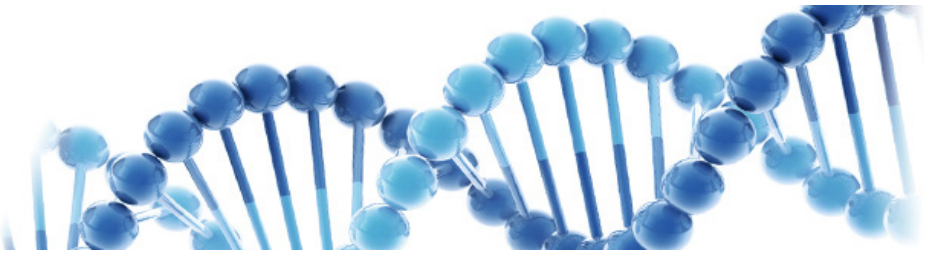
DIVISION OF BIOCHEMICAL TECHNOLOGY
OF THE AMERICAN CHEMICAL SOCIETY

BIOT



Call for Papers

255th ACS National Meeting
March 18-22, 2018, New Orleans, Louisiana

BIOT Program Chairs:
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Abstracts Accepted: August 21, 2017 - October 16, 2017

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

ACS BIOT 2018 PROGRAM

Upstream Processes

- Mammalian Cell Culture and Engineering
- Microbial Metabolic Engineering
- Engineering of Non-Model Systems
- Synthetic Biology
- Systems Biology and Omics Applications
- Engineering Natural Products Biosynthesis
- Microbial Communities and Microbiomes
- General topics

Downstream Processing

- Advances in Chromatographic Separations
- Advances in Non-Chromatographic Separations
- Antibodies, Drug Conjugates and Novel Formats
- Emerging technologies for downstream processing of bionanoparticles
- Automated, high throughput and in silico technologies for DSP Development
- Challenges in Downstream Technology Transfer & Novel Processing Implement.

Biomolecular and Biophysical Processes

- Protein Engineering & Design
- Protein Structure & Function
- Prediction and Characterization of Biophysical Properties of Proteins
- Protein Interactions & Interfaces
- Protein Conjugates and Materials
- Protein Therapeutics: Developability and Manufacturability
- Protein Therapeutics: Formulation and Delivery

Biomedical and Emerging Technologies

- New Tools and Approaches for Cancer Applications
- Stem Cells and Regenerative Medicine
- Innovative Tools and Approaches for Cellular and Microbiome Engineering
- Disease & Biomedical Applications
- New strategies for the delivery of therapeutics: from proteins and genes to cells

End-to-End Biomanufacturing

- Disruptive Bioprocessing and Process Integration
- Scientific Challenges in Production of Biosimilars
- Process Analysis & Control of Product Quality Attributes
- Challenges in Tech Transfer
- Big Data and Knowledge Management
- Automated Technologies and High-Throughput Systems in Biologics Prod.
- Modeling applications for improved process and product design

Food-Energy-Water Nexus

BIOT Tank

Symposium: Upstream Processes

Symposium organizers:

Brian Pfleger	UW-Madison	brian.pfleger@wisc.edu
Peter Russo	Merck	peter.russo@merck.com
Rashmi Kshirsagar	Biogen	rashmi.kshirsagar@biogen.com

Session: Mammalian Cell Culture and Engineering

Session chairs:

Sadettin Ozturk	MassBiologics	s_ozturk@earthlink.net
Anne Tolstrup	Biogen	anne.tolstrup@biogen.com
Yongku Cho	Univ. of Connecticut	cho@uconn.edu
Nitya Jacobs	Amgen	njacob@amgen.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 to obtain highly productive clones, medium and feed development, bioreactor characterization, and process control to optimize conditions for desired productivity and product quality. This session will encompass multiple aspects of mammalian cell culture development, including advances in the development of improved expression vectors, novel clone selection strategies, engineering of host 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 and equipment strategies for ultra-high cell mass and productivity, new technologies to improve and/or characterize process performance, case studies on issues encountered during late stage process development including persistent or newer issues of low productivity, scale-up for commercialization, and management of raw material changes.

Session: Microbial Metabolic Engineering

Session chairs:

Ryan Sillers	Myriant	rsillers@myriant.com
Zhe Rui	REG Life Sciences	Zhe.Rui@regi.com
Kevin Solomon	Purdue University	kvs@purdue.edu
Antonius Van Maris	KTH	tonvm@kth.se

Session description:
Biotechnology and its associated disciplines are the focal point for the design and construction of efficient cell factories for 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 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: Engineering of Non-Model Systems

Session chairs:

John McBride	Lallemand	jmcbride@lallemand.com
Adam Guss	Oak Ridge Nat. Lab	gussam@ornl.gov
Christie Peebles	Colorado State Univ.	christie.peebles@colostate.edu
Zengyi Shao	Iowa State Univ.	zyshao@iastate.edu

Session description:
In the past decade, traditional mammalian and microbial hosts are increasingly being supplanted with non-model hosts such as non-CHO mammalian cell lines, algae, non-*E. coli* bacteria, industrial polyploid *Saccharomyces* strains, non-*Saccharomyces* yeasts, mycelial fungi, and photosynthetic microbes and plants to exploit their unique metabolism and physiology and to enable robust performance under demanding industrial conditions. There are examples of engineering complex post translational modification to enable production of complex proteins in non-model systems. These hosts are being engineered to access new feedstocks like lignocelluosic biomass, syngas, methane, methanol, glycerol, and carbon dioxide (among others) to increase sustainability and 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 non-model hosts.

This session will focus on the recent developments in engineering non-model hosts and development of non-model systems for production of biopharmaceuticals, biofuels, bulk chemicals and value-added specialty chemicals. Relevant topics include molecular and genetic tool development, global pathway engineering, process development, efforts to accelerate design-build-test loops by systematizing workflows, and enablement of better designs through cell-free systems, machine learning and other approaches. We welcome both industrial and academic contributors.

Session: Synthetic Biology

Session chairs:

Yasuo Yoshikuni	Joint Genome Inst.	yyoshikuni@lbl.gov
Thomas Mansell	Iowa State Univ.	mansell@iastate.edu

Session description:
Synthetic biology combines elements of engineering, mathematics, chemistry, and biology to synthesize novel systems from characterized biological components. The rapid progression of this discipline is fueled by recent advances in DNA sequencing and synthesis technologies which have enabled the application of recombinant DNA technologies to large pathways and even genomes in many different organisms. As in other engineering disciplines, synthetic biologists apply fundamental principles of math and science to assemble useful devices and products. Therefore, talks in this session will focus on identifying new biological components and quantitatively characterizing their biochemical or biological function, developing tools for quick assembly of novel systems comprised of biological components, engineering novel systems to solve problems and optimizing the performance of biological systems in the context of an evolving organism.

Session: Systems Biology and Omics Applications

Session chairs:

Chun Chen	Amgen	chunc@amgen.com
Christian Metallo	UC San Diego	cmetallo@ucsd.edu

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 Natural Products Biosynthesis

Session chairs:

Kristy Hawkins	Antheia	kristy.m.hawkins@gmail.com
Mike Smanski	Univ. of Minnesota	smanski@umn.edu

Session description:
Natural products remain an important source of biopharmaceuticals, biochemicals, and biofuels. Advances in bioinformatics-driven gene discovery, protein engineering, and metabolic engineering have continued to stimulate the discovery of complex small molecules. This session will focus on the discovery of novel natural products by genome mining, derivatization of natural scaffolds through combinatorial biosynthesis, and titer improvement through genome engineering or production in a heterologous host.

Session: Microbial Communities and Microbiomes

Session chairs:

Christopher McChalicher	Seres	chrismc@serestherapeutics.com
Cynthia Collins	RPI	ccollins@rpi.edu
Ophelia Venturelli	UW-Madison	venturelli@wisc.edu

Session description:
Microbial communities are ubiquitous in nature and have a wide range of practical applications; including in bio-remediation of toxic organic and inorganic compounds, production of biofuels and chemicals from complex substrates, and as therapeutics to treat disease. Synergistic interactions within microbial communities enable bio-transformations or host-signaling realized by metabolic activities partitioned among distinct populations and integrated into community-level functions and regulatory structures. The collective capabilities of microbial communities can be difficult to predict from isolated analyses of individual participants. The emerging field of synthetic ecology holds promise for the design of communities composed of complementary metabolic capabilities which, in sum, expand the known functional space.

This session invites participants to present efforts to understand the potential of native communities, approaches to engineer component strains and full consortia for improved community-level function during co-culture, and process analytical techniques used to monitor the progress of these heterogeneous systems.

Session: General topics

Session chairs:

Brian Pfleger	UW-Madison	brian.pfleger@wisc.edu
Peter Russo	Merck	peter.russo@merck.com
Rashmi Kshirsagar	Biogen	rashmi.kshirsagar@biogen.com

Session description:
This session will focus on the latest research, development, and future challenges involving the application of experimental or computational tools, novel techniques and principles from engineering, biology and chemistry to key issues in upstream processing. We invite submission of papers that may not clearly fit into the topics described in other upstream processing sessions. Symposium organizers may create additional focused sessions reflecting the content of the proposed papers.

Symposium: Downstream Processing

Symposium organizers:

David Wood	Ohio State Univ.	wood.750@osu.edu
Lars Pampel	Novartis	lars.pampel@novartis.com
Nooshafarin Sanaie	Gilead	Nooshafarin.Sanaie@gilead.com

Session: Advances in Chromatographic Separations

Session chairs:

Chairs: Steve Cramer	RPI	crames@rpi.edu
Jim Neville	Millipore	jim.neville@emdmillipore.com
David Robbins	MedImmune	RobbinsD@medimmune.com

Session description:
The session will examine both practical and theoretical aspects of current chromatographic applications ranging from high throughput screening (HTS) to scale-up and implementation in commercial manufacturing. Topics include the development of novel materials and formats, different processing strategies (e.g. continuous chromatography), examples utilizing process analytical technologies (PAT) to advance separation, advances in tools for high throughput process development (HTPD), process optimization and troubleshooting, advances in scale-up procedures and process scale implementation. Research focusing on mechanistic modeling of chromatographic processing and understanding of molecular-level interactions that govern protein or vaccine adsorption behavior on chromatography surfaces and that combine theory and practice in the above-mentioned topics are strongly encouraged.

Session: Advances in Non-Chromatographic Separations

Session chairs:

David Wood	Ohio State University	wood.750@osu.edu
Rahul Sheth	BioMarin Pharmaceutical	RSheth@bmrn.com
Andrew Zydney	Penn State Univ.	zydney@engr.psu.edu

Session description:
From centrifugation, flocculation, and filtration-based approaches for cell harvest/clarification, to nanofiltration for virus removal, to ultrafiltration for product concentration and final formulation, non-chromatographic separation techniques are essential to manufacturing of all biological products. These techniques enable many key separations required for purification of biomolecules and are being actively studied and improved to meet a higher demand for performance, be it harvesting from higher density cell cultures, improving throughputs of virus retentive filters or integration of unit operations for continuous/semi-continuous manufacturing. In addition, novel ways of using conventional unit operations have shown promise for solving both current and future bioprocessing challenges pertaining to high titer feedstocks and 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 all modes of centrifugation, filtration and membrane processes, aqueous multi-phase partitioning, precipitation, crystallization and polymer-aided flocculation as well as other more exotic bioseparation technologies. Both experimental and modeling submissions are welcome, with priority 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: Antibodies, Drug Conjugates and Novel Formats

Session chairs:

Eric Boder	UT Knoxville	boder@utk.edu
Bramie Lenhoff	Univ. of Delaware	lenhoff@udel.edu
Nooshafarin Sanaie	Gilead	Nooshafarin.sanaie@gilead.com

Session description:
Demand for bringing new and more potent therapeutics to the market has grown substantially in recent years. Since many monoclonal antibodies are not sufficiently potent to be therapeutically active on their own, there have been continued efforts toward coupling proteins with other molecular entities to create more targeted and innovative therapies (i.e. antibody-drug conjugates). Development of other novel biomolecular entities such as Fc – fusion proteins, antibody fragments, bispecific antibodies is also rapidly growing. Recent advances focused on generating these novel formats are constantly demanding more efficient downstream processes in order to handle high titers, highly concentrated process pools, and/or challenging process or product-related impurities.
This session calls for papers focused on new and enhanced downstream processing of antibodies and related molecules, including protein conjugates.
Following topics are particularly encouraged:

(1) Optimization of conjugation chemistry/unit operations, especially to increase the yield of the desired conjugated product
(2) Purification of the conjugation products, while addressing any challenges in removing undesired conjugation byproducts
(3) Creative approaches to handling unstable products or difficult-to-remove impurities
(4) Novel purification strategies for the recovery of modified molecules, especially PEGylated products

Session: Emerging Technologies for Downstream Processing of Bionanoparticles

Session chairs:

Sandeep Kumar	Pfizer	Sandeep.Kumar@pfizer.com
Meisam Bakhshayeshi	Biogen	meisam.bakhshayeshirad@biogen.com
Thomas Linden	Novartis	thomas.linden@novartis.com

Session description:
Viruses, viral vectors, virus like particles, exosomes, cells, synthetic RNA, plasmids, mini-chromosomes, and subcellular fractions are a potential class of very promising biopharmaceuticals often also referred to as bionanoparticles. Downstream processing of these biopharmaceuticals is different from conventional protein biologics with unestablished regulatory framework. These new entities have different size, size distribution, and other biophysical properties compared to proteins. Frequently, in-process control methods are not well established. In this session, strategies for purification of bionanoparticles will be covered. This includes the primary recovery from the culture broth, capture and further purification using chromatography media, membrane filtration, extraction technologies, differential centrifugation, and affinity technologies. In-process control methods will be also discussed and strategies for fast analytics to circumvent time consuming bioassays and imaging methods. We encourage submitting papers on laboratory scale processes, scale up, in-process control, process characterization, computational biophysical modeling, simulations, imaging as well as structural characterization to understand downstream processing of bionanoparticles.

Session: Automated, High Throughput and *in silico* Technologies for DSP Development

Session chairs:

Jan Griesbach	Roche	jan.griesbach@roche.com
Siddharth Parimal	GlaxoSmithKline	siddharth.x.parimal@gsk.com
Jurgen Hubbuch	Karlsruher Inst. for Technol.	Juergen.Hubbuch@kit.edu

Session description:
To align with the QbD (Quality by Design) paradigm and meet the ever-shrinking CMC (Chemistry, Manufacturing and Controls) timelines, biopharmaceutical companies are employing and evaluating various approaches to aid process development activities and gain a 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 other resources. A combination of high throughput methods and DoE (Design of Experiments) can be employed during early and late phase process development (to optimize individual unit operations), as well as during process characterization activities. An alternative methodology, mechanistic modeling of unit operations, which is based on scientific and physical understanding of the process, holds the promise of speeding up process development even further and also increasing process understanding. The tremendous increase in computational resources in the past decade or so has paved the way for development of molecular modeling tools (atomistic as well as coarse-grained) which can complement process understanding gained using experimental approaches. QSPR (Quantitative Structure Property Relations) modeling has been shown to be useful during various process development activities, e.g., resin screening and selection, platform fit assessment, etc. These *in silico* calculations can also be combined with high throughput experimentation, e.g., calibration of parameters for mechanistic models.
The advent of automation, high throughput and *in silico* technologies is believed to be absolutely central to the next great leap in downstream process development. In that spirit, we seek contributions from industry and academia which highlight advances in these fields that are targeted towards better and faster downstream process development.

Session: Challenges in Downstream Technology Transfer and Novel Processing Implementation

Session chairs:

Mark Brower	Merck	mark_brower@merck.com
Ben Roman	Millipore	benjamin.roman@emdmillipore.com

Session description:
While innovation and gains in process efficiency continue to be a focus in progressive downstream process development, suitable scaling methodology and sound technology transfer for implementation and commercialization of such advancements remain an industry need. We invite abstracts that address unique challenges or case studies in these areas and/or provide innovated solutions. These can include approaches with new technologies, innovations leading to increased productivity or reduction in the costs of manufacturing, new fundamental models, adjustments to existing approaches to account for observations made during implementation or general encountered challenges, as well as improvements to process understanding leading to improved regulatory filings. Cases with special consideration for evolving industry challenges, such as disposable technology implementation, local market manufacturing, product comparability challenges, and scaling and implementation of continuous or semi-continuous operations are also welcome.

Submissions to this session will be coordinated with the session titled "Challenges in Tech Transfer" in End-to-End Manufacturing Symposium

Symposium: Biomolecular and Biophysical Processes

Symposium organizers:

Pete Tessier	Univ. of Michigan	ptessier@umich.edu
Erinc Sahin	BMS	Erinc.Sahin@bms.com

Session: Protein Engineering and Design

Session chairs:

Melissa Geddie	Biogen	melissa.geddie@biogen.com
Yongku Cho	UConn	cho@engr.uconn.edu

Session description:
Advances in protein 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, structure-aided protein design, library design, and screening strategies. Combining technologies to develop and advance new scaffolds and platforms will also be of interest.

Session: Protein Structure and Function

Session chairs:

Ronak Shah	BMS	Ronak.Shah@bms.com
Xin Ge	UC Riverside	xge@engr.ucr.edu

Session description:
The physicochemical properties of biomolecules can greatly influence function as well as performance in the context of product development. For instance, conformational stability, molecular patterns of structure, chemistry, viscosity, and phase behavior are tied to the success of a biotechnology product. This session seeks presentations focused on theoretical and/or experimental approaches for predicting and modifying properties relevant to controlling biomolecular and biophysical processes using both native and non-native protein modifications. Properties of interest include but are not limited to: conformational stability and structure, chemical stability, adsorption equilibrium and transport, molecular recognition, membrane filtration, viscosity, solubility, aggregation, immunological and therapeutic properties. Approaches may include but are not limited to sequence alignment, molecular modeling, early stage screening and characterization, non-natural amino acid incorporation, low volume measurements, and others that may be of general interest across biotechnology applications.

Session: Prediction and Characterization of Biophysical Properties of Proteins

Session chairs:

Joseph Perchiacca	Janssen	jperchia@its.jnj.com
Anna Schwendeman	Univ. of Michigan	annaschw@umich.edu
Marcel Ottens	TU Delft	M.Ottens@tudelft.nl

Session description:
The behavior and developability of a protein is greatly guided by the understanding of its biophysical properties. These properties are normally determined through extensive assays and testing. A proper and timely understanding of protein properties necessitates a development of appropriate analytical methods and predictive characterization tools. This session will focus on new or improved technologies to characterize the biophysical properties of proteins, including but not limited to: folding, structure, aggregation propensity, binding affinity and specificity, stability, and solubility. Abstracts describing experimental, computational, or robust empirical approaches to measure, predict, or design protein properties of interest are welcome. Studies that seek to connect 'microscopic' molecular properties computed from atomistic or coarse-grained molecular models to the 'macroscopic' biophysical measurements performed on macromolecular solutions are particularly encouraged.

Session: Protein Interactions & Interfaces

Session chairs:

Will Weiss	Eli Lilly	weiss_william_f_iv@lilly.com
Hadley Sikes	MIT	sikes@mit.edu
Daniel Bracewell	Univ. College London	d.bracewell@ucl.ac.uk

Session description:
Understanding and mediating the interaction of proteins and cells in near surface environments is a critical challenge in many areas. For example, the efficacy and safety of protein-based vaccines, the sensitivity and specificity of biosensors, sorption events during bioprocessing and the biological response of implantable scaffolds may all be significantly impacted by the protein and cell-surface interactions. This session will focus on the development and use of biophysical as well as computational approaches to elucidate protein-surface and cell-surface interactions. Of particular interest are approaches that lead to a fundamental understanding of protein and cell adhesion to surfaces as well as surface-induced protein unfolding. Additionally, the development of novel methods and surface modifications to control the interaction of proteins and cells with materials and promote the retention of protein structure and function are also of interest.

Session: Protein Conjugates and Materials

Session chairs:

Bahar Demirdirek	BMS	Bahar.Demirdirek@bms.com
Greg Thurber	Univ of Michigan	gthurber@umich.edu

Session description:
Effective chemical conjugation strategies are leading to the development of protein conjugates and materials with uses in areas ranging from therapeutics and diagnostics to bioenergy, industrial catalysis, and responsive materials. This session focuses on the discovery, synthesis, modeling, characterization, and application of these molecules, nanoparticles, and materials. Examples of structures of interest include, but are not limited to, protein-small molecule conjugates (e.g. antibody-drug conjugates), cyclized peptides, protein-polymer or protein-nanoparticle conjugates, and macroscopic materials that incorporate a protein component. Ongoing challenges in the development of these structures are the high throughput identification of promising conjugates and/or the elucidation of structure-function relationships enabling the de novo design of structures with desired properties. Preference will be given to abstracts describing original approaches for the identification of therapeutic or diagnostic leads, creative new approaches to the synthesis of well-defined conjugates, or the compelling application of conjugates and materials in settings of health, materials or energy.

Session: Protein Therapeutics: Developability and Manufacturability

Session chairs:

Mary Krause	BMS	Mary.Krause@bms.com
James Van Deventer	Tufts	james.van_deventer@tufts.edu

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 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, 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 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 Therapeutics: Formulation and Delivery

Session chairs:

Shantanu Sule	Eli Lilly	shantanu.sule@lilly.com
Eric Furst	University of Delaware	furst@udel.edu
Juergen Hubbuch	KIT	juergen.hubbuch@kit.edu

Session description:
Novel drug delivery and controlled released strategies are evolving across the industry in response to unique challenges with pharmacokinetics, pharmacodynamics, efficacy and safety of biopharmaceuticals. In recent years, development of biotherapeutic drug products has advanced to include antibodies, a huge variety of next generation formats, antibody drug conjugates, and formats on the basis of proteins, peptides, and oligonucleotides. Delivery of these biomolecules can add an extra layer of complexity as compared to small-molecule counterparts, as biomolecules are often more sensitive to their environment, both before administration and once inside the body. This session invites presentations related to issues connected to formulation strategies of novel formats, innovative drug delivery and controlled release strategies and technologies, including nanoparticles, liposomes, hydrogels, as well as unique formulation approaches. The session also invites presentations on new progress in understanding bioavailability of large molecule therapeutics via subcutaneous delivery, new approaches for enhancing bioavailability, strategies for minimizing immunogenicity and advancements with *in vitro* and *in vivo* immunogenicity assays. Discussions of targeted delivery systems, as well as novel pulmonary and ocular technologies are also welcomed. Finally, the session also invites and hopes to share lessons learned in clinical and commercial formulation development of liposomes, nanoparticles, bispecific antibodies, antibody-drug conjugates, fusion proteins, oligonucleotides, regenerative medicine, gene therapy and cell therapy

Symposium: Biomedical and Emerging Technologies

Symposium organizers:

April Kloxin	Univ. of Delaware	akloxin@UDel.Edu
John Pieracci	Biogen	john.pieracci@biogen.com
Aaron Noyes	Codiak BioSciences	aaron.noyes@codiakbio.com

Session: New Tools and Approaches for Cancer Applications

Session chairs:

Jamie Spangler	Johns Hopkins	jamie.spangler@jhu.edu
Austin Boesch	Torque Therapeutics	austin@torque.email

Session description:
New tools for studying and treating cancer are critical for continued progress in the field. This session will encompass a variety of innovative methods and approaches in cancer applications, including research in model systems, detection, biomarkers and bioinformatics tools, targeted delivery, and immunotherapies.

Session: Stem Cells and Regenerative Medicine

Session chairs:

John Kim	Unvi. of Alabama	ykim@eng.ua.edu
Mike Kuczewski	Bluebird Bio	mkuczewski@bluebirdbio.com

Session description:
A substantial amount of effort in biotechnology research is focused on improving methods to culture, expand, and utilize various types of stem cells for numerous in vitro and in vivo applications, including the engineering of tissues and the delivery or directing of stem cells for therapeutic, regenerative medicine, and disease modeling applications. This session will focus on new enabling technologies for stem cell and tissue engineering. Topics will include, but are not limited to i) engineered biomaterials to promote the growth, patterning, and three dimensional culture of stem cells or tissue engineering constructs, ii) novel technologies to de novo engineer tissues, organs or bioreactor systems to provide controllable and reproducible culture environments, iii) systems to modify the genetic programming of the cell iv) biomimetic culture systems to study stem cell biology, and v) applications to expand and differentiate cells along tissue specific lineages, novel biomimetic platforms (e.g., chip based) for drug screening, transplantation methods, in vitro disease models, and new therapeutic applications of stem cells and engineered tissues.

Session: Innovative Tools and Approaches for Cellular and Microbiome Engineering

Session chairs:

Nikhil Nair	Tufts Univ.	nikhil.nair@tufts.edu
Aaron Noyes	Codiak BioSciences	aaron.noyes@codiakbio.com
April Kloxin	Univ. of Delaware	akloxin@UDel.Edu

Session description:
This session will focus on emerging technologies used for the engineering of cells and their interaction in the context of a community for various biotechnological applications. 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, cellular reprogramming, genetic circuit design, signal transduction, cell-cell communication, host-pathogen interaction and evolution. Of particular interest are efforts in studying and designing microbiome to realize complex and sophisticated cellular functions and provide extra gains in design efficiency and execution of bioengineering solutions.

Session: Disease & Biomedical Applications

Session chairs:

Hadley Sikes	MIT	sikes@mit.edu
Julie Albert	Tulane Univ.	jalbert6@tulane.edu

Session description:
This session will broadly focus on experimental and computational approaches to develop biomedically relevant molecules, tools, devices, and model systems and to analyze the tissue, cell, and molecular features that characterize disease and other biological processes. Topics will include, but are not limited to, the creation and utilization of biomaterials, in vitro disease models, engineered cell lines, and unique analytical-, imaging-, and bioinformatics-based tools to investigate complex and progressive illnesses.

Session: New Strategies for the Delivery of Therapeutics: From Proteins and Genes to Cells

Session chairs:

John Pieracci	Biogen	john.pieracci@biogen.com
Prabodhika Mallikaratchy	Lehman College	PRABODHIKA.MALLIKARATCHY@lehman.cuny.edu

Session description:
Targeted delivery is critically important in improving the therapeutic index of therapeutic medicines. Many new classes of molecules, including genes, proteins, cells and nano-materials such as liposomes and lipid nanoparticles are being developed to improve targeted delivery. The session will introduce novel delivery strategies currently being introduced from academic research groups and industrial research and development groups. The topics will include advances in gene therapy, discovery of novel targeting synthetic ligands such as aptamers, cell therapies, design of delivery vehicles, controlled release, re-dosing, and precision medicine. Abstracts are welcome that discuss the production, purification and formulation of these novel classes of therapeutic modalities.

Symposium: End-to-End Biomanufacturing

Symposium organizers:

Sarah Harcum	Clemson Univ.	HARCUM@clemson.edu
Venkatesh Natarajan	Biogen	venkatesh.natarajan@biogen.com
Nitin Rathore	Amgen	nrathore@amgen.com
Scott Tobler	Merck	scott_tobler@merck.com

Session: Disruptive Bioprocessing and Process Integration

Session chairs:

Art Hewig	Amgen	hewiga@amgen.com
Abraham Lenhoff	Univ. of Delaware	lenhoff@udel.edu
Matt Westoby	Biogen	matthew.westoby@biogen.com

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. The choice has often been to defer to the 'known' and established platform approach rather than risk potential upset during the regulatory approval process. Conversely, cost and timeline pressures motivate process development scientists and researchers – both industrial and academic – to find innovative and/or disruptive ways to produce consistent, high-quality proteins in manufacturing processes with a significant reduction in development timelines. Recent advances in targeted integration, process intensification, innovative facility designs, advanced process control, integrated continuous bioprocessing and single-use systems – among others – have enabled this new wave of innovation in process/facility design and process integration. In this session, presentations that cover the development, scale-up, and successful implementation of disruptive technologies in drug substance and drug product processes as well as new facility design concepts based on modular and reduced foot print setups are solicited. Case studies showcasing use of such technologies to accelerate development, to reduce the cost or to improve the quality of the product are especially encouraged. The development of continuous processes or connected process steps that enable straight-through processing are relevant. Presentations that challenge the need for disruptive change to established upstream, downstream and drug product processes are also encouraged.

Session: Scientific Challenges in Production of Biosimilars

Session chairs:

Tim Iskra	Pfizer	timothy.iskra@pfizer.com
Chakradhar Padala	Amgen	cpadala@amgen.com

Session description:
As noted in FDA guidance, the manufacturer of a proposed biosimilar product will likely have a different manufacturing process from that of the reference product and no direct knowledge of the manufacturing process for the reference product. Additionally, the biosimilar formulation may not match that of the reference product, yet the analytical methods must be developed to enable demonstration of "finger-print like similarity". The development of these manufacturing processes, formulations and analytical methods each present many challenges. This session will explore these challenges. Examples and case studies discussing strategies used in the development of biosimilar processes, formulations and analytics are requested. Some questions that are of interest:

- What points are considered in developing the Quality Target Product Profile of the intended biosimilar?
- What are the considerations when choosing a platform host cell line versus matching the host cell line used by the reference product?
- What tools have been used in cell line selection and cell culture process design to target difficult-to-match product quality attributes?
- How much is the upstream process relied upon to meet product quality endpoints versus using the downstream process to dial in certain attributes?
- Where have downstream platforms been able to meet the needs of a biosimilar manufacturing process? Where have deviations from platforms been required?
- What are the considerations when choosing to match the reference product formulation versus developing a new formulation?
- Are there any considerations for selecting the appropriate drug product filling technologies, or lyophilization cycles to match the attribute profile for the reference product?
- Where has the analytical toolbox needed to be expanded in order to meet the needs of a similarity assessment?
- How has reference product from different ICH regions, and the different presentations, been combined in the biosimilarity, prospective and side-by-side analyses?
- What is the relative significance of structure-functions studies in the biosimilarity package?
- Are there any scientific challenges encountered during the biosimilar marketing application regulatory review process that triggered redevelopment or required process/formulation changes?
- What statistical approaches have been used to establish similarity? Are covariate analyses applied to establish equivalence?

Session: Process Analysis & Control of Product Quality Attributes

Session chairs:

Greg Hiller	Pfizer	Gregory.hiller@pfizer.com
Canping Jiang	Biogen	canping.jiang@biogen.com
Pete Tessier	Univ. of Michigan	ptessier@umich.edu

Session description:
This session will focus on new methods to control drug substance or drug product critical quality attributes (CQAs). Such methods might include cell line engineering, raw material controls, process design or process controls or other innovations. Presentations that describe 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. Additional relevant topics might include the description of rationales for the selection of CQAs for drug substance and drug product processes, and methodologies for integrated control strategies which leverage enhanced product understanding for manufacturing process optimization or in regulatory submissions. This session will also include innovations in process analytical technology (PAT) tools and implementation of these tools into manufacturing processes to enable real-time control of CQAs.

Session: Challenges in Tech Transfer

Session chairs:

Paul Lewus	Amgen	plewus@amgen.com
John Erickson	GSK	john.c.erickson@gsk.com

Session description:
When transferring biotechnological processes to manufacturing facilities, the scaling and facility fit of unit operations into the facility is not always obvious and straightforward. Assuring successful implementation can require new approaches to scaling and/or modeling to gain additional insight in comparison to traditional approaches - particularly for cases where challenges related to scaling and facility fit were observed and novel solutions were required to drive successful implementation. Case studies covering adoption of new paradigms (including an increased reliance on single-use technologies) with a focus on increased commercial robustness and/or design space, as well as productivity increases and/or cost reduction through innovation are encouraged. Abstracts that highlight recent trends and areas of key focus during health authority review are relevant, including abstracts that cover technology transfer and product comparability challenges and how they were addressed. We would like to have papers covering upstream, downstream, and fill/finish tech transfer.

- Fitting of process to the facility (existing facility, facility design)
- Process modelling to predict and avoid tech. transfer problems
- Includes scale/up principles, and how differences in equipment or fit lead to different behaviors
- Challenges seen when process does not run as planned
- Instituting an appropriate control strategy, based on process knowledge
- Traditional vs emerging technologies (eg, single use, continuous manufacturing)
- Validation and comparability challenges (eg, leachables, CPV, site to site)
- Integration of analytics with process for product attribute control and real-time release

Submissions to this session will be coordinated with the session titled "Challenges in Downstream Technology Transfer and Novel Processing Implementation" in the Downstream Area

Session: Big Data and Knowledge Management

Session chairs:

Mohan Boggara	Amgan	mboggara@amgen.com
Scott Tobler	Merck	scott_tobler@merck.com

Session description:
With ever increasing availability of datasets in biomanufacturing spanning one or more aspects of “Big data” [velocity, variety, volume, veracity and value], it is becoming imperative to be able to analyze and extract valuable information for better understanding, decision making and control of complex processes. Such big data scenarios coupled with sophisticated computational analyses might reveal patterns that are otherwise difficult to intuit. This session encourages presentations focused on the application of data science to problems in biomanufacturing (including product discovery, upstream, downstream, formulation and drug product process development, and quality control). Presentations describing computational analyses, hybrid approaches combining big data analytics with first principles modeling or tools, techniques, and infrastructure for collecting isolated datasets into "big data" (and for processing those datasets) are encouraged. New approaches including data analytical predictive technologies from big data domain including electronic data transfer with suppliers, data standardization, and systematic data collection for component traceability and monitoring towards controlling raw material variability are also in scope.

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

Session chairs:

Jennifer Pollard	Merck	Jennifer_pollard@merck.com
Marcel Ottens	TU Delft	M.Ottens@tudelft.nl

Session description:
Automation has the potential to accelerate discovery of lead candidate biologics through realizing greater efficiencies, reduced timeframes and reductions in human error. In addition, timeline pressures due to intense competition require automation to develop well-characterized, scalable manufacturing processes for high-quality biotherapeutics.

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 (ii) integration of online 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 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: Modeling Applications for Improved Process and Product Design

Session chairs:

David Roush	Merck	david_roush@merck.com
Todd Przybycien	Carnegie Mellon Unvi.	todd@andrew.cmu.edu

Session description:
The complexity and diversity of molecules derived from bioprocessing (e.g. proteins, vaccines, cellular therapies and oligonucleotides) present an exquisitely challenging multifactorial problem. In this context, modeling that leverages first principles including mechanistic and computational biophysics can have a direct impact on process robustness and productivity. Specifically, mechanistic and computational biophysics modeling, independently or in tandem, can provide fundamental insights into the underlying processes (ex. protein/resin interactions) translating into increased productivity/efficiency of processes and a reduction in the requisite experimental requirements for development of a robust process.

The session focuses on modeling unit operations independently or concatenated to achieve process sequences or entire processes. Applications that leverage first principles or a mechanistic description of processes or product (ex. impact of mass transfer and diffusion in chromatography columns including scale-down, impact of shear of product quality) to support initial development or improvement robustness or efficiency of drug substance process or drug product design are specifically requested. Presentations that describe fundamental advancements in unit operation 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.

Symposium: BIOT Tank

Symposium organizers:

Mike Lynch	Duke University	michael.lynch@duke.edu
Varnika Roy	GSK	varnika.roy@gmail.com

Session: BIOT Tank

Session chairs:

Glen Bolton	Amgen	gbolton@amgen.com
Michael Laska		

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” type competition. Entrepreneurs are invited to give technical details of their company's core technologies as well as share their value proposition and rationale for their business model. Technology sectors will include, but are not limited to, diagnostics, medical devices, biologics and therapeutics, personized medicine, upstream and downstream bioprocessing, modeling software, process analytical technologies, and drug delivery systems. There will be awards including at least a $4000 for the first prize – awarded by the judges and a $1000- audience choice award selected by live voting using the web app. 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 2017 ACS BIOT conference was attended by over 100 scientists, entrepreneurs, venture capitalists, and angel group members, 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.

Entrepreneurs are encouraged 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: Food-Energy-Water Nexus

Symposium organizers:

Sharon Shoemaker	UC Davis	spshoemaker@ucdavis.edu
Maciek Antoniewicz	University of Delaware	mranton@udel.edu

Symposium: BIOT Poster Session

Symposium organizers:

Mark Blenner	Clemson University	blenner@clemson.edu
Nigel Reuel	Iowa State University	reuel@iastate.edu