



## **Call for Papers**

**ACS National Meeting**

**March 20 - 24, 2022**

**San Diego, CA**

### **BIOT Program Chairs:**

Danielle Tullman-Ercek, Northwestern University (ercek@northwestern.edu)

Nooshafarin Sanaie, Poseida Therapeutics (nsanaie@poseida.com)

**Abstracts Accepted: August 9, 2021 - October 8, 2021**

Submit abstracts to the BIOT Division at

[ACS Spring 2022](#)

Inquiries should be directed to the symposium organizers or program chairs.

## ACS BIOT Program

Symposium: Upstream Processes	3
Session: Mammalian: Media and Metabolism	3
Session: Mammalian: Novel Modalities and Innovative Technologies	4
Session: Perfusion and Reactor Engineering for Upstream Processing	4
Session: Engineering Microbes and Microbial Communities	5
Session: Synthetic Biology and Genome Engineering	5
Session: Case Studies in Upstream Process Development and Manufacturing	6
Symposium: Downstream Processes	7
Session: Chromatographic Separations for mAbs	7
Session: Chromatographic Separations for Novel Antibody Structures and Drug Conjugates	8
Session: Chromatographic Separations using Novel Stationary Phases	8
Session: Non-Chromatography Based Separation of Biomolecules	9
Session: Membrane-Based Downstream Bioprocessing	10
Session: In Silico and Mechanistic Modeling of Downstream Bioseparations	11
Session: Downstream Processing of Non-Antibody Modalities	12
Session: Case Studies in Tech Transfer, Scaleup, and Integrated Process Design	13
Session: Bioanalytical and Process Analytical Technologies (PAT) for Downstream Processing and Lot Release	13
Symposium: Cell and Gene Therapy	14
Session: Development and Manufacturing of Cell Therapy Products	14
Session: Development and Manufacturing of Gene Therapy and Viral Vector Products	15
Session: Next Generation Modalities in Gene and Cell Therapy	15
Session: Characterization of Gene and Cell Therapy Materials and Regulatory Perspectives	16
Session: Process Development and Challenges for Cell-Based Products	17
Symposium: Biomedical Technologies	18
Session: Stem Cell Therapy and Regenerative Medicine	18
Session: New Technologies for the Delivery and Targeting of Therapeutics	18
Session: Imaging, Diagnostics, and Other Integrative Approaches to Study and Model Diseases	19
Session: New Technologies in Cell and Microbiome Engineering	19

## ACS Spring 2022 BIOT Program

Symposium: Biomolecular and Biophysical Processes	20
Session: Challenges in Developing Novel Modalities	20
Session: Protein Developability and Stability	21
Session: Emerging Biophysical and Analytical Characterization Technologies (BPAC)	21
Session: Protein Structure and Function	22
Session: Enzyme Engineering for Biocatalysis	22
Session: Protein Engineering for Therapeutic, Diagnostic, and Sensor Applications	23
Session: New Technologies in Protein Engineering	23
Symposium: Big Data Science Approaches, Knowledge Management, and Artificial Intelligence	24
Session: Machine Learning Approaches to Synthetic Biology	24
Session: Big Data, Modeling and Machine Learning in Discovery and the Development of Biopharmaceuticals	25
Session: High-Throughput Screening, Data Analysis, and Multi-Scale Modeling in Development and Manufacturing	25
Session: Systems Biology & Omics: Tools and Applications	26
Symposium: Integrated and Continuous Processing	27
Session: Implementation: It's Happening!	27
Session: Perfusion Technologies and Process Development	28
Session: Automation, Control and PAT	28
Session: Integrated and Continuous Downstream Processing	29
Symposium: Emerging Topics and Emerging Leaders of Biotechnology	30
Session: Emerging Leaders of Biochemical Technology	30
Session: COVID-19 Vaccine Development, Therapies, and Diagnostics	31
Session: The Impact of COVID-19 on Biotechnology: New Practices and Lessons Learned for Speeding Up Development and Scale-Up	32
Session: Biomanufacturing 4.0	33
Session: Artificial Cells and Cell-Free Systems	33
Session: Supporting Diversity in Biotechnology Training, Recruitment, and Retention	34
Session: Development of Personalized and Emerging Novel Therapies	34
Symposium: Rapid Fire and Traditional Poster Session	35
BIOT TANK	35
BIOT-ESBES BioDesign-A-Thon	35

## Symposium: Upstream Processes

Symposium organizers:

Tara Deans	Univ of Utah	tara.deans@utah.edu
Aditya Kunjapur	Univ of Delaware	kunjapur@udel.edu
Matt Rehmann	BMS	Matthew.Rehmann@bms.com

Research focused on chemistries used to synthesize products from cellular and enzymatic biotechnologies

### Session: Mammalian: Media and Metabolism

Session Chairs:

Jamey Young	Vanderbilt University	j.d.young@vanderbilt.edu
Jianfa Ou	BMS	Jianfa.Ou@bms.com
Jackie Gonzalez	Takeda	jackie.gonzalez@takeda.com

Session Description:

The growth of mammalian cells in chemically defined, nutrient-enhanced media is a cornerstone technology for basic and applied biomedical and biotechnology research. Medium formulation is profoundly intertwined with the cell's metabolism and its response to the physicochemical environment. Therefore, changes in this formulation have significant impacts on cell behaviors, such as cell growth, viability, and productivity. Approaches for manipulation and optimization of medium components have become increasingly specific and sophisticated in order to achieve the desired culture phenotypes, high intensity cell culture production, and/or certain product quality attributes. Such rational design will move engineering and discovery forward by supporting reproducible research across labs and by enabling more productive and better controlled cell culture systems. This session will focus on the interplay between media, growth conditions (e.g., pH, dissolved oxygen, and feeding strategies), cell physiology, process control, and process robustness. Papers relevant to these topics are highly encouraged, including but not limited to those focusing on cell culture medium optimization, medium preparation and storage, medium chemistry understanding, medium impact on cell function and metabolism, effects of media in controlled environments, metabolic modeling, and 'omics analyses of mammalian cells in varying culture conditions.

**Session: Mammalian: Novel Modalities and Innovative Technologies**

Session Chairs:

Katie Galloway	MIT	katiegal@mit.edu
Peter Russo	Merck	russoa@alum.rpi.edu

Session Description:

Mammalian cell culture has emerged as a dominant sector of biotechnology, wherein cells are harnessed for vaccine production, recombinant protein synthesis, and cell-based therapies. Over the last decade transformative technologies that enable the rational engineering and design of mammalian cells have accelerated the development of novel therapeutics and associated manufacturing processes. These technologies include omics methods that identify and quantify therapeutic targets, mechanistic modeling techniques for predicting phenotypes, genome editing approaches for implementing cell designs, high throughput screening at various stages of development and characterization, and advances in manufacturing processes, including the application of in-process analytics (PAT) and automation for process parameter optimization and control. Talks in this session will focus on new and emerging technologies to engineer mammalian cells and to improve upstream cell culture process efficiency and quality for biotechnological purposes. Topics of interest include, but may not be limited to: techniques, methods, or tools for identifying and engineering therapeutic targets, accelerating the development of therapeutic cells or recombinant protein-producing cell lines, new technologies that enable or employ cell culture as well as substantial modifications to existing approaches, automation of cell line screening, or upstream process parameter optimization, and controlling upstream processes using predictive modeling or in-process analytics.

**Session: Perfusion and Reactor Engineering for Upstream Processing**

Session Chairs:

Seongkyu Yoon	UMass Lowell	Seongkyu_Yoon@uml.edu
Sen Xu	ALX Oncology Inc.	sen@alxoncology.com

Session Description:

In the last decade, technical advances in both upstream and downstream have led to the advent of integrated continuous biomanufacturing. Continuous manufacturing is becoming an attractive choice for process intensification of relatively stable products such as monoclonal antibodies and vaccines, in addition to the labile products for which continuous manufacturing (e.g., perfusion) has historically been used. Modern technology promises reduced manufacturing footprint, capital investment, and operating costs and increases productivity, ensures product quality consistency and enables flexible facility output. This session will encompass advances in upstream perfusion and continuous processing, including advances in process development, process characterization, bioreactor engineering and cell retention devices, scale-up and scale-down model development, and cell line engineering/adaptation. Papers relevant to these topics are highly encouraged, including those focusing on process control and handling operational complexity, cell retention, media development and process economy.

### **Session: Engineering Microbes and Microbial Communities**

Session Chairs:

Ophelia Venturelli	U. Wisconsin	venturelli@wisc.edu
Bernardo Cervantes	Concerto Biosciences	bernardo@concertobio.com

Session Description:

Advances in synthetic biology have enabled the design and construction of cell factories for the cleaner production of chemicals and other biological products important to humans. Metabolic engineering aims to develop tools and strategies that can be used in the optimization of biochemical pathways and in the design and implementation of non-native pathways, leading to more efficient biocatalysts and access to novel products. For this session we welcome presentations on topics related to microbial metabolic engineering, including the design, construction and testing of whole-cell biocatalysts, the development of tools for metabolic modeling and profiling, and the incorporation of novel substrates and biochemical reactions within biological systems. Additionally, we encourage submission of talks that engineer microbial communities for production of molecules, for therapeutic applications, or for other biotechnology objectives.

### **Session: Synthetic Biology and Genome Engineering**

Session Chairs:

Jorge Marchand	U. Washington	jmarcha@uw.edu
Lex Rovner	64x Bio	lex.rovner@64xbio.com

Session Description:

Synthetic biology and genome engineering are emerging as the dominant driving forces in our global bioeconomy. Next generation techniques in sequencing/synthesis have been decreasing costs and accelerating the rate at which we can engineer biology. Talks within this session will highlight the rapid advances within the fields of synthetic biology and genome engineering with a particular focus on: *de novo* genome design, multiplex genome editing, genetic engineering in non-model organisms and industrial hosts, transcriptional reprogramming, design of complex biological circuits and logic, biosensors, synthetic biology tool development, engineering metabolism, and engineering of artificial pathways. Talks will also aim to address how the former advances are creating opportunities for therapeutics development, disease diagnostics, production of biomaterials and biofuels, environmental remediation, and transforming our chemical industry.

**Session: Case Studies in Upstream Process Development and Manufacturing**

Session chairs:

Phillip Smith

GSK

phillip.2.smith@gsk.com

Camil Diaz

Genentech

diaz.camil@gene.com

Session description:

This session will focus on case studies demonstrating recent advances in upstream process development and manufacturing. Invited topics include but are not limited to: Examples of troubleshooting and resolving unexpected challenges in upstream process development, technology transfer, and/or manufacturing; strategies to control charge variant and glycosylation profiles; development, qualification, and use of bioreactor scale-down models; the use of computational modeling and digital tools in upstream process development (e.g. computational fluid dynamics); applications of upstream process analytical technology for bioreactor control; strategies to decrease upstream cost of goods, and novel approaches to bioreactor harvest to ensure cell or product purity. Case studies that incorporate multiple of these examples are of special interest.

## Symposium: Downstream Processes

Symposium organizers:

Elizabeth Goodrich	Millipore Sigma	elizabeth.goodrich@milliporesigma.com
Stefano Menegatti	North Carolina State Univ	smenega@ncsu.edu
Marcel Ottens	Delft Univ of Technology	m.ottens@tudelft.nl

Research focused on the separation of biological molecules and control of the purification processes

### Session: Chromatographic Separations for mAbs

Session chairs:

Christian Frech	Hochschule Mannheim	c.frech@hs-mannheim.de
Jing Guo	Bristol Myers Squibb	jing.guo@bms.com

Session description:

This session hosts contributions focusing on practical and theoretical approaches that advance and optimize antibody purification platforms. Topics include broadening platform applicability across the full range of *(i)* novel process technologies and modes of chromatographic operation designed to monitor and control antibody-related variants (e.g., charge, glycosylation, etc.); *(ii)* mechanistic and molecular-level characterization of antibody-related product variants (e.g., aggregates, clipped forms and fragments, etc.); *(iii)* clearance of impurities (e.g., difficult-to-remove HCPs, viruses and endotoxins, etc.); *(iv)* continuous vs. batch modes of purification for process intensification; *(v)* scale-down and high-throughput methodologies to evaluate platform fit for antibody candidates, and *(vi)* scale-up/process implementation to enable rapid and robust process transfer to manufacturing facilities.

**Session: Chromatographic Separations for Novel Antibody Structures and Drug Conjugates**

Session chairs:

Scott Husson  
Naveenkumar Singh

Clemson University  
Ambrx, Inc.

shusson@clemson.edu  
nksmalhan@gmail.com

Session description:

This session calls for papers focused on the downstream processing of novel antibody structures which may include, but are not limited to, bispecific antibodies, antibody drug conjugates (ADC), single-chain variable fragments (scFv), antigen binding fragments (Fab), novel antibody structures, or other protein conjugates. The scope may range from theory/modeling, early stage screening, early/late stage development, process scale-up, and/or large-scale manufacturing. The following topics are particularly encouraged and may include HTPD, process optimization, troubleshooting, and/or case studies focused on antibody derivatives or other protein conjugates: 1. Investigations for new drug modalities and novel chromatographic ligands (e.g., affinity, HIC, multimodal), 2. Optimization of conjugation chemistry/unit operations, 3. Purification of conjugation products addressing challenges in removing undesired conjugation byproducts and/or difficult-to-remove impurities, and 4. Creative approaches to handling unstable products.

**Session: Chromatographic Separations using Novel Stationary Phases**

Session chairs:

Thomas Elich  
Yamin Fan

MilliporeSigma  
Biogen

thomas.elich@milliporesigma.com  
yamin.fan@biogen.com

Session description:

Novel stationary phase matrices or ligand chemistries provide new possibilities and flexibilities for purification of biological products. This session calls for papers focused on new and enhanced downstream processing using novel or disruptive chromatographic technologies. Topics may cover advances in novel stationary phase ligands or matrices, including resins, membrane absorbers, fibers, or monoliths. Process streams involving monoclonal antibodies and monoclonal antibody derivatives, recombinant proteins, protein conjugates, plasma, viruses, and nucleic acids are considered. The scope may span from research and process development at the bench scale to larger scales including pilot and commercial scale manufacturing. Topics may include the establishment of novel materials and formats in high-throughput screening, process development, process optimization, troubleshooting, scale-up, mechanistic modeling, etc. Case studies in large scale clinical or commercial manufacturing leading up to regulatory filings are strongly encouraged.

**Session: Non-Chromatography Based Separation of Biomolecules**

Session chairs:

Melissa Holstein  
Ashley Slocum

Bristol Myers Squibb  
Pfizer, Inc.

holstm2@gmail.com  
ashley.slocum@pfizer.com

Session description:

Protein purification methods based on mechanical separations like centrifugation, hydro cyclones and elutriation along with depth filtration, multi-phase partitioning, precipitation, flocculation, and crystallization are widely used in biopharmaceutical industry. These techniques enable, enhance and complement many key and novel separations required for purification of biomolecules and are being actively studied and improved in order to meet evolving needs of industry and a higher demand for performance. This includes effective harvesting of higher density cell cultures; enhanced impurity clearance; enhanced performance of chromatography, sterile and virus filtration steps; in stand-alone, integrated, or continuous/semi-continuous manner. These technologies also play a pivotal role in identifying novel ways of using conventional unit operations to solve both current and future bioprocessing challenges of complex biological products. This session seeks to report advances in the development, fundamental understanding, and industrial application of non-chromatographic, non-membrane-based unit operations to achieve desired bio separations, as well as cases demonstrating the advantages/disadvantages of integrated processes thereof. Operations of interest may include; traditional unit operations, centrifugation, flocculation, depth filtration or less traditional unit operations, hydro cyclones, elutriation, acoustic separation, aqueous multi-phase partitioning, precipitation, crystallization and polymer-aided flocculation. In addition, we would like to welcome both experimental and modeling submissions. Priority will be given to those that provide insights and present approaches of general utility, and for whom experimental and/or manufacturing implementations are presented and compared with alternative approaches.

**Session: Membrane-Based Downstream Bioprocessing**

Session chairs:

David LaTulippe	McMaster University	latulippe@mcmaster.ca
Christine Pham	Tanvex Biopharma	christine.pham@tanvex.com
Abhiram Arunkumar	Voyager Therapeutics	Arunkumar@uwalumni.com
Alpana Naresh	anaresh@harpoontx.com	Harpoon Therapeutics

Session description:

Membrane-based separation techniques are essential for processing of a wide range of biopharmaceutical products including small molecules, monoclonal antibodies, vaccines, viral vectors, etc. These techniques are utilized in a wide range of applications in bioprocessing from cell harvest/clarification to virus removal, and product purification, concentration, and buffer exchange. Membrane-based techniques enable and complement many key and novel separations required for purification of biomolecules and are being actively studied and improved in order to meet a higher demand for performance, such as effective harvesting of higher density cell cultures, high-throughput virus filters, high-concentration formulation development, and/or integration of unit operations for continuous/semi-continuous manufacturing. These technologies also play a key role in identifying novel ways of using conventional unit operations to solve both current and future bioprocessing challenges of complex biological products such as use of new/modified membrane material and novel modes of operation. This session seeks to focus on process understanding surrounding membrane operations and to report advances in the development, fundamental understanding, industrial application, and novel implementations of membrane-based unit operations to achieve desired bioseparations. Operations of interest include traditional and novel filtration and membrane processes for clarification, bioburden reduction, virus removal, ultrafiltration and diafiltration, formulation, etc. Both experimental and modeling (mechanistic, statistical, hybrid, etc.) submissions are welcome to this session. Priority will be given to those presentations that provide insights and present approaches of general utility, and for which experimental and/or manufacturing implementations are presented and compared with alternative approaches.

**Session: In Silico and Mechanistic Modeling of Downstream Bioseparations**

Session chairs:

Dan Bracewell	University College London	d.bracewell@ucl.ac.uk
John Welsh	Merck & Co.	john.welsh2@merck.com
Nicholas Vecchiarello	MIT	vecchn@mit.edu
Rushd Khalaf	Moderna	rkhaf@modernatx.com

Session description:

Mechanistic models capable of describing bioseparations have long been available but have not yet managed to break into mainstream biopharmaceutical development. This is rapidly changing as the digital revolution is sweeping through the biopharmaceutical industry, resulting in new, computational workflows that can be readily integrated with modeling to achieve smart and disruptive downstream process development. The session invites speakers from all fields to share their advances and case studies in modeling of bioseparations. In particular, we invite speakers to share their advances in emerging modeling applications for all modalities (mAbs, therapeutic proteins and peptides, viral vectors, nucleotides, etc.), non-chromatography steps (filtration, viral clearance, etc.), and multi-step modeling. We also encourage submission of research involving hybrid modeling approaches such as machine learning and mechanistic modeling synergies, models that leverage protein sequence/structure, models that utilize developability/manufacturability data, and molecular modeling approaches (fundamental studies, predictive models, or hybrid molecular/mechanistic models). Finally, we invite research that addresses key practical considerations for mechanistic models in bioseparations including minimizing mechanistic modeling hurdles (resources, time, complexity, or analytical burden), assessing and improving model accuracy, transferring models as part of tech transfer and scale-up, or using models for regulatory filings or lifecycle management.

**Session: Downstream Processing of Non-Antibody Modalities**

Session chairs:

Pouria Motevalian	Pfizer, Inc.	<a href="mailto:pouria.motevalian@pfizer.com">pouria.motevalian@pfizer.com</a>
Oscar Bernal-Zuniga	MilliporeSigma	<a href="mailto:oscar.bernal-zuniga@milliporesigma.com">oscar.bernal-zuniga@milliporesigma.com</a>
Minni Aswath	Boehringer Ingelheim	<a href="mailto:minni.aswath@boehringer-ingelheim.com">minni.aswath@boehringer-ingelheim.com</a>
Alejandro Becerra-Arteaga	Thermo Fisher	<a href="mailto:alejandro.becerra@thermofisher.com">alejandro.becerra@thermofisher.com</a>

Session description:

Although monoclonal antibodies account for 70% of all the revenues generated by the biopharmaceutical industry they only make up slightly more than a third of approved therapeutics by number. Recent advances in first-in-class non-antibody therapeutic biologics have highlighted the benefits and unique challenges associated with the development and manufacturing of these novel therapeutic molecules. Potential applications include controlling global pandemics, addressing previously untreatable conditions and providing hope for rare genetic disorders. They also present exciting challenges since most have no templated downstream platform and in-process control/characterization methods are not very well established. Further, new non-antibody/protein modalities such as nucleic acids, virus-like particles (VLPs), conjugate vaccines, and novel delivery platforms are gaining interest while additional engineered and conventional peptide, proteins, and carbohydrates are also being developed. The diversity in the structures and physiochemical properties of these molecules is driving innovation in primary recovery, capture and polishing approaches, with processes that include membrane filtration, precipitation, chromatography, phase extraction, differential centrifugation, and affinity technologies. These innovations will be discussed in this session, along with potential platforms for process development based on quality-by-design principles (QbD) and associated in-process control methods and strategies for fast analytics. We encourage submitting papers on conventional/high throughput process development, scale up/down, process control/optimization, and quality attribute characterization to further establish new approaches for downstream processing of novel non-antibody therapeutic products.

**Session: Case Studies in Tech Transfer, Scaleup, and Integrated Process Design**

Session chairs:

Matt Brown	Boehringer Ingelheim	brownmox@gmail.com
Gisela Ferreira	AstraZeneca	gisela.ferreira@astrazeneca.com

Session description:

In the field of next generation manufacturing and interconnected bioprocessing, more companies are willing to adopt novel approaches. Due to many factors, each company finds themselves at a different stage of generating a viable system whether they are beginning to design an integrated process, understanding the technical issues that come with scale up/scale down, or advanced enough to undertake facility fit and tech transfer challenges. Assuring successful implementation in a facility can require new approaches to gain additional insight into scaling, simulation, and/or modeling. These may include fundamental/engineering models used to anticipate large scale performance, as well as development of appropriate small-scale models used for process characterization and/or troubleshooting. We seek abstracts that cover this broad range of development milestones which starts with companies seeking to take initial steps into interconnected bioprocessing with case studies focusing on pilot scale proof of concept systems. For more maturely developed systems, we seek scale-up and scale-down and tech transfer topics, particularly for cases where challenges related to scaling and single or multi-facility fit were observed, and novel solutions or technologies were required, with a special interest in those who have received feedback from health authority review.

**Session: Bioanalytical and Process Analytical Technologies (PAT) for Downstream Processing and Lot Release**

Session chairs:

Richard Willson	University of Houston	willson@uh.edu
Ujwal Patil	AstraZeneca	ujwal47@gmail.com

Session Description:

This session will focus on analytical technologies that enable real-time control, faster analysis, or improved process understanding for downstream processing and lot release. The development and implementation of in-line and/or at-line process analytics may include optical sensors such as Raman, fluorescence or infrared spectroscopy, particle imaging, variable pathlength technologies, cell and virus analysis tools, and biosensors, among others. Case studies showing how these tools can enable meeting in-process limits, with the goal of meeting a set of final critical quality attribute (CQA) limits, or how they provide a more in-depth understanding of the process are encouraged. Any implementation challenges and their impact on the overall control strategy may be presented. Topics also may include the implementation of integrated control strategies that leverage enhanced product understanding for manufacturing process optimization, process characterization, or regulatory submissions. Additionally, leveraging PAT for the understanding of downstream process capabilities and their impact on CQAs is of interest.

## Symposium: Cell and Gene Therapy

### Area Coordinators:

Joshua Leonard	Northwestern University	j-leonard@northwestern.edu
Bruno Marques	Century Therapeutics	bmarques@centurytx.com

Progress in development, upstream and downstream processing of cell and gene therapies

### Session: Development and Manufacturing of Cell Therapy Products

#### Session chairs:

In Hong Yang	UNC-Charlotte	InHong.Yang@uncc.edu
Tingting Cui	AstraZeneca	tingting.cui1@astrazeneca.com
Jamie Crawford	Iovance Biotherapeutics	jamie.crawford@iovance.com

#### Session Description:

Cell and gene therapies have demonstrated their efficacy to treat or be curative in severe diseases, chronic diseases, and cancers. The development and manufacturing of these cell therapy products remains a key part of the overall drug product development lifecycle. Multiple avenues have been explored in the cellular therapy space to increase the potency but also simplify the process of generating cell therapy products, for example, chimeric antigen receptor (CAR) T-cell therapy, T cell receptor (TCR) based therapies, and other gene-edited cells such as engineered natural killers (NKs), CRISPR-assisted CAR T cells. A multiple of new cellular drug products will be approved in the next five to ten years. Oftentimes the clinical process initiated for first in human proof-of-concept studies is not the same process as the later approved for commercial and beyond. A key problem to solve for future development of cell therapies is how to incorporate improvements during development and life cycle management (LCM), whether drug product is the same or a personalized product. In this session, the organizers would like to explore strategies to improve the manufacturing process that could lead to higher efficacy and/or patient access.

**Session: Development and Manufacturing of Gene Therapy and Viral Vector Products**

Session chairs:

Kimberly-Anne Mattia  
Matthew Luther

GlaxoSmithKline  
Scholar Rock

kimberly-anne.m.mattia@gsk.com  
mluther@scholarrock.com

Session Description:

Gene therapies continue to gain significant interest and increasing momentum in the pharmaceutical industry as viable and effective treatments for a wide array of diseases. With recent and upcoming commercial launches, numerous ongoing clinical trials, growing involvement from larger biopharmaceutical companies, increasing industrial collaborations with academia, and formation of new start-ups, the field of gene therapy promises to be a major player and potential game-changer for 21st century medicine. While demonstrating great promise, these therapies are still relatively new to the biopharmaceutical manufacturing industry and require further study to reach the depth of understanding typically associated with established biologic therapeutics. In that spirit, this session calls for abstracts focused on the development and production of Gene Therapies and Viral Vectors, in their various forms, from both academia and industry. The session organizers wish to include abstracts covering numerous aspects of this field for the session, such as advances in upstream production (plasmids, viral vectors, cell banks), advances in downstream purification process, drug product science, cGMP manufacturing and scale-up strategies, and in-process control and monitoring strategies.

**Session: Next Generation Modalities in Gene and Cell Therapy**

Session chairs:

Lawrence Stern  
Chris McMahon

U. South Florida  
Fujifilm Cellular  
Dynamics

SternL@usf.edu  
christopher.mcmahon@fujifilm.com

Session Description:

Cell and gene therapies represent a truly breakthrough modality for the treatment of human disease. This still nascent field is showing groundbreaking responses for patient therapy against a spectrum of previously intractable diseases with multiple commercialized therapies now available. Yet, we are only starting to explore the potential of these new therapeutic approaches, with many new technologies and advancements rapidly progressing towards the clinic. The Next Generation Modalities in Gene and Cell therapy session will focus on new technologies and strategies for therapeutic applications. Talks in this session will encompass cell and gene therapy and gene editing applications of ex vivo and in vivo technologies for the treatment of human disease, from both academia and the biopharmaceutical industry.

**Session: Characterization of Gene and Cell Therapy Materials and Regulatory Perspectives**

Session chairs:

Amanda Mack  
Boris Engels

Dark Horse Consulting  
Novartis

amack@darkhorseconsultinggroup.com  
boris.engels@novartis.com

Session Description:

Therapies that involve the isolation of cells from patients (autologous) or donors (allogeneic) that are genetically modified, expanded in culture, and re-introduced into patients to target malignant tumor cells have been the subject of significant attention and investment. These engineered cell products have demonstrated unprecedented clinical response rates and durability in severe hematological diseases. Examples of such drug products that have gone to market include gene modified T-cells (CART) and hematopoietic progenitor cells (CD34+) (e.g., Kymriah, Yescarta, Tecartus, Zynteglo, Strimvelis). This early success has catalyzed exponential investment and growth in the field including the development of affinity modified T-cell receptors that target solid tumors and intracellular antigens, improved gene-editing methodologies for allogeneic adaptive T-cells, and AAV-based gene therapies, to name a few. Not surprisingly, the generation of these disruptive cell therapies has unveiled a range of interesting challenges and innovations along the product development pipeline.

This session aims to provide a platform to present these cell therapies, critical development challenges, and regulatory considerations along the various stages of product development to both inform and empower the community. This includes a well-represented list of speakers to address topics spanning product characterization, establishment of in-process testing, lot release criteria and specifications, comparability studies, process validation, and clinical safety and efficacy.

## Session: Process Development and Challenges for Cell-Based Products

### Session Chairs:

Kassi Stein  
Bill Kelly

Vertex Cell & Genetic Therapies  
Villanova University

Kassi\_Stein@vrtx.com  
william.j.kelly@villanova.edu

### Session Description:

Cell and gene therapies have demonstrated their efficacy to treat or be curative in severe diseases, chronic diseases, and cancers. Multiple avenues have been explored in the cellular therapy space to increase the potency as well as simplify the process of generating cell therapy products like CAR-T, TCR-based therapies, and other gene-edited cells. This session will encompass various aspects of cell therapy process development where the cells, gene-modified cells, gene-edited cells, or cell-derived vectors which encode the gene of interest are the products. This would include advances in the isolation, culture, gene transfer and modification, process scale-up, culture medium design, testing, and characterization of cell-based therapy products. Papers relevant to these topics are highly encouraged, including those focusing on novel process improvements, control and optimization strategies, equipment design, and reagents design and characterization. The following topics in the autologous and allogeneic cell therapy manufacturing space may be discussed:

- New technologies and improvements of the manufacturing process impacting cell metabolism and/or cell differentiation
- Understanding, harnessing, and directing cellular heterogeneity, for example:
  - What is the impact of the heterogeneity in starting material on drug product potency?
  - How do clinical pre-treatments affect the starting material for the cell therapy product?
- Healthy donor & iPSC approaches to allogeneic cell therapeutics
- Gene editing technologies and transgene novel modifications
- Improved or novel viral vector production systems
- Novel drug product, cryopreservation, and delivery strategies for *in vivo* use
- New technologies or process improvements related to the isolation of viral vectors, cell(s) of interest, etc.

## Symposium: Biomedical Technologies

### Area Coordinators:

Mark Mimee	Univ of Chicago	mmimee@uchicago.edu
Shannon Servoss	Univ of Arkansas	sservoss@uark.edu
Rahul Sheth	BioMarin Pharmaceutical	rsheth@bmrn.com

Research focused on chemistries used in studying, diagnosing, and treating disease

### Session: Stem Cell Therapy and Regenerative Medicine

#### Session chairs:

Huanhuan Joyce Chen	Univ of Chicago	joycechen@uchicago.edu
Jorge Almodovar	Univ of Arkansas	jalomodo@uark.edu

#### Session description:

Advances in regenerative medicine are paving the way for developing more effective therapies for a wide range of diseases. The potential for repairing and regenerating multiple organs and cell types continues to drive novel solutions to improve human health. Talks in this session will focus on, but are not limited to, current developments in i) iPS and CAR T cell therapy, ii) tissue engineering, iii) cancer immunotherapy, and iv) biomaterial-based regenerative strategies.

### Session: New Technologies for the Delivery and Targeting of Therapeutics

#### Session chairs:

Xianghong Qian	Univ of Arkansas	xqian@uark.edu
Aaron Noyes	Codiak Biosciences	aaron.noyes@codiakbio.com

#### Session Description:

New technologies for delivering therapeutic constructs to specific cell types and tissues are necessary to unlock the potential of precision medicines and expand the therapeutic index of existing interventions. This session will focus on targeted delivery strategies currently being developed in both academia and industry for modalities including viral vectors, nanoparticles, proteins, nucleic acids, and small molecules. Other relevant topics for this session include enhancing endo-lysosomal escape/intracellular delivery, extending circulating half-life, design of novel delivery vehicles, discovery and optimization of targeting ligands, and strategies for controlling cargo release kinetics.

**Session: Imaging, Diagnostics, and Other Integrative Approaches to Study and Model Diseases**

Session chairs:

Catherine Fromen

Univ of Delaware

cfromen@udel.edu

Karthik Nayani

Univ of Arkansas

knayani@uark.edu

Session Description:

A comprehensive understanding of diseases coupled with their effective diagnosis and treatment is inherently linked to the technologies available to doctors, clinicians, and researchers. With the advent of personalized medicine, many times bioanalytical and biochemical approaches to study and treat diseases are limited by the available technology. This has led to new approaches to perform (i) high-throughput single cell analysis, (ii) point-of-care detection of biomolecules, viruses, and cells, (iii) large scale analysis and processing of massive data sets, and (iv) low volume detection of disease biomarkers. Researchers have harnessed a range of tools and approaches including nanoparticles, microfluidics, tissue engineering, peptides, proteins, DNA, RNA, 3D printing, microscopy, and spectroscopy to name a few. This has led to selective and sensitive biosensors with low limits of detection and high signal-to-noise ratios that can be incorporated into high-throughput or field ready approaches to rapidly analyze biological samples. Recent years have also produced novel *in vitro* models that better recapitulate the *in vivo* environment to increase the fundamental understanding of disease progression. This has led to new approaches in cell culture co-culture and 3D culture that incorporate more realistic biomaterials to better represent tissue.

**Session: New Technologies in Cell and Microbiome Engineering**

Session chairs:

Lauren Popov

Novome Biotechnologies

lpopov@novomebio.com

Tom Mansell

Iowa State Univ

mansell@iastate.edu

Session Description:

This session will focus on emerging technologies in engineering host or microbial cells and their interactions in the context of a natural or synthetic microbial community. Talks are welcome on a broad range of topics including, but not limited to, host cell engineering to improve protein production, genetic stability, post-translational modification including glycosylation, engineered probiotics, genetic circuit design, signal transduction, cell-cell communication, host-microbe interaction, synthetic consortia, and evolution of such systems. Of particular interest are efforts in studying and designing microbiomes to achieve biotechnological or biomedical goals.

## Symposium: Biomolecular and Biophysical Processes

### Area Coordinators:

Maryam Raeeszadeh-Sarmazdeh	Univ of Nevada Reno	maryamr@unr.edu
Laura Segatori	Rice Univ	segatori@rice.edu
Jennifer Tullman	Quantum-Si	jtullman@quantum-si.com

Research focused on the chemical and physical properties of biomolecules and their use in biotechnology

### Session: Challenges in Developing Novel Modalities

#### Session chairs:

Kate Galloway	MIT
Xiaoqing Gao	Stanford Univ
Isaac Hilton	Rice Univ

#### Session description:

Powerful, new modalities for therapeutics have emerged from advances in biotechnology, increased understanding of biological systems, and new production techniques including antibody drug conjugates (ADC), bispecifics, gene therapies, fusion proteins, CAR-T cell therapies, oligonucleotides, nanobodies, and vaccines. The simultaneous discovery of new biological targets for unmet needs and the rise of public health emergencies including the COVID-19 pandemic highlights the need to rapidly develop these powerful new modalities into approved therapeutics. This session will focus on the development and regulatory challenges of manufacturing novel therapeutic products and accelerated timeline challenges encountered in rapid development of therapeutics including COVID-19 therapeutics. Broad overviews discussing all of the challenges associated with developing a particular modality, or more detailed talks discussing specific challenges encountered during analytical characterization, upstream and downstream processes development, formulation development, validation of new modality processes and regulatory submission of viral, non-viral gene therapy, cell therapy, nanoparticles, fusion proteins, oligonucleotides and antibody drug conjugates, CAR-T cells and vaccines would be appropriate for this session.

**Session: Protein Developability and Stability**

Session Chairs:

Ben Hackel	Univ of Minnesota	hackel@umn.edu
Lawrence Stern	Univ of South Florida	SternL@usf.edu

Session description:

The need for efficacious biotherapeutics under rapidly accelerated timelines has never been more clearly evident. Confident, rapid selection of candidates to progress into development is vital to increasing our speed to the lab, clinic, and industrial processing. This session will focus on recent advances across academia and industry in computational and experimental approaches for 1) predicting and assessing therapeutic protein developability and 2) studying mechanisms of physical and chemical degradation, colloidal stability, and non-specific interactions.

**Session: Emerging Biophysical and Analytical Characterization Technologies (BPAC)**

Session chairs:

Luke Arbogast	NIST	luke.arbogast@nist.gov
Vince Price	Janssen	jprice35@its.jnj.com

Session description:

Biologics are rapidly expanding their already predominant role in the modern pharmaceutical market. Protein drugs (e.g. mAbs) exhibit inherent structural complexity, and emerging modalities (gene therapy, mRNA vaccines, etc.) consist of manifold combinations of various biomolecules. A critical task of biological drug development is to characterize the structural stability and integrity, including myriad post-translational modifications, of the drug substance(s), from upstream production through downstream purification, manufacture and product lifecycle and to assess these characteristics' potential as critical quality attributes (CQAs). For example, the highly flexible structure and dynamic nature of biomolecules significantly enhance the propensity of protein oligomerization, aggregation and fibrilization, while molecular interactions between the drug substance, its physical and/or chemical environment, and formulation excipients can lead to stabilizing or destabilizing events. These challenges grow as process intensification increases in an effort to increase plant efficiency and reduce cost-of-goods. Therefore, in-depth characterization of structural behaviors in all stages of drug development and manufacture is required. Innovative measurements must evolve to allow comprehensive product quality assessment and continually improve product stability amenable to global distribution. This session includes emerging, state-of-the-art high-resolution biophysical and analytical methods to characterize biopharmaceuticals including peptides, proteins, oligonucleotides, monoclonal and multispecific antibodies, viral and non-viral gene and cell therapies, and vaccines.

**Session: Protein Structure and Function**

Session chairs:

Carl Denard  
Daniel Woldring

Univ of Florida  
Michigan State Univ

cdenard@ufl.edu  
woldring@msu.edu

Session description:

Elucidating protein structure: function relationships is crucial to understand how proteins work and how to control and engineer their properties. The foundational understanding of protein structure and function is the main driver behind the expansive biotechnological applications of proteins, including the development of safe and efficacious protein-based biologics. This session seeks presentations focused on scientific approaches (wet lab and computational) to understand and decipher the fundamental principles connecting the primary and higher-order structures of proteins, post-translational modifications, and protein-protein interactions to their function and behavior in vitro and in vivo.

**Session: Enzyme Engineering for Biocatalysis**

Session chairs:

Keith Tyo  
Jerome Fox

Northwestern Univ  
Univ of Colorado Boulder

k-tyo@northwestern.edu  
jerome.fox@colorado.edu

Session description:

Enzymes enable the synthesis of structurally complex molecules under ambient—or otherwise mild—conditions; they offer a sustainable means of building a striking variety of chemicals. Recent years have witnessed the expansion of biocatalytic processes across the pharmaceutical industry and fine chemical sector. Advances in enzyme engineering have enabled the assembly of sophisticated biocatalytic cascades and accelerated the design and optimization of enzymes with novel functions and stabilities (e.g., activity at high temperatures or in mixed solvents). This session invites abstracts focused on enzyme engineering, broadly defined. Topics include advances in process development; the design, discovery, and evolution of enzymes and biocatalytic systems; and high throughput screens, structure-function analyses, and modeling. Papers relevant to biocatalytic cascades, green chemistry, environmental and waste management, biocatalysis under non-natural conditions (e.g., organic solvents), or that highlight applications in the pharmaceutical, food, textile, detergent, and paper industries are particularly encouraged. Unlisted topics relevant to enzyme engineering and biocatalysis are also welcome.

**Session: Protein Engineering for Therapeutic, Diagnostic, and Sensor Applications**

Session chairs:

Jamie Spangler  
Iman Farasat

Johns Hopkins Univ  
Janssen

jamie.spangler@jhu.edu  
iman.farasat@gmail.com

Session description:

Our ability to leverage and engineer desirable properties in proteins has ushered in a novel era for developing targeted disease interventions and designing sensitive and selective biosensors. This section focuses on newly-developed protein-based therapeutics, diagnostics, and sensors. Protein therapeutics may include studies about molecular engineering of antibodies for improved targeting and immunomodulation. Moreover, studies about engineered therapeutic proteins based on non-antibody scaffolds, as well as enzyme therapeutics, are encouraged. Protein-based diagnostics and sensors may include but are not limited to: genetically-encoded fluorescent and bioluminescent sensors, split and activatable proteins, small molecule- and light-responsive transcription factors, and engineered CRISPR-Cas proteins for improved molecular targeting and engineered specificity.

**Session: New Technologies in Protein Engineering**

Session chairs:

Allie Obermeyer  
Nikhil Nair

Columbia Univ  
Tufts Univ

aco2134@columbia.edu  
nikhil.nair@tufts.edu

Session description:

As protein engineering becomes more widely adopted for the development of therapeutics or sustainable materials, among other applications, new technologies are needed to enable the efficient and rapid engineering of proteins. This session will focus on advances in protein engineering technologies that are currently being developed in academia and industry. Relevant topics include, but are not limited to, new platforms for accelerating protein engineering, innovations in library generation, new screening approaches and high throughput technologies, and advances in computational strategies for protein design. Abstracts that discuss new tools for introducing non-standard amino acids or post-translational modifications and new approaches for engineering protein stability, functionality, and manufacturability are also encouraged.

## **Symposium: Big Data Science Approaches, Knowledge Management, and Artificial Intelligence**

Area Coordinators:

Hector Garcia-Martin	Lawrence Berkeley Natl Lab	hgmartin@lbl.gov
David Roush	Merck	david_roush@merck.com
Kevin Solomon	Univ of Delaware	kvs@udel.edu

Sessions on how to use big data sets to understand multiunit processes and properties of molecules

### **Session: Machine Learning Approaches to Synthetic Biology**

Zhimei Du	Merck	duzhim@merck.com
Yinjie Tang	WUSTL	yinjie.tang@wustl.edu

Session description:

Synthetic biology projects in cell line development, process development, systems biology technologies, and analytical development are producing an unprecedented wealth of data at various molecular and cellular levels, scales, culture media and process conditions. To make full use of the vast amount of data, we need data processing, data mining and machine learning approaches to effectively convert the data into applicable knowledge to improve development efficiency and quality. Novel data driven approaches will decipher the genome to phenotype relationship, guide rational strain design, and optimize the industrial bioprocess settings. In this conference session, we are accepting papers on following fields:

1. Assay and tool development for data collection, preparation, evaluation from DNA to cellular phenotypes
2. Development of user-friendly data management system
3. Machine learning algorithms and applications for omics analyses
4. Data driven computational pipelines and algorithms to predict and optimize bioprocesses and fermentation outcomes
5. AI assisted computational strain design for the development of synthetic biology strains
6. Knowledge mining and feature engineering algorithms and applications for developing structured synthetic biology databases
7. Integrative AI and mechanistic based modelling approaches for synthetic biology and bioprocess applications.

**Session: Big Data, Modeling and Machine Learning in Discovery and the Development of Biopharmaceuticals**

Camille Bilodeau

MIT

cbilod@mit.edu

Chris Williams

Roche

chris.williams.cw3@roche.com

Session description:

While computational methods for estimating the developability of biotherapeutics (i.e., manufacturability, safety, efficacy, and pharmacology) have existed for a number of years, the predictive power of these approaches has been limited. In the past few years, a new wave of discoveries in the field of deep learning have enabled longstanding challenges to be addressed, recently including the problem of protein folding. This has set the stage for the development of novel and disruptive technologies for protein engineering and design. The implication being safer, more efficacious therapeutics being discovered and developed with greater efficiency.

This session invites speakers from a variety of fields to share their advances in ML/AI methods for the engineering and design of biopharmaceuticals. We welcome insights to improvements in products and processes that have been realized through ML/AI methods. In particular, we invite speakers to share advances in protein representation/descriptor development, including structure-based and sequence-based approaches. Given that many of the relevant, publicly available databases are often too small to directly apply commonly used deep learning techniques, we invite the submission of research related to the generation and/or curation of large-scale protein property datasets. Similarly, we encourage the submission of research that explores machine learning solutions to this challenge including: machine learning methods that integrate heuristic approaches (e.g., developability indices), methods that leverage heterogeneous datasets through transfer learning techniques, or methods that combine machine learning techniques with mechanistic/physics-based modeling approaches. Finally, we invite submissions that demonstrate practical utility from applying these methods in an industrial setting.

**Session: High-Throughput Screening, Data Analysis, and Multi-Scale Modeling in Development and Manufacturing**

Benjamin Huffman

Pfizer

Benjamin.Huffman@pfizer.com

TBD

Session description:

Continued implementation of breakthrough automation solutions enable laboratory experiments that are more efficient and comprehensive. These efforts have revealed challenges in capturing and analyzing increasingly large and rich data sets for model development. This session will focus on solutions for generating, aggregating, and analyzing these large data sets across both upstream and downstream development as well as manufacturing. Additionally, verification or confirmation of models across multiple scales (e.g. empirical or mechanistic) should be considered.

**Session: Systems Biology & Omics: Tools and Applications**

Nich Sandoval

Tulane

nsandova@tulane.edu

Carrie Eckert

ORNL

eckertca@ornl.gov

Session description:

Living systems are complex and dynamic requiring understanding of both individual components and their interactions. Systems biology addresses this challenge with large scale data and/or mechanism-driven modeling to generate testable hypotheses. Systems of interest range from molecules and single cells to multicellular organisms and microbial consortia. This session will cover recent progress in the development and use of integrated methodologies incorporating datasets at multiple levels (both experimentally and computationally) to elucidate or exploit the internal mechanisms of biological systems. Areas of interest include the development and application of -omic analyses, biological network models, metabolic flux analysis, metabolic pathway simulations, and protein and/or genome engineering based on systems-level understanding. Overall, this session will highlight recent discoveries and opportunities provided by these tools to drive biological systems to new levels of performance.

## Symposium: Integrated and Continuous Processing

### Area Coordinators:

Abraham Lenhoff	Univ of Delaware	lenhoff@udel.edu
Jennifer Pollard	Merck	jennifer_pollard@merck.com
David Wood	Ohio State Univ	Wood750@osu.edu

The latest on continuous bioprocessing

### Session: Implementation: It's Happening!

#### Session chairs:

Julie Robinson	Merck	Robinjr41@gmail.com
Todd Przybycien	RPI	przybt3@rpi.edu
Kevin Brower	Sanofi	Kevin.brower@Sanofi.com

#### Session description:

The promise of integrated and continuous biomanufacturing is now becoming a reality. Thanks to advancements in technology and committed investment from management, the first integrated and continuous biomanufacturing facilities are online or nearing completion. Focus has shifted to characterizing at-scale processes, developing robust control strategies, and engaging regulatory agencies to address challenges and leverage opportunities related to this novel technology area. We invite presentations detailing implementation of integrated and continuous processes including strategies applied for validation, achievements in translating the technology into new or existing manufacturing facilities, management of safety related to adventitious agents, development or adaptation of process development methodologies, and business case analysis supporting investment and implementation. Talks can focus on the integration of two or more continuous operations or full end-to-end continuous platforms.

**Session: Perfusion Technologies and Process Development**

Session chairs:

Susan Sharfstein	SUNY Polytechnic Inst	sharfss@sunypoly.edu
Henry Lin	Sanofi	Henry.Lin@Sanofi.com
Avril Vermunt	Adverum Biotechnologies	avermunt@adverum.com

Session description:

Recent advances in perfusion processes have enabled novel approaches to manufacture a plethora of biologics. Along with the increased prevalence of GMP implementation, the Quality-by-Design concept for perfusion processes has matured significantly over the past several years. This session mainly focuses on case studies of scale-up/scale-down, innovative process characterization, cutting-edge PPQ strategies, and scientific and technological improvements successfully implemented in manufacturing. Topics such as process economics, cell line stability, operational complexity, and batch to continuous conversion are encouraged. In addition, this session will also capture advances in the areas of cell line development, media development, and novel cell retention devices for integrated and continuous processes. Applications of the aforementioned aspects to new modalities are also of high interest.

**Session: Automation, Control and PAT**

Session chairs:

Richard Braatz	MIT	braatz@mit.edu
Nuno Pinto	Merck	nuno.pinto@merck.com
Matt Brown	Codiak	brownmox@gmail.com

Session description:

Integrated and continuous manufacturing of biologics means connecting things, services, and people into a manufacturing system that facilitates rapid decisions, flexible production, and robust operations. Vital to this vision are PAT tools, measurement, automation, and on-line controls that autonomously connect the processing units and machines, with feedback of online measurements for disturbance rejection and online analytics for near real-time release. This session focuses on process analytical technologies and online process control strategies for integrated and continuous manufacturing including the development and implementation challenges of these systems. We are looking for a mixture of talks focusing on the development of enabling technologies and case studies or advances in analytics, automation, and control.

**Session: Integrated and Continuous Downstream Processing**

Session chairs:

Andrew Zydney	Pennsylvania State Univ	Alz3@psu.edu
Laura Crowell	Sunflower Therapeutics	laura@sunflowertx.com

Session description:

Batch processing, dominated by column chromatography and membrane systems, has been the cornerstone of downstream processing (DSP) in the biopharmaceutical industry. Interest in the development of end-to-end integrated and continuous DSP has increased significantly in recent years, driven by advances in perfusion cell culture and the potential for significant improvements in process economics and product quality. Due to a lack of widely accepted integrated and continuous downstream unit operations that can easily replace batch chromatography and membranes, there are exciting opportunities to develop new continuous technologies, as well as strategies to integrate multiple downstream unit operations so that they work together seamlessly. This session invites industrial and academic talks describing continuous, semi-continuous, or integrated downstream unit operations or processes, process development and characterization for integrated and continuous processes, and strategies for transitioning from batch to continuous processing during development or post-launch. Talks that provide tools for deciding which integrated and continuous unit operations are best for a given circumstance are highly encouraged.

## **Symposium: Emerging Topics and Emerging Leaders of Biotechnology**

Area Coordinators:

Varnika Roy	GlaxoSmithKline	Varnika.x.roy@gsk.com
Hadley Sikes	MIT	sikes@mit.edu
Peter Tessier	Univ of Michigan	ptessier@med.umich.edu

Progress in pandemic response in all areas of vaccines, therapies and diagnostics

### **Session: Emerging Leaders of Biochemical Technology**

Session Chairs:

Todd Przybycien	Rensselaer Polytechnic Inst	przybt3@rpi.edu
Nitya Jacob	Amgen	njacob@amgen.com

Session Description:

This session will highlight the work of the next generation of research leaders in BIOT. Speakers will be drawn from across the spectrum of subdisciplines comprising BIOT, their work serving to define the future directions of these subdisciplines and of BIOT. Speakers will also be asked to relate the metadata driving their scientific and technical success to help guide the BIOT community in terms of model routes to individual and team research leadership and of thoughts and ideas for programs and activities that encourage individual and team research leadership. While the intent is to draw broadly from all dimensions of the BIOT community, we anticipate that speakers in this session will typically be about 40 years young or younger at the time of the meeting.

**Session: COVID-19 Vaccine Development, Therapies, and Diagnostics**

**Session Chairs:**

Phil Smith	GSK	phillip.2.smith@gsk.com
Timothy Whitehead	Univ of Colorado Boulder	timothy.whitehead@colorado.edu

**Session Description:**

The global COVID-19 pandemic demonstrated the importance of rapidly developing safe and effective vaccines, diagnostics, and biotherapeutics. Vaccines, diagnostics, and biotherapeutics are critical to fighting viral spread, while biotherapeutics help minimize hospitalization time and loss of life. This session will highlight the development of innovations in each of these COVID-related applications. The topics solicited include but are not limited to case studies showcasing use of disruptive approaches as well as platform technologies for vaccine and antibody development, virus and antibody detection methods, solutions for accelerated process development for biotherapeutics, and strategies for speeding up the regulatory process to get the technologies to patients both quickly and safely.

**Session: The Impact of COVID-19 on Biotechnology: New Practices and Lessons Learned for Speeding Up Development and Scale-Up**

Session Chairs:

Michaela Wendeler	AstraZeneca	michaela.wendeler@astrazeneca.com
Brandon DeKosky	MIT, The Ragon Inst	dekosky@mit.edu

Session Description:

The urgent need for COVID-19 therapeutics challenged the traditional ways of drug development and prompted the adoption of novel approaches and highly accelerated development timelines. Technological advances, in combination with agile CMC strategies, higher regulatory flexibility, and the acceptance of higher business risks, paved the way for biotherapeutics development at an unprecedented pace.

To advance other lifesaving therapies to patients as rapidly and safely as possible, it is desirable to leverage the learnings and solutions from the COVID-19 pandemic to define new accelerated paths for drug development. In this session, we invite contributions that explore which of those innovations and strategies have the potential to transform our ways of biologics development in the post-pandemic world.

Topics of relevance to this session include, but are not limited to:

- Innovative process and analytical development strategies implemented for COVID therapeutics that will significantly accelerate other biotherapeutics from early stage through commercial development, control strategy definition and validation
- Technological advances and novel tools that can uniquely enable accelerated development of biotherapeutics in the future
- Case studies that illustrate process evolution on highly compressed timelines, as well as the scientific, business and regulatory drivers
- Challenges and solutions for rapid process-scale-up

### **Session: Biomanufacturing 4.0**

Session Chairs:

Ugwal Patil  
Anurag Rathore

IGM Biosciences  
IIT - Delhi

ajain@igmbio.com  
asrathore@biotechcmz.com

Session Description:

This session will focus on technologies and approaches that will enable Next-Generation manufacturing of biopharmaceuticals. Topics that are pertinent to this session include digital twins of biopharmaceutical unit operations and processes, mechanistic modeling, real-time process monitoring, statistical process control, model-based control, and risk assessment. Case studies that illustrate the application of these concepts towards facilitating consistency in process and product quality attributes, enhanced productivity, reduced cost of manufacturing, implementation of PAT and QbD would be of particular interest. Any constraints or challenges relating to technology implementation, regulatory considerations, and the subsequent impact on the widespread adoption may also be presented.

### **Session: Artificial Cells and Cell-Free Systems**

Session Chairs:

Abhinav Jain  
Rebecca Schulman

IGM Biosciences  
Johns Hopkins Univ

ajain@igmbio.com  
rschulm3@jhu.edu

Session Description:

Advancements in synthetic biology and metabolic engineering have ushered in a new revolution in the field of artificial cells and cell-free systems. Topics that are pertinent for the session including but are not limited to, a) indentifying, characterizing, and screening of components and biological circuits for new functions, such as synthesis, regulation, communication or characterization or optimized functions, such as increased efficiency of protein folding, stability, ability to direct or control post-translation modifications, b) development of improved materials for encapsulation, new components from biology, systems for control or self-organization c) development of high-throughput methods for cell-free system development and screening d) novel functionality and applications of these systems in agriculture, energy, diagnostics, and healthcare, e) bioinformatics toolkits and computational studies related to cell-free systems and f) manufacturing and commercialization.

**Session: Supporting Diversity in Biotechnology Training, Recruitment, and Retention**

Session Chairs:

Kelsey O'Donnell  
Jamie Spangler

Amgen  
Johns Hopkins Univ

kodonn01@amgen.com  
jamie.spangler@jhu.edu

Session Description:

Research shows that gender diversity leads to better science (1) and improved business outcomes (2), yet the lack of gender diversity in the leadership ranks of organizations persists (3). The ACS BIOT Executive committee wants to ensure that its members, especially students, are able to understand these benefits. ACS BIOT's mission statement is to support a diverse and inclusive environment where its members feel welcome and where tools are provided to champion this mission. In this session, we look forward to showcase initiatives that your current institution (academia, industry, government, etc.) is working on to support diversity in Biotechnology training, recruitment, and retention. There should be a focus on measurable outcomes and the benefits that have been realized a result of the initiatives.

References:

1. Neilsen et al "Gender diversity leads to better science," PNAS, February 21, 2017: Vol. 114 No. 8, 1740-1742
2. [https://www.ddiworld.com/DDI/media/trend-research/glf2018/global-leadership-forecast-2018\\_ddi\\_tr.pdf?ext=.pdf](https://www.ddiworld.com/DDI/media/trend-research/glf2018/global-leadership-forecast-2018_ddi_tr.pdf?ext=.pdf)
3. <https://www.catalyst.org/knowledge/women-sp-500-companies>

**Session: Development of Personalized and Emerging Novel Therapies**

Session Chairs:

Jin Kim Montclare  
Someet Narang

New York Univ  
Abbvie

jin@montclarelabs.net  
someet.narang@abbvie.com

Session Description:

Over the past couple of decades, with rapidly improving analytics, technologies and increased understanding of underlying mechanisms of diseases, efforts to treat individual or very small populations of patients with personalized medicines are materializing. These personalized and emerging novel therapies have spanned across several therapeutic modalities such as cell therapy, gene therapy and phage therapy. For this session, we are inviting contributions highlighting the drug development, delivery of these drugs, associated challenges, including case studies and the potential solutions to enable such personalized and novel therapies.

## Symposium: Rapid Fire and Traditional Poster Session

Poster Session Coordinators:

Nigel Reuel

Iowa State

[reuel@iastate.edu](mailto:reuel@iastate.edu)

Kristin Valente

Merck

[kristin\\_valente@merck.com](mailto:kristin_valente@merck.com)

Do you prefer a poster presentation? More engagement, less stress. Select abstracts may be invited to give a rapid-fire talk in a related oral session.

## BIOT TANK

Have an idea for a new business? Pitch it to our panel! Contact Nooshie or Danielle for more information.

## BIOT-ESBES BioDesign-A-Thon

Organizers:

Todd Przybycien

RPI

[przybt3@rpi.edu](mailto:przybt3@rpi.edu)

William Kelly

Villanova

[william.j.kelly@villanova.edu](mailto:william.j.kelly@villanova.edu)

This student competition event uses the “hack-a-thon” student competition format that is popular in computer science. Student teams can be formed in advance or spontaneously at the meeting, with scoring bonuses for teams which include students from different schools, countries, and continents. Contact us for more information about the format and rules!