Call for Papers

259th ACS National Meeting
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BIOT Program Chairs:
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Abstracts Accepted: August 12, 2019 - October 14, 2019

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

ACS BIOT 2020 PRELIMINARY PROGRAM

Note: This year, we are allowing the session chairs to create innovative session topics based on the abstract submissions received in general topics in each of the BIOT areas.

Upstream Processing

- Mammalian Cell Culture
- Microbial Metabolic & Bioprocess Engineering
- Systems Biology, Synthetic Biology & Emerging Technologies

Downstream Processing

- Chromatographic Separations
- Non-Chromatographic Separations
- Disruptive, Continuous & Integrated Downstream Processing
- Purification of Novel Modalities

Biomedical Technologies

- Cellular & Microbiome Engineering
- Precision Medicine, Bionanotech & Drug Delivery / Targeting
- Development & Manufacturing of Gene & Cell Therapies
- Regulatory Perspective & Analytical Assays for Gene & Cell Therapy

Biomolecular Technologies

- Protein Engineering, Bispecifics & Conjugates
- Protein Structure/Function, Stability & Developability
- Drug Delivery & Biotherapeutics Formulation

End-to-End Biomanufacturing

- Manufacturing Process Integration
- Manufacturing Beyond mAbs
- Process Scale Up/Down/Out & Characterization
- Continuous Manufacturing & Process Intensification

BIOT Interfaces

- Sustainability in Bioprocessing
- Making Use of Big Data & Modeling
- New Therapeutic Modalities: Impact on Manufacturing Paradigms
- Chemical Biology Across Process Development
- Bridging the Gaps in Process Development
- Emerging BIOT Leaders
- Emerging BIOT Research Areas

BIOT Poster Session

BIOT Tank

Symposium: Upstream Processes

Symposium organizers:

Nitya Jacob	Amgen	njacob@amgen.com
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Kevin Solomon	Purdue University	kvs@purdue.edu

Upstream Processes: Mammalian Cell Culture

Session Chairs:

John Blazeck	Georgia Tech	john.blazeck@chbe.gatech.edu
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Arnab Mukherjee	UCSB	arnabm@engineering.ucsb.edu
Vijay Janakiraman	Merck	vijay.janakiraman@merck.com
Lesley Chang	Bluebird Bio	LChan@bluebirdbio.com

Topic Description:

Mammalian cell culture and cellular engineering techniques have emerged as core sectors of biotechnology, wherein cells are harnessed to produce recombinant therapeutic proteins (*e.g.*monoclonal antibodies, bispecific antibodies), vaccines, and cell-based therapies. These advances are due largely to transformative technologies, which have drastically accelerated design/build/test cycles for mammalian cell engineering and enabled efficient and scalable biomanufacturing using engineered cells. These technologies include rational design, directed evolution, genome editing, omics methods, mechanistic modeling, scale-up and scale-down models, cell line development, process design, optimization and intensification, high-throughput screening techniques, and tissue microenvironment engineering. Talks in this session will focus on the utilization of traditional as well as novel technologies that enhance capacity to design, engineer or screen mammalian cells for the production and characterization of biotherapeutics in traditional biopharma settings, as well as engineered immune cells and other cell-based therapies, tissue analogs for regenerative medicine, vaccines, gene therapy vectors, antibodies, and other recombinant proteins. Talks on biosimilar development, as well as approaches for speed to clinic, speed to market and control strategy development are also of interest.

Upstream Processes: Microbial Metabolic & Bioprocess Engineering

Session Chairs:

Aindrila Mukhopadhyay	JBEI	amukhopadhyay@lbl.gov
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Andrew Yongky	BMS	Andrew.yongky@bms.com
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Christine Santos	Manus Bio	csantos@manusbio.com

Topic 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, fuels, and biological products. Metabolic engineering aims to develop strategies to analyze and engineer cell factories using modern synthetic biology tools and to design 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 may include metabolic pathway engineering, metabolic engineering for mammalian cell culture bioprocesses, design and engineering of microbial whole-cell biocatalysts, non-model microbial systems, consortium engineering, mathematical modeling of metabolic networks, and bioreactor engineering. These advances are applied to broad applications such as biofuels, biochemicals, pharmaceuticals, and more.

Upstream Processes: Systems Biology, Synthetic Biology & Emerging Technologies

Session Chairs:

Nathan Crook	NC State University	nccrook@ncsu.edu
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Topic Description:

Systems and synthetic biology have revolutionized our ability to understand and control biological systems by employing a rapid design-build-test-learn cycle, with the ultimate goals of parallelization, automation, and model-based design. This paradigm has been applied across scales ranging from single molecules, cell-free systems, living cells, and interspecies communities, both enabled by and enabling the development of new techniques for manipulating biology. These technologies include ‘omics methods that identify and quantify biological parts, mechanistic modeling techniques for predicting phenotypes, genome editing approaches for implementing designs, tools for high throughput design and screening of genetic parts and genome designs, and machine learning approaches to parse the resulting high-dimensional datasets. Talks in this session will highlight recent advances in the use of systems and synthetic biology across scales and domains of life, as well as methodological advances in our ability to design, build, test, and learn. Topics of interest include, but are not limited to, techniques for identifying engineering targets through omics and screening methods, high throughput technologies, tools for building traits via genome editing or synthesis, automation advances, computational strategies and simulation or machine learning strategies which enable predictive design and development.

Symposium: Downstream Processes

Symposium organizers:

Jennifer Pollard	Merck	jennifer_pollard@merck.com
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John Pieracci	Biogen	john.pieracci@biogen.com

Downstream Processes: Chromatographic Separations

Session chairs:

Jim Neville	Millipore Sigma	jim.neville@milliporesigma.com
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Abhijit Shirke	Teva Pharmaceuticals	abhijit.shirke@tevapharm.com
Steven Evans	MedImmune	evanss@medimmune.com

Session description:

The session will examine both empirical and theoretical aspects of chromatographic separations. Topics may include novel materials, new formats, ligand development, utilization of process analytical technologies (PAT), advances in tools for high throughput process development (HTPD), process optimization, process troubleshooting, advances in scale-up procedures, and process scale implementation. Submissions may cover the application of these topics at various scales (*e.g.*, small-scale, bench scale, and up to commercial manufacturing). Research focusing on mechanistic modeling of chromatographic processing is encouraged (*e.g.*, research that aims to understand molecular-level interactions that govern protein/vaccine adsorption behavior on chromatographic surfaces, research that combines theory and practice in the above-mentioned topics, *in-silico* methods to achieve improved process optimization, robustness, or characterization).

Downstream Processes: Non-Chromatographic Separations

Session chairs:

Akshat Gupta	MilliporeSigma	akshat.gupta@milliporesigma.com
Alejandro Becerra	Thermo Fisher Scientific	alejandro.becerra@thermofisher.com
David Latulippe	McMaster University	latulippe@mcmaster.ca
Meisam Bakhshayeshirad	Biogen	meisam.bakhshayeshirad@biogen.com
Stefano Menegatti	NC State University	stefano.menegatti@gmail.com

Session description:

Non-chromatographic separation methods are critical components of biopharmaceutical purification processes. These techniques complement the chromatographic separation methods utilized in the purification of a broad spectrum of therapeutic biomolecules and include flocculation, centrifugation, and the entire ‘spectrum’ of membrane filtration processes (e.g. depth filtration, microfiltration, ultrafiltration). The active research in both academia and industry is developing a better understanding of the fundamental mechanisms associated with these separation methods and further improving the efficiency and productivity of associated unit operations. Some of the key challenges in recent years include harvesting of high cell density cultures, developing effective clarification and purification methods for novel modalities as well as scale down models, and integrating high throughput screening methods for accurate and robust process development. Integrated and continuous processing techniques as well as the development of disruptive technologies have also gained significant interest. This session seeks to disseminate the recent advances in all these research areas. Unit operations of interest include the more traditional processes (e.g. flocculation, centrifugation, membrane filtration), less traditional processes (e.g. aqueous multi-phase partitioning, precipitation), as well as novel technologies. Submissions involving case-studies of integrated processes for non-chromatographic separations are particularly welcome. 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.

Downstream Processing: Disruptive, Continuous & Integrated Downstream Processing

Session chairs:

Nooshie Sanaie	Kite Biopharma	nasnaie@kitepharma.com
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Engin Ayturk	Mersana Therapeutics	eayturk@mersana.com
Mark Brower	Merck	mark_brower@merck.com
Hailey Yuan	Pfizer	hailey.yuan@pfizer.com

Session description:

Gains in process intensification, reduction in Cost of Goods and speed to clinic/market, continue to be the dominant driving force behind downstream bioprocess innovation. To achieve efficiencies in these areas, the industry is undertaking an array of valiant efforts and gaining a tremendous momentum for the development and adoption of disruptive, continuous and integrated downstream technologies that offer the promise to leapfrog our industry to the next level.

In this session, we would like to explore the next generation of disruptive tools in addition to advances in continuous and integrated downstream bioprocessing. This session would encompass the entire spectrum from early phase process development to late stage process characterization, technology transfer, and regulatory filing. Furthermore, we solicit papers that demonstrate the development, scale-up, and successful implementation of disruptive technologies. Papers that challenge the need for disruptive change to established downstream processes by leveraging novel process intensification approaches are also encouraged. Non-traditional processes that utilize innovative technologies, such as novel chromatographic supports and scaffolds, crystallization, precipitation, extraction, selective affinity tags and state-of-the-art purification or process analytical technologies (PAT), along with novel high throughput development and mechanistic modeling strategies, are welcome. We invite the submission of abstracts that address these questions comprehensively, i.e. as case studies that highlight the problem, the science behind the solution, and the implementation into practice.

Downstream Processes: Purification of Novel Modalities

Session chairs:

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Raymond Bourdeau	Codiak Bio	raymond.bourdeau@codiakbio.com

Session description:

The focus of this session is the purification of biopharmaceutical drug substances including viruses, virus-like particles, live virus vaccines, recombinant and conjugate vaccines, whole cells or subcellular fractions, exosomes, DNA, RNA, or other novel therapeutics. These modalities offer challenges related to their size, heterogeneity, and multi-component complexity. Additionally, they often require the development of fit for purpose control strategies and insightful and robust analytics. This session will cover strategies for the purification of these therapeutics using methodologies such as chromatography, membrane filtration, extraction technologies, centrifugation, and other novel technologies. In-process control methods and analytical strategies will be also discussed. We encourage submitting papers on laboratory scale methods, high throughput development or modeling,scale up, in-process control, and structural characterization to better understand the purification of novel therapeutic modalities.

Symposium: Biomedical Technologies

Symposium organizers:

Nooshie Sanaie	Kite Pharmaceutical	nsanaie@kitepharma.com
Jonathan Royce	Vironova	jonathan.royce@vironova.com
John Kim	Alabama	ykim@eng.ua.edu

Biomedical Technologies: Cellular & Microbiome Engineering

Session chairs:

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Ali Harandi	U. of Gothenburg	ali.harandi@microbio.gu.se
Tom Mansell	Iowa State	mansell@iastate.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.

Biomedical Technologies: Precision Medicine, Bionanotech & Drug Delivery / Targeting

Session chairs:

Christopher Canova	Janssen	canova.chris@gmail.com
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Allan David	Auburn	aed0022@auburn.edu

Session Description:

As the fundamental knowledge of human biology deepens and broadens, new technologies are being developed to combat diseases with increased precision and effectiveness. This session will focus on innovative technologies in industry and academia for treating cancer, understanding and employing bionanotechnology, and delivering and targeting new therapeutics. Both experimental and computational approaches are of interest for this session.

Recent biomedical advances have enabled the development of technologies for understanding, detecting and treating human cancers. This session will focus on recent developments in: (i) cancer diagnostics and therapy; (ii) imaging, (iii) delivery systems, (iv) biomarkers, (v) culture systems to model and study cancer progression, (vi) omics methods, and (vii) precision medicine in cancer treatment.

Bionanotechnology is a field of study that sits at the intersection of nanotechnology and biology. This session will focus on recent developments in: (i) advancing human health with nanotechnology; (ii) advanced imaging of biological systems; (iii) self-assembly of nano-sized building blocks to generate materials with specific functions; (iv) design of nanomaterials that support or regulate biological function; and (v) biomimetic and biohybrid nanomaterials.

Novel modalities such as, but not limited to, antibody-drug conjugates, nucleic acids, and cell and gene therapies are showing therapeutic promise. Biopharmaceuticals are also benefiting from the advent of CRISPR, the use of transposons or exosomes for delivery, and 3D printing for organoids and regenerative medicine. Many of these new therapeutic modalities are aided by targeted delivery approaches that improve the delivery of the therapy to the target tissue. Submissions related to the production, delivery, characterization, purification, and/or formulation of new and innovative modalities are encouraged. Relevance and novelty will be the key decisive criteria.

Biomedical Technologies: Development & Manufacturing of Gene & Cell Therapies

Session chairs:

Susan D'Costa	Brammer Bio	Susan.dcosta@brammerbio.com
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Session description:

Gene and cell therapies have significant relevance and increasing momentum in the pharmaceutical industry as of late. Cells as medicinal agents for immuno-oncology (CAR-T, TCR-T, NK-T, etc.) and rare diseases (modified HSCs, fibroblasts etc.) are being used as viable and effective treatments for a wide array of diseases. Viral vectors and other gene editing techniques are critical raw materials for these cell therapies as well as being products in their own right for in vivo gene therapies. These therapies are relatively new to the biopharmaceutical manufacturing industry and are complex, multi-stage and personalized processes that present many new product and process challenges as compared with more established biologic therapeutics.

This call for papers focuses on the development and production of gene and cell therapies, in its various forms, from both academia and industry, starting from the R&D of new technologies up through the implementation of commercial manufacturing processes. The session organizers wish to include abstracts covering numerous aspects of this field, topics to include but not limited to:

● Vector Design and Engineering
● Gene Editing Techniques
● Upstream/Downstream Production Systems
● Drug Product Sciences
● cGMP Manufacturing (i.e. designing multi-product facilities, automation and equipment design, scale-up/scale-out of processes)
● Characterization of Critical Raw Materials (i.e. vector quality, patient/donor cell characteristics)
● Development of Allogeneic Cell Lines
● Cellular Switches to Modulate Therapeutic Response (i.e. excessive cytokine release)

With the number of commercial launches approaching, ongoing clinical trials, growing involvement from larger companies, increasing industrial collaborations with academia, and continual formation of new start-ups, cell and gene therapies are set to be a major player and potential game changer for 21st century medicine.

Biomedical Technologies: Regulatory Perspectives & Analytical Assays for Gene & Cell Therapy

Session Chairs:

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In Hong Yang	UNC Charlotte	InHong.Yang@uncc.edu

Session Description:

Cell and gene therapies have become a reality in the health care system in difficult to treat diseases in the areas of genetic disorders, regenerative medicine and immune oncology indications. Since the commercial approvals of CAR T cell therapies (Kymriah and Yescarta) in 2017, there have been extraordinary efforts and resources poured into the cell and gene therapy sector. Many of the new cell and gene therapies are in late stage clinical development and poised to reach patients in the marketplace. Despite the recent successes, cell and gene therapy fields still face many challenges on multiple fronts such as complex manufacturing process control to produce a consistent, safe and potent product; robust analytical test methods used for product characterization, in-process and lot release testing; cold-chain supply controls, clinical protocol designs for rare disease indications; and cost of good containment.

Symposium: Biomolecular Technologies

Symposium organizers:

Mary Krause	BMS	mary.krause@bms.com
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Biomolecular Technologies: Protein Engineering, Bispecifics & Conjugates

Session chairs:

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Aditya Kunjapur	Delaware	aditya.kunjapur@udel.edu
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Qing Sun	Texas A&M	sunqing@tamu.edu

Session description:

The size and flexibility in protein design provides virtually limitless potential in generating unique compounds. These capabilities continue to expand beyond known protein structures such as antibodies to alternative formats, bispecifics, and conjugates to other protein domains, enzymes, small molecule drugs, and polymers. The challenge is identifying the appropriate molecular format and engineering the desired properties into the molecule. Novel designs and new protein engineering strategies are facilitating this process and are the subject of the sessions in this area.
Topics for these sessions include (but are not limited to): protein drug discovery, new design strategies for challenging targets, enzyme engineering, engineering multivalent interactions such as cellular interactions (bispecific T-cell engagers, immunocytokines, cell-scaffold interactions for tissue engineering), discovery of therapeutics with unique mechanisms of action (e.g. inducing conformational changes in their target), strategies to incorporate desirable properties early in screening, the use of non-standard amino acids either in protein design or for bioconjugation, programmable protein functions (e.g. multiplexed function regulation), development of non-antibody scaffolds, and vaccine and immunogen design. The development of unique conjugates, such as antibody-protein fusions, cyclized peptides, antibody drug conjugates, and macroscopic materials that incorporate proteins are also welcome. New tools that aid with these processes, such as machine learning, structure-aided protein design, advancements in Next-Gen sequencing and screening strategies will also be covered in these sessions.

Biomolecular Technologies: Protein Structure/Function, Stability & Developability

Session chairs:

Dorina Saro	Janssen	dasro@its.jnj.com
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Lawrence Stern	South Florida	stern167@umn.edu
Yongku Cho	UConn	cho@uconn.edu

Session description:

Protein therapeutics cover a wide range of molecular formats, including antibodies, proteins with enzymatic or regulatory activities, vaccines, and protein-based diagnostic agents. They comprise a significant and growing toolbox for the study and treatment of disease in almost every area of medicine. A deep understanding of the structure and characteristics of biomolecular technologies and how these modulate function is key to successful development of a biologic drug product. However, the properties of these molecules needed to succeed in clinical settings extend far beyond simple binding or enzymatic activities to include characteristics such as aggregation propensity, producibility, nonspecific binding, immunogenicity, and biodistribution/clearance profile. Sessions in this category will broadly relate to characterization of protein structure and function, as well as stability and developability of biotherapeutics. Areas include (but are not limited to) protein structure, protein structure/function relationships, protein-protein interactions, protein stability, characterization methods, biodistribution optimization, and developability/manufacturability of biotherapeutics.

Biomolecular Technologies: Drug Delivery & Biotherapeutics Formulation

Session chairs:

Shannon Servoss	Arkansas	sservoss@uark.edu
Yuan Chen	Regeneron	yuan.cheng@regeneron.com
Ian Shieh	Genentech	shieh.ian@gene.com
Jim Van Deventer	Tufts	james.van_deventer@tufts.edu
Catherine Fromen	Delaware	cfromen@udel.edu

Session description:

The favorable properties of biotherapeutics has resulted in tremendous growth within the pharmaceutical industry and supplanted small molecule drugs in terms of top 10 blockbuster agents. However, given their large size and unique characteristics, delivery of these agents from the site of administration to the site of action can be a significant challenge. Even prior to administration, the formulation of the drugs can be important to ensure the quality of the product by the time it reaches the patient. Fortunately, novel solutions to these challenges are actively being developed. Sessions in this category will broadly relate to the formulation and drug delivery strategies for biotherapeutics. Areas include (but are not limited to) protein stability/formulation, related measurement techniques, improving routes of administration and novel devices (e.g. subcutaneous, inhalation, oral), nanoparticle-based delivery systems, novel engineering approaches to improve delivery (e.g. prodrug development), dosing/pharmacokinetic strategies, and delivery to poorly accessible locations (e.g. intracellular targets or crossing the blood brain barrier).

Symposium: End-to-End Biomanufacturing

Symposium organizers:

Caryn Heldt	Michigan Tech	Heldt@mtu.edu
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Bruno Marques	GSK	bruno.f.marques@gsk.com

E2E: Manufacturing Process Integration

Session chairs:

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Bernt Nilsson	Lund University	bernt.nilsson@chemeng.lth.se
Melani Stone	Merck	melani.stone@merck.com

Session description:

Robust and effective control strategy is critical in biopharmaceutical manufacturing to consistently deliver product with desired product quality. Recent developments of a combination of capabilities (e.g. capacity to collect large amounts of data, ability to process and analyze large amounts of data, machine learning) has increasingly focused and evolved the control strategy in the production of biopharmaceuticals.

The combination of analytics advancement (e.g. multi-attribute and high sensitivity methods) and automation in biopharmaceutical production facilitates improved process control and can provide the accumulation of knowledge, therefore supporting the entire product lifecycle, from early development to post-commercial launch (e.g. in continuous process verification and improvement programs). Other technology such as molecular developability using in-silico prediction tool in early phases of development largely mitigate the risk of late-stage failure and supports a faster path of a product to market due to reduced development and manufacturing liabilities. Increased knowledge gained from these capabilities can be used to refine and improve process platforms through appropriate adjustments of process parameters and offers the potential to extrapolate useful information to processes of multiple molecular entities. Additionally, process and product understanding can better inform and support transferability across scales/ manufacturing facilities with a higher level of confidence on attaining intended process performance and product quality.

The session invites speakers to share their case studies on the integration of aspects such as big data application, automation, and platform approaches for process control strategy development and application:

- In-silico developability capabilities as a strategic approach to an efficient process development and robust manufacturing process;

- Process analytics as an enhanced approach to process control. Discussion on estimated gains in time and resources are encouraged, particularly over the lifecycle of projects, from clinical manufacturing through launch and beyond;
- Innovative approaches in the use of process analytical technologies;
- Leverage of product/ process large data sets to identify important control elements through process development, clinical production and/or commercial process experience. Cases where data is being used to make informed decisions on process outcomes, including continuous processes, will be of particular interest;
- Development of holistic models that are used for active process control and/or continuous process verification and/or challenges in developing an appropriate scale-down model;
- Uses of artificial intelligence and machine learning to understand and improve process platforms.
- Benefits of product, process understanding and adaptability during transfers across manufacturing sites;
- Flexibility and gains obtained from elements of process control as biopharmaceuticals and batch sizes can vary, from a small personalized application to processes that make biologics on demand to a blockbuster drug with a corresponding large market

E2E: Manufacturing Beyond mAbs

Session chairs:

Raquel Orozco	Boehringer Ingelheim	raquel.orozco@boehringer-ingelheim.com
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Anne Kantardjieff	Bluebird Bio	akantardjieff@bluebirdbio.com
Rahul Sheth	Biomarin	rsheth@bmm.com

Session description:

Unique challenges exist for bio-manufacturing of the rapidly increasing portfolio of non-mAb formats (e.g. bispecifics, mAb fragments, conjugates, fusion proteins), vaccines and cell and gene therapies due to the complexity of these products, as well as the multi-stage and personalized nature of these processes.

Talks in this session will encompass both product improvements and process challenges that extend through upstream, downstream and formulation operations (i.e. end-to-end).

For non-mAb formats (bispecifics, mAb fragments, conjugates, fusion proteins), these may encompass:

- Creative approaches to improving the half-life of smaller proteins;
- Disruptive manufacturing technologies aimed at increasing yield and desired product quality attributes;
- Addressing specific challenges associated with manufacturing of these non-mAb formats.

For cell and gene therapy products, this can include:

- Design, characterization and optimization of viral vector (eg: AAV, Lentiviruses) production processes, including identification and development of production cell lines for viral vectors;
- Identification of critical quality attributes for viral vectors used in gene therapy and gene-modified cell therapy;
- Development and optimization of cellular transduction processes (CAR-T Cells, Stem Cells);
- Development of allogeneic cell lines;
- Manufacturing of non-viral gene delivery vehicles.

E2E: Process Scale Up/Down/Out & Characterization

Session Chairs:

Matthew Stork	Pfizer	Matthew.Stork@pfizer.com
Gary Gilleskie	NC State	gary_gilleskie@ncsu.edu
Jun Tian	Shire	juntian8@gmail.com
Phillip Smith	GSK	phillip.2.smith@gsk.com

Session description:

Over the product lifecycle, process scale is a defining characteristic that changes from development studies through commercialization. As market forces increase the demand for flexible and efficient manufacturing processes, a cohesive strategy for manufacturing scale-up or scale-out should be based on a synthesis of small-scale process characterization knowledge and consideration of large-scale process economics and facility details.

Within the End to End Biomanufacturing Area, multiple sessions are planned that will cover the following elements of Process Scale Up/Down/Out and Process Characterization:

- The use of scale-down models together with manufacturing data to enhance process understanding. Of special interest is work that links small scale models with at-scale process performance to enable process improvements, make post-approval changes, and/or implement statistical models for comparability.
- The development of tools for predicting and/or comparing performance across multiple scales, including economic models, statistical models and CFD.
- Continuous manufacturing as a new frontier in process scale-up/down and characterization. Efficient approaches to characterization of continuous or integrated processes are of particular interest.
- Case studies in overcoming challenges related to process scale-up or scale-out, in particular for novel modalities or manufacturing platforms.
- New methodologies or technologies that enable more accurate process scale-up and/or scale-down.
- Economics and facility considerations related to scale-up or scale-out
- We invite case studies on holistic approaches to scale-up/down/out that cover cell culture and/or fermentation, purification, formulation, and fill/finish for modalities including recombinant proteins, viral vectors, and/or cell therapies.

E2E: Continuous Manufacturing & Process Intensification

Session Chairs:

Beth Goodrich	Millipore Sigma	elizabeth.goodrich@milliporesigma.com
Jack Huang	Merck	jack.huang1@merck.com
Sarah Harcum	Clemson	harcum@clemson.edu
Veronique Chotteau	KTH RIT	veronique.chotteau@biotech.kth.se

Session description:

Recent advancements in cell culture technology and downstream processing have revolutionized biologics manufacturing. The traditional low yield, low efficiency, and high COGs process model can now be substituted with high productivity, high efficiency, high flexibility, and low COGs bioprocesses in a fully-disposable, single-use facility. Specifically, advancement and maturation of process science and technology related to process intensification and continuous manufacturing has provided alternatives and means for immediate process improvement for labile proteins, mAbs, and other protein therapeutics. Although this success has been validated in both academia and industry, full realization of these benefits is yet to be accomplished, pending further technology development, demonstration of robust automation and control, innovative plant operation and design strategy and novel approaches to fully integrate process intensification with continuous manufacturing. This session will focus on technology, approaches, and ideas which are required to further realize the full advantages of process intensification and continuous manufacturing. The topics will encompass, but are not limited to, 1) novel process and reactor design to operate and maintain high process intensity, 2) cell culture medium intensification, concentration and usage reduction, 3) novel in-process control tools and process analytical technology (PAT) to aid in yield improvement and product quality control, 4) efficient use of facility capacity, optimizing run rate and plant occupancy, 5) improving the biological system to be more amenable for high intensity continuous production, 6) innovative and creative approaches for enhancing the resilience and yield of downstream continuous processing and 8) green bioprocessing (sustainability). Additional approaches and studies that can facilitate process development and implementation of intensified process and continuous manufacturing are also encouraged.

Symposium: BIOT Interfaces

Symposium organizers:

Danielle Tullman-Ercek	Northwestern	ercek@northwestern.edu
Ben Hackel	Minnesota	hackel@umn.edu
David Roush	Merck	David_roush@merck.com

BIOT Interfaces: Sustainability in Bioprocessing

Session chairs:

Michael Köpke	LanzaTech	Michael.Koepke@lanzatech.com
Andrew Zydney	Penn State	Zydney@engr.psu.edu

Session Description

With a 2-degree Celsius temperature rise on the horizon, we need to deploy the full range of sustainable solutions for a resource and energy efficient world. Innovative approaches that meet key sustainability criteria will play a key role in meeting these challenges without impacting growth and quality of life. Biotechnology and green chemistry will play a key role in this new reality, with smarter, more sustainable bioproducts and bioprocesses becoming an integral part of the economy.

New technologies, innovations and applications across multiple disciplines provide opportunities to create new low-carbon products. A critical step is the utilization of all available feedstocks including efficient use of renewable feedstocks, waste feedstocks and carbon capture and utilization technologies through genetic engineering and process development. Process intensification and downstream process improvements can have a significant positive impact on source reduction for water. Life-cycle assessments (LCA) can quantify impacts and help to uncover opportunities to reduce the environmental footprint of biologics processes and products, including the tradeoffs involved with single use technologies. Incorporation of circular economy principles into biotechnology practices can result in more efficient operations and lead to reduced waste.

This session invites talks on all aspects around the development of sustainable bioprocesses, including but not limited to the reduction of waste and improvements in energy efficiency in upstream and downstream processes as well as engineering organisms to convert renewable substrates to valuable products with lower environmental footprint. We are also interested in having a roundtable discussion on key themes of Resources, Technology/Conversions and Markets, including key players from across the bioprocessing supply chain.

BIOT Interfaces: Making Use of Big Data & Modeling

Session chairs:

Amanda Lewis	BMS	amanda.lewis@bms.com
Casim Sarkar	Minnesota	csarkar@umn.edu
Gabe Rocklin	Northwestern	grocklin@gmail.com

Session description:

Advances in biotechnology including DNA sequencing, proteomics, microfluidics, laboratory automation, imaging, process development and PAT have led to enormous increases in the amount of data that can be collected from biological systems, with small numbers of observations being replaced by large-scale quantitative measurements. At the same time, the methods available for interpreting and modelling this “big data” have also seen tremendous advances, from ever-easier tools for clustering and regression to the growing use of deep learning. These advances in technologies for data acquisition and analysis offer the promise that we will be able to make accurate, data-driven predictions for a wide range of biotechnological applications, but achieving this promise remains a daunting challenge.

This session explores approaches that generate and/or utilize large biological datasets, with an emphasis on using these datasets to draw conclusions and/or optimize biological systems. General areas of interest include, but are not limited to:

- Data-driven engineering of proteins, nucleic acids, cells, biomaterials, and other biotechnology products
- New high-throughput experimental technology to generate large biological datasets
- Integration of diverse types of large-scale data to improve prediction and modelling, e.g. large sequence databases with more limited functional data
- Mathematical/mechanistic, statistical or hybrid modelling of bioprocesses upstream, cell culture, downstream and product quality
- Advances in design-of-experiment approaches in process optimization and biomolecular engineering
- Application of multivariate statistics and machine learning for predictive modelling, monitoring and process control
- Utilization of big data and unstructured database technologies for biopharmaceutical production and/or merging related data sets
- Systems biology approaches for cellular engineering, process development and/or process understanding.
- Applications of big data in personalized medicine

BIOT Interfaces: Chemical Biology Across Process Development

Session chairs:

Jamie Spangler	Johns Hopkins	jamie.spangler@jhu.edu
Justin Klesmith	Zoetis	justin.klesmith@zoetis.com

Session description:

ACS BIOT will be programming a new area for 2020 that focuses on interdisciplinary research that spans both traditional and emerging frontiers for chemical biology. This session will showcase research from all BIOT symposia, including upstream and downstream processing, biotechnologies, biomanufacturing, and therapeutic platform design, with the goal of integrating diverse viewpoints at each stage of development. Talks that highlight research at the interface of biomolecular engineering and bioconjugate chemistry or the design of processes to create products at this interface will be the focus of this cross-disciplinary session. The session will feature approaches that are computational, experimental, or a hybrid between the two. We particularly encourage presentations that consider the critical steps involved with advancing cutting-edge research from concept to prototype to translation.

BIOT Interfaces: Bridging the Gaps in Process Development

Session chairs:

Sumit Bhatnagar	AbbVie	sumit.bhatnagar@abbvie.com
Amish Patel	U Penn	pamish@seas.upenn.edu

Session description:

This session aims at integrating all the facets of BIOT. A holistic understanding of all the processes involved in BIOT can help provide immense insight into the lifecycle of biotechnologies and highlight opportunities to streamline their development. This session will look to bring together processes of development – protein/ biomolecular engineering, characterization, novel biomedical/ biomolecular technologies – and manufacturing to provide a clear and integrated picture of BIOT. Talks should be at the interface of two or more BIOT areas of upstream and downstream processing, development and manufacturing. For example, a relevant talk might describe the link between molecular design and structure activity relationships (SAR) to help identify clinically relevant proteins early on in development.

BIOT Interfaces: New therapeutic modalities: Impact on manufacturing paradigms

Session chairs:

Aaron Noyes	Codiak	aaron.noyes@CODIAKBIO.COM
Laura Segatori	Rice University	segatori@rice.edu

Session description:

Emerging therapeutic modalities, ranging from cell and gene therapies to exosomes, require integration of technology development and manufacturing across the disciplines of biology, biochemical engineering, and biophysics. Success is often found through combining basic research and molecular insight into novel approaches for molecular engineering and development of production processes. Novel therapeutic classes where quality attributes have not been fully identified can benefit from innovative approaches for connecting construct design with the control of processes. This session will encompass diverse aspects of cell, particle, and protein engineering, including advances in antibody conjugates, development and production of gene therapies, the engineering of cell- and particle-based therapies, and design of cell factories for biomanufacturing.

BIOT Interfaces: Emerging BIOT Leaders

Session chairs:

Pete Tessier	Michigan	ptessier@med.umich.edu
Varnika Roy	GSK	varnika.x.roy@gsk.com

Session description:

This session aims to feature research from rising stars (pre-tenure or equivalent) in industry, academia, and government labs in diverse areas related to biochemical technology. All areas of biochemical technology research are appropriate for this session, including those ranging from fundamental to applied and computational to experimental. The speakers will be highlighted in the meeting programming in order to expose the BIOT community to the next generation of leaders in the field of biochemical technology.

BIOT Interfaces: Emerging BIOT Research Areas

Session chairs:

Kevin Solomon	Purdue	kvs@purdue.edu
David Roush	Merck	david_roush@merck.com

Session description:

This session will consist of short talks followed by brief Q&A and a panel discussion around nascent but potentially transformational or disruptive innovations in biotechnology. Papers describing powerful new technologies and/or innovations that showcase relevant and viable ways of carrying out substantially faster, smarter, more economical, or more robust process development are invited. Areas include new materials or approaches to upstream, downstream, drug product, devices, process intensification, and process analytics technology are welcome. Submissions that incorporate innovative approaches to utilizing existing technologies for new biological therapeutic modalities or accelerating biological platform development (e.g. microbial cell factories, mammalian cell culture) are also encouraged.

Session: BIOT Poster Session

Session chairs:

Krunal Mehta	Amgen	kmehta@amgen.com
Tom Mansell	Iowa State University	mansell@iastate.edu
Nanette Boyle	Colorado School of Mines	nboyle@mines.edu
Christopher Gillespie	Immunogen	gillescche@gmail.com

Session description:

This year's poster session will run for over 3.5 hours to accommodate the growing number and quality of poster submissions. A small number of abstracts will be selected to give short rapid-fire talks on Tuesday during the regular programming. Posters will be placed on display during the day and highlighted in the guidebook. Stay tuned for information about poster awards!

Session: BIOT Tank

Session chairs:

Nigel Reuel	Iowa State University	reuel@iastate.edu
Varnika Roy	GSK Vaccines	varnika.x.roy@gsk.com
Ganesh Sriram	University of Maryland College Park	gsriram@umd.edu

Session Description:

INVITING ENTREPRENEURS TO THE BIOT TANK 2020
ACS-BIOT PHILADELPHIA 2020- March 22nd2020 5-6:30pm

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 cash 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, business incubator directors, and technology leaders from large and small technology companies.

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

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.

To be considered for this session please submit a 200 word abstract and 60 second pitch YouTube video* link in the following form:

https://forms.gle/ja4uSA93uvqeFKHm7

* This video will be used on the BIOT website and at the public conference. Do not share proprietary information.