STACK FAMILY
CENTER FOR BIOPHARMACEUTICAL EDUCATION AND TRAINING

Industry Training Series

Title: Mammalian Cell Culture: Upstream

Date: October 18 - 22, 2021

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

Why Attend This Course:

This five-day intensive, hands-on training course will offer a comprehensive overview of upstream processing of mammalian cell systems utilized by biopharmaceutical companies today. Through a combination of morning lectures and afternoon laboratory experiments, participants will gain real-world experience in culturing and subculturing techniques for both suspension and anchorage-dependent cells. Emphasis will be placed on process design including cell density and viability measurements, scale-up strategies, media optimization, quality control, error prevention for risk mitigation, and more.

What Will You Learn:

- Suspension and anchorage-dependent cell culture
- Scale-up strategies for mammalian cell systems
- Experience on multiple bioreactor platforms: stirred tank, hollow-fiber, perfusion, microcarrier, single-use systems
- Metabolite analyses and media optimization
- QbD and PAT, process Intensification, and QA/QC

Who Should Attend:

- Scientists and bioprocess engineers
- Biomanufacturing supervisors and managers
- QA/QC, validation, and GMP staff
- Pharmacists, health scientists, and recent graduates interested in developing a pathway to industry
- Vendors who supply the industry with equipment and components

Instructors

Judy Carmody, Ph.D., Founder and Principal Consultant, Carmody Quality Solutions, LLC
Payel Datta, Ph.D., ACPHS-CBET
Oumou Diallo M.S., ACPHS-CBET
Ehsan Mahdinia, Ph.D., ACPHS-CBET
Kenneth Murphy, Bioprocess Engineer, Eppendorf
Naveen Pathak, Ph.D., Director of Bio-Process Development, Takeda
Kamal Rashid Ph.D., ACPHS-CBET
Julian Rosenberg Ph.D., ACPHS-CBET
Eric Yaeger, Ph.D., ACPHS-CBET

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Schedule

Day 1 **Mon, Oct 18**	*AM Lecture*	• Overview of Mammalian Cell System • Expression Systems and Recombinant Protein Production • Bioreactor Design and Operation
	PM Lab	• Bioreactor Preparation, Setup, and Sterilization, Conditioning O/N
Day 2 **Tues, Oct 19**	*AM Lecture*	• Media Design and Optimization
	AM Lab	• Bioreactor conditioning, DO calibration, and growth parameters set-up
	PM Lecture	• Scale-Up of Animal Cells in Culture: An Overview
	PM Lab	• Bioreactor inoculation, sampling and analyses, monitoring and control
Day 3 **Wed, Oct 20**	*AM Lecture*	• Batch, Fed-Batch, Perfusion in stirred tank bioreactors, Anchorage vs. Suspension • Hollow-Fiber Cell Culture Technology for Anchorage-dependent Cells • Microcarrier Cell Culture Technology for Anchorage-dependent Cells
	PM Lab	• Adherent cell growth and expansion in T-flasks, Spinner flask • Demonstration of iCELLis bioreactor, WAVE bioreactor and XDR-10 bioreactor
Day 4 **Thurs, Oct 21**	*AM Lecture*	• Growth Kinetics • Metabolic Pathways and Metabolic Engineering • Cell-based Vaccine Manufacturing
	PM Lab	• Bioreactor follow-up and perfusion N-1 • CEDEX Bio Analyzer utilization for metabolites measurement including glucose uptake, lactate, IgG and ammonia production
Day 5 **Fri, Oct 22**	*AM Lecture*	• QbD and PAT in mammalian cell systems • Process Intensification • Quality Assurance and Quality Control
	PM Lab	• Final sample collection and data analysis • Bioreactor harvest • Troubleshooting techniques • Graphical presentation of daily data collections, general discussion and Q&A

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

Cost
Per Person $4,250

Register
cbet.acphs.edu/industry-training/register-for-industry-training/

Instructor Bios

Judy Carmody, Ph.D., Carmody Quality Solutions, LLC

Dr. Judy Carmody is the founder and Principal Consultant of Carmody Quality Solutions, LLC. Dr. Carmody has 25+ years of specific expertise driving vision in operations, Quality assurance, control, systems, validation, and analytical development. She has held Quality leadership positions at several pharma/biopharma companies and built Quality management systems for both start-up and Fortune 500 companies. She is the former founder and president of Avatar Pharmaceutical Services, an FDA-registered contract research organization and registered manufacturer which was acquired by Vertex Pharmaceuticals in 2010.

Prior to founding Avatar, Dr. Carmody spent 10 years in the (bio)pharmaceutical industry, developing methods for small molecules and oligonucleotides, managing QC, Analytical, and Validation groups.

Dr. Carmody holds a Bachelor of Science degree in Chemistry from Worcester State University, and a Master of Science degree and a Ph.D. in Analytical Chemistry from Clark University in Worcester, Massachusetts.

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.

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.

Kenneth Murphy, Bioprocess Engineer, Eppendorf
Mr. Kenneth Murphy has over 30 years of experience in industries involving Aerospace, Medical, Semiconductor and the Life Sciences, many of which involved material science, capital equipment, software control and process development. He is a patent holder for innovations relating to semiconductor process equipment. Mr. Murphy experience includes time in Japan working with some of the top semiconductor chip manufacturers in the world. Presently he is with Eppendorf North America leading the East Team as the Regional Account Manager with extensive experience in bioreactor set-up and operations. Mr. Murphy graduated from Drexel University with a Bachelor of Science degree in Mechanical Engineering. He played on Drexel's Rugby FC and several years on Blackthorne RFC, a Philadelphia Division II team.

Naveen Pathak, Ph.D., Director of Bio-Process Development, Takeda
Naveen Pathak is Director of Bio-Process Development at Takeda. Naveen currently leads a team that owns deployment of QbD and Process Validation. Prior to joining Takeda/Shire, Naveen has worked at leading biotech and pharmaceutical companies, including Genzyme, Amgen, DSM, and Novartis in Process Development and Manufacturing Science functions. Naveen is a seasoned biopharmaceutical industry professional with more than 25 years of experience in process development and technical services spanning non-clinical, clinical, and commercial manufacturing. He has a Master's degree in Chemical Engineering from the University of Oklahoma and a graduate certificate in Quality and Regulatory Affairs from Temple University. Naveen is also actively engaged in teaching QbD-related courses at graduate schools in US and is an Adjunct Faculty member at Keck Graduate Institute in Claremont, CA.

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.

Eric Yager, Ph.D., ACPHS

Dr. Eric Yager is an Associate Professor of Microbiology in the Department of Basic and Clinical Sciences at the Albany College of Pharmacy and Health Sciences. Additionally, as a faculty member of the College's Center for Biopharmaceutical Education and Training Dr. Yager is involved with student instruction, the development of workshops for workforce training, and helping to identify opportunities for partnerships and collaborations in industry and academia. Dr. Yager brings more than 15 years of experience in the areas of virology, immunology, antibody-based therapies, antivirals, and vaccines. His current research focuses on human diseases caused by enveloped RNA viruses including COVID-19, influenza, AIDS, and congenital Zika syndrome.

Dr. Yager earned his Doctoral degree in Biomedical Sciences from the University at Albany. He has authored more than 25 peer-reviewed publications, has given invited talks at several regional and national scientific conferences, and has been interviewed by several media outlets including CNN and NBC News. Dr. Yager is also enthusiastic about educating individuals on viruses and vaccines, as demonstrated by his continuing guest spot on talk radio to discuss the COVID-19 pandemic and his public webinars on vaccine confidence.