of upstream and downstream processing. Dr. Rosenberg earned his Ph.D. in Chemical and Biomolecular Engineering from Johns Hopkins University, where he developed novel molecular genetic tools and scale-up strategies to leverage microalgae for sustainable bioprocessing. Dr. Rosenberg has authored more than 25 peer-reviewed publications, including three book chapters, and is listed as an inventor on four issued patents. His research interests span the continuum of industrial biotechnology with emphasis on recombinant protein biologics, biofuels, and large-scale sterilization.