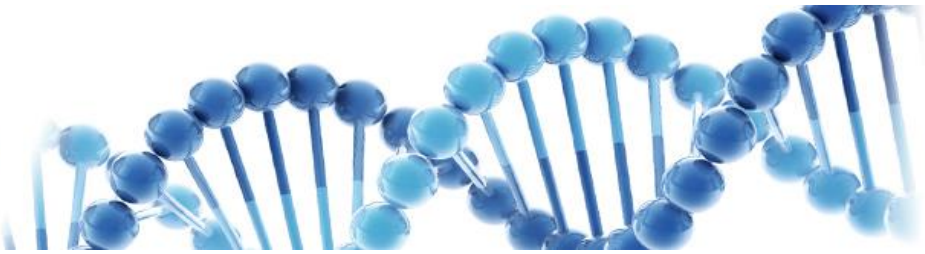
DIVISION OF BIOCHEMICAL TECHNOLOGY
OF THE AMERICAN CHEMICAL SOCIETY

BIOT



Call for Papers

257th ACS National Meeting
March 31-April 4, 2019, Orlando, Florida

BIOT Program Chairs:
Brian Pfleger, University of Wisconsin-Madison (brian.pfleger@wisc.edu)
Jim Neville, MilliporeSigma (jim.neville@emdmillipore.com)

Abstracts Accepted: August 20, 2018 - October 29, 2018

Submit abstracts to the BIOT Division at http://maps.acs.org. Inquiries should be directed to the symposium organizers or program chairs.

ACS BIOT 2019 PROGRAM

Upstream Processes

- Mammalian: Media and Metabolism
- Mammalian: Innovative Technologies
- Mammalian: Novel Modalities
- Mammalian: Advances in Perfusion and Continuous Processing
- Systems Biology & Omics: Tools and Applications
- Engineering Microbial Communities and Non-Model Systems
- Process development and challenges for cell based products
- Microbial Metabolic Engineering
- Synthetic Biology and Genome Engineering

Downstream Processing

- Downstream Processing of Novel Therapeutic Modalities
- Chromatographic Separations of mAbs including platform improvements
- Chromatographic Separations of novel antibody structures
- Continuous and Integrated Downstream Bioprocessing - I&II (Panel Discussion/Keynote)
- Non-Chromatography Based Separation of Biomolecules - I & II
- High-Throughput Screening & Automation of Downstream Purification
- In-Silico Modeling of Chromatographic Separations

Biomedical Technologies

- Development and Production of Cellular Therapies
- Development and Production of Gene Therapies
- New Strategies for the Delivery and Targeting of Therapeutics
- Precision Medicine: Biomarkers, Imaging and Diagnostics
- Cellular and Microbiome Engineering

Biomolecular Technologies

- Therapeutic Protein Discovery
- Engineering & Characterizing Protein Developability
- Protein Conjugates & Fusions
- Protein Structure, Function & Interactions
- Biomolecular Engineering & Design
- Engineering Cellular Interactions

End-to-End Biomanufacturing

- Process Analysis and Control of Product Quality Attributes
- Design my Process: Big Data & Machine Learning
- Scale-Up, Scale-Out & Tech Transfer Case Studies
- Beyond the Platform: Vaccines and Cell Therapies
- Beyond the Platform: Non mAbs, Bispecifics , Fusion Proteins, ADCs
- Automated Technologies & High-Throughput Systems in Biologics Production
- Continuous and Agile End-to-End Biomanufacture

Frontiers in BIOT

- BIOT Frontiers: A Vision for the Next 25 Years
- BIOT Frontiers: A Vision for the Next 5 Years

- E2E Machine Learning
- Beyond Earth - BIOT's Role in Space
- Frontiers in Sustainable Production

BIOT Tank

BIOT Poster Session

Symposium: Upstream Processes

Symposium organizers:

Pamela Peralta-Yahya	Georgia Tech	pperalta-yahya@chemistry.gatech.edu
Pete Russo	Merck	Peter.russo@merck.com
Cong Trinh	Tennessee	ctrinh@utk.edu

Session: Mammalian: Media, Microenvironments, and Metabolism

Session chairs:

Karmella Haynes	Arizona State University	karmella.haynes@asu.edu
Henry Lin	Boehringer Ingelheim	henry.lin@boehringer-ingelheim.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. The formulation of culture media can have a substantial impact on cell behaviors, such as cell growth, viability and productivity. Medium formulation is profoundly intertwined with the cell's metabolism and its response to the physicochemical environment. Scientists are leveraging insights from basic research to advance the rational design of culture media, culture growth conditions, and biomaterials as support systems such as for microtissues. 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 and aspects of cell physiology including genotypes, phenotypes, and metabolic pathways. Papers relevant to these topics are highly encouraged, including but not entirely limited to those focusing on cell culture medium optimization, medium chemistry understanding, medium impact on cell function and metabolism, tissue microenvironment design, and 'omics analyses of mammalian cells in varying culture conditions.

Session: Mammalian: Innovative Technologies

Session chairs:

Nathan Lewis	University of California, San Diego	n4lewis@ucsd.edu
Lakshmi Cella	Merck & Company, Inc.	Lakshmi.cella@merck.com

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. The acceleration in mammalian cells is due in part to transformative technologies, which have matured over the past decades to enable the rational engineering and design of mammalian cells for biotechnology applications. These technologies include omics methods that identify and quantify cell parts, mechanistic modeling techniques for predicting phenotypes, genome editing approaches for implementing cell designs, and finally tools for high throughput design and screening of genetic parts and cell line designs. Talks in this session will focus on the development and use of emerging technologies to engineer mammalian cells for biotechnological purposes. Topics of interest include, but may not be limited to, techniques for identifying engineering targets through omics and screening methods, tools for engineering in those traits, and methods for speeding up the development of cells used for biotechnological applications, including stem cells, engineered immune cells, and cells used for producing macromolecules for biotherapeutic and industrial use.

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Session: Mammalian: Novel Modalities

Session chairs:

Ben Hackel	University of Minnesota, Twin Cities	hackel@umn.edu
Laurie Hazeltine	Eli Lilly	laurie.hazeltine@lilly.com

Session description:

Mammalian cell culture continues to widen its impact on biotechnology with applications ranging from research and development tools to production hosts to therapeutic products. This session will focus on new modes of utility and/or substantially new modifications to existing modes for mammalian cells. The session will balance contributions from research/development tools, recombinant production, and cellular products.

Session: Mammalian: Advances in Perfusion and Continuous Processing

Session chairs:

Andreas Castan	General Electric	Andreas.castan@ge.com
Pamela Peralta-Yahya	Georgia Tech	pperalta-yahya@chemistry.gatech.edu
Cong T. Trinh	U of Tennessee	ctrinh@utk.edu

Session description:

About a dozen or more marketed recombinant protein products from mammalian cell culture are manufactured using perfusion or continuous processing technologies. Traditionally, perfusion and continuous processing has been used for unstable molecules and enzymes, but has in recent years also been applied for mAbs and vaccines. The technology promises reduced costs, increased productivity, improved quality and increased flexibility. This session will encompass multiple aspects of perfusion and continuous processing, including advances in process development, process characterization, scale-up and scale-down model development and cell line stability. 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: Systems Biology & Omics: Tools and Applications

Session chairs:

Rajib Saha	University of Nebraska, Lincoln	rsaha2@unl.edu
Chun Chen	Amgen Inc	river6@gmail.com

Session description:

Living systems are dynamic and complex, and their behaviors may be hard to predict from the properties of individual components. Systems biology focuses on the study of biological entities as a whole. Such studies aim to understand a defined system by comprehensively characterizing its components as well as the interactions among them, and interpreting their functions using both data-driven and/or mechanism-driven modeling, followed by systems-based findings or hypothesis that can be validated or tested by perturbation, and manipulation of its elements. The quantitative analyses of interactions between components are applied to study these biological systems ranging from molecules and cells to organisms or entire species. Recent technological advances have improved quantification of the intracellular components and their interactions. This session will focus on recent progress in the development and utilization of cutting-edge tools and the application of integrated methodologies (both experimental and computational) to elucidate or exploit the internal mechanisms of biologics expressing systems in the context of observed phenotypes. Areas of interest include the development and application of individual or combined-omic analysis, biological network models, metabolic flux analysis, metabolic pathway simulations, protein or genome engineering based on systems-level understanding, etc. Studies with validation of systems-based finds are in particularly welcomed. This session will highlight the insights and opportunities provided by these tools to drive biological systems to new levels of performance.

Session: Engineering Microbial Communities and Non-Model Systems

Session chairs:

Cynthia Collins	Rensselaer Polytechnic Institute	ccollins@rpi.edu
Adam Guss	Oak Ridge National Laboratory	gussam@ornl.gov

Session description:

In the past decade, traditional microbial hosts are increasingly being supplanted with non-model hosts or with mixtures of microbes to address limitations including catalytic capabilities and overall productivity. The unique metabolism and physiology of non-model hosts, such as industrial polyploid Saccharomyces strains, non-Saccharomyces yeasts, mycelial fungi, and photosynthetic microbes, are being exploited to enable robust performance under demanding industrial conditions. A division of labor approach is being applied to mixtures of microbes, either isolated from the environment or assembled from a combination of (model or non-model) organisms, where each population synthesizes a subset of the biological components that are required for the community to carry out a coordinated action. These new hosts and communities are being engineered to access important feedstocks like lignocellulosic biomass, syngas, methane, methanol, glycerol, electricity, and carbon dioxide (amongst others), to increase sustainability, and to decrease costs of production of biopharmaceuticals, biofuels, bulk chemicals and value-added specialty chemicals. Driving the development of these processes are a wealth of new tools and approaches in systems biology, synthetic biology, metabolic engineering, next-generation sequencing, and other enabling -omics technologies, which have improved our understanding and ability to engineer these complex systems. This session will focus on the recent developments in engineering non-model hosts and microbial communities for the production of biopharmaceuticals, biofuels, bulk chemicals and value-added specialty chemicals. Relevant topics include molecular and genetic tool development, pathway and community engineering, engineering community composition and optimizing divisions of labor, process development, and efforts to accelerate design-build-test loops through systematizing workflows, machine learning and other approaches. We welcome both industrial and academic contributors.

Session: Process development and challenges for cell based products

Session chairs:

Samira Kiani	Arizona State University	samira.kiani@asu.edu
Peter Russo	Merck	peter.russo@merck.com

Session description:

Mammalian cell culture has become an essential means for production of an ever increasing number of viral vaccines, recombinant proteins, monoclonal antibodies and other biopharmaceuticals. In addition, the role of cell culture is even further expanded with the advent of cell-based therapy and gene therapy, where the desired products are the cells (e.g., t-cells and stem cells) or viral vectors encoding the gene of interest. The field has matured into a multidisciplinary activity including cell line engineering, medium and feed development, bioreactor characterization, and process control to optimize conditions for the desired product and product quality, particularly control of adventitious agents. This session will encompass multiple aspects of cell culture development where the cells are the products, including advances in the development of cell lines, cell expansion strategies, metabolic pathway analysis, media development, multivariate analysis of processes and innovative process development. Papers relevant to these topics are highly encouraged, including those focusing on process development, characterization and equipment strategies.

Session: Microbial Metabolic Engineering

Session chairs:

Zengyi Shao	Iowa State University	zyshao@iastate.edu
Kevin Solomon	Purdue University	kvs@purdue.edu
Zhe Rui	Renewable Energy Group	ruizhebio@gmail.com

Session description:

Biotechnology and its associated disciplines are the focal points for the design and construction of efficient cell factories for the robust production of desired chemicals and biological products. Metabolic engineering aims to develop methods and concepts to analyze and engineer cell factories using modern synthetic biology tools and to design and construct non-native biological systems. The synergy between these two distinct yet complementary approaches holds great promise to further advance the manufacturing of biotechnological products. The topics of this session include, but may not be limited to, metabolic pathway engineering, design and engineering of microbial whole-cell biocatalysts, and other biological networks for different market applications such as fuels, chemicals, pharmaceutical products, etc.

Session: Synthetic Biology and Genome Engineering

Session chairs:

Hal Alper	University of Texas, Austin	halper@che.utexas.edu
Taeksoon Lee	Lawrence Berkeley National Laboratory	tslee@lbl.gov

Session description:

Synthetic biology approaches have revolutionized how we engineer organism by embodying a rapid design-build-test-learn cycle with the goal of parallelization and automation. To this end, advances in DNA sequencing and synthesis technologies have expanded the capacity to rapidly read, write, and edit DNA even at the genome level. In this regard, we are rapidly moving away from a template-based biology and into a new era of custom, synthetic genes and genomes. Likewise, advances in synthetic parts and editing tools enable more rapid phenotype exploration in both model and non-model hosts. Talks within this session will highlight the rapid advances in the fields of synthetic biology with a focus on genome engineering applications and tools, biofoundries, rapid strain engineering, and new synthetic part design and development.

Symposium: Downstream Processes

Symposium organizers:

Srinivas Chollangi	Bristol-Myers	srinivas.chollangi@bms.com
Mats Gruvegard	GE	mats.gruvegard@ge.com
Caryn Heldt	Michigan Tech	heldt@mtu.edu

Session: Downstream Processing of Novel Therapeutic Modalities

Session chairs:

Benjamin Roman	MilliporeSigma	benjamin_roman@yahoo.com
Meisam Bakshayesh	Biogen	Meisam.bakhshayeshi@biogen.com

Session description:

Many therapeutic modalities such as viruses, viral vectors, virus like particles, exosomes, cells, nucleic acids, plasmids, mini-chromosomes, subcellular fractions and non-antibody proteins have emerged as classes of potential promising biopharmaceuticals in addition to traditional vaccines. Downstream processing of these biopharmaceuticals is different from conventional antibody biologics with many cases of unestablished regulatory framework for more novel therapeutics. New entities may have different size, size distribution, and other biophysical properties compared to proteins or traditional constructs, and existing purification technologies might not be suitable for downstream processing of these modalities. In this session, strategies for isolation and purification of such bionanoparticles will be covered. Topics will include, but are not limited to, i) primary recovery technologies, ii) purification using chromatography and membrane processes, iii) precipitation and extraction technologies, iv) product variants and impurities, v) regulatory issues regarding residual impurities, vi) viral clearance strategies and challenges, vii) stability and comparability issues, viii) scale up and manufacturing challenges, and ix) disposable processing technologies. Submissions that address these issues are encouraged.

Session: Chromatographic Separations of mAbs Including Platform Improvements

Session chairs:

James Woo	Gilead	James.Woo@gilead.com
Cecilia Roque	Universidade Nova de Lisboa	cecilia.roque@fct.unl.pt
Sanchayita Ghose	BMS	sanchayita.ghose@bms.com

Session description:

This session will examine practical and theoretical aspects that can lead to improvements in the current antibody purification platform design. Topics include, but are not limited to, broadening platform applicability across the full range of antibody diversity; novel process technologies and modes of chromatographic operation designed to monitor and control antibody-related product variants; scale-down methodologies to evaluate platform fit for antibody candidates; and scale-up/process implementation considerations to enable rapid and robust process transfer to a manufacturing facility. Research focusing on mechanistic and molecular-level characterization of the attributes of antibody-related product variants (aggregate, LMW species, charge variants, glycosylation variants etc.), leading to platform-ready downstream processing solutions are highly encouraged.

Session: Chromatographic Separations of Novel Antibody Structures

Session chairs:

Steven Cramer	RPI	crames@rpi.edu
Jonathan Royce	GE	jonathan.royce@ge.com
Steven Evans	MedImmune	evanss@medimmune.com

Session description:

Purification schemes for novel antibody structures using chromatographic methods or other purification techniques will be examined in this session. The novel antibody structures may include bispecific antibodies, antibody fragments, antibody drug conjugates, novel antibody structures, or other protein conjugates. This session calls for papers focused on new and enhanced downstream processing of these novel antibody structures and related molecules. The scope may span from process development at the bench scale to larger scales including pilot and commercial scale manufacturing. Topics may include novel materials and formats, high-throughput screening, process optimization, troubleshooting, case studies in scale-up, and/or case studies in large-scale manufacturing. Research focusing on novel affinities and/or the interaction of novel antibody structures with traditional chromatographic moieties (e.g., HIC, IEX and multimodal chemistries), either in theory or in practice, are strongly encouraged. Presentations on alternatives to traditional chromatography techniques are also welcome.

Session: Continuous and Integrated Downstream Bioprocessing - I & II

Session chairs:

Lars Pampel	Novartis	lars.pampel@novartis.com
John Pieracci	Biogen	john.pieracci@biogen.com
Thomas Muller-Speath	ChromaCon	thomas.mueller-spaeth@chromacon.ch
Veena Warikoo	Roche	veena.warikoo@roche.com

Session description:

Continuous processing offers a step improvement in productivity, supply flexibility, product quality and capital efficiency. In biopharmaceutical downstream processing, integrated and fully continuous manufacturing schemes are currently being evaluated and implemented at GMP scale. As general process principles of continuous chromatography are well understood, attention is drawn to aspects relevant to clinical manufacturing, where the technology is expected to provide the largest cost savings and subsequent process scalability to commercial production. Most approaches are using a stepwise entry into fully continuous manufacturing by replacing individual steps of standard single-column platform processes by continuous multi-column processes. Moreover single-column chromatography steps are integrated to eliminate any hold steps and to automate the downstream processing. Without hold steps, process monitoring and control are getting increasingly important to maintain product quality and consistent continuous process operation. In this session, presentations covering continuous downstream bioprocessing, connected/integrated processes eliminating or reducing holding steps, advanced process controls, Process Analytical Technology (PATs) enabling in-line / at-line monitoring, scale-up and process scale implementation including facility fit and process modeling are solicited. Case studies on the use of such technologies are especially encouraged.

Session: Non-Chromatography Based Separation of Biomolecules - I & II

Session chairs:

Akshat Gupta	EMD Millipore	akshat.gupta@emdmillipore.com
Engin Ayturk	Biogen	Engin.ayturk@biogen.com
Christopher Gillespie	ImmunoGen	gillescche@gmail.com
Bharat Bhut	Merck	bharat.bhut@merck.com
Jenny Lawler	Dublin City University	jenny.lawler@dcu.ie

Session description:

Non-chromatographic separation techniques are essential to manufacture biopharmaceutical products and cover a wide-range of technologies that include but are not limited to: centrifugation, flocculation, and filtration-based approaches for cell harvest/clarification, nanofiltration for virus removal, and ultrafiltration for protein separations, product concentration and final formulation of the bulk drug substance. These 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 and/or integration of unit operations for continuous/semi-continuous manufacturing. These technologies also play key 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 unit operations to achieve desired bioseparations, as well as cases demonstrating the advantages/disadvantages of integrated processes thereof. Operations of interest may include; traditional unit operations, centrifugation, flocculation, filtration and membrane processes or less traditional unit operations, 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: High-Throughput Screening & Automation of Downstream Purification

Session chairs:

Marcel Ottens	Delft University of Technology	m.ottens@tudelft.nl
Matthew Stork	Pfizer	matthew.stork@pfizer.com
Jennifer Pollard	Merck	jennifer_pollard@merck.com

Session description:

To align with the QbD (Quality by Design) paradigm and accelerated program timelines, the biopharmaceutical industry is evaluating and developing various approaches to aid process development activities and gain better understanding of the manufacturing process. Automation has been at the forefront of this innovation and there have been significant advances in the use of automation to develop high throughput technology which can drastically reduce the utilization of time and material needed. A combination of high throughput methods and DOE can be employed during early and late phase process development to optimize individual unit operations as well support process characterization activities, generating large experimental datasets in a rapid, cost-effective manner. However, the adoption of automation and HTS techniques has come with a new set of challenges, including the need for scale-down qualification of high-throughput models and the creation of workflows for high-throughput analytical testing and data analysis.

In this session, we would like to focus on the strategies and challenges of utilizing high throughput techniques for downstream process development. In addition to well established applications for chromatography, case studies on more complex unit operations to scale down, such as depth and tangential flow filtration, and other non-chromatographic steps such as cell harvest are encouraged. Also, as high throughput techniques are further reduced in scale to nano platforms, we would like to explore the practical limitations of these tools. For all applications, we are particularly interested in the integration of high throughput analytics into the workflow to be mindful of not shifting the process bottleneck downstream. We hope to explore advances in automated data analytics, with a particular interest in automated testing as well as proteomics techniques for the analysis of contaminate distributions. Finally, we hope to complete the session with a discussion of new approaches to the analysis of large datasets obtained through high-throughput screening and evaluating automated collection and potential IT solutions toward data mining. To this end, we seek contributions from industry and academia which highlight advances in these fields that are targeted towards better and faster downstream process development.

Session: In-Silico Modeling of Chromatographic Separations

Session chairs:

Jürgen Hubbuch	KIT	juergen.hubbuch@kit.edu
Alexander Hanke	Novartis	alexander.hanke@novartis.com
Gunnar Malmquist	GE	gunnar.malmquist@ge.com

Session description:

Models capable of describing chromatographic separations have long been available but never quite managed to break their way into mainstream biopharmaceutical development. This is rapidly changing as the digital revolution is sweeping through the pharmaceutical industry and DSP developers are recognizing that having the right models is key to unlocking smart and disruptive downstream process development and control approaches in the Biotechnology Industry 4.0.

Advances in artificial intelligence and machine learning are opening new possibilities to overcome many of the hurdles traditionally connected to chromatography modelling by leveraging on the vast amounts of knowledge buried in the Data Lakes that companies are filling with a constantly growing array of sensors and analytical technologies deployed across development labs and manufacturing facilities.

The session invites speakers to share their advances in smart model-supported process development, including novel mechanistic-statistical hybrid approaches and integration of molecular modeling, proteomic and online analytics for rapid and comprehensive model parameterization. Case studies highlighting the expansion of model capabilities to new molecular and chromatographic modalities, multi-step integrated process optimization potentially including chemical modifications, and innovative applications in use of models for gaining insights and supporting activities across the product lifecycle, from discovery through process development to regulatory filings and commercial manufacturing, are highly encouraged.

Symposium: Biomedical Technologies

Symposium organizers:

Rahul Sheth	Biomarin	RSheth@bmrn.com
Greg Thurber	Michigan	gthurber@umich.edu
Matt Westoby	Juno/Celgene	matthew.westoby@junotherapeutics.com

Session: Development and Production of Cellular Therapies

Session chairs:

William J. Kelly	Villanova University	william.j.kelly@villanova.edu
Lesley Chan	Bluebird Bio	lchan@bluebirdbio.com
Bruno Marques	GlaxoSmithKline	bruno.f.marques@gsk.com

Session description:

The year 2017 was a hallmark year for *ex vivo* cellular therapies, with two autologous CAR-T products gaining FDA approval. These approvals herald the emerging trend of using cells as medicinal agents for immuno-oncology (CAR-T, TCR-T, NK-T, etc.) and rare diseases (modified HSCs, fibroblasts etc.) in the Biopharmaceutical industry. These new treatments typically involve isolating a patient's cells, using a viral vector to integrate a coding sequence for a receptor or corrected protein, and then reinfusing these modified cells back into the patient. The complex, multi-stage and personalized process presents many new product and process challenges. This inaugural session in cellular therapies will focus on the development of new and improved therapies, as well as the identification and solution to manufacturing challenges of cellular therapies.

Talks in this session will encompass both product improvements and CMC challenges related to *ex vivo* cellular therapies. Cell therapy product improvements may encompass approaches to the development of allogeneic cell lines, new modalities for immuno-oncology, implementation of kill switches in response to excessive cytokine release, and defining the right product phenotype. Papers relevant to CMC challenges may include the design and operation of upstream and downstream bioprocesses to achieve target *ex vivo* expansion, building a platform process, process characterization efforts, designing multi-product facilities and overcoming quality/regulatory challenges, improving efficiencies through process automation, and scale-out or scale-up approaches to meet market demands. Critical raw materials of these products are viral vectors and the patient's cells. Approaches to dealing with the variation in cell populations from patients, as well as designing the vector manufacturing process to include definition of critical quality attributes and conditions promoting high productivity and sufficient impurity removal are highly relevant for this session.

Session: Development and Production of Gene Therapies

Session chairs:

Christopher Morrison	Voyager Therapeutics	cmorrison@vygr.com
Sergei Zolotukhin	University of Florida	szlt@ufl.edu
Aravind Asokan	Duke University	aravind.asokan@duke.edu

Session Description:

Gene Therapy continues 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 soon to be expected commercial launches, numerous ongoing clinical trials, growing involvement from larger companies, increasing industrial collaborations with academia, and continual formation of new start-ups, the Gene Therapy field is set to be a major player and potential game changer for 21st century medicine. While demonstrating great promise, these therapies are relatively new to the biopharmaceutical manufacturing industry and require further study to reach the depth of understanding now typically associated with other more establish biologic therapeutics. In that spirit, this session calls for papers focused on the development and production of Gene Therapy, in its various forms, from both academia and industry. The session organizers wish to include abstracts covering numerous aspects of this field for the session, topics to include but not limited to:

- Vector Design and Engineering
- Gene Editing Techniques
- Upstream Production Systems
- Downstream Purification Steps
- Drug Product Sciences
- cGMP Manufacturing
- Analytical Assay Development and Product Characterization

Session: New Strategies for the Delivery and Targeting of Therapeutics

Session chairs:

Aaron Noyes	Codiak BioSciences	aaron.noyes@codiakbio.com
Angela Brown	Lehigh University	acb313@lehigh.edu
Xianghong Qian	University of Arkansas	xqian@uark.edu

Session description:

Targeted delivery is critically important in improving the efficacy of medicines, including small molecules, nucleic acids, proteins, viral vectors and nanoparticles. Many new classes of molecules, carriers, and particles are being developed to improve delivery of these therapeutic agents to the desired tissue(s). This session will focus on novel delivery strategies currently being investigated in academia and industry. Relevant topics include advances in gene therapy, discovery of novel targeting ligands, design of delivery vehicles, controlled release strategies, and precision medicine approaches. Abstracts that discuss the production, characterization, purification and/or formulation of these novel classes of therapeutic modalities are particularly welcome.

Session: Precision Medicine: Biomarkers, Imaging, and Diagnostics

Session Chairs:

Kelly D Orcutt	Invicro, A Konika Minolta Company	orcutt@invicro.com
Shannon Servoss	University of Arkansas	sservoss@uark.edu
Peter Tessier	University of Michigan	ptessier@umich.edu

Session Description:

There is increasing interest in precision medicine for detecting and treating a wide range of human disorders. This is due to many key biomedical advances that – for the first time – are enabling the implementation of diverse types of precision medicine technologies. This session will focus on recent developments in: i) molecular diagnostics; ii) genomic, proteomic and glycomics methods; iii) imaging; iv) biomarkers; and v) data mining and artificial intelligence methods related to precision medicine and human health.

Session: Cellular and Microbiome Engineering

Session chairs:

Nikhil Nair Tufts University Nikhil.Nair@tufts.edu

Session description:

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

Symposium: Biomolecular Technologies

Symposium organizers:

Ben Hackel	Minnesota	hackel@umn.edu
Bruno Marques	GlaxoSmithKline	bruno.f.marques@gsk.com

Session: Therapeutic Protein Discovery

Session chairs:

Gabe Rocklin	U. Washington	grocklin@gmail.com
Joe Jardine	Protein Innovations	joseph.jardine@proteininnovation.org

Session description:

The space of proteins therapeutics is continually expanding due to the development of new protein formats, new modes of action, new screening technologies, and new design tools. This session will focus on recent advances in therapeutic protein discovery in academia and industry. Suggested topics include: new design strategies for challenging targets, therapeutic candidates with unusual modes of action (such as therapeutic proteins with enzymatic activity, therapeutics that stabilize, destabilize, or induce or conformational change in their targets, or induce association between multiple targets), novel strategies for therapeutic proteins to function in the cytosol, strategies to incorporate desirable properties early in the screening or design process (such as enhanced stability, resistance to aggregation, and immune tolerance), new approaches to antibody engineering, the development of non-antibody scaffolds, and the design of immunogens and vaccines.

Session: Engineering & Characterizing Protein Developability

Session chairs:

Jim Schneider	Carnegie Mellon	schneider@cmu.edu
Mary Krause	BMS	Mary.Krause@bms.com

Session description:

Protein therapeutics cover a wide range of molecular formats including antibodies, proteins with enzymatic or regulatory activities, vaccines, and protein-based diagnostics. They comprise a significant and growing toolbox for the study and treatment of diseases in almost every area of medicine. However, the properties of proteins needed to increase the likelihood of success in clinical settings extend far beyond simple binding or enzymatic activities to include characteristics such as aggregation propensity and nonspecific binding. This session focuses on the process of engineering and identifying candidate proteins and other biologics with properties suitable for therapeutic and diagnostic applications, as well as process controls and risk mitigation tools that can be used to enable development of challenging candidates. Topics of interest include, but are not limited to, protein engineering, novel antibody/protein discovery platforms and assays, protein library design methods, high-throughput screening systems, in vitro and in vivo characterization methods, and mitigation strategies for addressing the manufacture of unconventional and/or difficult assets. Contributions that describe novel methods for assessing developability/manufacturability or strategies for avoiding the discovery of candidates with undesirable properties in early stage discovery are especially encouraged.

Session: Protein Conjugates & Fusions

Session chairs:

Jamie Spangler	Johns Hopkins	jamie.spangler@jhu.edu
Siddharth Parimal	GSK	siddharth.x.parimal@gsk.com

Session description:

Protein conjugates and fusions are expanding the toolkit for development of new molecules with wide-ranging applications as bioanalytical reagents and biomedical tools for disease diagnosis and therapy. As protein engineering and production platforms become increasingly sophisticated, there is a unique opportunity to capitalize on new technologies to develop molecules with complex modalities (fusions, bispecifics, dAbs, ADCs, etc.) as research tools and potential therapeutics. This session will focus on cutting-edge approaches and methodologies for engineering, manufacturing, formulating, and characterizing proteins in this growing class of biologics. Examples of interest include, but are not limited to, protein-small molecule conjugates, multi-specific antibody-protein fusions, cyclized peptides, protein-polymer or protein-nanoparticle conjugates, and macroscopic materials that incorporate a protein component. Abstracts will be prioritized that present advances in protein-bioconjugate construction, new classes of protein drugs, innovative targeting strategies, novel applications of protein conjugates and fusions, and unique processing strategies which take advantage of the biomolecular properties offered by these classes of molecules.

Session: Protein Structure, Function & Interactions

Session chairs:

Philip Romero	Wisconsin-Madison	promero2@wisc.edu
Joanna Swain	Cogent Therapeutics	jswain@cogentherapeutics.com

Session description:

New protein technologies often rely on a deep understanding of three-dimensional structure and how it can be modulated or leveraged to enable new functions. Advances in our understanding of the relationships between protein sequence, structure, allostery and dynamics are enabling the design of molecular switches, agonists/antagonists and allosteric modulators. Structural evaluation of large multi-subunit protein complexes is increasingly facilitated by evolving techniques such as Cryo-EM. Systems and multiscale approaches are helping to define the behavior of protein interaction networks on a more global scale. This session seeks presentations focused on theoretical and/or experimental approaches to study structure and function at the single protein, protein complex or systems level.

Session: Biomolecular Engineering & Design

Session chairs:

Brandon DeKosky	Kansas	dekosky@ku.edu
Kristin Brown	GSK	Kristin.K.Brown@gsk.com

Session description:

Advances in biomolecular engineering technology have created opportunities to improve biochemical and biophysical properties of proteins. This session will focus on approaches that use computational and experimental methodologies to design proteins with improved function and stability for therapeutic and biotechnology applications. Topics include, but are not limited to: machine learning and/or structure-aided protein design, library design, advancements in NextGen sequencing and screening strategies. Combining technologies to develop and advance novel biomolecules and platforms will also be of interest.

Session: Engineering Cellular Interactions

Session chairs:

Larry Stern	City of Hope	lstern@coh.org
John Rhoden	Eli Lilly	rhoden_john_j@lilly.com

Session description:

Cellular interactions are critical to cellular and tissue level biological phenomena across physiological and pathological states. Recently, strategies to engineer and manipulate cellular interactions have been successfully employed for a variety of applications. Chimeric antigen receptor T cell therapy has revolutionized treatment of certain hematologic malignancies, building interest in engineering additional synthetic immune receptors for a variety of immune cell subsets. Molecules designed to bridge multiple cells for therapeutic benefit, such as bispecific T cell engagers or immunocytokines, have proven effective in certain contexts, but challenges remain to more broadly understand and apply these modalities. It has recently become apparent that agonism of many receptors may require clustering through cell-cell binding interactions in trans to mediate signaling. Cell-cell interactions are also extremely important in stem cell differentiation and tissue engineering.

Presentations in this session will focus broadly on new and emerging strategies for engineering cellular interactions and characterization of the benefits and challenges of various approaches. Novel tools to probe the mechanistic basis of cellular interactions as well as engineering strategies to improve and advance the field are encouraged. Examples of relevant topics include but are not limited to: engineering synthetic immune receptors, understanding and harnessing the impacts of cell-cell interactions in various stem cell populations, engineering protein therapeutics for efficient and safe agonism of cellular receptors through trans binding interactions, and optimizing cell-cell and cell-ECM interactions in tissue engineering.

Symposium: End-to-End Biomanufacturing

Symposium organizers:

Jean Bender	Medimmune	Benderj@medimmune.com
Chris Love	MIT	clove@mit.edu
Varnika Roy	GlaxoSmithKline	varnika.x.roy@gsk.com

Session: Process Analysis and Control of Product Quality Attributes

Session chairs:

Nooshafarin Sanaie	Gilead Inc.	Nooshafarin.Sanaie@gilead.com
Tiffany Rau	Bioprocess Technology Consultants (BPTC)	trau@bptc.com

Session description:

This session will focus on new methodologies to control drug substance or drug product critical quality attributes (CQAs) and advanced process analytics which can be employed for meeting the target level of all CQAs throughout the process. More specifically, topics covering integrated approaches to control final target product quality attributes starting from cell line engineering all the way through final formulations are desired.

The main focus of the session will be on identification of innovative tools and implementation of those in the manufacturing processes to enable meeting in process limits with goal of meeting the final critical quality attributes or allowing real time release (RTR) and real-time control of CQAs. Furthermore, challenges facing introduction of these implementation of PAT technologies into “historic” processes and how the technologies have impacted 2nd or 3rd generation processes and the regulatory and clinical aspects of the changes if and when implemented.

Additional relevant topics may include Rationale for selection of CQAs for drug substance and integrated control strategies for meeting Quality Target Product Profile (QTPP). Implementation of integrated control strategies which leverage enhanced product understanding for manufacturing process optimization or regulatory submissions, along with understanding the process capabilities and their impact on CQAs are among the topics of interest. For examples, approaches for enhanced cellular level control of protein post-translation (e.g. cellular quality control, glycosylation, and chemical functionalization), molecule selection based on manufacturability, Quality Target Product Profile based process/product design and integration with Quality by Design (QbD) principles, either experimentally or computationally are welcome.

Session: Design my Process: Big Data & Machine Learning

Session chairs:

Shahid Rameez	KBI Biopharma Inc.	srameez@kbibiopharma.com
Justin Chartron	Univ. California, Riverside	jchartron@engr.ucr.edu

Session description:

The last decade saw tremendous advances to data-generating domains such as automated, high-throughput experimentation and knowledge management. As a result, large datasets now exist that cover every stage of biomanufacturing. Approaches taken from data science can mine such “Big Data” to reveal unforeseen relationships between the controllable variables of bioprocessing and the quality or yield of final products. Machine learning can optimize and accelerate future product discovery and development. This session encourages presentations focused on the application of data science and machine learning to problems in several areas of biomanufacturing process design, including product discovery, upstream, downstream, formulation and drug product process development, and quality control. Presentations describing practical aspects of using machine learning to understand Big Data are encouraged, including data preprocessing, feature engineering, supervised and unsupervised learning, and model regularization using linear, nonlinear or deep learning methods. We welcome case studies describing the implementation of machine learning models to guide new process design. Data collection, as well as tools, techniques, and infrastructure for gathering isolated datasets into Big Data (and for processing those datasets) are also within scope.

Session: Scale-Up, Scale-Out & Tech Transfer Case Studies

Session Chairs:

Melani Stone	Merck	melani.stone@merck.com
Phillip Smith	GSK	phillip.2.smith@gsk.com

Session description:

Different manufacturing strategies are considered when developing a process. Traditionally, scaling-up has been the go-to option. However, with increased need for flexibility in manufacturing to meet challenges in forecasting clinical and commercial demands or managing a multi-product portfolio, a new paradigm of scaling-out (i.e. process scale is fixed and additional process trains are built out as needed) is emerging.

When transferring a Biopharmaceutical process to manufacturing, multiple factors play into a decision between options to scale-up versus scale-out. For example, technical challenges associated with scale-up must be balanced against economies of scale lost through scale-out; manufacturing philosophies and manufacturing site capabilities must be considered (e.g., single-use or stainless steel); and speed to clinic must be weighed against process lifecycle management planning. In this session we invite case studies illustrating practical and science-based approaches to the development of scale-up and scale-out manufacturing strategies and execution of technology transfer. Presentations should cover cross-functional topics (e.g. upstream, downstream, formulation, analytics, fill finish) when possible. Presentations that include one or more of the following themes are of special interest:

- Novel manufacturing approaches to meeting demand forecasts, and responding to changes in market demands post approval
- Strategies for managing multi-site technology transfer and manufacture of the same product
- Integrated technology transfer including control strategy for scale-out vs scale-up
- Engagement with regulatory authorities while scaling-out or scaling-up capacity for an approved product
- Development of tools for predicting and/or comparing process performance between scaled-up and scaled-out processes
- Accelerated technology transfer from lab-scale to manufacturing-scale; challenges faced from clinical to commercial manufacturing
- Disruptive bioprocessing for scale-out vs scale-up technology transfer

Session: Beyond the Platform: Vaccines and Cell Therapies

Session Chairs:

Kunal Aggarwal	GSK	kunal.x.aggarwal@gsk.com
Nitin Agrawal	George Mason Univ.	Nagrawa2@gmu.edu

Session description:

Historically, the bioprocess industry has relied on familiar, proven although sometimes aging techniques to meet the need for boosting speed to clinic and speed to market. Conversely, cost and timeline pressures have motivated industry and academia to find innovative and/or disruptive ways to produce consistent, high-quality products in manufacturing processes with a significant reduction in development timelines.
This session focuses on recent advances in the development, scale-up and successful implementation of disruptive technologies in drug substance and drug product processes in the vaccines and cell therapy areas. The topics solicited include but are not limited to:

- Challenges in manufacturing and formulating adjuvants, recombinant proteins, DNA & RNA vaccine prototypes, virus like particles and viral vectors.
- Understanding the role of extracellular vesicles (EVs) (e.g. exosomes and liposomes) carrying generic material in cell-cell communication and their utilization as therapeutic mediators.
- Novel platform technologies and plug-and-play approaches for rapid response to emerging diseases and associated variabilities.
- Case studies showcasing use of disruptive approaches to accelerate development, reduce cost and/or to improve product quality.
- Bioprocessing scalability and availability of integrated vaccine and cell based therapies to widespread population.

Session: Beyond the Platform: Non mAbs, Bispecifics , Fusion Proteins, ADCs

Session Chairs:

Albert Schmelzer MedImmune schmelzera@medimmune.com
TBN

Session description:

Over the past year, new modalities have had significant clinical and commercial success, including viral vectors, cell therapy, antibody combinations, and antibody-drug conjugates (ADCs). These modalities respond to the insufficient therapeutic potency of single monoclonal antibodies. Building on this success, there have been continued efforts on these and other novel biomolecular entities such as Fc – fusion proteins, antibody fragments, and bispecific antibodies, among others. The continuing evolution of these novel formats have challenged the manufacturing paradigm with respect to titer, product quality, and process- and product-related impurities.

This session calls for papers focused on novel and disruptive manufacturing technologies to address these challenges, with particular focus on case studies that cross-functionally cover upstream, downstream, and/or formulation. The following topics are particularly encouraged:

- Disruptive manufacturing technologies, especially to increase the yield and product quality of the desired product
- Case studies for developing end-to-end processes with non-mAbs, including challenges faced and lessons learned
- Creative approaches to handling unstable products or difficult-to-remove impurities
- Innovative methodologies to accelerate the process development of novel modalities

Session: Automated Technologies & High-Throughput Systems in Biologics Production

Session Chairs:

Elizabeth Goodrich MilliporeSigma elizabeth.goodrich@emdmillipore.com
Sarah W. Harcum Clemson University harcum@clemson.edu

Session description:

Automation has the potential to accelerate discovery of lead candidate biologics through greater efficiencies, shorter timeframes, and fewer human errors. In addition, intense competition drives a need for automated ultra-small-scale tools to rapidly develop well-characterized, scalable manufacturing processes for high-quality biotherapeutics utilizing a minimum of material. In this session, presentations are encouraged that focused on miniaturization, automation, and massively parallel synthesis and analysis of protein-based drugs such as recombinant proteins and monoclonal antibodies. This includes the latest developments in (i) experimental approaches for high-throughput formulation design and protein production and purification, including plate-based formulation screening, microbioreactors and miniature columns and filtration strategies, (ii) integration of on-line or at-line analytics for biomanufacturing, (iii) computational approaches necessary to support experimental innovations, and (iv) application of such approaches to key biomedical systems relevant in biotechnology, therapeutic development, and biologics scale-up and production. Examples include but are not limited to: high throughput formulation screening, automated methods in protein expression, high-throughput perfusion scale-down models, self-tuning/optimizing bioreactors and purification unit operations, and automated/integrated quality and metabolite analysis. Case studies demonstrating high throughput process development (HTPD) strategies for early and late stage process development, as well as efforts evaluating new high throughput technologies, are especially encouraged.

Session: Continuous and Agile End-to-End Biomanufacture

Session Chairs:

Suzanne Farid	University College London	s.farid@ucl.ac.uk
Arick Brown	MedImmune	brownar@medimmune.com

Session description:

Biopharmaceutical companies are increasingly looking outside of their tried-and-true playbooks for cost-effective, robust and flexible manufacturing options. The concept of agile end-to-end manufacturing, with reliance on more integrated or continuous processing options, is becoming more popular with recent unit operation improvements. Yet widespread adoption for drug candidates relies on teams generating proof-of-concept data, developing novel process technologies to close any gaps, integrating analytical technologies, modelling capabilities to enable monitoring and control and obtaining management buy-in.

This is a new session to ACS BIOT, and presentations are sought that illustrate cross-functional collaboration in the development and implementation of next generation continuous and agile end-to-end bioprocesses. This can include fully continuous end-to-end processes with operations such as perfusion culture, multi-column chromatography (SMB), continuous virus clearance, and single-pass concentration/diafiltration. In addition the session scope covers hybrid processes with a combination of continuous and connected steps that enable straight-through processing. Case studies are encouraged that demonstrate how these concepts translate into increased agility on the factory floor and more cost-effective processes. The case studies can be for different scenarios such as centralized or localized manufacturing scenarios and single or multiproduct facilities. In addition they can address strategies to handle perturbations in the end-to-end processes with tools such as process analytical technologies (PAT) and predictive models. Applications of these continuous and agile concepts to the end-to-end production of biologics, including recombinant proteins, oligonucleotides, and virus- and cellular-based biotherapeutics, are particularly encouraged.

Symposium: Emerging Frontiers in BIOT

Symposium organizers:

Mark Blenner	Clemson	Blenner@clemson.edu
Carrie Eckert	CU-Boulder	Carrie.eckert@colorado.edu
David Roush	Merck	David_roush@merck.com

Session: BIOT Frontiers: A Vision for the Next 25 Years

Session chairs:

Pete Tessier	University of Michigan	ptessier@umich.edu
Varnika Roy	MedImmune	royv@medimmune.com

Session description:

The BIOT division is proud to celebrate its 55th anniversary this year. BIOT is one of the oldest and largest divisions of ACS, and it has been a leading scientific forum since the inception of the field of biotechnology in the 1960s. BIOT members have pioneered numerous transformative technologies that now define the modern biotech industry, ranging from recombinant DNA and the first licensed recombinant protein produced in E. coli (insulin) to continuous manufacturing methods for producing monoclonal antibodies in mammalian cells. The evolution of new therapeutic modalities (e.g., cell and gene therapies), advances in synthetic biology and development of next-generation of therapeutics, vaccines and energy solutions are at the innovative core of BIOT. This session will highlight the opportunities and challenges in the biotech industry that need to be addressed in the next 25 years to achieve the BIOT vision of “advancing biotechnology to improve life”.

Session: Bioprocessing in 2024: Disruptive Technological Innovation in Industry and Academia

Session chairs:

Name	Institution	Email
Charles Haynes	University of British Columbia	**israels@mail.ubc.ca**
John Erickson	Glaxo Smith Kline	**john.c.erickson@gsk.com**

Session description:

The bioprocessing industry has been dominated by mAbs made in large quantities with high selling prices for the past couple decades. In 2017, spending on new biotherapeutic pipelines was estimated to be $200B and prices are now being challenged intensely. Moreover, the blockbusters of the past will probably be replaced by a much larger number of targeted therapies that are more potent against specific disease subclasses. These two trends will likely require the industry to make dramatic reductions in development and manufacturing costs while we lose economies of scale. This session invites industrial and academic talks that articulate specific limitations to current bioprocessing science and present disruptive opportunities to overcome those barriers, particularly those that could be reduced to practice at least at pilot scale in the next 5 years. Papers from across the BIOT spectrum are encouraged, including the disciplines of upstream and downstream processing, fill/finish, and analytical testing, as well as papers on proteins and newer modalities like cell and gene therapies. Examples of disruptive innovations could include bioprocessing innovation, novel mechanistic and computational approaches to formulation or upstream/downstream bioprocess design, new scalable and cost-effective production or purification operations, and advanced control and monitoring (analytical) methods that enable robust continuous manufacturing of complex biologics. But presentations on any technologies and methodologies that can serve to improve manufacturing capabilities and costs across scales are welcome. So please join us for a forward-looking discussion that seeks to identify the drivers that will shape future areas of value within bioprocessing science.

Session: E2E Machine Learning

Session chairs:

Name	Institution	Email
David Roush	Merck	david_roush@merck.com
Diwakar Shukla	University of Illinois	diwakar@illinois.edu

Session description:

Mechanistic and computational biophysics modeling, independently or in tandem, can provide fundamental insights into the underlying processes translating into increased productivity/efficiency of processes or improvements in product quality. Significant advances in modeling and computational efficiency had allowed for the development of first principle techniques including mechanistic and computational biophysics modeling that can have a direct impact on process robustness and productivity. The next stage of this evolution is to connect these models to machine learning algorithms to direct experimental or molecular design, enhance computational efficiency and when combined with Process Analytical Technologies (PAT), allow for autonomous fed-back control of processes.
The session focuses on examples of advanced modeling techniques and the combination with machine learning approaches to support development of upstream, downstream and connected or continuous processes utilizing PAT. Case studies that describe fundamental advancements in unit operation (e.g. systems biology) or process modeling for combination drug product/device design are also encouraged. Research papers that utilize in silico models or analysis for molecule design and refinement (including SAR approaches) driving certain quality attributes and/or efficacy, from a manufacturability perspective would be excellent contributions to complete the session. Potential application of these techniques beyond the current bioprocessing space to create new therapies or molecular entities would be of interest as well.

Session: Beyond Earth - BIOT's Role in Space

Session chairs:

Mark Blenner	Clemson	blenner@clemson.edu
Mike Roberts	NASA--CASIS	mrobets@iss-casis.org

Session description:

Space is humanity's final frontier. Exploring, utilizing, and living in space presents unique challenges and opportunities that drive technological innovation, while potentially paying short term dividends for earth-based applications. This session will focus on the role that biochemical technology is and will play in the exploration, commercialization, and habitation of space. It also focuses on technologies that could play important role in space that are not currently developed for this purpose.

Talks for this session are solicited from academics, industry, national labs and NASA scientists that include but are not limited to: 1) the use of biotechnology for space exploration, human performance, life support systems (e.g., biosynthesis of food and materials), 2) the use of space for studying or improving a biotechnologically important process (e.g., effects of micro-gravity on crystallization or cell behaviors), 3) the use of biotechnology to utilize space resources (e.g., CO2, minerals, etc.). Furthermore, technologies that could have a potential impact for space, that are not currently motivated for space are particularly of interest.

Session: Frontiers in Sustainable Production

Session chairs:

Kate Brown	NREL	kate.brown@nrel.gov
Jack Gavin	Merck	john.gavin@merck.com

Session description:

Future resource scarcity has the potential to negatively impact the growth of biotechnology. Competition for inputs such as water are expected to escalate with increased population and an expanding global middle class. Technologies and practices focused on sustainability are essential for meeting future energy, food and environmental needs without compromising the Earth's resources, and without generating excessive waste. Biotechnology, at both the academic and industrial level, can provide building blocks for a sustainable future through practices and technologies that reduce the use of nonrenewable resources and increase efficient use of renewable resources. A focus on sustainability can uncover risks that would not be identified otherwise, and can lead to innovation. Metrics such as process mass intensity (PMI) and lifecycle assessment (LCA) are quantifying impacts and are helping to uncover opportunities to reduce the environmental footprint of biologics processes and products. Incorporation of circular economy principles into biotechnology practices can result in more efficient operations and lead to reduced waste.
This session will focus on biotechnology research and practices across a range of technical readiness levels that is geared towards improving sustainability across bioprocessing and agriculture.

Session: BIOT Frontiers Poster Session

Session chairs:

Name	Institution	Email
Krunal Mehta	Amgen	kmehta@amgen.com
Tom Mansell	Iowa State	mansell@iastate.edu

Session description:

This BIOT Frontiers Special Poster Session will highlight research across the sessions in this area: Cutting edge research towards future vision, machine learning in end to end processes, space research, and advances in sustainability. We welcome posters that will serve as a springboard for more in depth discussions and insights in addition to the invited area speakers.

Session: BIOT Tank

Session chairs:

Nitya Jacob	Amgen	njacob@amgen.com
Anne Kantardjieff	bluebird bio	akantardjieff@bluebirdbio.com
Samet Yildirim	Boehringer Ingelheim	samet.yildirim@boehringer-ingelheim.com

Session Description:

Start-up, early stage companies and teams of entrepreneurs seeking to develop and commercialize novel medical, healthcare, and biotechnology products are invited to compete in a Shark Tank-like competition. Entrepreneurs are invited to give technical details of their company's core technologies as well as share their value proposition and business model rationale. Technology sectors will include but are not limited to, diagnostics, medical devices, biologics and therapeutics, personalized medicine, upstream and downstream bioprocessing, modeling software, process analytical technologies, and drug delivery systems.

Winners will be selected during the session and awards include a $4000 first prize selected by the judges, as well as a $1000 audience choice award selected by live voting. The judges will consist of a select group of venture capitalist, angel funding group leaders, and technology leaders from large and small technology companies.

The previous BIOT tank at the 2018 ACS BIOT conference was attended by more than 200 scientists, entrepreneurs, and venture capitalists, leading to great exposure for all companies selected to present.

Early stage companies without customer revenue and companies being founded by student teams are also encouraged to participate.

Entrepreneurs are requested to submit the following information: Technology Differentiation, Size of Company, Years in Business (zero is fine, for teams just getting started), Number of Customers (zero is fine, only shown if helpful for company), Revenue (zero is fine, only shown if helpful for company).

Symposium: BIOT Poster Session

Symposium organizers:

Kevin Solomon	Purdue	kvs@purdue.edu
Ian Wheeldon	UC-Riverside	iwheeldon@engr.ucr.edu

New in 2019. A small number of abstracts will be selected to give short rapid-fire talks within each of the BIOT tracks. Posters will be placed on display during the day and highlighted in the guidebook.