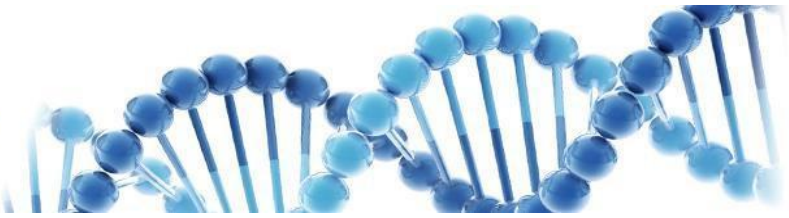
DIVISION OF BIOCHEMICAL TECHNOLOGY
OF THE AMERICAN CHEMICAL SOCIETY

BIOT



Call for Papers

ACS National Meeting
August 22 - 26, 2021
Atlanta, GA and Online

BIOT Program Chairs:

Caryn Heldt, Michigan Technological University (heldt@mtu.edu)
Aaron Noyes, Codiak BioSciences (aaron.noyes@codiakbio.com)

Abstracts Accepted: March 15, 2021 - April 8, 2021

Submit abstracts to the BIOT Division at
ACS Fall 2021

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

ACS BIOT Program

Symposium: Upstream Processes

Symposium organizers:

Melisa Carpio	Horizon Discovery	mcarpio@gmail.com
Nitya Jacobs	Amgen	njacob@amgen.com
Danielle Tullman-Ercek	Northwestern Univ	dtercek@gmail.com

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

Session: Mammalian: Media and Metabolism

Session Chairs:

Andrew Yongky	Amgen	ayongky@amgen.com
Susan Sharfstein	SUNY	ssharfstein@sunypoly.edu
Jeraldine Mendoza	Thermo Fisher Scientific	jeraldine.mendoza@thermofisher.com

Session Description:

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

Session: Mammalian: Innovative Technologies

Session Chairs:

Tara L. Deans	Univ of Utah	tara.deans@utah.edu
Siguang Sui	Alexion Pharmaceuticals	siguang.sui@alexion.com

Session Description:

Mammalian cell culture has emerged as a dominant sector of biotechnology, wherein cells are harnessed for vaccine production, recombinant protein synthesis, and cell-based therapies. The acceleration in mammalian cell culture is due in part to transformative technologies, which have matured over the past decades to enable the rational engineering and design of mammalian cells and manufacturing processes for biotechnology applications. These technologies include omics methods that identify and quantify therapeutic targets, mechanistic modeling techniques for predicting phenotypes, genome editing approaches for implementing cell designs, high throughput screening of genetic parts and cell lines, and application of in-process analytics and automation for process parameter optimization. Talks in this session will focus on the development and use of emerging technologies to engineer mammalian cells and improve upstream cell culture process efficiency and quality for biotechnological purposes. Topics of interest include, but may not be limited to, techniques, methods or tools for identifying and engineering therapeutic targets, speeding up the development of therapeutic cells or recombinant protein producing cell lines, automation of cell line screening or upstream process parameter optimization, and controlling upstream process using predicative modeling or in-process analytics.

Session: Mammalian: Novel Modalities

Session Chairs:

Joshua N Leonard	Northwestern Univ	j-leonard@northwestern.edu
Tiffany Rau	Rau Biotech	tiffany@raubiotech.com

Session Description:

Mammalian cell culture is of increasing importance in biotechnology, with applications ranging across research and development tools, production hosts for recombinant and gene therapy products, and therapeutic cell-based products. This session will focus on new technologies that enable or employ cell culture as well as substantial modifications to existing approaches. The session invites contributions including any of the aforementioned applications.

Session: Advances in Perfusion and Reactor Engineering for Upstream Processing

Session Chairs:

Huong Le	Amgen	jhuongl@amgen.com
Matthew Rehmann	Bristol Myers Squibb	matthew.rehmann@bms.com

Session Description:

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

Session: Systems Biology & Omics: Tools and Applications

Session Chairs:

Davinia Salvachua	National Renewable Energy Laboratory	Davinia.Salvachua@nrel.gov
Kevin Solomon	Univ of Delaware	kvs@udel.edu

Session Description:

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

Session: Engineering Microbial Communities and Non-Model Systems

Session Chairs:

Michael Koepke	LanzaTech, Inc.	Michael.Koepke@lanzatech.com
Mark Mimee	Univ of Chicago	mmimee@uchicago.edu

Session Description:

Microbial communities and non-model organisms are increasingly used as production platforms for a wide range of biofuels, biochemical and biopharmaceuticals or in biomedical and bioremediation applications. The unique metabolism and physiology of non-model hosts can complement traditional hosts such as *E. coli* and yeast and address limitations including catalytic capabilities and overall productivity, while microbial communities are being exploited to enable robust performance under demanding industrial conditions. Several non-model organisms (e.g. *Bacillus, Clostridium, Corynebacterium, Lactobacillus, Zymomonas*) are already employed industrially for their ability to grow autotrophically, novel metabolic reactions, pathways and products, or high tolerance for common inhibitory compounds. These new hosts and communities are being engineered to access important feedstocks like lignocellulosic biomass, syngas, methane, methanol, glycerol, electricity, and carbon dioxide (amongst others), to increase sustainability, to enable novel biomedical and bioremediation application, and to decrease production costs. This session will focus on the recent developments in engineering non-model hosts and microbial communities for the production of biopharmaceuticals, biofuels, bulk chemicals and value-added specialty chemicals or in biomedical and bioremediation applications. Relevant topics include molecular and genetic parts and tool development, application of high-throughput approaches, pathway and community engineering, engineering community composition and optimizing divisions of labor, process development, and efforts to accelerate design-build-test loops through systematizing workflows, machine learning and other approaches. We welcome both industrial and academic contributors.

Session: Process Development and Challenges for Cell Based Products

Session Chairs:

Bruce Levine	Univ of Pennsylvania	levinebl@pennmedicine.upenn.edu
Krishanu Mathur	Voyager Therapeutics	krishanu1@gmail.com

Session Description:

Technological advances in the approaches and methods for ex vivo cell, tissue, and gene manipulation have led to investigations of cells, gene modified cells, and tissues endowed with enhanced potency and unique functions, with promise of a new generation of infused therapeutics. Cell-based therapies began with experimental blood transfusions and bone marrow or hematopoietic stem cell transplants. With greater understanding of the biology, new technologies have evolved so that a new pillar of medicine is now being created. Translation of research findings to a final drug product requires strategic merging of science and technology with emphasis on safety, purity, potency, and identity of the product. This session will encompass multiple aspects of cell therapy process development where the cells, gene modified cells, gene edited cells, or cell derived vectors which encode the gene of interest are the products intended for investigation in humans or veterinary applications. This would include advances in the isolation, culture, gene transfer and modification, process scale up, culture medium design, testing, and characterization of cell-based therapy products. Papers relevant to these topics are highly encouraged, including those focusing on novel process improvements, control and optimization strategies, equipment and reagents design and characterization.

Session: Microbial Metabolic Engineering

Session Chairs:

Aditya Kunjapur	Univ of Delaware	kunjapur@udel.edu
Quinn Mitrovich	Amyris	mitrovich@amyris.com

Session Description:

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

Session: Synthetic Biology and Genome Engineering

Session Chairs:

Peng Xu	Univ of Maryland	pengxu@umbc.edu
Arpan Bandhopadhyay	Merck & Co.	arpan.bandyopadhyay@merck.com

Session Description:

Synthetic biology and genome engineering represent the most fascinating areas in engineering biology. They offer innovative approaches to engineer new biological systems or reprogram existing ones for various applications. By harnessing these tools, we have been able to discover new drug molecules, detect viruses, engineer efficient microbial cell factories to produce high value chemicals, encode decision-making functions, store digital information as well as cure genetic diseases inside living cells. Combined with genome evolution and high throughput phenotyping, we are rapidly expanding our horizon and translating the applications across molecular, cellular or multi-species levels. Further, the progresses made in the fields of synthetic biology and genome engineering have advanced our basic understanding of the complex traits in microbial, plant, and mammalian cells. Talks within this session will highlight the rapid advances in the fields of synthetic biology and genome engineering with a focus on synthetic biology tools development, genome design and evolution, multiplexed gene editing, rapid strain engineering, transcriptional reprogramming, biosensors, engineering of unnatural species, and applications to biotherapy, diagnostics, environment, medicine, and chemical industry.

Session: High-Throughput Screening and Automation of Upstream Process Development

Session Chairs:

Doug Densmore	Boston Univ	dougd@bu.edu
Grant Murphy	Merck & Co.	grant.murphy@merck.com
Samuel MD Oliveira	Boston Univ	smdo@bu.edu

Session Description:

The discovery and development of biotherapeutics and biotechnologies depends on successful upstream process development to identify the ideal protein variant and cell line construct, culture media, bioreactor, and fermentation process. Enhancements in laboratory automation, DNA synthesis, and Synthetic Biology have led to rapid advances in the scale and approaches taken in upstream process development. The application of technologies such as cell-free expression, microfluidics, and automated bioreactors enables the rapid design and testing of increasingly large numbers of variant constructs and production conditions in reasonable timelines. Advances in machine learning and other computational methods are being combined with the multidimensional data sets generated during upstream process development to drive process decision-making and generate cross-program learning. This session will focus on developing and applying experimental and computational tools, workflows, and processes that increase our ability to perform construct discovery and development in a high-throughput, automated fashion. This session will highlight the benefits of laboratory automation workflows as robust data screening and preparation methods and automate genetic construct data analytics. This session will explore advances in functional AI algorithms for accurate sampling of property landscape, analytical characterization, and the rational design of biological materials and functions. Finally, of particular interest, this session will foster discussion on the use of community standards and initiatives to improve these processes as new ways to distribute and share data across the community.

Symposium: Downstream Processes

Symposium organizers:

Wai Keen Chung	Biogen	waikeen.chung@gmail.com
Dan Bracewell	Univ College London	d.bracewell@ucl.ac.uk
Elizabeth Goodrich	MilliporeSigma	Elizabeth.goodrich@milliporesigma.com

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

Session: Advances in Chromatographic Separations for mAbs

Session chairs:

Melissa Holstein	Bristol Myers Squibb	melissa.holstein@bms.com
Stefano Menegatti	North Carolina State Univ	smenega@ncsu.edu

Session description:

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

Session: Advances in Chromatographic Separations for Novel Antibody Structures and Drug Conjugates

Session chairs:

Asif Ladiwala	Genentech	ladiwala.asif@gene.com
Brandon Coyle	Avitide	brandonlcoyle@gmail.com

Session description:

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

Session: Advances in Chromatographic Separations using Novel Stationary Phases

Session chairs:

Minni Aswath	Boehringer-Ingelheim	minni.aswath@boehringer-ingelheim.com
Scott Husson	Clemson Univ	shusson@clemson.edu

Session description:

Purification schemes using novel stationary phases will be examined in this session. The stationary phases may include novel resins, membrane adsorbers, fibers, or monoliths. Process streams involving monoclonal antibodies and monoclonal antibody derivatives, recombinant proteins, protein conjugates, plasma, viruses, and nucleic acids are considered. This session calls for papers focused on new and enhanced downstream processing using novel or disruptive technologies. The scope may span from research and process development at the bench scale to larger scales including pilot and commercial scale manufacturing. Topics may include the establishment of novel materials and formats in high-throughput screening, process optimization, troubleshooting, scale-up, mechanistic modeling, etc. Case studies in large scale clinical or commercial manufacturing leading up to regulatory filings are strongly encouraged.

Session: Non-Chromatography Based Separation of Biomolecules

Session chairs:

Mahsa Rohani	Amgen	Mrohani@amgen.com
Akshat Gupta	MilliporeSigma	akshat.gupta@milliporesigma.com

Session description:

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

Session: Membrane-Based Downstream Bioprocessing

Session chairs:

Mahsa Hadidi	Sanofi	mahsa.hadidi@gmail.com
Ranil Wickramasinghe	Univ of Arkansas	ranil.wickramasinghe@uark.edu

Session description:

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

Session: High-Throughput Screening and Automation of Downstream Process Development

Session chairs:

Steve Timmick	GlaxoSmithKline	steven.x.timmick@gsk.com
Andrea Rayat	Univ College London	andrea.rayat@ucl.ac.uk

Session description:

To align with the QbD (Quality by Design) paradigm and to facilitate accelerated program timelines, the biopharmaceutical industry is evaluating and developing various approaches to aid process development activities and gain better understanding of manufacturing processes. Automation has been at the forefront of this innovation and there have been significant advances in the use of automation alongside high-throughput technologies which can drastically reduce both the material and the time needed for process development. A combination of high-throughput methods, design of experiments (DOE), multivariate data analysis (MVDA), and in-silico analyses can be employed during early and late phase process development to optimize individual unit operations as well as support process characterization activities, generating large experimental datasets in a rapid and cost-effective manner. However, the adoption of automation and high-throughput screening (HTS) techniques has come with a new set of challenges, including the need for scale-down verification of high-throughput models and the incorporation of high-throughput analytical testing and data analysis within these workflows. In this session, we will focus on the strategies, challenges, and opportunities of using automation and HTS for downstream process development. Note that HTS is applied here in its broadest sense, referring to workflows or techniques which aim to reduce the time or material required in all phases of downstream process development. In addition to well-established applications for chromatography, case studies on more complex unit operations to scale down such as depth filtration, tangential flow filtration, and other non-chromatographic steps are encouraged. For all applications, we are particularly interested in the integration of high-throughput analytics into the workflow, being mindful of not shifting the bottleneck to other areas of process development. Finally, we would like to explore advances in in-silico process development and optimization which have been enabled by high-throughput experimentation and innovations in automated data analytics.

Session: in Silico and Mechanistic Modeling of Downstream Bioseparations

Session chairs:

Gunnar Malmquist	Cytiva	gunnar.malmquist@cytiva.com
Camille Bilodeau	MIT	cbilod@mit.edu

Session description:

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

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

Session chairs:

Arne Staby	Novo Nordisk	ast@novonordisk.com
Jim Neville	MilliporeSigma	jim.neville@milliporesigma.com

Session description:

When transferring biotechnological processes to manufacturing facilities, the scale-up and scale-down of downstream unit operations is not always obvious and straightforward. Assuring successful implementation in a facility can require new approaches to scaling, simulation, and/or modeling to gain additional insight in comparison to traditional approaches. These may include fundamental/engineering models used to anticipate large scale performance, as well as development of appropriate small-scale models used for process characterization and/or troubleshooting. We seek abstracts covering these scale-up and scale-down topics, particularly for cases where challenges related to scaling and facility fit were observed and novel solutions or technologies were required to drive successful implementation. Case studies covering adoption of new paradigms, including advances in integrated process designs that utilize closed non-classified process operations and related commercial robustness, are encouraged. This also includes approaches focusing on design space, as well as productivity increases and/or cost reduction through innovation. Abstracts that highlight recent trends and areas of key focus during health authority review are relevant.

Session: Downstream Processing of Non-Antibody Modalities

Session chairs:

Srinivas Chollangi	Voyager Therapeutics	schollangi@gmail.com
David W. Wood	Ohio State Univ	wood.750@osu.edu

Session description:

Although monoclonal antibodies account for 70% of all the revenues generated by the biopharmaceutical industry they only make up slightly more than a third of approved therapeutics by number. The remaining non-antibody modalities present exciting challenges since most have no established downstream platform and in-process control and characterization methods are not well established. Further, new modalities such as nucleic acids and novel delivery platforms are gaining interest while additional non-antibody engineered and conventional proteins are also being developed. The diversity in the structures and chemical properties of these molecules is driving innovation in primary recovery, capture and polishing approaches, with processes that include membrane filtration, chromatography extraction, differential centrifugation and affinity technologies. These innovations will be discussed in this session, along with potential platforms for process development and associated in-process control methods and strategies for fast analytics. We encourage submitting papers on laboratory scale methods, scale up, process control and quality attribute characterization to further establish new methods for downstream processing of non-monoclonals.

Session: Advances in Process Analytical Technologies for Measurement and Control in Downstream Processing

Session chairs:

Jennifer M Pollard	Merck & Co.	jennifer_pollard@merck.com
Steven Evans	AstraZeneca	steven.evans@astrazeneca.com

Session Description:

This session will focus on process analytic technologies (PAT) that enable real-time control, faster batch release, or improved process understanding for downstream processing. The development and implementation of in-line and/or at-line process analytics may include sensors based on, for example, Raman or infrared spectroscopy, particle size imaging, variable pathlength flow concentration measurement technologies or other technologies. In this session, we'd like to explore the identification of innovative tools or a novel implementation of established methods in downstream manufacturing processes for one or more downstream unit operations. Case studies showing how these tools can enable meeting in-process limits, with the goal of meeting a set of final critical quality attribute (CQA) limits, or how they provide a more in depth understanding of the process are encouraged. Any challenges with the implementation of such PAT solutions and their impact on the overall control strategy may be presented. Topics may include implementation of integrated control strategies that leverage enhanced product understanding for manufacturing process optimization, process characterization, or regulatory submissions. Additionally, leveraging PAT to enable understanding of downstream process capabilities and their impact on CQAs are among topics of interest.

Symposium: Biomolecular and Biophysical Processes

Area Coordinators:

Mary Krause	Bristol Myers Squibb	mary.krause@bms.com
Krishna Mallela	Univ Colorado Denver	krishna.mallela@cuanschutz.edu
Cesar Calero	Sanofi	Cesar.Calero@sanofi.com

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

Session: Challenges in Developing Novel Modalities

Session chairs:

Thomas Tolbert	Univ of Kansas	tolbert@ku.edu
Kiran Bangari	Takeda	kiran.bangari@takeda.com

Session description:

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

Session: Protein Developability; Physical and Chemical Stability

Session Chairs:

Yongku Cho	Univ Connecticut	cho@uconn.edu
Michael Marlow	Boehringer Ingelheim	michael.marlow@boehringer-ingelheim.com

Session description:

The need for efficacious biotherapeutics under rapidly accelerated timelines has never been more clearly evident. Confident selection of candidates to progress into Development as early as possible is vital to increasing our speed to the clinic and benefiting patients. This session will focus on recent advances across academia and industry in computational and empirical approaches for 1) predicting and assessing therapeutic protein developability and 2) understanding, engineering, and mitigating mechanisms of physical and chemical degradation, colloidal stability, and non-specific interactions. Suggested topics include: strategies for cross-functional candidate selection, including managing the Research/Development interface; use and confirmation of computational (AI/ML), homology modelling, or small-scale predictive assays; design, implementation, and interpretation of high-throughput screening; predicting process fit and impact of process impurities; integrating physical and chemical forced degradation, accelerated and stress assessments, formulation screening, immunogenicity and PK/PD modelling into candidate engineering/selection.

Session: Protein Aggregation and Immunogenicity

Session chairs:

Kayla Sprenger	CU Boulder	kayla.sprenger@colorado.edu
Daniela Verthelyi	FDA	Daniela.Verthelyi@fda.hhs.gov
Cavan Kalonia	AstraZeneca	cavan.kalonia@astrazeneca.com

Session description:

Protein aggregation and particle formation pose substantial challenges during the development of new biotherapeutics due to their potential for eliciting undesirable and harmful immune responses. This session will focus on recent advances from both academia and industry to characterize the link between protein aggregates and immunogenicity, towards improving mitigation and control strategies. Suggested topics include, but are not limited to: 1) new approaches for understanding the molecular mechanisms of protein aggregation and aggregation mitigation strategies at both the formulation and bioprocessing stages (e.g. assessing conformational and colloidal stability due to changes in pH or chemical modification of biotherapeutics), 2) methods to characterize visible and subvisible protein aggregates; 3) new methods for predicting protein aggregation tendencies; and 4) approaches to correlate and predict the impact of protein aggregates on immunogenic responses. Computational and experimental (in vitro, in vivo, or clinical) approaches are welcome.

Session: Formulation Strategies and Novel Routes of Administration

Session chairs:

Arvind Srivastava	Avantor	arvind.srivastava@avantorsciences.com
Catherine Fromen	Univ of Delaware	cfromen@udel.edu

Session description:

Biotherapeutics are complex molecules with numerous routes of both chemical and physical instability, which can lead to increased production costs, loss of the biological function, and immunogenic responses from patients. The clinical and commercial success of biotherapeutics depends on the careful selection of excipients and route of administration to achieve optimal safety and efficacy. This section will focus on formulation development strategies utilizing excipients and adjuvants to control physical and chemical properties, including stability, charge, degradation, and maintain or enhance therapeutic effect. The session also focuses on various aspects of medical devices, drug-device combinations, and non-intravenous routes of administration (i.e., intranasal, pulmonary, intradermal, etc.) that in combination of suitable formulation strategies can improve the clinical and commercial success of biotherapeutics.

Session: Advances in Process Development and Manufacturing of Biologic Drug Products

Session chairs:

Sanket Patke	Sanofi	sanket.patke@sanofi.com
Anna Schwendeman	Univ of Michigan	annaschw@med.umich.edu

Session description:

The space of biologic therapeutics is continually expanding due to the development of new protein, gene therapy and cell therapy formats, new modes of action, new screening technologies, and new design tools. This session will focus on recent advances in drug product process development and manufacturing. Suggested topics include: Scale-down pilot models, computational modeling and digital tools, effects of excipients, freeze and spray drying, suspensions, non-aqueous biologic drug products, aerosols, biosimilars and vaccines manufacturing. The scope of this session will also include the topic of process development pertaining to gene therapy, cell therapy, CART-T, and lipid nanoparticle-based therapeutics.

Session: Emerging Biophysical and Analytical Characterization Technologies (BPAC)

Session chairs:

Yongchao Su	Merck & Co.	yongchao.su@merck.com
John Schiel	National Institute of Standards and Technology	john.schiel@nist.gov

Session description:

Biologics are rapidly expanding their already predominant role in the modern pharmaceutical market. Protein drugs (e.g. mAbs) carry inherent structural complexity, and emerging modalities (gene therapy, mRNA vaccines, etc.) consist of increasingly complex combinations of various biomolecules. A critical task of biological drug development is to identify critical quality attributes (CQAs) and maintain structural integrity and stability of the drug substance(s) through manufacturing, production, and product lifecycle. For example, the highly flexible structure and dynamic nature of biomolecules significantly enhance the propensity of protein oligomerization, aggregation and fibrilization. Molecular interactions between the drug substance and formulation excipients can lead to stabilizing or destabilizing events. Therefore, in-depth characterization of structural behaviors in all stages of drug development is required. Innovative measurements must evolve to allow comprehensive product quality assessment and continually improve product stability amenable to global distribution. This session includes innovative high-resolution biophysical and analytical methods to analyze biopharmaceuticals including peptides, proteins, oligonucleotides, monoclonal antibodies, viral and non-viral gene and cell therapies, and vaccines.

Session: Protein Structure and Function

Session chairs:

Surinder Singh	Bristol Myers Squibb	surinder.singh@bms.com
Chiwook Park	Purdue Univ	park6@purdue.edu

Session description:

Elucidation of the protein structure and function relationship is crucial for gaining deeper insights into the protein(s) molecular mechanism of action. Understanding protein structure and function is a key driver in devising an effective control strategy for developing various biotechnological applications of proteins, such as safe and efficacious protein-based drugs in the bio-pharmaceutical industry. This session seeks presentations focused on scientific approaches to understand and decipher the fundamental principles connecting the primary and higher-order structures of proteins, post translational modifications, and protein-protein interactions to their function and behavior in vitro and in vivo.

Symposium: Biomedical Technologies

Area Coordinators:

John Kim	Univ Alabama	ykim@eng.ua.edu
Maryam Raeeszadeh-Sarmazdeh	Univ of Nevada-Reno	maryamr@unr.edu

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

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

Session chairs:

Adam Melvin	Louisiana State Univ	melvin@lsu.edu
Divya Chandra	Merck & Co.	divya.chandra@merck.com
Christopher Canova	Janssen	ccanova@its.jnj.com

Session Description:

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

Session: Stem Cell Therapy and Regenerative Medicine

Session chairs:

Samira Azarin	Univ of Minnesota	azarin@umn.edu
Marjan Rafat	Vanderbilt Univ	marjan.rafat@vanderbilt.edu
Nikhil Ramsubramaniam	Bristol Myers Squibb	nikhil.ramsubramaniam@bms.com

Session description:

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

Session: New Technologies in Cell and Microbiome Engineering

Session chairs:

Nich Sandoval	Tulane Univ	nsandova@tulane.edu
Tom Mansell	Iowa State Univ	mansell@iastate.edu

Session Description:

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

Session: New Technologies for the Delivery and Targeting of Therapeutics

Session chairs:

James Van Deventer	Tufts Univ	james.van_deventer@tufts.edu
Kevin Dooley	Codiak BioSciences	kevin.dooley@codiakbio.com

Session Description:

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

Symposium: Big Data

Area Coordinators:

Sandeep Kumar	Boehringer Ingelheim	sandeep_2.kumar@boehringer-ingelheim.com
Jim Lalonde	Inscripta	jimjlalonde@yahoo.com

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

Session: Machine Learning Approaches to Genome Engineering

Session chairs:

Richard Fox	Infinome Biosciences	richard.fox@infinomebio.co
Hector Garcia Martin	Berkeley Lab	hgmartin@lbl.gov

Session description:

The complexity and large data sets generated in the engineering and scale up of novel strains lend itself to harvesting Big Data for the creation of higher order models. More precise tools such as CRISPR gene editing, NextGen sequencing and high throughput automation have led to an explosion in size of data sets and our ability to create models relating genotype and phenotype. This session will focus on the creation of ML models for genomic discovery and forward engineering programs.

Session: Big Data in Discovery and Development of Biopharmaceuticals

Session chairs:

Stanley Krystek	Bristol Myers Squibb	Stanley.Krystek@bms.com
Iman Farasat	Janssen	iman.farasat@gmail.com

Session description:

Use of Big data and analytical tools such as ML and AI to guide protein engineering, design and selection efforts aimed at improved developability (Manufacturability, Safety, efficacy and pharmacology) of biopharmaceuticals.

Symposium: Integrated and Continuous Processing

Area Coordinators:

Lars Pampel	Novartis	lars.pampel@novartis.com
Nihal Tugcu	Sanofi	Nihal.Tugcu@sanofi.com
Tim Tully	Pfizer	Timothy.Tully@pfizer.com

The latest on continuous bioprocessing

Session: Implementation: It's happening!

Session chairs:

Arch Creasy	Pfizer	Arch.Creasy@pfizer.com
Suzanne Farid	Univ College London	s.farid@ucl.ac.uk

Session description:

The promise of integrated and continuous biomanufacturing is now becoming a reality. Thanks to advancements in technology and committed investment from management, the first integrated and continuous biomanufacturing facilities are online or nearing completion. Focus has shifted to characterizing at-scale processes, developing robust control strategies, and engaging regulatory agencies to address novel technical challenges. We invite presentations detailing the implementation of integrated and continuous processes including developing the business case, the challenges facing CMC including validation, translating the technology into manufacturing facilities, feedback from interactions with regulators, managing safety related to adventitious agents, and continuous process qualification. Talks can focus on the integration of two or more continuous operations or full end-to-end continuous platforms.

Session: Advances in Perfusion Technologies and Process Development

Session chairs:

Thomas Villiger	Fachhochschule Nordwestschweiz FHNW	thomas.villiger@fhnw.ch
Jiuyi Lu	Sanofi	Jiuyi.Lu@sanofi.com

Session description:

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

Session: Advances in Automation, Control and PAT

Session chairs:

Raquel Orozco	Bayer	raquel.orozco@bayer.com
Bernt Nilsson	Lund Univ	bernt.nilsson@chemeng.lth.se

Session description:

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

Session: Integrated and Continuous Downstream Processing

Session chairs:

Mehdi Ghodbane	GlaxoSmithKline	mehdi.x.ghodbane@gsk.com
John Erickson	National Institute for Innovation in Manufacturing Biopharmaceuticals	erickson@udel.edu

Session description:

Batch chromatography has been the workhorse of downstream processing (DSP) in the biopharmaceutical industry. The demand for end to end integrated and continuous DSP has increased in recent years as advances have been made in perfusion cell culture. Because there are not widely accepted integrated and continuous downstream unit operations that can easily replace batch chromatography, there is an opportunity to develop new continuous technologies. Because multiple downstream steps are still likely to be needed to achieve acceptable purity, there is an additional challenge of integrating multiple downstream unit operations to work together seamlessly. This session invites industrial and academic talks describing continuous or semi-continuous downstream unit operations or processes, process development and characterization for integrated and continuous processes, and strategies for changing from batch to continuous processing during development or post-launch. Talks that provide tools for deciding which integrated and continuous unit operations are best for a given circumstance are highly encouraged.

Symposium: Cell and gene therapy

Area Coordinators:

Bill Kelly	Villanova Univ	william.j.kelly@VILLANOVA.EDU
Nooshi Sanaie	Kite Pharma	nsanaie@kitepharma.com
Mercedes Segura	Avro Bio	mercedes.segura@avrobio.com

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

Session: Development and Manufacturing of Cell Therapy Products

Session chairs:

Azadeh Golipour	Avro Bio	azadeh.golipour@avrobio.com
Sakis Mantalaris	Georgia Tech Univ	sakis.mantalaris@gatech.edu
Boris Engels	Novartis	Boris.engels@novartis.com
Liz Pratico	bluebird bio	EPratico@bluebirdbio.com

Session Description:

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

Session: Development and Manufacturing of Gene therapy and Viral Vector Products

Session chairs:

Jay Elmer	Villanova Univ	Jacob.elmer@villanova.edu
James Woo	Kite Pharma/Gilead	jwoo02@kitepharma.com
Meisam Bakhshayeshi	Biogen	Meisam.bakhshayeshi@biogen.com
Steve Cramer	Rensselaer Polytechnic Institute	crames@rpi.edu

Session Description:

Gene Therapy continues to gain significant interest and increasing momentum in the pharmaceutical industry as viable and effective treatments for a wide array of diseases. With recent and upcoming commercial launches, numerous ongoing clinical trials, growing involvement from larger companies, increasing industrial collaborations with academia, and continual formation of new start-ups, the field of gene therapy promises to be a major player and potential game changer for 21st century medicine. While demonstrating great promise, these therapies are relatively new to the biopharmaceutical manufacturing industry and require further study to reach the depth of understanding now typically associated with other more established biologic therapeutics. In that spirit, this session calls for papers focused on the development and production of Gene Therapies and Viral Vectors, in their various forms, from both academia and industry. The session organizers wish to include abstracts covering numerous aspects of this field for the session, topics to include but not limited to: advances in upstream production (incl. plasmids, viral vectors, cell banks), advances in downstream purification process, drug Product Sciences, cGMP Manufacturing and scale-up strategies, and in-process control and monitoring strategies.

Session: Next Generation Modalities in Gene and Cell therapy

Session chairs:

Eliana Clark	Intellia Therapeutics	eliana.clark@intelliatx.com
Andy Snowdan	Kite Pharma/ Gilead	asnowden01@kitepharma.com

Session Description:

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

Session: Characterization of Gene and Cell Therapy Starting Material and Final Products and Regulatory Perspectives

Session chairs:

James Powell	Bristol Myers Squibb	James.powell@bms.com
Ilya Shestopalov	bluebird bio	ishestopalov@bluebirdbio.com
Victor Lu	Innovative Cellular Therapeutics	victorlu@ictbioinc.com

Session Description:

Gene-modified cellular therapies achieve through stable viral transduction, such as CAR-T cells and gene-modified CD34 cells, have reached commercialization stages (e.g., Kymriah, Yescarta, Tecartus, Zynteglo, Strimvelis) with unprecedented clinical response rates and durability in oncology and complete correction of severe hematologic diseases. The early success of these therapies inspired a deluge of investment in the field, including affinity modified TCRs for targeting solid tumors and intracellular antigens, along with gene-editing approaches via CRISPR/Cas for allogeneic adaptive T cells and hematologic diseases and gene therapies based on an AAV viral vector. In this session, we will also cover regulatory challenges regarding product characterization with in-process, lot release specification establishment, comparability studies, process validation, and clinical safety and efficacy. Each topic at different stages of the product development cycle will be covered. We strive to have a well-represented speaker list to cover all the topics.

Symposium: Protein Engineering

Area Coordinators:

Nik Nair	Tufts Univ	Nikhil.nair@tufts.edu
Zhe Rui	Codexis	ruizhebio@gmail.com

Progress in protein engineering

Session: Protein Conjugates, Fusions, and Formulations

Session chairs:

Julie Champion	Georgia Institute of Tech	julie.champion@chbe.gatech.edu
Xuejun Zhu	Texas A&M Univ	xjzhu@tamu.edu

Session description:

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

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

Session chairs:

Carl Denard	Univ of Florida, Gainesville	cdenard@ufl.edu
Matthew Weinstock	AbSci Bio	mweinstock@abscibio.com

Session description:

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

Session: Advances in Protein Engineering Technologies

Session chairs:

Aditya Kunjapur	Univ of Delaware	kunjapur@udel.edu
Joyce Liu	Codexis	joyce.liu@codexis.com

Session description:

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

Session: Protein Engineering: Enzyme Engineering and Biocatalysis

Session chairs:

Jerome Fox	Univ of Colorado, Boulder	Jerome.Fox@colorado.edu
Jovana Nazor	Codexis	Jovana.nazor@codexis.com

Session description:

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

Symposium: COVID Vaccine, therapies, and diagnostics

Area Coordinators:

Varnika Roy	GlaxoSmithKline	varnika.x.roy@gsk.com
Shannon Servoss	Univ Arkansas	sservoss@uark.edu
Frank Kotch	Pfizer	Frank.W.Kotch@pfizer.com

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

Session: COVID Therapeutics: From Discovery to Super-Accelerated CMC Development

Session Chairs:

Peter Tessier	Univ of Michigan	ptessier@umich.edu
Michaela Wendeler	AstraZeneca	michaela.wendeler@astrazeneca.com

Session Description:

The COVID-19 pandemic has impacted many aspects of life around the world. It has also initiated an unprecedented race to develop therapeutics and vaccines, necessitating paradigm shifts in drug development. For this session, we invite contributions that highlight the development of innovative COVID therapeutics, especially focusing on solutions for accelerated process development and fast-tracked CMC strategies. We also welcome case studies that describe challenges and technical advances for developing different biotherapeutic modalities, as well as presentations that highlight the scientific, regulatory, and business decisions associated with the pandemic pace. Of interest are strategies that addressed the early need for accelerated drug development, discovery and translation to the clinic, as well as approaches for process characterization, control strategy definition, and process validation. Finally, we welcome presentations highlighting innovative technologies and CMC strategies developed in the face of the pandemic that can likely be leveraged for future development of biotherapeutics in ‘normal’ times.

Session: COVID Vaccines: From Discovery to the Fastest Vaccine Development in History

Session Chairs:

Kunal Aggarwal	GlaxoSmithKline	kunal.x.aggarwal@gsk.com
Andreas Kuhn	BioNTech	Andreas.Kuhn@biontech.de

Session Description:

Given the emergence of the global COVID-19 pandemic, a lot of work has been initiated in early 2020 to rapidly develop vaccines against the corresponding virus, SARS-CoV-2. Such a human vaccine is essential initially for the protection of high-risk individuals and health care workers and ultimately to obtain so-called herd or community immunity. Traditional approaches to prophylactic vaccine development (e.g. attenuated strains of viruses, heat-inactivated viruses or recombinant proteins) have lengthy development timelines to establish safety and efficacy. This session will focus on talks that highlight the challenges associated with accelerated vaccine development in the face of a global pandemic and that provide examples of how these have been tackled. The topics solicited include but are not limited to case studies showcasing use of disruptive approaches to accelerate vaccine development, use of platform technologies to develop COVID-19 vaccines under rapid timelines, innovative approaches in addressing long lead times associated with analytical development, characterization and release testing, and process scale-up and manufacturing to meet the demand of billions of vaccine doses.

Session: COVID-19 Diagnostics and Detection: Technologies, Challenges & the Scale-Up of Testing

Session chairs:

Robert Pantazes	Auburn Univ	rjp0029@auburn.edu
Shannon Servoss	Univ of Arkansas	sservoss@uark.edu

Session description:

As the COVID-19 pandemic spread across the globe, it quickly became clear that detection of SARS-CoV-2 infection is a key necessity in fighting viral spread. As such, numerous detection methods, both established and novel, were implemented for the detection of current and past SARS-CoV-2 infections. This session will focus on the development of virus and antibody detection methods, as well as other COVID-19 diagnostics. Challenges on speed for commercialization including but not limited to regulatory hurdles to get these novel technologies to patients faster in a pandemic situation would be discussed.

Session: How COVID-19 Changed My Research Path: The Good, the Bad, and The Ugly

Session Chairs:

Yu-Shan Lin	Tufts Univ	Yu-Shan.Lin@tufts.edu
Catherine Fromen	Univ of Delaware	cfromen@udel.edu

Session Description:

COVID-19 has drastically changed everyone's life. The sudden shutdown of research labs and the significant reduction of space capacity has impacted many chemists in terms of research productivity and paths. Many academic, industrial, and government labs have also shifted their research directions for the urgent need to understand, prevent, and treat the disease. This session calls for scientists to share how their research paths have changed in response to COVID-19. Topics of interest include unexpected but exciting new research directions and findings; identifying opportunities and making shifts to COVID-19 research and therapeutics; strategies to mitigate the negative impacts of COVID-19 on research and researchers.

Symposium: Rapid Fire and Traditional Poster session

Area Coordinators:

Kristin Vallente	Merck & Co.	kristin_valente@merck.com
Kelsey O'Donnell	Amgen	kodonn01@amgen.com

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Area Coordinators:

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John Welsh	Merck & Co.	john.welsh2@merck.com

Have an idea for a new business? Pitch it to our panel!