20TH ANNIVERSARY

PEPTALK VIRTUAL

CONFERENCE & EXPO

JANUARY 19-21, 2021

Pacific Standard Time (UTC-8:00)

THE PROTEIN SCIENCE AND PRODUCTION WEEK

2021 PIPELINES

- PROTEIN ENGINEERING & DEVELOPMENT
- PROTEIN & ANTIBODY THERAPEUTICS
- CHARACTERIZATION & ANALYTICS
- AGGREGATION & IMPURITIES
- PROCESS TECHNOLOGIES & PURIFICATION
- BIOTHERAPEUTIC EXPRESSION & PRODUCTION

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Conference Programs

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PEPTALK VIRTUAL CONFERENCE & EXPO

Continuing 20 Years of Advanced Protein Science and Innovation

While a lot has changed since PepTalk was launched in 2001, our number one goal has always been the same: to serve and unite the biotherapeutics community.

PepTalk has served as annual gathering place for key players in the industry, connecting countless people around the world, fostering knowledge sharing, and accelerating biotherapeutics development.

It's now more important than ever for our industry to come together, to share experiences, explore the opportunities and overcome the challenges in this new reality.

As we celebrate our 20th year, we are excited to offer a fully integrated virtual event that will continue to serve as a content hub for the latest research and developments, provide a 1:1 networking platform, offer an interactive exhibit hall, live Q&A sessions, breakout groups, research posters, and so much more.

Join your peers and colleagues from around the world to share insights, case studies, cutting-edge research, and form collaborations to advance biotherapeutics development.

12 VIRTUAL CONFERENCES covering protein and antibody engineering and therapeutics, characterization of biotherapeutics, cell and gene therapies, protein expression, production, and more.

120 PRESENTATIONS from top pharma, biotech, academic, and government institutions

CUSTOMIZED AGENDA created by you using our integrated scheduling tool

600 GLOBAL PARTICIPANTS sharing biotherapeutic protein drug development opportunities

LIVE Q&A SESSIONS, BuzZ Session breakout groups, speed networking, chat rooms with exhibitors, sponsors, and fellow delegates

INTERACTIVE EXHIBIT HALL featuring 50+ companies showcasing novel technologies and solutions

100 RESEARCH POSTERS featuring the latest in biotherapeutics discovery

SPONSORED TALKS by leading technology and service providers showcasing new offerings

ON-DEMAND LIBRARY archive of presentations to access on your own time

EVENT AT-A-GLANCE 2021

PEPTALK VIRTUAL CONFERENCE & EXPO

click stream or track titles to view full agenda

	Tuesday, January 19-Wednesday, January 20	Wednesday, January 20-Thursday, January 21
PROTEIN ENGINEERING & DEVELOPMENT	Optimizing Biotherapeutic Discovery	Biotherapeutic Targeting Strategies
PROTEIN & ANTIBODY THERAPEUTICS	Hindsight Is 2020: Application of Accelerated Vaccines and Therapeutics Development	Bispecific Antibodies and Combination Therapies
CHARACTERIZATION & ANALYTICS	Characterization of Biotherapeutics	Characterization and Analytics for Cell and Gene Therapies
AGGREGATION & IMPURITIES	Detection and Characterization of Particulates and Impurities	Protein Aggregation and Emerging Analytical Tools
PROCESS TECHNOLOGIES & PURIFICATION	Higher-Throughput Protein Production and Characterization	Protein Purification and Recovery
BIOTHERAPEUTIC EXPRESSION & PRODUCTION	Cell Line Development Strategies	Recombinant Protein Expression and Production

"PepTalk was a brilliant way to make new connections and showcase my own research. The high quality of presentations at the event, from both industry and academia, was a great way to keep up to date with recent advancements the field."

Jessica E., Researcher, Astbury Center for Structural Molecular Biology, University of Leeds, United Kingdom

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PROTEIN ENGINEERING & DEVELOPMENT

PepTalk's Protein Engineering & Development pipeline for 2021 offers a unique meeting combination for R&D scientists working to discover and develop unique and differentiated biotherapeutics quickly and efficiently. By attending, you'll travel the continuum from early discovery through the engineering steps needed to reach drug targets previously thought to be inaccessible. PepTalk also allows you to customize your conference experience by combining these programs with pipelines dedicated to analytical characterization, expression and production, process technologies, and therapeutic modalities.

January 19-20

Optimizing Biotherapeutic Discovery

AGENDA

January 20-21

Biotherapeutic Targeting Strategies

AGENDA

TUESDAY, JANUARY 19

NEXT-GENERATION TOOLS FOR ANTIBODY DISCOVERY AND ENGINEERING

9:00 am Engineering Synthetic Adaptive Immune Receptors for Enhanced Specificity and Therapeutic Properties

Sai Reddy, PhD, Associate Professor, Systems and Synthetic Immunology, ETH Zurich, Switzerland

Adaptive immunity is driven by a highly diverse set of adaptive immune receptors [B cell receptors (BCRs)/secreted antibodies, and T cell receptors (TCRs). This presentation will explain how our group is using genome editing, deep sequencing, and machine learning to identify patterns of antigen specificity in adaptive immune receptors. Furthermore, I will explain how these approaches can be used for antibody drug discovery and T cell immunotherapy.

9:25 Development of Machine Learning Methods for the Analysis, Prediction and Generation of Antibody Repertoires

Victor Greiff, PhD, Associate Professor, Immunology, University of Oslo, Norway

Antibody repertoires are instrumental in both fighting and causing disease. Past and current immune events are recorded in the antibody repertoire throughout an individual's lifetime. Computational immunology is increasingly used to decipher the immune record in antibody repertoires. We will show how computational and machine learning methods may be used to analyse fundamental aspects of adaptive immunity, predict immune events and antigen binding, as well as generate antibodies *in silico*.

9:50 Sponsored Presentation *(Opportunity Available)*

9:50 From Patient Sample to Antibody Lead in Three weeks: A Real-Time Response to COVID-19

AbCellera

Kevin Heyries, Ph.D., Co-Founder and Head of Business Development, Business Development, AbCellera

In 23 days, AbCellera identified 24 lead candidate antibodies for the treatment and prevention of COVID-19 directly from a blood sample of a convalescent patient. AbCellera is a technology company that searches, decodes, and analyzes natural immune systems to find antibodies that its partners can develop into drugs to prevent and treat disease.

10:20 Late 2020 Research Findings and New Published Results

Claire Marks, PhD, Research Software Engineer, Structural Bioinformatics, University of Oxford, United Kingdom

Computational tools are becoming increasingly important in the field of therapeutic antibody discovery. Our SAbDab-SAbPred platform is a toolbox of software applications and databases. The latest addition to the platform is our humanisation tool, which exploits the rapidly growing amount of antibody repertoire data. Given a sequence, the tool aims to mutate that sequence, such that it does not elicit an immune response, without impacting its efficacy as a therapeutic.

10:45 Next-Generation Neurotoxin Therapeutics

Karen A. Bunting, PhD, Director, Protein Sciences, Neurotoxin Drug Discovery, Ipsen Bioinnovation, United Kingdom

Recombinant expression of botulinum neurotoxins enables protein engineering to exploit the modularity of these proteins, with potential for an increased range of indications. Enhanced strategies around protein modelling, engineering, and characterization have been exploited to increase the numbers of novel neurotoxins produced, extending the early exploration of design space and supporting selection of candidates with optimal function and improved developability.

11:20 LIVE PANEL DISCUSSION: Next-Generation Tools for Antibody Discovery and Engineering

Moderator: Victor Greiff, PhD, Associate Professor, Immunology, University of Oslo, Norway

Panelists:

Karen A. Bunting, PhD, Director, Protein Sciences, Neurotoxin Drug Discovery, Ipsen Bioinnovation, United Kingdom

Claire Marks, PhD, Research Software Engineer, Structural Bioinformatics, University of Oxford, United Kingdom

Sai Reddy, PhD, Associate Professor, Systems and Synthetic Immunology, ETH Zurich, Switzerland

Kevin Heyries, Ph.D., Co-Founder and Head of Business Development, Business Development, AbCellera

11:40 PepTalk Connects - View Our Virtual Exhibit Hall

Make LIVE Connections with Fellow Attendees, Speakers and Solution Providers

12:20 pm BuzZ Sessions

Facilitated, small-group interactive discussions around focused topics.

12:40 Session Break

NEW UNDERSTANDINGS OF TARGET STRUCTURE AND FUNCTION

1:00 Using Cryo-EM to Understand Nucleic Acid Gymnastics

Elizabeth A. Kellogg, PhD, Principal Investigator, Molecular Biology and Genetics, Cornell University

A core research goal of my lab is to study the macromolecular machines that contribute to genome organization and structure. To this end we have been focused on understanding the DNA rearrangements that occur during transposition. I will talk about recent work from our lab to understand the mechanism of action of DNA-transposases as they carry out the reactions that result in their replication and to modify the host genome.

1:25 Chemical Diversification of Synthetic Antibodies on the Yeast Surface

James A. Van Deventer, PhD, Assistant Professor, Chemical and Biological Engineering, Tufts University

Antibodies are cornerstones of modern biotechnology, but antibody properties, including chemical reactivity and mode of target binding, can be constrained by the limited chemistries found in the genetic code. In this work, we describe our yeast display-based approach to identifying antibody variable domains with properties augmented by noncanonical amino acids. This presentation will highlight proof-of-principle demonstrations of how this approach provides important opportunities for discovering and engineering more "druglike" antibodies.

1:50 Presentation to be Announced

ICOSAGEN

Mart Ustav Jr, CSO, Icosagen

2:20 Engineered Fc-Glycosylation Switch to Eliminate Antibody Effector Function

Qun Zhou, PhD, Senior Principal Scientist, US Biologics Research, Sanofi Genzyme R&D Center

We created antibody variants with altered glycosylation sites to eliminate the effector functions. The lead mutant NNAS with the engineered glycosylation at Asn298 shows no detectable binding to all FcγRs/C1q and effector functions. Structural study confirmed the successful glycosylation switch that would cause a clash of N-glycans with FcγRs. Our work provides a novel approach for generating therapeutic antibodies devoid of any effector function.

2:45 Application of Mammalian Display Coupled with *In Vitro* Antibody Library Technology to Membrane Protein Multi-spanner Targets

Agnieszka Kielczewska, PhD, Principal Scientist, Cell Sciences, Amgen, Canada

Multi-spanner receptors, including GPCRs, constitute a therapeutically interesting yet technically challenging target class for therapeutic antibodies. Factors contributing difficulty of targeting these receptors include high homology across species resulting in immune silencing during immunization, relatively low or transient cell-surface expression levels, and difficulty in formulation as a soluble protein applicable to immunogen and screening reagent applications. This talk will cover some examples of approaches to overcome these challenges.

3:20 LIVE PANEL DISCUSSION: New Understandings of Target Structure and Function

Moderator: James A. Van Deventer, PhD, Assistant Professor, Chemical and Biological Engineering, Tufts University

Panelists:

Elizabeth A. Kellogg, PhD, Principal Investigator, Molecular Biology and Genetics, Cornell University

Agnieszka Kielczewska, PhD, Principal Scientist, Cell Sciences, Amgen, Canada

Qun Zhou, PhD, Senior Principal Scientist, US Biologics Research, Sanofi Genzyme R&D Center

Mart Ustav Jr, CSO, Icosagen

3:40 Close of Day

WEDNESDAY, JANUARY 20

8:15 Breakfast BuzZ Sessions

Facilitated, small-group interactive discussions around focused topics.

BuzZ Session: Discovery Strategies: From Human B Cells to mAbs

Scott Dessain, MD, PhD, Professor, Clinical Oncology and Research, Lankenau Medical Center; CSO, OCMS Bio

- Antigen selection for high throughput mAb screening applications
- Hit to lead strategies in mAb discovery
- Patient sourcing strategies
- Complementary technologies for collaborative mAb discovery

8:45 Session Break

INNOVATIONS IN REPERTOIRE ANALYSIS, LIBRARY DESIGN AND HIGH-THROUGHPUT ENGINEERING

9:00 Late 2020 Update: Cloning Diagnostic Antibodies from COVID-19 Patients Using On-Cell mAb Screening (OCMS™)

Scott Dessain, MD, PhD, Professor, Clinical Oncology and Research, Lankenau Medical Center; CSO, OCMS Bio

Human mAbs are ideal diagnostic reagents for infectious disease and autoimmunity, but diagnostic Abs must meet different performance criteria than therapeutic antibodies. On-Cell mAb Screening (OCMS™) is a hybridoma method in which patient-derived B cells express their antibodies on cell surface. OCMS mAbs are screened for binding to fluorescent antigens using HT imaging techniques. Case studies will be shown with antibodies to poliovirus, the NMDAR receptor, and SARS-CoV-2 Spike protein.

9:25 Late 2020 Update: Case Studies of Lessons Learned from COVID-19 Antibody and Vaccine Research

Gregory C. Ippolito, PhD, Research Assistant Professor, Molecular Biosciences, University of Texas at Austin

A deeper understanding of protective humoral immunity to SARS-CoV-2 should aid in the discovery and design of therapeutic interventions. Here, I will present a molecular, functional, and structural analysis of convalescent-phase IgG monoclonal antibodies mined from the blood of COVID-19 survivors. The talk will include a comparative analysis of these serological repertoires vs. B cell repertoires described by other research groups.

9:50 Computer-aided *De novo* Antibody Design & Discovery

Synbio Technologies Genes for Life

Hun Lee PhD, Global Leader of Protein Design, Data Science, Synbio Technologies

Synbio Technologies provides fast and customized one-stop solutions for antibody discovery. SynoAb platform is a structure-based ***in silico*** antibody discovery method and can screen hits for antigens for wet-lab evaluation, followed by affinity maturations using controlled permutation libraries. The SynoAb will offer highly flexible supports and services for antibody discovery.

10:05 Developability Assessment and Property Prediction by pH-Dependent Conformational Sampling

Chemical Computing Group

Andrew Henry, Principal Scientist, Chemical Computing Group

mAb candidates identified from high-throughput screening or binding affinity optimization often present liabilities for developability, such as aggregation-prone regions or poor solution behavior. In this work, we developed a method for modeling proteins and performing pH-dependent conformational sampling, which can enhance property calculations such as hydrophobic patches, charge and pI. A retrospective data analysis demonstrates that these 3D descriptors, averaged over conformational sampling and stochastic titration, can accurately predict pI values, screen candidates and enrich libraries with favorable developability properties for a range of biotherapeutics. The clinical landscape of antibodies is also analyzed and its property profile and insights thereof are presented.

10:20 Late 2020 Update: Isolation and Characterization of Nanobodies for SARS-CoV-2

Mitchell Ho, PhD, Senior Investigator; Deputy Chief, Laboratory of Molecular Biology; Head, Antibody Therapy Section; Director, Antibody Engineering Program, National Cancer Institute (NCI)

My laboratory has established unique, large, single-domain antibody (also called "nanobody") phage display libraries from camels (***Camelus dromedarius***) and sharks (***Ginglymostoma cirratum***) to develop nanobodies against SARS-CoV-2 and other disease antigens. In my talk, I will discuss: (i) construction and sequencing analysis of our camel (V_HH) and shark (V_{NAR}) nanobody phage libraries; (ii) screening of nanobodies to SARS-CoV-2 spike (S) protein; and (iii) binding features of these novel nanobodies.

10:45 Platformization of Multi-Specific Protein Engineering: Leveraging High-Throughput Screening Data for *in silico* Antibody Design

Norbert Furtmann, PhD, Section Head, Data Science & Computational Design, Biologics Research, Sanofi, Germany

Our novel, automated high-throughput engineering platform enables the fast generation of large panels of multi-specific biotherapeutics (up to 10.000), giving rise to large data sets (more than 100.000 data points). By combining data science and structure-based design workflows, we leverage the potential of our unique data sets to guide the engineering of our next-generation antibody therapeutics.

11:20 LIVE PANEL DISCUSSION: Innovations in Repertoire Analysis, Library Design and High Throughput Engineering

Moderator: Gregory C. Ippolito, PhD, Research Assistant Professor, Molecular Biosciences, University of Texas at Austin

Panelists:

Scott Dessain, MD, PhD, Professor, Clinical Oncology and Research, Lankenau Medical Center; CSO, OCMS Bio

Norbert Furtmann, PhD, Section Head, Data Science & Computational Design, Biologics Research, Sanofi, Germany

Mitchell Ho, PhD, Senior Investigator; Deputy Chief, Laboratory of Molecular Biology; Head, Antibody Therapy Section; Director, Antibody Engineering Program, National Cancer Institute (NCI)

Andrew Henry, Principal Scientist, Chemical Computing Group

Hun Lee PhD, Global Leader of Protein Design, Data Science, Synbio Technologies

11:40 PepTalk Connects - View Our Virtual Exhibit Hall

Make LIVE Connections with Fellow Attendees, Speakers and Solution Providers

12:20 LIVE DISCUSSIONS: Women in Science Meet-Up and Early Faculty Career Networking

View more details on the Event Features page.

CO-PRESENTATION: Women In Science Meet-Up

Kelly Kemp, PhD, Director, Process Development, ViaCyte Inc.

Elizabeth S. Hecht, PhD, Associate Scientist, Microchemistry, Proteomics & Lipidomics, Genentech, Inc.

CO-PRESENTATION: Early Faculty Career Networking Meet-Up

Jamie B. Spangler, PhD, Assistant Professor, Biomedical Engineering and Chemical & Biomolecular Engineering, Johns Hopkins University

Erik Procko, PhD, Assistant Professor, Biochemistry, University of Illinois Urbana-Champaign

- Management of time and responsibilities in starting up a research lab
- Navigating unique challenges due to COVID-19 pandemic
- Recruiting students and postdocs
- Seeking out mentorship resources needed for success

12:40 Session Break

12:55 Close of Optimizing Biotherapeutic Discovery Conference

WEDNESDAY, JANUARY 20

8:15 Breakfast BuzZ Sessions
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BuzZ Session: Discovery Strategies: From Human B Cells to mAbs
Scott Dessain, MD, PhD, Professor, Clinical Oncology and Research, Lankenau Medical Center; CSO, OCMS Bio

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12:40 Session Break

SELECTIVE ACTIVATION, BBB REGULATION AND SIGNALING IN SINGLE CELLS

1:00 Tumor-Selective Activation of Immunotherapies
Ronan O'Hagan, Senior Vice President, Research & Translational Sciences, Xilio Therapeutics, Inc.

Immunotherapies have provided significant benefit for cancer patients. However, the use of highly potent immunotherapeutic agents is limited by associated toxicities that result from systemic immune activation. We have developed a rational approach to design therapeutics that are selectively activated in the tumor micro-environment. This approach has the potential to improve the safety and efficacy of cytokine-based therapies and immune checkpoint inhibitors, and can be applied broadly to protein-based therapeutics.

1:25 Novel Platforms for Biotherapeutics Delivery
Nitin Joshi, PhD, Instructor, Harvard Medical School

We have developed an inflammation-responsive hydrogel platform from small-molecule amphiphilic gelators, which we have identified through our screening of the FDA's generally recognized as safe (GRAS) list of compounds. This talk will discuss our previously published and currently ongoing work to advance this hydrogel platform. I will also discuss our recent work on blood-brain barrier pathophysiology-independent delivery of nucleic acid-based therapeutics in traumatic brain injury.

1:50 Session Break

2:20 Blood-Brain Barrier Regulation of Brain Function and Behavior
Richard Daneman, PhD, Assistant Professor, Pharmacology, University of California San Diego

Vascular endothelial cells in the central nervous system (CNS) form a barrier that restricts the movement of molecules and ions between the blood and the brain. This blood-brain barrier (BBB) is crucial to ensure proper neuronal function and protect the CNS from injury and disease. We are interested in identifying how the BBB interacts with the neural circuitry to regulate brain function and behavior.

2:45 Fine Tuning Receptor Signaling
Mariana Lemos Duarte, PhD, Postdoctoral Fellow, Icahn School of Medicine at Mount Sinai

In this talk, I will present how to use high-throughput microscopy to explore temporal dynamics of signaling in single cells. I am presenting a subset of antibodies targeting opioid receptors to examine the effect of treatment with opiates, such as morphine and fentanyl, that have played central roles in the worsening of the 'Opioid Epidemic.'

3:20 LIVE PANEL DISCUSSION: Selective Activation, BBB Regulation and Signaling in Single Cells
Moderator: Mariana Lemos Duarte, PhD, Postdoctoral Fellow, Icahn School of Medicine at Mount Sinai

Panelists:

Richard Daneman, PhD, Assistant Professor, Pharmacology, University of California San Diego

Nitin Joshi, PhD, Instructor, Harvard Medical School

Ronan O'Hagan, Senior Vice President, Research & Translational Sciences, Xilio Therapeutics, Inc.

3:40 20th Anniversary Celebration - View Our Virtual Exhibit Hall
Reunite with old friends and new, share memories, and raise a glass with your peers in an open video reunion.

4:00 Close of Day

THURSDAY, JANUARY 21

ADOPTIVE T CELL THERAPIES, IMPROVED ADCs, TARGETING MEMBRANE PROTEINS AND TUMOR-LOCALIZED ACTIVATION

9:00 am Engineering Receptors for Adoptive T Cell Therapies of Cancer

Preeti Sharma, PhD, Postdoctoral Research Associate, Biochemistry Department, University of Illinois at Urbana-Champaign

Adoptive T cell therapies using T cells expressing synthetic chimeric antigen receptors (CARs), or engineered native T cell receptors (TCRs) have been successful in treating some cancers. This approach harnesses the inherent potency of T cells and redirects their recognition toward cancer antigens. While many challenges remain (e.g. cross-reactivity with self-antigens and antigen escape), protein engineering can offer solutions for such issues.

9:25 Engineering ADCs to Increase Cytotoxic Payload Delivery and Minimize Off-Target Effects

E. Sally Ward, PhD, Director, Translational Immunology; Professor, Molecular Immunology, Centre for Cancer Immunology, University of Southampton

We have recently modulated the endosomal trafficking behavior of a HER2-specific antibody-drug conjugate (ADC) to improve the efficiency of cytotoxic payload delivery to lysosomes. This approach, called ALTA technology (for ADCs with increased lysosomal trafficking activity), is expected to enable therapeutic efficacy using lower doses, thereby leading to decreased off-tumor toxicities. Consequently, this strategy may allow tumors with a broad range of HER2 expression levels to be targeted.

9:50 Applications of Proteomics and Antibody Sequencing to Improve Reproducibility in the Life Sciences

RAPID NOVOR

Clayton Moore, Senior Scientific Sales Executive, Rapid Novor Inc

Antibodies have become an integral tool in the life sciences and yet very little is done to ensure that we are working with good and reliable antibodies. Because antibodies are characterized by what they bind rather than their physical characteristics there is still much we do not understand about reagents we use every day. At best they do not bind reliably, and at worst they bind to entirely different targets. Antibody sequencing has advanced dramatically over the past five years to the point where antibodies can be sequenced reliably and affordably. Historically antibody mixtures and polyclonal antibody samples could not be characterized, however, by applying novel proteomics techniques sequencing on these complex samples is finally possible.

10:05 Sponsored Presentation *(Opportunity Available)*

10:20 Membrane Protein Tools for Drug Discovery

Anass Jawhari, PhD, Independent Consultant

Membrane proteins such as GPCRs and ion channels represent more than 60% of therapeutic targets. In my presentation I will provide a comprehensive overview of MP isolation tools, and discuss expression, solubilization, purification & stabilization of unmutated MPs. The use of detergents, amphiphilic copolymers, nanodisc, extracellular vesicles or liposomes to successfully enable antibody discovery, FBDD and SBDD of MPs will be presented. Trends in ML/AI-based approaches will be discussed.

10:45 Designing Tumor-Localized Chemical Biology Activation into Immune Checkpoint Antibodies

John Karanicolas, PhD, Professor, Molecular Therapeutics, Fox Chase Cancer Center

Antibodies are typically administered systemically and act throughout the body, which can cause on-target toxicity away from the disease site. We developed a strategy whereby an antibody can be de-activated by mutation, then re-awakened upon addition of a complementary ligand. Because our design is built upon conserved residues in the antibody framework, the same mutation/ligand pair can be used to modulate antigen binding in many different clinically relevant antibodies.

11:20 LIVE PANEL DISCUSSION: Adoptive T Cell Therapies, Improved ADCs, Targeting Membrane Proteins and Tumor-Localized Activation

Moderator: Anass Jawhari, PhD, Independent Consultant

Panelists:

John Karanicolas, PhD, Professor, Molecular Therapeutics, Fox Chase Cancer Center

Preeti Sharma, PhD, Postdoctoral Research Associate, Biochemistry Department, University of Illinois at Urbana-Champaign

E. Sally Ward, PhD, Director, Translational Immunology; Professor, Molecular Immunology, Centre for Cancer Immunology, University of Southampton

Clayton Moore, Senior Scientific Sales Executive, Rapid Novor Inc

11:40 PepTalk Connects - View Our Virtual Exhibit Hall

Make LIVE Connections with Fellow Attendees, Speakers and Solution Providers

12:20 BuzZ Sessions

Facilitated, small-group interactive discussions around focused topics.

BuzZ Session: Trends to Improve Drug Efficacy While Reducing Side Effects

Anass Jawhari, PhD, Independent Consultant

- How can novel cell therapy approaches contribute to successful drug discovery? What are the trends?
- Why can improved ADCs be key to reducing toxicity while maintaining efficiency? What will be the next generation of ADCs?
- How can local administration of antibodies help reduce on-target toxicity? What about indications other than Cancer?
- Engineering versus working with the native target. What strategy to adopt?

12:40 Session Break

NOVEL STRATEGIES FOR BIOTHERAPEUTIC TARGETING

1:00 Exquisitely Specific Anti-KRAS Biodegraders Inform on the Cellular Prevalence of Nucleotide-loaded States

Anthony Partridge, PhD, Senior Principal Scientist, Merck Sharp & Dohme, Singapore

To understand the advantages and feasibility of KRAS-targeted degradation, we developed KRAS bioPROTACs - chimeric proteins consisting of high-affinity RAS binders fused to an E3 ligase. These provided definitive evidence for RAS degradability and elucidated the consequences of RAS degradation. These also informed on the degradation kinetics of KRAS mutants and prevalence of nucleotide states in WT/mutant KRAS. If delivery challenges can be addressed, RAS bioPROTACs may be exciting clinical candidates.

1:25 Conditionally Active T Cell Engager Engineered for the Treatment of Solid Tumors

Robert DuBridge, PhD, Executive Vice President, Research & CTO, Maverick Therapeutics

T cell-engaging bispecific antibodies have demonstrated potent cytotoxicity against cancer cells. This potency can engender off-tumor, on-target toxicity when targeting solid tumors. Maverick Therapeutics has developed a bispecific platform called COBRA™, which includes two active tumor-targeting domains and inactive T cell-engaging domains, that become active within the tumor microenvironment. This presentation will demonstrate the efficacy of these molecules against human tumor cells ***in vitro*** and ***in vivo***.

1:50 Session Break

2:20 Mapping Epitopes by HDX-MS and Impacts on Therapeutic Antibody Targeting

Joey Sheff, PhD, Research Associate, National Research Council Canada

Recent technological advancements in HDX-MS have enabled the rapid investigation of biotherapeutic antibodies and their interactions. We are developing a sophisticated HDX-MS platform to support antibody development against difficult-to-analyze protein targets. Described here is the dynamic epitope mapping and conformational characterization by HDX-MS of two distinct antigenic targets, CA-IX and IGF1R. The unique contribution of HDX-MS findings to the development pipeline will be explored.

3:40 Close of Conference

2:45 Molecular Simulation and Learning for the Design of Finely Tuned Biotherapeutics

Ron Dror, PhD, Associate Professor, Computer Science, Artificial Intelligence Lab, Stanford University

The vision of structure-based drug design has long been to predict how ligands will influence the function of their targets. This is finally becoming a reality, thanks to advances in computational methods and technologies. I will present recent studies in which we used molecular dynamics simulations and machine learning to guide the design of ligands that selectively bind desired targets and selectively stimulate desired functions.

3:20 LIVE PANEL DISCUSSION: Novel Strategies for Biotherapeutic Targeting

Moderator: Robert DuBridge, PhD, Executive Vice President, Research & CTO, Maverick Therapeutics

Panelists:

Ron Dror, PhD, Associate Professor, Computer Science, Artificial Intelligence Lab, Stanford University

Anthony Partridge, PhD, Senior Principal Scientist, Merck Sharp & Dohme, Singapore

Joey Sheff, PhD, Research Associate, National Research Council Canada

1:55 Session Break

PROTEIN & ANTIBODY THERAPEUTICS

Providing efficacious vaccines and therapeutics for human welfare is an essential component of modern life. As we have been reminded recently, vaccines provide protection from diseases that can greatly alter life and prosperity. In addition, there is an abundance of diseases such as cancer that impact longevity and quality of life. The Protein & Antibody Therapeutics pipeline investigates the strategies and technologies employed for developing vaccines and therapies that provide security, freedom, and better health.

January 19-20

Hindsight Is 2020: Application of Accelerated Vaccines and Therapeutics Development

AGENDA

January 20-21

Bispecific Antibodies and Combination Therapies

AGENDA

HINDSIGHT IS 2020: APPLICATION OF ACCELERATED VACCINES AND THERAPEUTICS DEVELOPMENT

What COVID-19 Has Taught Us and How It Applies beyond Pandemics

TUESDAY, JANUARY 19

COVID-19: SCIENCE - SEQUENCE - STRUCTURE

9:00 am FEATURED PRESENTATION: Tackling COVID-19 Drug Discovery Using Structural Genomics

Karla Satchell, PhD, Professor, Microbiology-Immunology; Principal Investigator and Co-Director, Center for Structural Genomics of Infectious Diseases, Northwestern University

SARS-CoV-2 is the etiological agent of COVID-19. We conducted an X-ray crystallographic study of multiple SARS-CoV-2 protein structures, including the nsp16/nsp10 2'-*O*-methyltransferase complex that modifies the cap of viral mRNAs to avoid immune surveillance. Nsp16 is one of the most conserved proteins of SARS-CoV-2 and related coronaviruses, and thus, these high-resolution structures are expected to be useful as models for developing new antiviral therapeutics to treat coronavirus diseases.

9:25 FEATURED PRESENTATION: Antibodies against SARS-CoV-2: A Global Consortium

Erica Ollmann Saphire, PhD, Professor, La Jolla Institute for Immunology

Therapeutic antibodies can provide key protection or lifesaving treatment for those who haven't been or can't be vaccinated, or when vaccines don't "take". We galvanized a Gates- and NIAID-funded consortium to understand which antibodies are most protective and why, and to broadly mobilize therapeutics where needed. We will present the results thus far of the comprehensive research study and epitopes on the viral spike protein best recognized.

9:50 Leave No Hit Behind: Accelerating Lead Molecule Discovery Against Difficult Targets

BERKELEY LIGHTS

Anupam Singhal, PhD, Senior Product Manager, Antibody Discovery, Marketing, Berkeley Lights, Inc.

Traditional hybridoma and phage display methods have failed to yield therapeutic antibodies against difficult targets like most GPCRs and ion channels. This presentation will introduce Berkeley Lights' new Opto™ Plasma B Discovery 4.0 workflow that enables recovery of 1000s of hits by screening >100,000 plasma B cells, down-selection of lead candidates by functional screening, and sequencing and re-expression of 1000s of functionally-characterized antibodies… all in just 1 week. By maximizing the diversity of antibodies through direct functional profiling of plasma B cells, the Opto™ Plasma B Discovery 4.0 workflow will allow users to tackle even the most challenging targets.

10:20 Artificial Intelligence Driven Drug-Discovery Strategies for COVID-19

Arvind Ramanathan, PhD, Computational Biologist, Argonne National Laboratory

From understanding basic mechanisms of how various SARS-CoV-2 proteins function to discovering new molecules that can interact and potentially inhibit various viral protein targets, we provide an overview of how artificial intelligence methods are being used to study COVID-19. We provide an overview of some of these AI methods and how they have enabled novel insight into the function of SARS-CoV-2 proteins.

10:45 Optimizing High-Yield Production of SARS-CoV-2 Soluble Spike Trimers for Serology Assays

William Gillette, PhD, Principal Scientist, Protein Expression Laboratory, Leidos Biomedical Research

Accelerated development almost by definition means going out of your comfort zone. A case study on our lab's pivot to support the NIH COVID19 Serosurvey by providing recombinant SARS-CoV-2 proteins will be presented. The balance between speed, efficiency, and productivity is fraught with decisions that often have little supporting data. Nevertheless, general lessons learned in the past are critically important.

11:20 LIVE PANEL DISCUSSION: COVID-19: Science - Sequence - Structure

Moderator: Karla Satchell, PhD, Professor, Microbiology-Immunology; Principal Investigator and Co-Director, Center for Structural Genomics of Infectious Diseases, Northwestern University

Panelists:

William Gillette, PhD, Principal Scientist, Protein Expression Laboratory, Leidos Biomedical Research

Arvind Ramanathan, PhD, Computational Biologist, Argonne National Laboratory

Erica Ollmann Saphire, PhD, Professor, La Jolla Institute for Immunology

Anupam Singhal, PhD, Senior Product Manager, Antibody Discovery, Marketing, Berkeley Lights, Inc.

11:40 PepTalk Connects - View Our Virtual Exhibit Hall

Make LIVE Connections with Fellow Attendees, Speakers and Solution Providers

12:20 BuzZ Sessions

Facilitated, small-group interactive discussions around focused topics.

BuzZ Session: When Time Really Matters: Will the Next Emergency Protein Fit into Your Pipeline?

William Gillette, PhD, Principal Scientist, Protein Expression Laboratory, Leidos Biomedical Research

- What expression platforms might you need to ramp up?
- To clone or bring in plasmids/cell lines?
- Are your screening platforms (both expression and purification) up to the task?
- Expect the unexpected: flexibility in staffing (e.g. social distancing)
- Project tracking and communication; what needs to change?

12:40 Session Break

VACCINE R&D

1:00 Accelerated Development of Molecular Clamp-Based Recombinant Protein Subunit Vaccine for COVID-19

Trent Munro, PhD, Director, National Biologics Facility; Program Director, Rapid Response Vaccine Pipeline, Australian Institute for Bioengineering and Nanotechnology, The University of Queensland

Working alongside CEPI and a team of Australian and International collaborators, the UQ team shifted its Molecular Clamp rapid response program to development of a vaccine candidate for COVID-19. We have moved rapidly through pre-clinical testing and are currently completing early phase clinical studies. We have also

partnered with CSL, who are currently advancing both large-scale manufacturing and pivotal stage clinical development for widespread distribution and use.

1:25 A Novel Low-Immunogenic DNA Plasmid Encoded with a Therapeutic Antibody for Long-Lasting Expression *in vivo* against COVID-19

Henry H. Ji, PhD, Chairman, President & CEO, Sorrento Therapeutics Inc.

Sorrento Therapeutics acquired SmartPharm, a gene-encoded therapeutics company developing non-viral DNA and RNA gene delivery platform. Through this collaboration/acquisitions Sorrento has identified STI-2020dna (DNA plasmid injection), an antibody encoded DNA plasmid candidate derived from Sorrento's proprietary STI-1499 (COVI-GUARD™). STI-2020dna has generated antibodies ***in vivo*** directed against the SARS-CoV-2 virus, including D614G-bearing virus isolates. STI-2020dna is currently under development with the potential to generate long-lasting anti-viral protection with a single intra-muscular administration.

1:50 When science gets lucky: Targeting Spike protein for effective vaccine and therapeutics against SARS-CoV-2

Prajwal Paudel, PhD, Product Development Scientist, Product Development, ACROBiosystems

The global SARS-CoV-2 pandemic has challenged healthcare systems around the world even after almost a year of efforts to contain spread and treat patients. One of the brightest spots has been the record pace of scientific and medical discoveries that have led to generation of promising vaccines and antibody therapeutic against SARS-CoV-2 centered on Spike protein (S). ACROBiosystems is proud to support development of vaccines and therapeutics against COVID-19.

2:20 Particle-Based Presentation Enhances Immunogenicity of the SARS-CoV-2 RBD

Jonathan Lovell, PhD, Associate Professor, Biomedical Engineering, SUNY Buffalo

The receptor-binding domain (RBD) of the SARS-CoV-2 spike protein is a candidate vaccine antigen that binds angiotensin-converting enzyme 2 (ACE2), leading to virus entry. Here, it is shown that rapid conversion of recombinant RBD into particulate form via admixing with liposomes containing cobalt-porphyrin-phospholipid (CoPoP) potently enhances the functional antibody response. These results confirm that adjuvant and presentation strategies can help induce strongly neutralizing antibody responses against SARS-CoV-2.

3:20 LIVE PANEL DISCUSSION: Vaccine R&D

Moderator: Trent Munro, PhD, Director, National Biologics Facility; Program Director, Rapid Response Vaccine Pipeline, Australian Institute for Bioengineering and Nanotechnology, The University of Queensland

Panelists:

Keith Chappell, PhD, Principal Research Fellow, School of Chemistry and Molecular Biosciences; Affiliate Senior Research Fellow, Australian Institute for Bioengineering and Nanotechnology, The University of Queensland

Henry H. Ji, PhD, Chairman, President & CEO, Sorrento Therapeutics Inc.

Jonathan Lovell, PhD, Associate Professor, Biomedical Engineering, SUNY Buffalo

Prajwal Paudel, PhD, Product Development Scientist, Product Development, ACROBiosystems

3:40 Close of Day

WEDNESDAY, JANUARY 20

8:15 Breakfast BuzZ Sessions

Facilitated, small-group interactive discussions around focused topics.

BuzZ Session: Glycosylation of Therapeutic Proteins

Bjørn Voldborg, MSc, Director, CHO Cell Line Development, Novo Nordisk Foundation Center for Biosustainability, Technical University of Denmark

- Why is it important?
- How do we handle it?
- Future perspectives

8:45 Session Break

BIOTHERAPY R&D

9:00 Co-Presentation: Cellular Nanosponges Inhibit SARS-CoV-2 Infectivity

Anthony Griffiths, PhD, Associate Professor, Microbiology; Investigator, National Emerging Infectious Diseases Laboratories (NEIDL), Boston University School of Medicine

Liangfang Zhang, PhD, Professor, Department of Nanoengineering; Director, Chemical Engineering Program, University of California San Diego

We report cellular nanosponges, made of the plasma membranes derived from human lung epithelial cells or human macrophages, as an effective medical countermeasure to SARS-CoV-2 virus. It is shown that following incubation with the nanosponges, SARS-CoV-2 is neutralized and unable to infect cells. The nanosponges will be able to neutralize the infection, providing abroad-acting countermeasure resistant to mutations and protective against this and other emerging coronaviruses.

9:25 Nanobodies to SARS-CoV-2 Proteins

Louis B. Hersh, PhD, Professor, Molecular & Cellular Biochemistry; Director, Protein Core, University of Kentucky College of Medicine

Nanobodies (single domain antibodies) against the SARS-CoV-2 spike protein represent a promising agent for anti-SARS-CoV-2 therapy. We are developing anti-spike protein nanobodies from alpacas that block the attachment of SARS-CoV-2 to its cellular receptor, angiotensin converting enzyme-2 (ACE2). Such nanobodies can act as neutralizing nanobodies. The most effective of these will be explored as a treatment for COVID-19 through nasal delivery.

9:50 Considerations for Optimizing High-Throughput Synthesis of SARS-CoV-2 Peptides for Epitope Analysis

Andrew Kennedy, PhD, Global Product Manager, Gyros Protein Technologies

The speed and flexibility of peptide synthesis is a major advantage when handling rapidly evolving conditions, such as SARS-CoV-2 infection and vaccine development. These applications demand high peptide purity and yield, and the ability to quickly synthesize many peptides in parallel for timely treatment. Here we present examples of how peptide-based epitopes and therapeutics are synthesized for COVID-19 and neoantigen applications.

10:20 Decoy Receptor Has Potent Neutralizing Activity against SARS-CoV-2

Erik Procko, PhD, Assistant Professor, Biochemistry, University of Illinois Urbana-Champaign

The spike proteins S of SARS-associated coronaviruses bind with moderate affinity to ACE2 on host cells as an entry receptor. Guided by deep mutagenesis, ACE2 was engineered as a high affinity soluble decoy that blocks receptor-binding sites on S of SARS-CoV-2 and related betacoronaviruses. The engineered decoys potently neutralize infection with an efficacy that rivals affinity-matured monoclonal antibodies.

10:45 Antibody-Like Nanodisc as a Potential Therapy for SARS-CoV-2 Infection

Mahmoud Nasr, PhD, RPh, Assistant Professor, Medicine, Brigham and Women's Hospital, Harvard Medical School

We will present a modular method to produce Antibody-Like Nanodiscs (ANL). Using our method, we have created and tested ANL against SARS-CoV-2 infection. The method for making these ANL as well as the neutralization of SARS-CoV-2 data will be presented and discussed.

11:20 LIVE PANEL DISCUSSION: Biotherapy R&D

Moderator: Louis B. Hersh, PhD, Professor, Molecular & Cellular Biochemistry; Director, Protein Core, University of Kentucky College of Medicine

Panelists:

Anthony Griffiths, PhD, Associate Professor, Microbiology; Investigator, National Emerging Infectious Diseases Laboratories (NEIDL), Boston University School of Medicine

Andrew Kennedy, PhD, Global Product Manager, Gyros Protein Technologies

Mahmoud Nasr, PhD, RPh, Assistant Professor, Medicine, Brigham and Women's Hospital, Harvard Medical School

Erik Procko, PhD, Assistant Professor, Biochemistry, University of Illinois Urbana-Champaign

Liangfang Zhang, PhD, Professor, Department of Nanoengineering; Director, Chemical Engineering Program, University of California San Diego

11:40 PepTalk Connects - View Our Virtual Exhibit Hall

Make LIVE Connections with Fellow Attendees, Speakers and Solution Providers

12:20 LIVE DISCUSSIONS: Women in Science Meet-Up and Early Faculty Career Networking

View more details on the Event Features page.

CO-PRESENTATION: Women In Science Meet-Up

Kelly Kemp, PhD, Director, Process Development, ViaCyte Inc.

Elizabeth S. Hecht, PhD, Associate Scientist, Microchemistry, Proteomics & Lipidomics, Genentech, Inc.

CO-PRESENTATION: Early Faculty Career Networking Meet-Up

Jamie B. Spangler, PhD, Assistant Professor, Biomedical Engineering and Chemical & Biomolecular Engineering, Johns Hopkins University

Erik Procko, PhD, Assistant Professor, Biochemistry, University of Illinois Urbana-Champaign

- Management of time and responsibilities in starting up a research lab
- Navigating unique challenges due to COVID-19 pandemic
- Recruiting students and postdocs
- Seeking out mentorship resources needed for success

12:40 Session Break

12:55 Close of Hindsight Is 2020: Application of Accelerated Vaccines and Therapeutics Development Conference

CHARACTERIZATION & ANALYTICS

Traditional biologics, new modalities, cell and gene therapies, and biosimilars are flooding discovery and development pipelines. Thus, the analytical function is rapidly evolving, demanding high-throughput and high-resolution tools, focused biomolecular and biophysical assays, and rapid characterization and profiling tools. The Characterization & Analytics pipeline features in-depth perspectives on the latest developments and most critical steps in the characterization of biologics and cell and gene therapy products such as CMC, stability studies, characterization, analysis, impurities, and quality control.

January 19-20

Characterization of Biotherapeutics

AGENDA

January 20-21

Characterization and Analytics for Cell and Gene Therapies

AGENDA

TUESDAY, JANUARY 19

CHARACTERIZATION FOR NOVEL BIOTHERAPEUTICS

9:00 am KEYNOTE PRESENTATION: Characterization of Biotherapeutics Carrying Synonymous Mutations

Chava Kimchi-Sarfaty, PhD, Deputy Associate Director for Research, Office of Tissues and Advanced Therapies, CBER, FDA

Optimization of codons is achieved by altering the DNA sequence while retaining the primary amino acid sequence by exploiting the redundancy of the genetic code. Using recombinant ADAMTS13 and recombinant factor IX as examples of therapeutic proteins we demonstrate that synonymous mutations introduced during optimization affect protein structure and function and thus affect protein quality.

9:50 High Throughput Platforms to Evaluate the Stability of Bispecific Antibodies

Jen Carlstrom, Senior Application Scientist, Global Discovery Applications Group, PerkinElmer

Fast and accurate methods for functionally evaluating and characterizing the stability of bispecific antibodies (bsAb) are necessary during both discovery and development stages. Here, we describe high throughput no wash homogenous immunoassays using two different technologies to evaluate the binding activity and to show if both sites on the bsAb can bind the target proteins. We also developed a homogeneous multiplex assay to measure the two separate binding events simultaneously.

10:20 Perspectives on the Development of Robust CAR T Formulation

Bharathi Kumar, Scientist, Janssen

10:45 Size Distribution Analysis of AAV Gene Therapy Vectors

Susumu Uchiyama, PhD, Professor, Biotechnology, Osaka University

Recombinant adeno-associated virus (rAAV) for gene therapy has a size distribution due to the presence of empty and intermediate rAAV particles and aggregates. Though the influence of such particles on the efficacy and safety is under investigation, reliable and proper assessments of rAAV size distribution are highly preferable. In this talk, I'll introduce currently available methods for rAAV size distribution analysis and advantageous point of each method including analytical ultracentrifugation.

11:40 PepTalk Connects - View Our Virtual Exhibit Hall

Make LIVE Connections with Fellow Attendees, Speakers and Solution Providers

12:20 BuzZ Sessions

Facilitated, small-group interactive discussions around focused topics.

BuzZ Session: Techniques for Aggregation Mechanism Determination

Elizabeth S. Hecht, PhD, Associate Scientist, Microchemistry, Proteomics & Lipidomics, Genentech, Inc.

12:40 Session Break

DEVELOPABILITY, RISK ASSESSMENT, HTS SCREENING, AND ASSAYS

1:25 Instant Formulation of Multispecific Binders Using LassoGraft Technology®

Junichi Takagi, PhD, Professor, Institute for Protein Research, Osaka University

We found that the pharmacophore sequences of a RaPID-derived peptides can be implanted to a surface-exposed loop of recombinant proteins without losing the function of both the grafted peptide and the scaffold protein. By this method, any chosen proteins could be endowed with binding capability toward various receptors, allowing us to quickly formulate bi-, tri-, and even tetra-specific binder molecules.

1:50 Presentation to be Announced

Speaker To Be Announced, Nano Temper Technologies

2:20 Studying Excipient Modulated Colloidal Stability and Viscosity of Monoclonal Antibody Formulations Using Small Angle X-Ray/Neutron Scattering

Amy Xu, PhD, Assistant Professor, Chemistry, Louisiana State University

Using kD and B22 to predict the PPI in concentrated mAb formulations was evaluated through S(q)eff extracted from SAXS/SANS measurements. Disagreements between PPI determined from dilute (kD/B22) and concentrated solutions highlight the necessities of performing measurements directly from concentrated mAb solutions. The correlation between measured and predicted viscosity results suggests a need for better understanding of the relationship between PPI and solution viscosity, so more reliable predictions can be made.

2:45 HR Multi-Attribute Method Workflow to Track the Behaviour of Predefined Quality Attributes of Monoclonal Antibodies and the Benefit of New Peak Detection (NPD) as Non-Targeted Purity Assay

Silvia Millan Martin, PhD, Biopharmaceutical Applications Scientist, Characterisation & Comparability Lab, National Institute for Bioprocessing Research & Training NIBRT

We implemented a powerful workflow for the determination of multiple PQAs in a single analysis in combination with NPD capability which enables simultaneous determination of purity and identity. Use of high-resolution mass detection is essential for unambiguous analysis of PQAs when using the retention time plus accurate mass-targeted approach. We investigate the implementation of high-resolution MAM for PQA determination at various stages of the biopharmaceutical manufacturing process.

3:20 LIVE PANEL DISCUSSION: Developability, HTS Screening, and Assays

Moderator: Junichi Takagi, PhD, Professor, Institute for Protein Research, Osaka University

Panelists:

Silvia Millan Martin, PhD, Biopharmaceutical Applications Scientist, Characterisation & Comparability Lab, National Institute for Bioprocessing Research & Training NIBRT

Amy Xu, PhD, Assistant Professor, Chemistry, Louisiana State University

Speaker To Be Announced, Nano Temper Technologies

3:40 Close of Day

WEDNESDAY, JANUARY 20

8:15 Breakfast BuzZ Sessions

Facilitated, small-group interactive discussions around focused topics.

BuzZ Session: Analytical Challenges in Cell and Gene Therapies

Kuldip Sra, PhD, Executive Director, Tech Operations, CRISPR Therapeutics

8:45 Session Break

CHARACTERIZATION OF SURFACTANTS AND IMPURITIES IN BIOLOGICS

9:00 FEATURED PRESENTATION: Novel Degradation Mechanisms of Polysorbate: Complex Reaction Pathways of a Complex Surfactant

Christian Schoeneich, PhD, Takeru Higuchi Distinguished Professor & Chair, Pharmaceutical Chemistry, University of Kansas Lawrence

Polysorbates are frequently present in protein formulations. Generally, pharmaceutical scientists are concerned about the impact of polysorbate degradation products on the integrity of proteins. Here, we will show that the chemical degradation of proteins can induce polysorbate degradation, likely via intermediary radicals. These radicals add to the double bonds of (poly)unsaturated fatty acids, and promote cis-trans isomerization as well as polysorbate oxidation.

9:25 Effect of Photo-Induced Protein Radicals on Cis/Trans Isomerization of Unsaturated Fatty Acids in Polysorbate 80

Indira Prajapati, PhD, Scientist I, AstraZeneca PLC

The structural integrity of polysorbate (PS) is important for its function as a surfactant to protect proteins from aggregation. We have explored the role of light-induced, protein-derived radicals on the cis/trans isomerization of unsaturated fatty acids in PS80. A mechanistic study performed with a combination of N-acetyltryptophan amide and glutathione disulfide suggested the involvement of thiyl radicals, generated by photoinduced electron transfer from Trp to the disulfide, in cis/trans isomerization.

9:50 Talk Title to be Announced

Speaker Andrew Hanneman, PhD, Scientific Advisor, Mass Spectrometry Laboratory, Charles River

10:20 Novel Mechanistic Insights into the Role of Micelles for Polysorbate Degradation in Biopharmaceuticals

Andrea Hawe, PhD, CSO, Coriolis Pharma Research GmbH

Polysorbate 20 and 80 are essential excipients to stabilize biopharmaceutical formulations. However, polysorbate is prone to degradation induced by (enzymatic) hydrolysis and/or oxidation. An overview on degradation pathways and analytical tools for polysorbate (focus on LC-CAD and LC-MS) will be given. For LC-MS analysis, novel universal markers for oxidation will be presented, as well as a novel hypothesis on the role of micelles for polysorbate oxidation.

10:45 Evolution of Hyphenated Chromatographic Methods for Characterization of Polysorbate 80 to Support Product Understanding and Formulation Development

He Meng, Senior Scientist, Analytical Development, Sanofi

A minimal concentration of PS80 is required to maintain its effectiveness for preventing aggregation. Here we present several hyphenated chromatographic methods recently developed in analytical development for characterization of PS80, including HPLC-CAD, 2D HPLC-CAD, and UPLC-QDa. We demonstrate that these methods can be used to quantitatively and qualitatively determine the PS80 content and investigate the degradation pathways, to support product understanding and formulation development.

11:20 LIVE PANEL DISCUSSION: Characterization of Surfactant-Related and Product Impurities

Moderator: Andrea Hawe, PhD, CSO, Coriolis Pharma Research GmbH

Panelists:

Christian Schoeneich, PhD, Takeru Higuchi Distinguished Professor & Chair, Pharmaceutical Chemistry, University of Kansas Lawrence

Indira Prajapati, PhD, Scientist I, AstraZeneca PLC

Speaker Andrew Hanneman, PhD, Scientific Advisor, Mass Spectrometry Laboratory, Charles River

He Meng, Senior Scientist, Analytical Development, Sanofi

11:40 PepTalk Connects - View Our Virtual Exhibit Hall

Make LIVE Connections with Fellow Attendees, Speakers and Solution Providers

12:20 LIVE DISCUSSIONS: Women in Science Meet-Up and Early Faculty Career Networking

View more details on the Event Features page.

CO-PRESENTATION: Women In Science Meet-Up

Kelly Kemp, PhD, Director, Process Development, ViaCyte Inc.

Elizabeth S. Hecht, PhD, Associate Scientist, Microchemistry, Proteomics & Lipidomics, Genentech, Inc.

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Jamie B. Spangler, PhD, Assistant Professor, Biomedical Engineering and Chemical & Biomolecular Engineering, Johns Hopkins University

Erik Procko, PhD, Assistant Professor, Biochemistry, University of Illinois Urbana-Champaign

- Management of time and responsibilities in starting up a research lab
- Navigating unique challenges due to COVID-19 pandemic
- Recruiting students and postdocs
- Seeking out mentorship resources needed for success

12:40 Session Break

12:55 Close of Characterization of Biotherapeutics Conference

WEDNESDAY, JANUARY 20

8:15 Breakfast BuzZ Sessions

Facilitated, small-group interactive discussions around focused topics.

BuzZ Session: Analytical Challenges in Cell and Gene Therapies

Kuldip Sra, PhD, Executive Director, Tech Operations, CRISPR Therapeutics

8:45 Session Break

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- Management of time and responsibilities in starting up a research lab
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- Seeking out mentorship resources needed for success

12:40 Session Break

REGULATIONS, STANDARDS AND ANALYSIS

1:00 KEYNOTE PRESENTATION: History and Application of Biological Standardisation to Biological Products, and Relevance to ATMP

Christopher Bravery, PhD, Consulting Regulatory Scientist, Consulting on Advanced Biologicals Ltd.

Unlike chemicals, biological substances cannot be fully characterised by physiochemical methods and require, in addition, biological characterisation. This has led to the need to standardise biological analysis in an attempt to bring its reliability closer to that of chemical analysis. Thus, biological standardisation has evolved hand in hand with biological medicines, the latest chapter of which includes yet more complex biological substances in the form of cell and gene therapy.

1:25 Cell and Gene Therapy Standards

Jim Richardson, PhD, Senior Science and Standards Liaison, Global Biologics, U.S. Pharmacopeia

USP is engaging with stakeholders to identify and develop documentary and physical standards to support cell and gene therapy developers by streamlining development and increasing confidence in analytical data. This presentation will provide an update on documentary and physical reference standards under development in areas such as plasmid DNA, AAV Empty/Full Capsid Analysis, and AAV Vector Genome Titer.

1:55 Know your AAV inside out. Answers from quantification to stability with Stunner, Uncle and Big Tuna

UNCHAINED LABS

Nelis Denys, Product Manager, Marketing, Unchained Labs

Getting almost any information on AAVs takes too much sample and time. See how the new tools from Unchained Labs help with buffer exchange and get you answers on empty/full ratio, quantification, aggregation and the stability of your capsids with teeny-tiny sample volumes.

2:20 Establishing Comparability for Gene Therapy Products

Mo Heidaran, PhD, Vice President Technical, PAREXEL Consulting, PAREXEL International; Former FDA Reviewer

Making changes to the manufacturing process is an inevitable part of making a better product. For gene therapy products, often the major manufacturing change involves changes of manufacturing platform and/or manufacturing site. I will discuss major challenges and technical considerations for establishing product comparability, and provide real-life examples in this talk.

3:20 LIVE PANEL DISCUSSION: Regulations and Standards

Moderator: Christopher Bravery, PhD, Consulting Regulatory Scientist, Consulting on Advanced Biologicals Ltd.

Panelists:

Mo Heidaran, PhD, Vice President Technical, PAREXEL Consulting, PAREXEL International; Former FDA Reviewer

Jim Richardson, PhD, Senior Science and Standards Liaison, Global Biologics, U.S. Pharmacopeia

Nelis Denys, Product Manager, Marketing, Unchained Labs

3:40 20th Anniversary Celebration - View Our Virtual Exhibit Hall

Reunite with old friends and new, share memories, and raise a glass with your peers in an open video reunion.

4:00 Close of Day

THURSDAY, JANUARY 21

ASSAYS, TOOLS, AND IMPURITIES

9:25 am Switching from qPCR to Digital PCR

Santoshkumar L. Khatwani, PhD, Associate Director, Analytical Development, Sangamo Therapeutics

- Rational approach to designing a ddPCR assay
- Improved method performance throughput method life cycle
- ?Analytical study to compare qPCR to ddPCR assay

9:50 Mass photometry: a novel, rapid and labelfree analysis method for biological molecules and AAV's

REFEYN

James Wilkinson, PhD, Sales Director, Sales, Refeyn

Mass photometry is a rapid, labelfree, ultra-sensitive microscopy technique, which allows mass determination at the single-molecule level based on detecting scattering signal (contrast) generated by an object. We present the technology and some examples analysing biologics, including for gene therapy, measurement of AAV particles to determine full / empty ratios.

10:45 Particulate Impurities in Cell-Based Medicinal Products Traced by Flow Imaging Microscopy Combined with Deep Learning for Image Analysis

Tim Menzen, PhD, CTO & Pharmacist, Coriolis Pharma Research GmbH

We developed a method based on flow imaging microscopy, combined with an image classification approach, based on a convolutional neural network for the analysis of subvisible particulate impurities in cell-based medicinal products. Jurkat cells and Dynabeads were used as representation of cellular material and non-cellular particulate impurities, respectively. Our method successfully detected and quantified Dynabeads and cells with other process-related impurities, such as cell agglomerates, cell-bead adducts, and debris.

11:20 LIVE PANEL DISCUSSION: Assay, Tools and Impurities

Moderator: Santoshkumar L. Khatwani, PhD, Associate Director, Analytical Development, Sangamo Therapeutics

Panelists:

Tim Menzen, PhD, CTO & Pharmacist, Coriolis Pharma Research GmbH

11:40 PepTalk Connects - View Our Virtual Exhibit Hall

Make LIVE Connections with Fellow Attendees, Speakers and Solution Providers

12:20 BuzZ Sessions

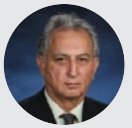
Facilitated, small-group interactive discussions around focused topics.

BuzZ Session: Raw and Starting Materials

Jim Richardson, PhD, Senior Science and Standards Liaison, Global Biologics, U.S. Pharmacopeia

12:40 Session Break

CHARACTERIZATION AND CMC STRATEGIES FOR CELL AND GENE THERAPIES



1:00 FEATURED PRESENTATION: Challenges Associated with Characterization of Cell and Gene Therapy Products

Kuldip Sra, PhD, Executive Director, Tech Operations, CRISPR Therapeutics

Cell and gene (C&G) therapy products are complex based upon nature and characteristics of the starting materials and manufacturing processes (cell activation, cell isolation, transfection, EP, expansion, harvest, cryopreserving). Characterization of starting materials, in process testing and drug product lot release are very challenging. In addition, the samples volume for testing are very limited. Raw Materials are also required to be tested with validated assays to verify Vendor COA results.

1:25 Analytical Method Development for the Characterization of AAV-Based Products: Challenges and Outcomes

George Bou-Assaf, PhD, Scientist, Analytical Development – Product & Technology Development, Biogen

Adeno-associated viruses are the most common vectors used in gene therapy. The complexity of the AAV particles presents several challenges for the development of analytical methods aimed at the characterization of these products. Here, we explore several case studies which highlight the challenges associated with characterization of critical quality attributes, and we propose solutions to overcome them.

2:20 Analytical Challenges and Strategies for the Development of Allogeneic Cell-Based Therapeutics

Kelly Kemp, PhD, Director, Process Development, ViaCyte Inc.

Cell-based products tend to be novel and more complex compared to other biologics, presenting analytical challenges. For example, product understanding is essential as therapies progress through clinical trials, however, the development of bioassays to identify CQAs and evaluate potency and comparability can be limiting. Moreover, some cell-based products have a short shelf-life or small-batch sizes that necessitate alternative testing approaches. These considerations for analytical development will be discussed.

2:45 Importance of Donor-Starting Material Characterization in Developing Scalable Cell Therapies

Dominic Clarke, PhD, ISCT Process & Product Committee Co-Chair and Global Head, Cell Therapy, HemaCare Corp.

Cell and gene therapies (CGTs) offer tremendous excitement and potential. CGTs are inherently complex and often highly variable, which represents a critical industry challenge. Developing robust, scalable processes and products are necessary to enabling clinical translation and, ultimately, commercialization. Establishing highly characterized and reliable critical raw materials will aid in reducing risk and improve overall consistency contributing to CGT commercial success and global patient access.

3:20 LIVE PANEL DISCUSSION: Characterization and CMC Strategies

Moderator: Kelly Kemp, PhD, Director, Process Development, ViaCyte Inc.

Panelists:

Dominic Clarke, PhD, ISCT Process & Product Committee Co-Chair and Global Head, Cell Therapy, HemaCare Corp.

Kuldip Sra, PhD, Executive Director, Tech Operations, CRISPR Therapeutics

George Bou-Assaf, PhD, Scientist, Analytical Development – Product & Technology Development, Biogen

3:40 Close of Conference

AGGREGATION & IMPURITIES

As the industry advances biotherapeutic development, the formulation and development functions play important roles, supporting the selection and optimization of molecules with better developability, stability, safety, and efficacy. The popular Aggregation & Impurities pipeline presents case studies of the latest tools, technologies, and cutting-edge approaches on detection and control of emerging contaminants, particles, product and process-related impurities, protein aggregates, and immunogenicity issues related to the progression of biologics into the development of high-quality biotherapeutic products.

January 19-20

Detection and Characterization of Particulates and Impurities

AGENDA

January 20-21

Protein Aggregation and Emerging Analytical Tools

AGENDA

TUESDAY, JANUARY 19

PARTICLES, AGGREGATES, IMMUNOGENICITY, AND STABILITY

9:00 am Unwanted Immunogenicity of Biotherapeutics: Lessons Learned

Inna Miroshnyk, Lake Erie College of Osteopathic Medicine

The focus of this presentation will be on the strategies used for preventing immunogenicity-mediated adverse reactions of biotherapeutics.

9:25 Novel Technologies That Aid the Detection and Differentiation of Proteinaceous Impurities in Biologic Drug Substance and Drug Product

Danny K. Chou, PharmD, PhD, President, Biopharmaceutical Characterization and Formulation Development, Compassion BioSolution, LLC

The goal of this presentation is to share recent developments in the analytical approaches to detect, quantify, and differentiate impurities in biologics that are the result of protein-container interaction and aggregation.

9:50 Protein or Not? Advanced High Throughput Aggregate Analysis with the Aura

halo labs

Bernardo Cordovez, PhD, Chief Science Officer and Founder, Halo Labs

In protein-based formulations, distinguishing aggregated API from other particle types is important for understanding the root cause of instability. Until now, existing methods have been either unreliable or too cumbersome and difficult to use in many workflows. Here we introduce the Aura, a 96-well low-volume aggregate and particle imaging system that can rapidly size, count, and characterize particles and identify them as proteins, non-proteins, hydrophobic, or other types of molecules.

10:20 Role on Interfaces in Particulate Formation in Liquid Formulations of Biologics

Itzel Condado Morales, PhD, Biochemical Engineering Laboratory, Institute for Chemical and Bioengineering, ETH Zurich

10:45 New Reference Standards for Improved Characterization of Proteinaceous Particles in Biotherapeutics

Srivalli Telikepalli, PhD, Research Chemist, Biomolecular Measurement Division, NIST

11:20 LIVE PANEL DISCUSSION: Particulate and Aggregates in Biologics

Moderator: Danny K. Chou, PharmD, PhD, President, Biopharmaceutical Characterization and Formulation Development, Compassion BioSolution, LLC

Panelists:

Itzel Condado Morales, PhD, Biochemical Engineering Laboratory, Institute for Chemical and Bioengineering, ETH Zurich

Bernardo Cordovez, PhD, Chief Science Officer and Founder, Halo Labs

Srivalli Telikepalli, PhD, Research Chemist, Biomolecular Measurement Division, NIST

Inna Miroshnyk, Lake Erie College of Osteopathic Medicine

11:40 PepTalk Connects - View Our Virtual Exhibit Hall

Make LIVE Connections with Fellow Attendees, Speakers and Solution Providers

12:20 BuzZ Sessions

Facilitated, small-group interactive discussions around focused topics.

BuzZ Session: Host Cell Protein Coverage Analysis

Santoshkumar L. Khatwani, PhD, Associate Director, Analytical Development, Sangamo Therapeutics

12:40 Session Break

PROCESS-RELATED IMPURITIES

1:00 KEYNOTE PRESENTATION: Analysis of New Therapeutic Modalities: Challenges, Opportunities, and New Methods

Sunny Zhou, PhD, Professor, Chemistry & Chemical Biology, Northeastern University

New modalities present new challenges in their analysis. For example, due to their intrinsic structural complexity and complicated manufacture processes, viral capsids or particles (e.g., adeno associated virus, AAV) are markedly more heterogenous than well-established modalities. In this talk, both new methods and findings (e.g., PTM's) will be presented. Furthermore, I will also discuss analytical artifacts, which are common yet under-appreciated, thereby often leading to erroneous interpretation and counterproductive approaches.

1:25 Low Endotoxin Recovery: How to Design an LER Study and When to Perform the Study During Development

Nick Almaguer

Low Endotoxin Recovery (LER) is a phenomenon that can occur during LAL compendial tests. This is sometimes caused by components in the formulation that mask the endotoxin in the sample. Due to safety issues that can be caused by LER, the FDA's Center for Drug Evaluation and Research requests that LER studies be conducted. Study design and the appropriate stage of development to perform an LER study will be discussed.

1:50 Sponsored Presentation *(Opportunity Available)*

ASSAYS AND TECHNIQUES

2:20 Studying Excipient Modulated Colloidal Stability and Viscosity of Monoclonal Antibody Formulations Using Small Angle X-Ray/Neutron Scattering

Amy Xu, PhD, Assistant Professor, Chemistry, Louisiana State University

Using kD and B22 to predict the PPI in concentrated mAb formulations was evaluated through S(q)eff extracted from SAXS/SANS measurements. Disagreements between PPI determined from dilute (kD/B22) and concentrated solutions highlight the necessities of performing measurements directly from concentrated mAb solutions. The correlation between measured and predicted viscosity results suggests a need for better understanding of the relationship between PPI and solution viscosity, so more reliable predictions can be made.

2:45 *In Vivo* Serum Reversibility Assay for Assessing the Impact of Aggregates and HMW

Cathie Xiang, Scientist, Attribute Science, Amgen, Inc.

High Molecular Weight Species (HMWS) is important to monitor and control due to its potential impact on efficacy and safety. Some HMWS could reverse soon after administration to patients. The dissociation of HMWS reduces its exposure in patients, thereby

mitigating potential HMWS associated risk. Here, we developed an ***in vitro*** model system to study reversibility of HMWS in a biologically relevant environment that mimics ***in vivo*** context.

3:20 LIVE PANEL DISCUSSION: Analysis and Characterization of Product Related Impurities

Moderator: Sunny Zhou, PhD, Professor, Chemistry & Chemical Biology, Northeastern University

Panelists:

Nick Almaguer

Cathie Xiang, Scientist, Attribute Science, Amgen, Inc.

Amy Xu, PhD, Assistant Professor, Chemistry, Louisiana State University

3:40 Close of Day

WEDNESDAY, JANUARY 20

8:15 Breakfast BuzZ Sessions

Facilitated, small-group interactive discussions around focused topics.

BuzZ Session: Digitally Optimized Analytical Workflows: Merging of digital tools with experimental analytical studies

Cesar Calero-Rubio, PhD, Senior Scientist, Biologics Drug Product Development & Manufacturing, Sanofi

8:45 Session Break

SURFACTANT-RELATED AND PRODUCT IMPURITIES

9:00 FEATURED PRESENTATION: Novel Degradation Mechanisms of Polysorbate: Complex Reaction Pathways of a Complex Surfactant

Christian Schoeneich, PhD, Takeru Higuchi Distinguished Professor & Chair, Pharmaceutical Chemistry, University of Kansas Lawrence

Polysorbates are frequently present in protein formulations. Generally, pharmaceutical scientists are concerned about the impact of polysorbate degradation products on the integrity of proteins. Here, we will show that the chemical degradation of proteins can induce polysorbate degradation, likely via intermediary radicals. These radicals add to the double bonds of (poly)unsaturated fatty acids, and promote cis-trans isomerization as well as polysorbate oxidation.

9:25 Effect of Photo-Induced Protein Radicals on Cis/Trans Isomerization of Unsaturated Fatty Acids in Polysorbate 80

Indira Prajapati, PhD, Scientist I, AstraZeneca PLC

The structural integrity of polysorbate (PS) is important for its function as a surfactant to protect proteins from aggregation. We have explored the role of light-induced, protein-derived radicals on the cis/trans isomerization of unsaturated fatty acids in PS80. A mechanistic study performed with a combination of N-acetyltryptophan amide and glutathione disulfide suggested the involvement of thiyl radicals, generated by photoinduced electron transfer from Trp to the disulfide, in cis/trans isomerization.

9:50 Sponsored Presentation *(Opportunity Available)*

10:20 Novel Mechanistic Insights into the Role of Micelles for Polysorbate Degradation in Biopharmaceuticals

Andrea Hawe, PhD, CSO, Coriolis Pharma Research GmbH

Polysorbate 20 and 80 are essential excipients to stabilize biopharmaceutical formulations. However, polysorbate is prone to degradation induced by (enzymatic) hydrolysis and/or oxidation. An overview on degradation pathways and analytical tools for polysorbate (focus on LC-CAD and LC-MS) will be given. For LC-MS analysis, novel universal markers for oxidation will be presented, as well as a novel hypothesis on the role of micelles for polysorbate oxidation.

10:45 Evolution of Hyphenated Chromatographic Methods for Characterization of Polysorbate 80 to Support Product Understanding and Formulation Development

He Meng, Senior Scientist, Analytical Development, Sanofi

A minimal concentration of PS80 is required to maintain its effectiveness for preventing aggregation. Here we present several hyphenated chromatographic methods recently developed in analytical development for characterization of PS80, including HPLC-CAD, 2D HPLC-CAD, and UPLC-QDa. We demonstrate that these methods can be used to quantitatively and qualitatively determine the PS80 content and investigate the degradation pathways, to support product understanding and formulation development.

11:20 LIVE PANEL DISCUSSION: Characterization of Surfactant-Related and Product Impurities

Moderator: Andrea Hawe, PhD, CSO, Coriolis Pharma Research GmbH

Panelists:

Christian Schoeneich, PhD, Takeru Higuchi Distinguished Professor & Chair, Pharmaceutical Chemistry, University of Kansas Lawrence

Indira Prajapati, PhD, Scientist I, AstraZeneca PLC

He Meng, Senior Scientist, Analytical Development, Sanofi

11:40 PepTalk Connects - View Our Virtual Exhibit Hall

Make LIVE Connections with Fellow Attendees, Speakers and Solution Providers

12:20 LIVE DISCUSSIONS: Women in Science Meet-Up and Early Faculty Career Networking

View more details on the Event Features page.

CO-PRESENTATION: Women In Science Meet-Up

Kelly Kemp, PhD, Director, Process Development, ViaCyte Inc.

Elizabeth S. Hecht, PhD, Associate Scientist, Microchemistry, Proteomics & Lipidomics, Genentech, Inc.

CO-PRESENTATION: Early Faculty Career Networking Meet-Up

Jamie B. Spangler, PhD, Assistant Professor, Biomedical Engineering and Chemical & Biomolecular Engineering, Johns Hopkins University

Erik Procko, PhD, Assistant Professor, Biochemistry, University of Illinois Urbana-Champaign

- Management of time and responsibilities in starting up a research lab
- Navigating unique challenges due to COVID-19 pandemic
- Recruiting students and postdocs
- Seeking out mentorship resources needed for success

12:40 Session Break

12:55 Close of Detection and Characterization of Particulates and Impurities Conference

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12:40 Session Break

MECHANISM OF AGGREGATION & ANALYSIS

1:00 Measurement Methods for Protein Aggregates

Richard Cavicchi, PhD, Research Physicist, Biomolecular Measurement Division, Material Measurement Laboratory, National Institute of Standards and Technology

We will discuss different methods available for measurement of subvisible particles, especially protein aggregates, in biopharmaceuticals. Sometimes different methods will give different results and better understanding of what the instrument measures and the properties of the particles can improve the usefulness of the data. We will present examples using aggregates of NISTmAb as a model system.

1:25 Characterization of Cyclic Peptide Aggregation Behavior Using Biophysical, Intact Mass, and Top-Down Disulfide Mapping Approaches

Elizabeth S. Hecht, PhD, Associate Scientist, Microchemistry, Proteomics & Lipidomics, Genentech, Inc.

Cyclic peptides (CPs) constitute a promising biotherapeutics class. Thermal stress studies were conducted to characterize CP stability using multiple biophysical assays, revealing mixed-mode aggregates. New methods were required to decipher the structure of the covalent aggregates. Here, ECD top-down analysis is discussed in the context of mapping CP linkages. The totality of this work gives insights into the *in vitro* aggregation mechanism, C-C bond lability, and extends disulfide mapping approaches.

2:20 Understanding the Mechanism of Surface-Mediated Protein Aggregation

Cavan Kalonia, PhD, Scientist II, Formulation, AstraZeneca Biologics

Interface mediated protein aggregation poses a substantial development challenge because it can occur during manufacturing, shipping, storage and/or administration. In this work, we use state of the art metrology and modeling tools to investigate the mechanism of interface mediated protein aggregation for several monoclonal antibodies and a fusion protein. We also investigate the impact of intact and degraded polysorbate 80 on this protein degradation pathway.

2:45 Identification and Reduction of Subvisible Particles in Biopharmaceuticals

Susumu Uchiyama, PhD, Professor, Biotechnology, Osaka University

Talk will address automatic identification of the stress sources of protein aggregates using flow imaging microscopy images, container closure system for suitable for biopharmaceuticals and influence of silicone oil droplets in biopharmaceuticals on immune system.

3:20 LIVE PANEL DISCUSSION: Understanding and Prediction of Protein Aggregation

Moderator: Cavan Kalonia, PhD, Scientist II, Formulation, AstraZeneca Biologics

Panelists:

Susumu Uchiyama, PhD, Professor, Biotechnology, Osaka University

Elizabeth S. Hecht, PhD, Associate Scientist, Microchemistry, Proteomics & Lipidomics, Genentech, Inc.

Richard Cavicchi, PhD, Research Physicist, Biomolecular Measurement Division, Material Measurement Laboratory, National Institute of Standards and Technology

Anthony Person, Ph.D., Sr. Director, Protein Business Unit, Bio-Techne

3:40 20th Anniversary Celebration - View Our Virtual Exhibit Hall

Reunite with old friends and new, share memories, and raise a glass with your peers in an open video reunion.

4:00 Close of Day

THURSDAY, JANUARY 21

PREDICTING PROTEIN AGGREGATION

9:25 am KEYNOTE PRESENTATION: Structure and Characterization of Monoclonal Antibody Self-Association Complex Reveals Specific Face-to-Face Interaction: Developability and Predictive Implications

Carl Mieczkowski, PhD, Associate Principal Scientist, Protein Sciences, Merck Research Labs

We unraveled novel aspects of self-association, including mapping the self-interaction of an antibody utilizing individual domains, solving a novel crystal structure complex of the associated complex, determined binding affinites of the self-interaction, modulated self-interaction through mutagenesis, and have interesting computational approaches involving patch analysis and docking that agree with the crystal structure.

9:50 Probing Protein Aggregation with Shear Rate & Temperature Dependent Viscosity Measurements

Stacey Elliott, PhD, Principal Scientist, Research and Development, RheoSense, Inc.

Viscosity measurements reflect changes in PPI and the resulting microstructure. Cluster arrangements commonly formed by inherently attractive proteins have a predictable effect on shear rate and temperature dependent viscosity measurements. We illustrate these effects with model protein solutions formulated with individual amino acid excipients to modify PPI and aggregate structure.

10:20 Early-Phase Shipping Studies for Predicting Aggregation

Christine Siska, Senior Scientist, Just Biotherapeutics, Inc.

An early-phase product development shipping study was designed to observe the stability of liquid protein formulations under normal shipping conditions. Shipments were monitored for location, temperature, and shock events. Formulations were evaluated post-shipment for the presence of aggregates and sub-visible and visible particles, and compared against non-shipped and lab-dropped control formulations. The findings demonstrated that factors beyond shock events occurring during shipment are necessary for particle formation in shipped formulations.

10:45 How to Apply Empirical Experimental Strategies that Leverage Our Mechanistic Insights into Protein Stability to Aid Biologic Drug Development

Danny K. Chou, PharmD, PhD, President, Biopharmaceutical Characterization and Formulation Development, Compassion BioSolution, LLC

The purpose of this presentation is to describe a practical strategy to increase chances of successful translation of promising biologic drug candidates into more stable and commercially feasible drug products.

11:20 LIVE PANEL DISCUSSION: Prediction, Analytical Tools, and Screening

Moderator: Carl Mieczkowski, PhD, Associate Principal Scientist, Protein Sciences, Merck Research Labs

Panelists:

Christine Siska, Senior Scientist, Just Biotherapeutics, Inc.

Danny K. Chou, PharmD, PhD, President, Biopharmaceutical Characterization and Formulation Development, Compassion BioSolution, LLC

Stacey Elliott, PhD, Principal Scientist, Research and Development, RheoSense, Inc.

11:40 PepTalk Connects - View Our Virtual Exhibit Hall

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12:20 BuzZ Sessions

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BuzZ Session: Amyloid Induction

Rizwan Hasan Khan, PhD, Professor, Interdisciplinary Biotechnology, Aligarh Muslim University

12:40 Session Break

HIGH CONCENTRATION PROTEIN FORMULATIONS

1:00 Ambient Light and UV Emission: Effect of Protein Concentration and Surface-Exposed Tryptophan on Monoclonal Antibody Aggregation

Haresh T. More, PhD, Senior Research Investigator I, Bristol-Myers Squibb Co.

Surface exposed tryptophan is the major contributor for mAb light sensitivity and this factor was considered for the selection of mAbs based on the number of surface exposed Trp residues. In this study, a conc. dependent CWF light sensitivity is evaluated for different mAbs. The study shows an increase in aggregation with mAb concentration and surface exposed trp residues.

1:25 Leveraging Automation to Enable High-Concentration Formulation Development

Peter Soler, PhD, Senior Research Investigator, Bristol-Myers Squibb Co.

Biologics drug development has experienced rapid growth in recent years. To meet the need, biologics formulation development has quickly acquired a set of automation tools and analytical techniques to provide robust drug products for patients. The push for more effective therapeutics and better patient care options has demanded higher concentrations. This has motivated adaptation of our tools to meet the increases in process complexity for the benefit of patients globally.

1:50 Sponsored Presentation *(Opportunity Available)*

2:20 Aggregation in High Concentration Protein Formulations vs Biophysical Analysis

Cesar Calero-Rubio, PhD, Senior Scientist, Biologics Drug Product Development & Manufacturing, Sanofi

Protein biophysical properties are hypothesized to be predictive of protein aggregation under accelerated and long-term storage conditions. Relationship between biophysical properties and protein aggregation is yet to be generalized across a broad selection of mAbs and formulation buffers. We revised historical hypotheses regarding protein physical stability and biophysical properties by combining statistical analysis of the solution behavior of several mAbs mimicking developability and formulation screening workflows.

2:45 Protein Aggregation and Inhibition by Anti Tuberculosis Drugs

Rizwan Hasan Khan, PhD, Professor, Interdisciplinary Biotechnology, Aligarh Muslim University

Protein aggregation and amyloid fibrillation are responsible for several serious pathological conditions. Therefore, a molecule that can inhibit the amyloid fibrillation and potentially clear amyloid fibrils is of great therapeutic value. We investigated the anti-amyloidogenic potential of various natural compounds like vitamins, taurine using various biophysical techniques. Aggregation kinetics data, as monitored by ThT fluorescence, inferred that these compounds retards amyloid fibrillation

3:20 LIVE PANEL DISCUSSION: Aggregation in High Concentration Formulations

Moderator: Haresh T. More, PhD, Senior Research Investigator I, Bristol-Myers Squibb Co.

Panelists:

Peter Soler, PhD, Senior Research Investigator, Bristol-Myers Squibb Co.

Cesar Calero-Rubio, PhD, Senior Scientist, Biologics Drug Product Development & Manufacturing, Sanofi

Rizwan Hasan Khan, PhD, Professor, Interdisciplinary Biotechnology, Aligarh Muslim University

3:40 Close of Conference

PROCESS TECHNOLOGIES & PURIFICATION

Processing proteins in the quest for developing therapeutics has evolved significantly in recent years. High-throughput techniques and innovating traditional technologies are bolstered by continually emerging research into genetic engineering and systems biology. The Process Technologies & Purification pipeline explores emerging technologies along with how conventional techniques are being renovated and renewed.

January 19-20

Higher-Throughput Protein Production and Characterization

AGENDA

January 20-21

Protein Purification and Recovery

AGENDA

TUESDAY, JANUARY 19

INCREASING OUTPUTS AND EFFICIENCIES OF PROTEIN PRODUCTION PLATFORMS

9:00 am KEYNOTE PRESENTATION: Rise of the Machines: Optimizing Workflows for Compatibility with Automation

Sarah M. Rue, PhD, Associate Director, Advanced Automation Technologies, Genomics Institute of the Novartis Research Foundation

When considering automation of protein sciences workflows, scientists typically judge how well proposed hardware will recapitulate established protocols. The power of automation is realized when we challenge known paradigms, practices, and procedures, leading to truly disruptive advancements in automated workflows. Here, we will describe the enabling adaptation of a hybridoma workflow and several protein expression workflows to automation, as well as future plans to adapt an ELISA workflow to automation.

9:25 Production of SARS-CoV-2 Proteins for Serological Assay Development

Nicola A. Burgess-Brown, PhD, Principal Investigator, Biotechnology, Structural Genomics Consortium, University of Oxford

The Centre for Medicines Discovery (CMD), established in August 2020, comprises a number of disease-focused groups and small research facilities (SRF). The biotech facility provides protein production services for academic and industrial customers. In this talk, our well established expression platforms for production and validation of intracellular, secreted, and membrane proteins will be presented, with a highlight on production of SARS-CoV-2 proteins for serological assay development.

9:50 Move fast with hands-off formulation screens on Big Tuna and Uncle

UNCHAINED LABS

Ross Walton, PhD, Application Scientist, Marketing, Unchained Labs

Buffer exchange sucks up precious hands-on time and limits the exploration of formulation conditions. This talk will cover how to accelerate a screen of 15 antibody/ formulation combinations using Big Tuna for automated buffer exchange and Uncle for in-depth stability and aggregation analysis – all with just 1 hour of hands-on time.

10:20 Session Break

ULTRA HIGH-THROUGHPUT SCREENING AND CHARACTERIZATION

10:45 Platformization of Multi-Specific Protein Engineering IV: Realization of Challenging Multi-Specific Target Protein Profiles through Format Agnostic, Ultra High-Throughput Variant Profiling

Joerg Birkenfeld, PhD, Head, High Throughput Biologics, Sanofi Germany GmbH

We recently established a novel, end-to-end automated process for the fast generation and characterization of very large panels of multi-specific biotherapeutics (up to 10,000). Here, we report on how we apply this unique engineering platform for the identification and optimization of next-generation, multi-specific biotherapeutics addressing novel mechanisms of action.

11:20 LIVE PANEL DISCUSSION: Increasing Outputs and Efficiency

Moderator: Mark L. Chiu, PhD, CSO, Tavotek Biotherapeutics

Panelists:

Sarah M. Rue, PhD, Associate Director, Advanced Automation Technologies, Genomics Institute of the Novartis Research Foundation

Nicola A. Burgess-Brown, PhD, Principal Investigator, Biotechnology, Structural Genomics Consortium, University of Oxford

Joerg Birkenfeld, PhD, Head, High Throughput Biologics, Sanofi Germany GmbH

Ross Walton, PhD, Application Scientist, Marketing, Unchained Labs

11:40 PepTalk Connects - View Our Virtual Exhibit Hall

Make LIVE Connections with Fellow Attendees, Speakers and Solution Providers

12:20 BuzZ Sessions

Facilitated, small-group interactive discussions around focused topics.

BuzZ Session: Analytical Considerations during Transitions from Biologics Discovery to Development

Mark L. Chiu, PhD, CSO, Tavotek Biotherapeutics

- Hit to lead (session feedback)
- Early stage biologics development
- Late stage biologics development

12:40 Session Break

ULTRA HIGH-THROUGHPUT SCREENING AND CHARACTERIZATION *(CONT.)*

1:00 A High-Throughput Analysis for Screening WRD5-Win Motif Interactions

Liviu Movileanu, PhD, Professor, Physics, Syracuse University

WD-40 repeat protein-5 (WDR5) interacts specifically with a conserved arginine-containing motif, simply called the Win motif, in all six members of the SET1 family of histone 3 lysine 4 (H3K4) methyltransferases, MLL1-4 and SETd1/AB. We have developed a battery of analytical approaches, both in low- and high-throughput settings, for a comprehensive analysis of WDR5-Win motif interactions present in all six SET1 members of H3K4 methyltransferases.

1:25 Therapeutic Biologics: Challenges in Production and Analytics for Discovery

John E. Harlan, PhD, Senior Group Leader, AbbVie Inc.

We will explore the implications of empowered biologics and novel formats for Discovery Biologics support, focusing primarily on Downstream processes. We will discuss the importance of enhanced analytics with the goal of ensuring the best molecule is moving forward.

1:50 Novel Solution For High Throughput Antibody And Protein Purification Using Magnetic Beads

GenScript Make Research Easy

Sean Taylor, PhD, Field Application Scientist Manager, Catalog Products, GenScript

With the ever increasing demand for antibody and protein-based therapeutics, a flexible purification platform that can handle low to high sample volumes and expression levels is critical for screening. Protein purification using traditional chromatography is limited by throughput and requires time-consuming, labour-intensive sample preparation (centrifugation and filtration) processes to avoid column clogging and to achieve volumes that are amenable to this platform. Magnetic beads-based purification permits the incubation of the beads directly into cell culture (for secreted proteins) or crude lysates regardless of sample volume. This provides a simplified approach to direct target capture while eliminating much of the sample preparation steps and potentially improving the quality of the purified product. The tools and their application to simplify and significantly augment protein purification and screening cost-effectively will be described.

2:20 Rethinking HT Biologics Workflows From Screening to Scale Up: Automation, Informatics and Comprehensive Analytics

Daniel Yoo, Senior Scientist, Therapeutic Discovery, Amgen Inc.

As biologic therapeutics continue to increase in complexity, innovative approaches to candidate screening, characterization and development are more important than ever. Our approaches to high throughput protein production incorporate advanced analytics, automation and high-quality informatics to enable robust molecule screening, selection and scale up. These enhancements improve the speed, quality and productivity of our biologics development pipeline.

2:45 Serendipity with Biologics Architecture

Mark L. Chiu, PhD, CSO, Tavotek Biotherapeutics

There is still much cooperativity associated with domain interactions in the design of multispecific biologics agents. Empirical assessments of structure and function are critical for hit to lead selection. A review of approaches to efficiently assess different architectures will be presented.

3:20 LIVE PANEL DISCUSSION: Optimizing Protein Design and Screening

Moderator: Renaud Vincentelli, PhD, Head, Protein Production, Structural Biology Facility, CNRS Aix Marseille University

Panelists:

Liviu Movileanu, PhD, Professor, Physics, Syracuse University

Mark L. Chiu, PhD, CSO, Tavotek Biotherapeutics

Daniel Yoo, Senior Scientist, Therapeutic Discovery, Amgen Inc.

John E. Harlan, PhD, Senior Group Leader, AbbVie Inc.

Sean Taylor, PhD, Field Application Scientist Manager, Catalog Products, GenScript

3:40 Close of Day

WEDNESDAY, JANUARY 20

OPTIMIZING PROTEIN DESIGN

9:00 am FEATURED PRESENTATION: High-Throughput Investigation of Protein Energy Landscapes in Non-Antibody Scaffolds

Gabriel J. Rocklin, PhD, Assistant Professor, Pharmacology, Northwestern University

An ideal therapeutic scaffold should possess both high folding stability and minimal conformational fluctuations, but to date, it has not been possible to measure conformational fluctuations on a large scale. We developed a multiplexed, hydrogen-deuterium exchange, mass spectrometry-based approach for measuring stability and conformational fluctuations for thousands of designed protein scaffolds in parallel. These data should reveal the structural determinants of conformational fluctuations, and enable the design of optimize scaffolds.

9:25 Application of the High-Throughput Hold-Up for the Development of New Peptide Therapeutics

Renaud Vincentelli, PhD, Head, Protein Production, Structural Biology Facility, CNRS Aix Marseille University

The identification of protein-peptide networks offers attractive opportunities for drug development. We proposed the "Hold-up" assay, which has a wide potential for the identification and quantification of protein-protein and protein-peptide interactions at a pace of 1,000 interactions/day. During this session, we will present the last evolution of this assay, and how we used it to determine the affinities and specificities of various peptide drug candidates for PDZ domains.

9:50 CO-PRESENTATION: Higher-Throughput Protein Production and Characterization

Mike Piazza, Ph.D, Systems Integration Manager, Nicoya

Soleil Grisé, Senior Application Specialist, Nicoya

Surface plasmon resonance (SPR), the gold standard of biomolecular characterization, enables targeted protein selection for biotherapeutic and diagnostic applications. Yet, high-throughput applications of SPR are often limited by high operational costs and cumbersome maintenance. During this session, we will demonstrate the application of this powerful technique in designing a rapid COVID-19 diagnostic assay, and discuss how digital microfluidics and nanotechnology are powering the next-generation of high-throughput SPR platforms.

10:20 One-Shot Optimisation of Protein Stability and Activity Through Evolution-Guided Atomistic Design

Sarel J. Fleishman, PhD, Principal Investigator, Biomolecular Sciences, Weizmann Institute Of Science

Marginal stability and low molecular activity are the cardinal impediments to applying proteins in research and technology. We have developed a hybrid approach that combines structure-bioinformatics analyses with Rosetta atomistic design to improve protein stability, expressibility, binding affinity, catalytic rate and selectivity. Applied to very diverse biologics, this strategy has led to orders of magnitude improvement in these properties through one-shot calculations and experimental analysis.

10:45 One-Shot Design and Engineering of Portable *in Vitro* and *in Vivo* Biosensors

Timothy A Whitehead, PhD, Associate Professor, Chemical & Biological Engineering, University of Colorado, Boulder

Biosensors transduce a binding event into a measurable output. I will describe a versatile biosensor platform technology based on plant hormone receptors that can be used ***in vitro*** and ***in vivo*** in application areas as diverse as screening for novel synthetic cannabinoids to developing plant sentinels that can perceive chemical warfare agents that then change plant phenotypes in a way that can be observed by drone or satellite.

11:20 LIVE PANEL DISCUSSION: Optimizing Protein Design

Moderator: Renaud Vincentelli, PhD, Head, Protein Production, Structural Biology Facility, CNRS Aix Marseille University

Panelists:

Gabriel J. Rocklin, PhD, Assistant Professor, Pharmacology, Northwestern University

Sarel J. Fleishman, PhD, Principal Investigator, Biomolecular Sciences, Weizmann Institute Of Science

Timothy A Whitehead, PhD, Associate Professor, Chemical & Biological Engineering, University of Colorado, Boulder

Mike Piazza, Ph.D, Systems Integration Manager, Nicoya

Soleil Grisé, Senior Application Specialist, Nicoya

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- Management of time and responsibilities in starting up a research lab
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12:55 Close of Higher-Throughput Protein Production and Characterization Conference

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Jamie B. Spangler, PhD, Assistant Professor, Biomedical Engineering and Chemical & Biomolecular Engineering, Johns Hopkins University

Erik Procko, PhD, Assistant Professor, Biochemistry, University of Illinois Urbana-Champaign

- Management of time and responsibilities in starting up a research lab
- Navigating unique challenges due to COVID-19 pandemic
- Recruiting students and postdocs
- Seeking out mentorship resources needed for success

12:40 Session Break

PURIFICATION OF ANTIBODIES

1:00 KEYNOTE PRESENTATION: Continuous Precipitation – Microfiltration for Initial Purification of Monoclonal Antibodies
Andrew Zydney, PhD, Bayard D. Kunkle Chair & Professor, Chemical Engineering, Pennsylvania State University
There is growing interest in using precipitation for capture of therapeutic proteins in integrated continuous bioprocesses. We have demonstrated the use of ZnCl2 and polyethyleneglycol for precipitation of a monoclonal antibody product directly from harvested cell culture fluid. The precipitates were then dewatered and continuously washed using tangential flow filtration, with a countercurrent-staged configuration, providing a very effective alternative to Protein A for continuous antibody capture/purification.

1:25 FEATURED PRESENTATION: Can a Nucleotide Binding Site Ligand Replace Protein A/G Function on Chromatography and Spin Columns for Antibody Purification?
Basar Bilgicer, PhD, Associate Professor, Chemical & Biomolecular Engineering, University of Notre Dame
The protein A/G affinity chromatography has been the workhorse of antibody purification for decades, despite having well-established limitations that are overlooked due to lack of reliable options. By targeting the conserved nucleotide-binding site (NBS) of immunoglobulins, we have developed an affinity method for antibody capture. Using this method, we achieve purity over 99% with >99% column efficiency.

1:50 Session Break

2:20 Determination of Interactions between Antibody Biotherapeutics and Copper by Size Exclusion Chromatography (SEC) Coupled with Inductively Coupled Plasma Mass Spectrometry (ICP/MS)
Yanxin Luo, PhD, Scientist, Process Development, Amgen
Size-exclusion HPLC, coupled with ICP/MS (SEC-ICP/MS), was applied to assess metal binding to Immunoglobulin G (IgG) mAbs. IgG1s and IgG2 drugs were investigated. Cu(II) was selected as the metal of interest due to its known ability to bind and enhance the degradation of mAbs. In conjunction with other techniques, this method may provide in-depth knowledge to probe the mechanisms of metal-induced mAb degradation and biophysical properties in biologics process development.

2:45 Assessment of a Stabilized Sporicidal Solution for Affinity Resins
Maria Znidarsic, Engineer I, Downstream Development, Biogen
Previous work has demonstrated that 20 mM peracetic acid is a highly effective sporicidal solution that is compatible with 316L stainless steel and can be utilized to mitigate bioburden contamination. Perasan® A (Enviro Tech), a stabilized peracetic acid solution, was studied as an alternative sporicidal cleaning solution that could be implemented in manufacturing. Work presented herein demonstrated Perasan® A is a suitable replacement for peracetic acid.

3:20 LIVE PANEL DISCUSSION: Meeting the Challenge of Antibody Purification
Moderator: David W. Wood, PhD, Professor, Chemical & Biomolecular Engineering, The Ohio State University
Panelists:
Andrew Zydney, PhD, Bayard D. Kunkle Chair & Professor, Chemical Engineering, Pennsylvania State University
Basar Bilgicer, PhD, Associate Professor, Chemical & Biomolecular Engineering, University of Notre Dame
Yanxin Luo, PhD, Scientist, Process Development, Amgen
Maria Znidarsic, Engineer I, Downstream Development, Biogen

3:40 20th Anniversary Celebration - View Our Virtual Exhibit Hall
Reunite with old friends and new, share memories, and raise a glass with your peers in an open video reunion.

4:00 Close of Day

THURSDAY, JANUARY 21

CHROMATOGRAPHY

9:00 am Accelerating Development of Applied Molecular Transport Clinical Candidates through Downstream Process Development

Amir Porat, PhD, Principal Scientist, Protein Purification Process Development, Applied Molecular Transport

Applied Molecular Transport (AMT) constructed a pipeline of therapeutic proteins consisting of a human therapeutic domain, covalently attached to a bacterial carrier domain. Subsequently, AMT has developed a proprietary downstream process utilizing ***E. coli*** inclusion bodies (IB) of the heterologous proteins. The process steps include IB isolation, IB solubilization, refolding, TFF, and classical preparative protein chromatography protocols employing unique chromatography resins. This DSP development work has yielded several patent applications.

9:25 Chromatography Process Modeling for Process Efficiency and Risk Mitigation for Accelerated Timeline

Yuyi Shen, PhD, Associate Director, Process Development & Manufacturing, Bolt Biotherapeutics, Inc.

This talk will cover computational modelling that can be used to simulate chromatographic process performance, including economic analysis utilizing process modeling, as well as presenting case studies and lessons learned from modeling vs. experimentation.

9:50 Rational Use of DoE in Chromatography Development

Somaieh Mohammadi, PhD, Staff Scientist, Statistics and Computational Engineering, Data Science, FUJIFILM Diosynth Biotechnologies

Design of Experiments (DoE) is commonly used during process development, however the type of design that can be utilized depends on the objective of the study. This presentation discusses the establishment of appropriate designs and subsequent analysis for the optimization of individual chromatography steps or establishing the robustness of a platform purification process containing affinity, cation exchange (CEX) and anion exchange (AEX) chromatography steps, using a combination of risk assessment and rational design selection.

10:20 High-Efficiency and Throughput Protein (Exosome and Virus Particle) Separations via Hydrophobic Interaction Chromatography on C-CP Fiber Phases

R. Kenneth Marcus, PhD, Professor, Chemistry, Biosystems Research Complex, Clemson University

Hydrophobic interaction chromatography (HIC) provides a facile method of biomacromolecule separation, relying more on the global characteristics of solvated proteins rather than the charge-state specificity of ion exchange methods. HIC separations on polyester C-CP fibers provide for high-velocity separations without mass transfer limitations. We demonstrate these concepts in terms of analytical and preparative protein separations. The same protocols allow for rapid purification of therapeutically-relevant exosomes and virus particles.

10:45 High-Resolution Purification of PEGylated Proteins Using Membrane Chromatography

Raja Ghosh, PhD, Professor & Chair, Chemical Engineering, McMaster University

Laterally-fed membrane chromatography (LFMC) combine high speed with high resolution in separation. In this presentation we discuss the use of the latest version of LFMC devices, i.e., the z2LFMC device, for purification of PEGylated proteins. The purification of these protein-polymer conjugate molecules, which are increasingly being used as biopharmaceuticals is challenging as the molecules being separated differ only very slightly in terms of their physicochemical properties.

11:20 LIVE PANEL DISCUSSION: Achieving High-Efficiency Chromatography

Moderator: David W. Wood, PhD, Professor, Chemical & Biomolecular Engineering, The Ohio State University

Panelists:

Amir Porat, PhD, Principal Scientist, Protein Purification Process Development, Applied Molecular Transport

Yuyi Shen, PhD, Associate Director, Process Development & Manufacturing, Bolt Biotherapeutics, Inc.

R. Kenneth Marcus, PhD, Professor, Chemistry, Biosystems Research Complex, Clemson University

Raja Ghosh, PhD, Professor & Chair, Chemical Engineering, McMaster University

Somaieh Mohammadi, PhD, Staff Scientist, Statistics and Computational Engineering, Data Science, FUJIFILM Diosynth Biotechnologies

11:40 PepTalk Connects - View Our Virtual Exhibit Hall

Make LIVE Connections with Fellow Attendees, Speakers and Solution Providers

12:20 BuzZ Sessions

Facilitated, small-group interactive discussions around focused topics.

CO-PRESENTATION: BuzZ Session: Protein Tag Technologies

David W. Wood, PhD, Professor, Chemical & Biomolecular Engineering, The Ohio State University

Richard Altman, Field Application Scientist, Life Science Solutions, Thermo Fisher Scientific

Dominic Esposito, PhD, Director, Protein Sciences, Frederick National Laboratory

Alexei Yeliseev, PhD, Staff Scientist, Group Leader, LMBB, NIH/NIAAA

Dennis Karthaus, MSc, Director, Protein Products & Assays, IBA Lifesciences

12:40 Session Break

CHALLENGING TARGETS – MEMBRANE PROTEINS, PROTEIN-PROTEIN

1:00 Affinity Purification of GPCR

Alexei Yeliseev, PhD, Staff Scientist, Group Leader, LMBB, NIH/NIAAA

Affinity tags have been widely applied to purification of G protein-coupled receptors (GPCRs) for structural studies. We developed a novel calcium-dependent, EF-based affinity system that allows capture and high recovery of GPCR from dilute solutions. The binding of the EF1 tag to the resin is very strong (high picomolar to low nanomolar range) that allows efficient purification, without any loss of the target protein.

1:25 Power to the Protein: Spy&Go to Access a Covalent Spy Toolbox

Mark Howarth, PhD, Associate Professor, Biochemistry, University of Oxford

Proteins are extraordinarily diverse, so generic approaches are needed to harness their potential. The SpyTag peptide spontaneously reacts with the protein SpyCatcher. SpyTag-linked proteins can be purified by Spy&Go, detected sensitively, anchored irreversibly, or linked to an effector or multimerization toolbox. Applications include SARS-CoV-2 and influenza vaccination, diagnostics and antibodies.

1:50 Session Break

2:20 Direct Capture into Peptidisc Particles for Improved Exploitation of Membrane Proteins

Franck Duong, PhD, Professor, Biochemistry & Molecular Biology, University of British Columbia

Membrane proteins are prime targets for drug discovery, yet challenging to purify and manipulate due to their facile aggregation. Our laboratory develops methods to streamline their isolation by direct transfer from crude membrane to water-soluble Peptidiscs in the presence of native lipids. This workflow increases stability and facilitates downstream exploitation in biochemical, structural and pharmacologic laboratory settings.

2:45 Decoding Allosteric Regulation of Protein-Protein Interactions in Natural Product Biosynthesis

Michael Burkart, PhD, Professor, Chemistry & Biochemistry, University of California San Diego

Carrier proteins play an essential role in shuttling substrates between appropriate enzymes in metabolic pathways. We demonstrate a unique communication mechanism between the acyl carrier protein and partner enzymes, using NMR spectroscopy and molecular dynamics to elucidate allostery dependent on fatty-acid chain length. These results illuminate details of cargo communication by ACP that can serve as a foundation for engineering carrier protein dependent pathways for specific, desired products.

3:20 LIVE PANEL DISCUSSION: Meeting the Challenge of Purifying GPCRs, Protein-Proteins & Other Difficult Targets

Moderator: David W. Wood, PhD, Professor, Chemical & Biomolecular Engineering, The Ohio State University

Panelists:

Alexei Yeliseev, PhD, Staff Scientist, Group Leader, LMBB, NIH/NIAAA

Mark Howarth, PhD, Associate Professor, Biochemistry, University of Oxford

Franck Duong, PhD, Professor, Biochemistry & Molecular Biology, University of British Columbia

Michael Burkart, PhD, Professor, Chemistry & Biochemistry, University of California San Diego

3:40 Close of Conference

1:50 Session Break

BIOTHERAPEUTIC EXPRESSION & PRODUCTION

The demand for high-quality biotherapeutics has never been greater. Higher-throughput protein expression, production and purification as well as more flexible expression systems and techniques are necessary to meet the demands for both biotherapeutic research and manufacturing pipelines. The Biotherapeutic Expression & Production pipeline explores the newest data, innovations and strategies to make the expression of therapeutic proteins more efficient, effective and trouble-free.

January 19-20

Cell Line Development Strategies

AGENDA

January 20-21

Recombinant Protein Expression and Production

AGENDA

TUESDAY, JANUARY 19

ALTERNATIVE EXPRESSION STRATEGIES

9:00 am Comprehensive Flow Cytometry Analysis of Transient VLP Expression in HEK293 Cells for Enhanced Process Visualization and Understanding

Daniel J. Blackstock, PhD, Senior Scientist, Generation Bio

We developed a method to comprehensively track PEI-based transient expression of VLPs for deeper process understanding and control. Our analysis focused on monitoring cell population responses during transfection, understanding how process changes affected these responses, and determining patterns in cell performance over culture duration. For enhanced process visualization, plasmid labeling and cell staining were employed for flow cytometry evaluation and for drawing correlations between plasmid DNA uptake and VLP expression.

9:25 Potential Use of Transient Gene Expression to Generate Clinical-Grade Material

Sara Rodriguez Conde, PhD, Cell Culture & Fermentation Sciences, BioPharmaceuticals Development, R&D, AstraZeneca, Cambridge, UK

Antibodies were produced using AstraZeneca's proprietary CHO-based transient expression system at different scales to explore the potential for using transient expression processes to generate clinical-grade material. The presentation will highlight the scalability and productivity of the process up to 200L, along with analytical data from independent batches. The benefits and risks of using transient platforms to rapidly generate clinical material will be discussed.

10:20 Advances in Cell-Free Protein Expression

Javin Oza, PhD, Assistant Professor, Chemistry & Biochemistry, California Polytechnic State University

Cell-free protein expression is emerging as a viable alternate to traditional ***in vivo*** expression of proteins. The field is rapidly advancing to reduce barriers to entry for new users, improve yields, cost, and throughput. This presentation will outline some of these advances, as well as limitations that new users should be aware of.

10:45 KEYNOTE PRESENTATION: New Methods for Cell-Free Presentation of Proteins for Functional Analysis

Joshua LaBaer, PhD, Executive Director, Arizona State University Biodesign Institute

Self-assembling protein microarrays made through cell-free synthesis have been used widely to study protein interactions with drugs and other proteins, to search for enzyme substrates and to find disease biomarkers. Recent methodological advances now enable new types of studies including highly multiplexed analysis, testing the effects of post-translational changes on protein interactions and providing highly quantitative readouts with significantly reduced background noise.

11:20 LIVE PANEL DISCUSSION: Alternative Expression Strategies

Moderator: Daniel J. Blackstock, PhD, Senior Scientist, Generation Bio

Panelists:

Sara Rodriguez Conde, PhD, Cell Culture & Fermentation Sciences, BioPharmaceuticals Development, R&D, AstraZeneca, Cambridge, UK

Joshua LaBaer, PhD, Executive Director, Arizona State University Biodesign Institute

Javin Oza, PhD, Assistant Professor, Chemistry & Biochemistry, California Polytechnic State University

11:40 PepTalk Connects - View Our Virtual Exhibit Hall

Make LIVE Connections with Fellow Attendees, Speakers and Solution Providers

12:20 BuzZ Sessions

Facilitated, small-group interactive discussions around focused topics.

CO-PRESENTATION: BuzZ Session: Common Issues with Transient Protein Production

Richard Altman, Field Application Scientist, Life Science Solutions, Thermo Fisher Scientific

Henry C. Chiou, PhD, Director, Cell Biology, Life Science Solutions, Thermo Fisher Scientific

Dominic Esposito, PhD, Director, Protein Sciences, Frederick National Laboratory

- What are the current challenges to transient protein production?
- What are the keys to optimizing expression?
- What scale of expression and level of throughput are commonly being used
- HEK293 versus CHO?
- Characterization of transiently produced proteins
- How to optimize the protein expression workflow?

12:40 Session Break

GENOME ENGINEERING

1:00 FEATURED PRESENTATION: High-Throughput, Efficacious Gene Editing & Genome Surveillance in Chinese Hamster Ovary Cells

Steven Huhn, PhD, Senior Scientist, Merck Research Labs

Genome engineering of CHO cells has been challenged by a lack of efficacious, high throughput, and low-cost gene editing modalities and screening methods. In this work, we demonstrate an improved method for gene editing in CHO cells using CRISPR RNPs and characterize the endpoints of Cas9 and ZFN mediated genetic engineering. we validate sequence decomposition as a cost effective, rapid, and accurate method for assessing mutants and clonality.

1:25 FEATURED PRESENTATION: The Cumate Gene-Switch: An Efficient Inducible Expression System for Easy- and Difficult-to-Express Recombinant Proteins

Yves Durocher, PhD, Research Officer & Head, Mammalian Cell Expression, National Research Council Canada

During the generation of stable cell lines, high-level expression of recombinant protein may impose a metabolic burden and many cells may not survive the selection process. The cumate-inducible expression system allows for selection in the "off-mode" and yields stable pools with up to 3-fold higher productivity compared to selection in the "on-mode" (mimicking constitutive promoters). This is observed with both "hard-to-express" and "easy-to-express" proteins, including the SARS-CoV-2 trimeric spike antigen.

1:50 Presentation to be Announced

FyoniBio

Speaker To Be Announced, Glycotope

2:20 CRISPR/Cas9 Strategy for Homology-Directed Multiple Targeted Integration of Transgenes in CHO Cells

Jae Seong Lee, PhD, Assistant Professor, Applied Chemistry & Biological Engineering, Ajou University

Site-specific integration has emerged as a promising strategy for precise CHO cell line engineering and predictable cell line development. CRISPR/Cas9 with the homology-directed repair pathway enables precise integration of transgenes into target genomic sites, but the low targeting efficiency hinders multiplexed gene knock-ins, as well as high-throughput screening. Here, I will present a simple optimized strategy that allows efficient CRISPR/Cas9-mediated knock-in of transgenes in a transient setup in CHO cells.

2:45 FEATURED PRESENTATION: CHO Cell Engineering to Enhance High-Quality Biotherapeutic Protein Production: EPO and BMP-4

Gyun Min Lee, PhD, Full Professor, Animal Cell Engineering Lab, KAIST

Fed-batch culture, which supports high productivity, is commonly used for large-scale production of mAbs because of its operational simplicity and reliability. However, fed-batch culture is not used for EPO and BMP-4 production due to the significant reduction in EPO sialylation and autocrine BMP-signaling, respectively, during the later phase of CHO cell cultures. In this presentation, we'll discuss CHO cell engineering for EPO and BMP-4 production in fed-batch mode.

3:20 LIVE PANEL DISCUSSION : Genome Engineering

Moderator: Steven Huhn, PhD, Senior Scientist, Merck Research Labs

Panelists:

Yves Durocher, PhD, Research Officer & Head, Mammalian Cell Expression, National Research Council Canada

Gyun Min Lee, PhD, Full Professor, Animal Cell Engineering Lab, KAIST

Jae Seong Lee, PhD, Assistant Professor, Applied Chemistry & Biological Engineering, Ajou University

Speaker To Be Announced, Glycotope

3:40 Close of Day

WEDNESDAY, JANUARY 20

8:15 am Breakfast BuzZ Sessions

Facilitated, small-group interactive discussions around focused topics.

CELL LINE SELECTION

9:00 Sequence Variant and Post-Translational Modification Analysis during Cell Line Selection via High-Throughput Peptide Mapping and Intact Mass Analysis

Chongfeng Xu, PhD, Senior Scientist, Biogen

We present a high-throughput (HT) peptide mapping workflow, which can be applied at early stages of cell line selection, for testing of dozens of clones to report critical information, such as sequence variants and post-translational modifications, and enable biopharmaceutical development (CF Xu, Adv Exp Med Biol. 2019, 1140:225-236). We will also demonstrate the use of native mass spectrometry to exclude potentially problematic clones containing unprocessed leader sequences.

9:25 The Predictive Cellular and Protein Effects of Glycoengineering

Nathan Lewis, PhD, Associate Professor, Pediatrics, University of California, San Diego (UCSD)

With most top blockbuster drugs therapeutics being glycoproteins, there is a growing interest in engineering their glycan structures for improved safety, efficacy, and manufacturing. Using our systems biology approaches, we can predict the modifications needed to effectively glycoengineer proteins. We further have explored the more global impact glycoengineering has on the host cell, thus helping to define the design space of CHO produced glycoproteins.

9:50 Modernizing Laboratory Informatics To Accelerate Cell Line Development

Benchling

Prem Mohanty, Product Marketing Manager, Marketing, Benchling

With increasing complexity of cell line selection and development, the need for a fit-for-purpose data management platform is greater than ever. This talk will focus on the key considerations in selecting a modern lab informatics platform and how such a platform can transform cell line development.

10:20 The Unusual Suspects in Cell-Line Characterization

Harsha Gunawardena, PhD, Senior Scientist, Mass Spectrometry, Janssen Pharmaceutical Companies of Johnson & Johnson

Mass spectrometry is a powerful technique in the identification and characterization of biologics. New engineering design of sequences have resulted in the immergence of unexpected product quality attributes. These unexpected modifications or "unusual suspects" are analytically more challenging yet important considerations for cell-line development. In this presentation, we show several case studies, highlighting the techniques used to decipher unusual post-translation modifications, sequence extensions, and isomeric sequence substitutions in biologics.

10:45 Investigation of Gene Expression Patterns in Stable and Unstable Clonally Derived CHO Cell Lines

Theodore Peters, PhD, Senior Scientist, Cell Line Development, Seattle Genetics

Development of biologic-producing CHO clones in accelerated timelines is encumbered by demonstrating production stability in candidate cell lines. Screening out unstable lines earlier in development could mitigate the risk of advancing unstable candidates. Our work reveals significant phenotypic heterogeneity in clonal populations by characterizing subclones from stable and

unstable clones. This highlights the prevalence of phenotypic drift in clonal cell lines providing a basis for investigating gene expression patterns.

11:20 LIVE PANEL DISCUSSION: Cell Line Selection

Moderator: Nathan Lewis, PhD, Associate Professor, Pediatrics, University of California, San Diego (UCSD)

Panelists:

Harsha Gunawardena, PhD, Senior Scientist, Mass Spectrometry, Janssen Pharmaceutical Companies of Johnson & Johnson

Theodore Peters, PhD, Senior Scientist, Cell Line Development, Seattle Genetics

Prem Mohanty, Product Marketing Manager, Marketing, Benchling

Chongfeng Xu, PhD, Senior Scientist, Biogen

11:40 PepTalk Connects - View Our Virtual Exhibit Hall

Make LIVE Connections with Fellow Attendees, Speakers and Solution Providers

12:20 LIVE DISCUSSIONS: Women in Science Meet-Up and Early Faculty Career Networking

View more details on the Event Features page.

CO-PRESENTATION: Women In Science Meet-Up

Kelly Kemp, PhD, Director, Process Development, ViaCyte Inc.

Elizabeth S. Hecht, PhD, Associate Scientist, Microchemistry, Proteomics & Lipidomics, Genentech, Inc.

CO-PRESENTATION: Early Faculty Career Networking Meet-Up

Jamie B. Spangler, PhD, Assistant Professor, Biomedical Engineering and Chemical & Biomolecular Engineering, Johns Hopkins University

Erik Procko, PhD, Assistant Professor, Biochemistry, University of Illinois Urbana-Champaign

- Management of time and responsibilities in starting up a research lab
- Navigating unique challenges due to COVID-19 pandemic
- Recruiting students and postdocs
- Seeking out mentorship resources needed for success

12:40 Session Break

12:55 Close of Cell Line Development Strategies Conference

WEDNESDAY, JANUARY 20

8:15 am Breakfast BuzZ Sessions
Facilitated, small-group interactive discussions around focused topics.

11:40 PepTalk Connects - View Our Virtual Exhibit Hall
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12:20 LIVE DISCUSSIONS: Women in Science Meet-Up and Early Faculty Career Networking
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- Management of time and responsibilities in starting up a research lab
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- Seeking out mentorship resources needed for success

12:40 Session Break

UNIQUE PROTEINS AND ALTERNATIVE HOSTS

1:00 Plant-Made Virus-Like Particle Production
Hugh S. Mason, PhD, Associate Professor, Immunotherapy, Vaccines & Virotherapy, Biodesign Institute, Arizona State University

Virus-like particles (VLPs) were produced in stable transgenic plants in the 1990s, leading to clinical trials showing oral immunogenicity. Later, we developed transient expression systems for plants using viral replicons that enable robust production of recombinant proteins. These have been optimized for very efficient production of VLPs used for display of heterologous antigens, and when co-delivered with plant-made recombinant immune complexes, they produced strong immune synergy in mice.

1:25 Large-Scale Protein Production in *Vibrio natriegens* Can Beat *E. coli*
Simon A. Messing, PhD, Scientist II, Frederick National Lab & Protein Expression Lab, Leidos Biomedical Research Inc.

Production of recombinant proteins in ***E. coli*** is key to many drug discovery efforts. These protein reagents can be the rate-limiting step. Bacterial host, ***Vibrio natriegens,*** has recently shown promise as an alternative to ***E. coli***. Here, we present a set of general protocols for its use. Moreover, we show that ***Vibrio natriegens*** can outproduce ***E. coli*** for certain protein reagents, and/or solubilize protein where ***E. coli*** fails.

1:55 Talk Title to be Announced
Speaker to be Announced

SAMSUNG BIOLOGICS

2:20 Producing pMHC-I in Mammalian Cells Using the Molecular Chaperone TAPBPR
Sara M. O'Rourke, Project Scientist, MCD Biology, The University of California, Santa Cruz

Current approaches for generating major histocompatibility complex (MHC) Class-I proteins with peptides (pMHC-I) are limited by the inherent instability of empty MHC-I molecules. Using the properties of the chaperone, TAP-binding protein related (TAPBPR), we have developed a robust method to produce soluble, peptide-receptive MHC-I molecules in Chinese Hamster Ovary cells at high yield, completely bypassing the requirement for laborious refolding from inclusion bodies expressed in ***E. coli.***

2:45 Key Learnings and Approaches for Establishing a High-Throughput, Multi-Host Protein Expression Testing and Purification Platform for All Protein Types
Edward Kraft, PhD, Senior Scientific Manager, BioMolecular Resources, Genentech

The increasing demands for protein reagents needed for drug discovery efforts drive the development of an efficient methodology for recombinant protein production. Within the BioMolecular Resources Department at Genentech, we have developed a platform for high throughput construct generation and expression screening in baculovirus, ***E coli*** and mammalian transient systems applicable to all protein types and localizations.

3:20 LIVE PANEL DISCUSSION: Unique Proteins and Alternative Hosts
Moderator: Hugh S. Mason, PhD, Associate Professor, Immunotherapy, Vaccines & Virotherapy, Biodesign Institute, Arizona State University

Panelists:

Edward Kraft, PhD, Senior Scientific Manager, BioMolecular Resources, Genentech

Simon A. Messing, PhD, Scientist II, Frederick National Lab & Protein Expression Lab, Leidos Biomedical Research Inc.

Sara M. O'Rourke, Project Scientist, MCD Biology, The University of California, Santa Cruz

Speaker to be Announced

3:40 20th Anniversary Celebration - View Our Virtual Exhibit Hall
Reunite with old friends and new, share memories, and raise a glass with your peers in an open video reunion.

4:00 Close of Day

THURSDAY, JANUARY 21

MEMBRANE PROTEINS

9:00 am High-Level Production of Recombinant Membrane Proteins in the Engineered *Escherichia coli* Strains SuptoxD and SuptoxR
Georgios Skretas, PhD, Principal Investigator & Research Associate Professor, Institute of Chemical Biology, National Hellenic Research Foundation; Founder & CEO, ResQ Biotech

We will describe the development of ***E. coli*** SuptoxD and SuptoxR, two specialized strains for high-level recombinant membrane protein (MP) production. These engineered strains can: (1) suppress

the toxicity that frequently accompanies MP overexpression, thus enabling enhanced levels of final bacterial biomass; and (2) markedly increase the cellular accumulation of membrane-embedded protein. Combined, these two positive effects result in dramatically enhanced volumetric yields for various prokaryotic and eukaryotic recombinant MPs.

9:25 Purification of Recombinant DHHC Proteins Using an Insect Cell Expression System

Martin Ian Malgapo, PhD, Postdoctoral Research Fellow, Department of Molecular Medicine, Cornell University

The DHHC palmitoyltransferase enzymes are membrane proteins that catalyze protein S-fatty acylation. While the library of identified S-fatty acylated proteins has grown tremendously, biochemical and mechanistic studies on DHHC enzymes remain challenged by the innate difficulty of preparing a functional enzyme. In this talk, I will describe a protocol we developed for successfully expressing and purifying recombinant DHHC proteins, using a two-column affinity purification followed by size exclusion chromatography.

9:50 Presentation to be Announced

Speaker To Be Announced, Selexis, Inc.

10:20 Functional Expression and Purification of Multidrug Resistance Protein 4 MRP4/ABCC4

Alice Rothnie, DPhil, Senior Lecturer, Biochemistry, Aston University

Multidrug resistance protein 4 (MRP4/ABCC4) can transport a range of organic anionic compounds out of the cell, and has been linked with cancer, inflammation and cell signalling. MRP4 was expressed in three different expression systems: mammalian, insect, and yeast cells, to gain the highest yield possible. Subsequently MRP4 was solubilised and purified using novel detergents or polymers that conferred increased stability to the protein.

10:45 Loss of a Newly Identified Small Non-Coding RNA Leads to Increased NGNA (Neu5Gc) Sialylation of Monoclonal Antibodies in CHO Cells

Simon Fischer, PhD, Head, Cell Biology, Boehringer Ingelheim Pharma GmbH & Co. KG

Monoclonal antibodies (mAbs) produced in CHO cells usually show N-glycan patterns with only little sialylation. However, we have recently identified a CHO cell line producing mAbs with greater than 30% NGNA sialylation. NGNA sialylation represents a critical quality attribute supposed to induce immunogenic reactions. In-depth transcriptomic and non-coding RNA expression analyses revealed a novel putative regulatory circuit around protein sialylation in CHO cells.

11:20 LIVE PANEL DISCUSSION: Membrane Proteins

Moderator: Alice Rothnie, DPhil, Senior Lecturer, Biochemistry, Aston University

Panelists:

Simon Fischer, PhD, Head, Cell Biology, Boehringer Ingelheim Pharma GmbH & Co. KG

Martin Ian Malgapo, PhD, Postdoctoral Research Fellow, Department of Molecular Medicine, Cornell University

Georgios Skretas, PhD, Principal Investigator & Research Associate Professor, Institute of Chemical Biology, National Hellenic Research Foundation; Founder & CEO, ResQ Biotech

Speaker To Be Announced, Selexis, Inc.

11:40 PepTalk Connects - View Our Virtual Exhibit Hall

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12:20 BuzZ Sessions

Facilitated, small-group interactive discussions around focused topics.

BuzZ Session: Where are the New Expression Systems for Production of Non-antibody Proteins?

Edward Kraft, PhD, Senior Scientific Manager, BioMolecular Resources, Genentech

- Do we have good protein production cell lines and/or expression systems to support this work?
- Are there forgotten technologies of the past that are worth revisiting?
- Have we painted ourselves into a corner by having a world too focused on CHO?
- What is your experience with using antibody-optimized expression systems for producing challenging proteins?
- Are those advocating niche expression systems missing the mark by not considering end-to-end feasibility?

12:40 Session Break

PROTEIN PRODUCTION CHALLENGES

1:00 LIVE PANEL DISCUSSION: Protein Production Lab Challenges: Methodologies, Strategies, and the Art of Managing Multiple Projects

Moderator: Richard Altman, Field Application Scientist, Life Science Solutions, Thermo Fisher Scientific

Panelists:

Dominic Esposito, PhD, Director, Protein Sciences, Frederick National Laboratory

Edward Kraft, PhD, Senior Scientific Manager, BioMolecular Resources, Genentech

Balaji Somasundaram, PhD, Strategy & Operations Manager, Protein Expression Facility, University of Queensland

Elizabeth Stangle, Senior Research Associate, Protein Engineering, Zymeworks Inc.

Bjørn Voldborg, MSc, Director, CHO Cell Line Development, Novo Nordisk Foundation Center for Biosustainability, Technical University of Denmark

Jessica A. Williamson, PhD, Protein Production Lead, UCB

1:50 Talk Title to be Announced

Speaker to be Announced

2:20 Recombinant Production of a G-Protein Coupled Receptor Using an *Escherichia coli* Cell-Free Expression System

Ho Leung Ng, PhD, Associate Professor, Biochemistry & Molecular Biophysics, Kansas State University

Recombinant expression of GPCRs is difficult but important for developing assays, producing antigens for antibodies, and structural biology. We describe using cell-free expression with ***E. coli*** lysate to produce the G-protein coupled estrogen receptor (GPER). GPER was produced in microgram quantities, precipitated, and reconstituted. We describe the first use of recombinantly expressed GPER in a functional liquid chromatography-mass spectrometry assay to validate binding with known ligands.

2:45 An Antibody's Story: A Journey from Phage Library to an IND of STI 1499

Robert D. Allen, PhD, Vice President, Antiviral and Oncolytic Immunotherapy Development, Sorrento Therapeutics Inc.

Utilizing a naïve phage display antibody library, the clinical candidate antibody, STI-1499, and the affinity-engineered variant, STI-2020, were isolated, profiled ***in vitro***, and evaluated for ***in vivo*** efficacy in the Syrian golden hamster model of COVID-19. Both antibodies demonstrated potent disease protection and a dose-dependent reduction of virus load in the lungs. DNA-based delivery of STI-2020 and development of antibody cocktail therapeutics are in progress.

3:20 LIVE PANEL DISCUSSION: It's a Wrap

Moderator: Dominic Esposito, PhD, Director, Protein Sciences, Frederick National Laboratory

Panelists:

Robert D. Allen, PhD, Vice President, Antiviral and Oncolytic Immunotherapy Development, Sorrento Therapeutics Inc.

Ho Leung Ng, PhD, Associate Professor, Biochemistry & Molecular Biophysics, Kansas State University

3:40 Close of Conference

PEPTALK VIRTUAL
CONFERENCE & EXPO

via pathable

Pathable is a robust event platform, designed to enhance the online conference experience and selected by CHI for its full range of opportunities to present, target, connect and

expand your reach.

OFFERING A FULL SCOPE OF ENGAGEMENT OPPORTUNITIES

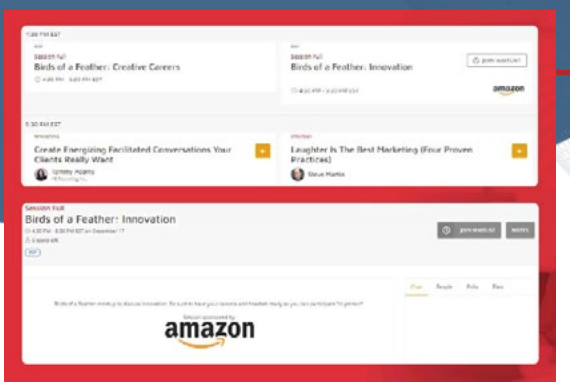
- INTUITIVE INTERFACE
- COMPANY BRANDING
- VIRTUAL BOOTH
- PRODUCT VIDEOS
- GAMIFICATION
- DOWNLOADS
- LIVE CHAT
- 1:1 NETWORKING
- MATCHMAKING
- PRODUCT DIRECTORY
- BREAKOUT GROUPS
- LIVE SESSIONS
- RECORDED SESSIONS
- INTEGRATED SCHEDULER
- POSTER SESSIONS

Company Profiles

Attendees can search & filter from an alphabetical listing to easily find your company listing.

PROFILE HIGHLIGHTS INCLUDE:

- Logo Branding
- Company Description
- Offerings Tags
- Upload Videos & Files
- Showcases Sponsored Sessions
- Displays Booth Personnel
- Networking Options



Sponsored Sessions & Breakout Discussions

Stand out with consistent logo branding everywhere your talk or breakout is listed.

FURTHER DETAILS WITHIN EACH AGENDA ITEM INCLUDE:

- Abstracts
- Direct Link to Your Live or Pre-Recorded Presentation
- Link to Speaker Profile
- Files Relevant to Your Presentation
- Polls

Networking

The People section makes it easy to find the right connections. Search or filter an alphabetical listing to view attendee profiles and start networking.

WAYS TO CONNECT INCLUDE:

- Create a Want to Meet List
- Send a Message Request for a 1:1 Meeting

SPONSORSHIP & EXHIBIT OPPORTUNITIES

SPONSORSHIP PACKAGES

CHI offers sponsorship packages to maximize your exposure before, during and after each event. Our team can help you customize an integrated marketing program that targets your objectives and achieves your goals for the entire year. Opportunities include but are not limited to exhibits, presentations, branding and webinars using our extensive database of over 800,000 Life Science professionals.

PREMIER SPONSOR
(limited availability)

- Presentation
- Pre & Post Email Blast to all attendees
- Post event, CHI will provide full contact information (GDPR compliant) for your specific session and the full conference attendee list
- Virtual Exhibit Booth Space
- and much MORE!

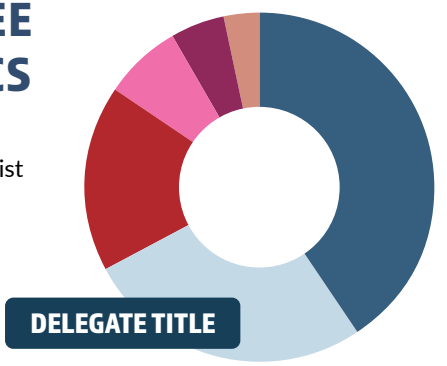
CORPORATE SPONSOR

- Presentation
- Post event, CHI will provide full contact information of attendees who participated in your specific session
- Virtual Exhibit Booth Space
- and much MORE!

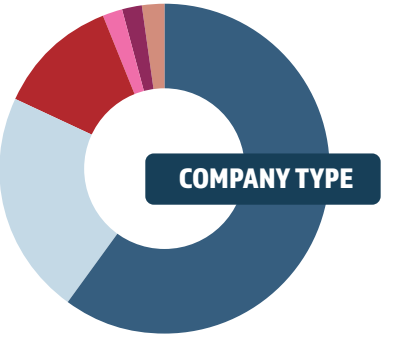
CORPORATE SUPPORT SPONSOR

- Virtual Exhibit Space
- Two main conference registrations
- Corporate logo placed on conference materials
- and MORE!

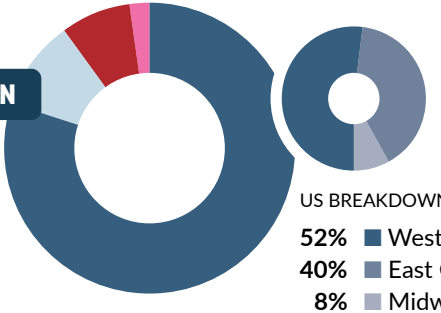
2020 ATTENDEE DEMOGRAPHICS



40%	Scientist/Technologist
26%	Executive/Director
19%	Sales & Marketing
7%	Manager
5%	Professor
3%	Assistant



60%	Biotechnical/ Commercial/CRO
22%	Pharmaceutical
12%	Government/Academic
2%	Healthcare
2%	Services
2%	Other



80%	United States
10%	Europe
8%	Asia
2%	Rest of World

US BREAKDOWN

52%	West Coast
40%	East Coast
8%	Midwest

FOR MORE INFORMATION ON SPONSORSHIP, PLEASE CONTACT:

COMPANIES A-K
Jason Gerardi
Sr. Manager, Business Development
781-972-5452
jgerardi@healthtech.com

COMPANIES L-Z
Ashley Parsons
Manager, Business Development
781-972-1340
ashleyparsons@healthtech.com

2021 MEDIA SPONSORS

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- Receive $50 off your registration. (Product and service providers not eligible for discount.)
- Your poster abstract will be published in our conference materials.

To ensure your poster presentation is included in the conference materials, your full submission must be received, and your registration paid in full by December 18, 2020.

Virtual scientific poster presentation materials will include:

- Poster title
- Text-only abstract. It can be an in-depth, one-page abstract, or just a short description
- 3-5 Minute voice-over PowerPoint presentation. You may substitute the PowerPoint with a one-page, static PDF of your poster

Full time graduate students and PhD candidates are encouraged to attend and present a poster. See chi-peptalk.com/posters for details.

WHAT'S THE BUZZ ABOUT?

BuzZ sessions

PepTalk BuzZ Sessions are focused, stimulating discussions in which delegates discuss important and interesting topics related to upstream protein expression and production through downstream scale-up and manufacturing. This is a moderated discussion with brainstorming and interactive problem-solving between scientists from diverse areas who share a common interest in the discussion topic.

Continue to check the event website for detailed discussion topics and moderators.

PEPTALK VIRTUAL CONFERENCE & EXPO

THE PROTEIN SCIENCE AND PRODUCTION WEEK

2021

JANUARY 19-21, 2021 Pacific Standard Time

PRICING & REGISTRATION INFORMATION

STANDARD REAL-TIME VIRTUAL

(Includes access to all virtual conferences and event features, and On-Demand access. You are allowed to move between virtual sessions to attend presentations taking place at the same time.)

	Commercial	Academic, Government, Hospital-Affiliated
Advance Rate until January 15	$999	$599
Standard Registration after January 15	$1199	$699

STANDARD POST-EVENT ON-DEMAND

(Includes post-event recorded access to ALL conferences. Does not include Q&A sessions or networking.)

Advance Rate until January 15	$799	$449
Standard Registration after January 15	$949	$499

BASIC REAL-TIME VIRTUAL

(Includes access to one virtual conference and event features, and On-Demand access. You are allowed to move between virtual sessions to attend presentations taking place at the same time.)

Advance Rate until January 15	$599	$399
Standard Registration after January 15	$699	$499

BASIC POST-EVENT ON-DEMAND

(Includes post-event recorded access to ONE conference. Does not include Q&A sessions or networking.)

Advance Rate Until January 15	$449	$299
Standard Registration After January 15	$549	$399

CONFERENCE DISCOUNTS*

GROUP DISCOUNTS ARE AVAILABLE! Special rates are available for multiple attendees from the same organization. For more information on group discounts contact David Cunningham at 781-972-5472, cunningham@healthtech.com

ALUMNI DISCOUNT - SAVE 20%: CHI appreciates your participation at its events. As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate.

POSTER SUBMISSION - DISCOUNT ($50 OFF): Poster materials are due by January 4, 2021.

Once your registration has been fully processed, we will send an email with a unique link and instructions for submitting your abstract and other materials. If you do not receive this email within 5 business days, please contact jring@healthtech.com.

CHI reserves the right to publish your poster title and abstract in various marketing materials and products.

** Alumni, Twitter, LinkedIN, Facebook or any other promotional discounts cannot be combined.*

ADDITIONAL REGISTRATION DETAILS

Each registration includes all conference sessions, posters and exhibits, and access to the on-demand library.

To view our Substitutions/Cancellations Policy, go to healthtech.com/regdetails

How to Register: CHI-PepTalk.com

reg@healthtech.com

P: 781.972.5400 or Toll-free in the U.S. 888.999.6288

Please use keycode **PTK F** when registering!

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