23rd Annual

PEPTALK

JANUARY 16-19, 2024 | SAN DIEGO, CA | HILTON SAN DIEGO BAYFRONT

THE PROTEIN SCIENCE AND PRODUCTION WEEK

Revolutionizing the Future of Biotherapeutics

Innovative Solutions in Antibody Development, Biologics Characterization, and Expression Platforms

2024 PROGRAMS

- ANTIBODY DISCOVERY & ENGINEERING
- BISPECIFIC ANTIBODY DEVELOPMENT
- CHARACTERIZATION & AGGREGATION IN BIOPHARMACEUTICALS
- VECTOR DESIGN & DELIVERY
- HIGHER-THROUGHPUT BIOPRODUCTION
- TS TRAINING SEMINARS

FINAL DAYS TO REGISTER

PLENARY KEYNOTE SPEAKERS

Steven M. Cramer, PhD, Rensselaer Polytechnic Institute

Jennifer Giottonini Cayer, CBO, Pulmocide

Deborah Moore-Lai, PhD, Senior Director, Protein Development & Production, R&D Leadership, Abcam

Carter A. Mitchell, PhD, Kemp Proteins, LLC

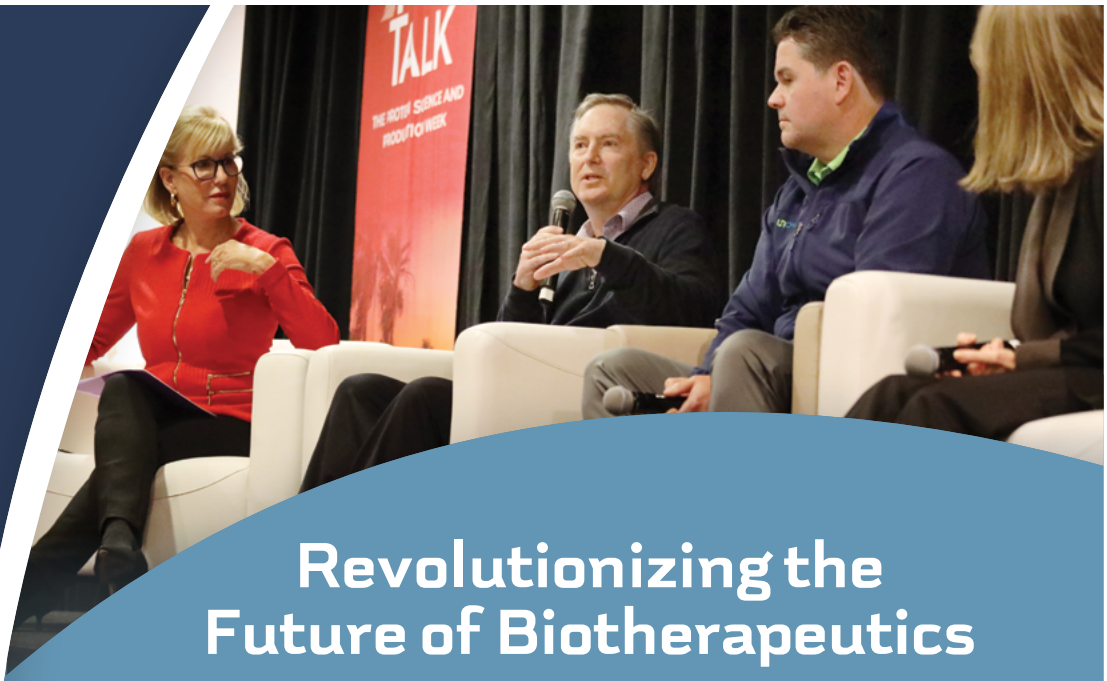
Eric Vajda, PhD, OmniAb

TABLE OF CONTENTS

CHI-PepTalk.com

PREMIER SPONSOR UNCHAINED LABS

Organized by Cambridge Healthtech Institute



Revolutionizing the Future of Biotherapeutics

Innovative Solutions in Antibody Development, Biologics Characterization, and Expression Platforms

PepTalk provides a comprehensive program and innovative solutions for optimizing biotherapeutics. Conference tracks cover a range of topics including antibody engineering, bispecific antibody development, characterization of biologics, viral vector engineering, and protein expression platforms. Learn from expert speakers, engage with a devoted community, and gain valuable tools to advance your research.

Join us for four days of immersive learning, world-class presentations, poster sessions, keynotes, breakout groups, panel discussions, training seminars, exhibitions, and collaboration and networking opportunities.

"PepTalk is the perfect place for networking and solutions from companies, organizations and universities."

CONFERENCE PROGRAMS feature keynote presentations, case studies, and new unpublished data from influential leaders in academia and industry.

TRAINING SEMINARS offer focused instruction in topics related to your field using a mix of lecture and interactive discussion formats and are led by experienced instructors. These may be combined with conferences to customize your week at PepTalk.

BUZZ SESSION BREAKOUT GROUPS initiate discussions about current research and trends.

EXHIBIT HALL provides face-to-face networking with technology & service providers ready to share their latest products and services.

POSTER SESSIONS showcase cutting-edge, ongoing research. Over 100 posters will be presented!

ON-DEMAND ARCHIVE of presentations to access on your own time.

CHI-PepTalk.com #CHIPepTalk

THE PROTEIN SCIENCE AND PRODUCTION WEEK

23rd Annual PEPTALK 2024

January 16-19, 2024 | San Diego, CA
HILTON SAN DIEGO BAYFRONT AND ONLINE

TABLE OF CONTENTS

CONFERENCE PROGRAMS

click title to view program

ANTIBODY DISCOVERY & ENGINEERING

- Intelligent Antibody Discovery Part 1
- Intelligent Antibody Discovery Part 2

BISPECIFIC ANTIBODY DEVELOPMENT

- Developability of Bispecific Antibodies
- Safety & Efficacy of Bispecific Antibodies

CHARACTERIZATION & AGGREGATION IN BIOPHARMACEUTICALS

- Characterization of Biotherapeutics
- Characterizing Protein Aggregates and Impurities

VECTOR DESIGN & DELIVERY NEW

- Viral Vector Engineering

HIGHER-THROUGHPUT BIOPRODUCTION

- Cell Line Optimization
- Recombinant Protein Expression and Production

CHI-PepTalk.com

#CHIPepTalk

SPONSORS

PREMIER SPONSOR

UNCHAINED LABS

CORPORATE SPONSORS

ABLEXIS
AlivaMab BIOLOGICS

BIOSYSTEMS Acro

Agilent
Trusted Answers

AJINOMOTO

AZENTA LIFE SCIENCES

bio-techne

cytiva

GenScript
Make Research Easy

halo labs

OmniAb

Pfanstiehl

primrose bio

Purolite
An Ecolab Company

VALIDOGEN
Formerly VTU technology

WuXi Biologics
Global Solution Provider

XtalPi

CORPORATE SUPPORT SPONSORS

aragen

FORMULATRIX®

ICHOR LIFE SCIENCES

SHANGHAI MODEL ORGANISMS

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. These are moderated discussions with brainstorming and interactive problem-solving among 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 2024

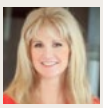
CONFERENCE PROGRAMS

	Tuesday, January 16– Wednesday, January 17	Thursday, January 18– Friday, January 19
ANTIBODY DISCOVERY & ENGINEERING	Intelligent Antibody Discovery – Part 1	Intelligent Antibody Discovery – Part 2
BISPECIFIC ANTIBODY DEVELOPMENT	Developability of Bispecific Antibodies	Safety & Efficacy of Bispecific Antibodies, ADCs and Combination Therapy
CHARACTERIZATION & AGGREGATION IN BIOPHARMACEUTICALS	Characterization of Biotherapeutics	Characterizing Protein Aggregates and Impurities
VECTOR DESIGN & DELIVERY	Viral Vector Engineering & Scale-Up Considerations	
HIGHER-THROUGHPUT BIOPRODUCTION	Cell Line Optimization	Recombinant Protein Expression and Production
TRAINING SEMINARS	Introduction to Multispecific Antibodies	Biomanufacturing 101: An Overview on Animal Cell Culture Technology from Cell Line Development to Scale-Up Strategies
	Introduction to Antibody Engineering	Introduction to CMC for Biotech, Cell & Gene Therapy Products
	Introduction to Machine Learning for Biologics Design	Label-Free Biosensor Tools in Biotherapeutic Discovery: SPR, BLI & KinExA
	Advanced Purification of Engineered Biologics and Research Protein Tools	Antibody Drug Discovery: From Target to Lead

PLENARY KEYNOTE SESSIONS

WEDNESDAY, JANUARY 17 | 9:00 AM

PLENARY FIRESIDE CHAT: SUPPORTING AND DRIVING BIOTECH: Past, Present, and Future




MODERATOR: **Jennifer Giottonini Cayer**, CBO, Pulmocide

PANELISTS: **Deborah Moore-Lai, PhD,** Senior Director, Protein Development & Production, R&D Leadership, Abcam

Carter A. Mitchell, PhD, CSO, Purification & Expression, Kemp Proteins, LLC

Eric Vajada, PhD, Vice President, Preclinical R&D, OmniAb

THURSDAY, JANUARY 18 | 4:35 PM

PLENARY KEYNOTE: PROTEIN AND GENE THERAPY BIOTHERAPEUTICS: Biophysics, Simulations and Analytical Tools to Shed Light on Biomanufacturability and Downstream Bioprocessing

Steven M. Cramer, PhD, William Weightman Walker Professor, Isermann Department of Chemical and Biological Engineering, Rensselaer Polytechnic Institute

Training SEMINARS

By Cambridge Healthtech Institute

IN-PERSON ONLY

TUESDAY, JANUARY 16, 2024 9:00 AM - 5:45 PM
WEDNESDAY, JANUARY 17, 2024 11:05 AM - 2:00 PM

TS6A: Introduction to Multispecific Antibodies

Instructor:

G. Jonah Rainey, PhD, Senior Director, Protein Engineering, Eli Lilly and Company

Introduction to Multispecific Antibodies will be organized as an informative and practical guide to getting up to speed on critical aspects of bispecific antibody therapeutics. Topics will include historical successes, failures, and lessons learned. Specific practical instruction will span mechanisms of action, engineering, developability, regulatory considerations, and translational guidelines. Perspectives on the ideal implementation of multispecifics as targeted and immunomodulatory approaches will be discussed.

TS7A: Introduction to Antibody Engineering

Instructor:

Andrew R.M. Bradbury, PhD, CSO, Specifica, Inc.

In this training seminar, students will learn about antibody basics, including structure, genetics, and the generation of diversity, as well as the generation of potential therapeutic antibodies. This latter part will include antibody humanization, affinity and specificity maturation, display technologies, creation of naïve libraries, and antibody characterization. The seminar will be fully interactive with students providing ample opportunities to discuss technology with instructors.

TS8A: Introduction to Machine Learning for Biologics Design

Instructor:

Christopher R. Corbeil, PhD, Research Officer, Human Health Therapeutics, National Research Council Canada

This course offers an introduction to concepts, strategies, and machine learning methods used for biologics design. It includes presentations and demonstrations of the methods used in the field, covering techniques such as triaging sequences, modulating affinity, and designing antibody libraries, along with increasing manufacturability. The course is directed at scientists new to the field and protein engineers wanting an introduction to how machine learning can aid in guiding biologics design.

TS9A: Advanced Purification of Engineered Biologics and Research Protein Tools

Instructor:

John K. Kawooya, PhD, Private Consultant of Robotics-Plate-Based-Ultra-HT Biologics Purification

Nominating engineered biologics lead drug candidates for treating diseases with complex metabolic pathways is a challenging endeavor. This is attributable to a plethora of Achilles heels along the production process for these molecules. The production pitfalls of engineered biologics include immunogenicity, toxicity, poor manufacturability, low potency, long production cycle-time, the high cost of production, and labor intensity. Screening out these detrimental attributes requires production, purification, and characterizing thousands of molecules through a battery of robust low protein consumptive HT-assays. This course presents two high-throughput (HT) "plug-and-play" single-cycle protein purification strategies. From crude cell cultures with cells, the first strategy delivers ample high-quality proteins at low cycle time, cost, and labor intensity for lead nomination. Parallel to the above strategy is a second high-HT pneumatic purification strategy for biologics or tagged protein panels from filtered cell cultures.

THURSDAY, JANUARY 18, 2024 8:30 AM - 4:15 PM
FRIDAY, JANUARY 19, 2024 9:00 AM - 1:00 PM

TS6B: Biomanufacturing 101: An Overview on Animal Cell Culture Technology from Cell Line Development to Scale-Up Strategies

Instructor:

Kamal A. Rashid, PhD, President, International Biotechnology Associates

During this one and a half day of presentations and discussions, we will take an in-depth look at the modern cell culture techniques from a frozen stock to bioreactor design and operations. After the completion of this seminar, the participants will have a clear understanding of the principles and techniques utilized in culturing animal cells for production of biologics, quality control of a cell culture laboratory and avoiding batch failure, cell line development and clone selection with optimized nutrients for increased productivity and the scale-up strategies for both suspension and anchorage dependent cells. utilizing stirred tank bioreactors, hollowfiber bioreactors and microcarrier cell culture technology.

TS7B: Introduction to CMC for Biotech, Cell & Gene Therapy Products

Instructor:

Kevin Zen, PhD, Senior Director, IGM Biosciences

This interactive course will provide a comprehensive CMC overview of therapeutic biological products. It introduces a variety of therapeutic modalities including recombinant proteins, Mab and cell and gene therapy in the context of IMPD and IND regulatory filing. You will learn scientific, technical, and operational aspects of overall biologics CMC activities as well as quality compliance and regulatory requirements. The instructor will present common pitfalls and share the best industry practices.

Training SEMINARS

By Cambridge Healthtech Institute

IN-PERSON ONLY

TS8B: Label-Free Biosensor Tools in Biotherapeutic Discovery: SPR, BLI & KinExA

Instructor:

Yasmina Abdiche, PhD, Vice President, Exploratory Research, OmniAb Inc.

This training seminar will cover the main applications of commonly used commercial label-free biosensors in the interaction analysis of biologics and guidelines for best practices to generate reliable and reproducible data. We will primarily focus on Surface Plasmon Resonance (SPR), Biolayer Interferometry (BLI), and Kinetic Exclusion Assay (KinExA) technologies and their application in drug discovery (binding kinetics and affinity, blocking and epitope binning).

TS9B: Antibody Drug Discovery: From Target to Lead

Instructor:

Zhiqiang An, PhD, Professor, Robert A. Welch Distinguished University Chair in Chemistry; Director, Texas Therapeutics Institute; Director, CPRIT Core for Antibody Drug Discovery; Vice President, Drug Discovery, University of Texas Health Science Center at Houston

At least 100 antibody therapies have been approved for the treatment of cancer, immune disorders, metabolic, cardiovascular, and infectious diseases, and among the top 20 bestselling prescription medicines in 2020, 14 are antibody-based. This trend will continue as about 50% of the new drugs in various stages of clinical development are antibodies. This course will review state-of-the-art concepts, methodologies, and current trends in therapeutic antibody discovery and development.

CHI Training Seminars Offer:

- 1.5-day instruction
- Morning and afternoon refreshments (as applicable; specific times included in the onsite agendas)
- Registered Attendees Receive:
  A hardcopy handbook for the specific seminar of registration (limited additional handbooks are available for non-registered attendees)

CHI requests that Training Seminars not be interrupted once they have begun. We ask that attendees commit to attending the entire program to not disturb the hands-on style instruction being offered to other participants.

PEPTALK Plaza

SOCIALIZE. NETWORK. COLLABORATE.

Located in the Exhibit Hall, the PepTalk Plaza is a gathering place to facilitate connections and provides a meeting spot for people with similar interests to convene and construct a plan to take advantage of all that PepTalk: The Protein Science and Production Week has to offer.

Visit CHI-PepTalk.com for more details.

ANTIBODY DISCOVERY & ENGINEERING

PepTalk's **Antibody Discovery & Engineering** pipeline offers a forum for protein scientists who are working to quickly and efficiently discover and develop differentiated biotherapeutics for unmet medical needs. For 2024, the pipeline presents the two-part Intelligent Antibody Discovery program, with Part 1 focused on methods and technologies that offer predictive insight into function, binding, and developability in support of improved candidate selection, and Part 2 considering current progress in integrating machine learning into discovery and engineering workflows.

JANUARY 16-17

Intelligent Antibody Discovery – Part 1

AGENDA

JANUARY 18-19

Intelligent Antibody Discovery – Part 2

AGENDA

INTELLIGENT ANTIBODY DISCOVERY - PART 1

Tools and Technologies for Improving the Pace and Predictability of Discovery-Stage Screening

TUESDAY, JANUARY 16

7:00 am Conference Registration and Morning Coffee

8:55 Organizer's Welcome Remarks

Kent Simmons, Senior Conference Director, Cambridge Healthtech Institute

9:00 Chairperson's Remarks

Paul Parren, PhD, CSO, Gyes; Professor, Molecular Immunology, Leiden University Medical Center

9:05 KEYNOTE PRESENTATION: Predicting Antibody Developability at the Discovery Stage

Peter M. Tessier, PhD, Albert M. Mattocks Professor, Pharmaceutical Sciences & Chemical Engineering, University of Michigan

The development, delivery, and efficacy of therapeutic antibodies are strongly influenced by three types of molecular interactions mediated by their variable regions, namely, affinity, off-target, and self-interactions. Here we report interpretable machine learning models for identifying high-affinity mAbs at the discovery stage with optimal combinations of low off-target binding and low self-association, and demonstrate that these co-optimal antibodies display drug-like *in vitro* (formulation) and *in vivo* (pharmacokinetic) properties.

9:50 Keynote Chat

Peter M. Tessier, PhD, Albert M. Mattocks Professor, Pharmaceutical Sciences & Chemical Engineering, University of Michigan

9:50 Interviewed By:

Paul Parren, PhD, CSO, Gyes; Professor, Molecular Immunology, Leiden University Medical Center

10:35 Networking Coffee Break

NEXT-GENERATION FUNCTIONAL SCREENING

10:55 Chairperson's Remarks

Adrian Grzybowski, PhD, Principal Scientist, Antibody Engineering, Triplebar Bio

11:00 Moving Functional Assays Higher in the Screening Cascade

Elizabeth England, PhD, Associate Director, Biologics Engineering, AstraZeneca

Targets for biologic drugs, and drug modalities themselves, are becoming more and more complex. In addition, increasing focus is being placed on drug mechanism-of-action. Due to this advancement in biologic drug technology, it has become critical to include assays measuring complex functional activity higher in the screening cascade. I will describe how we have been developing and implementing these high-throughput functional assays to screen for complex biology.

11:30 Function-First Microfluidic Screening for Immune Engagers

Adrian Grzybowski, PhD, Principal Scientist, Antibody Engineering, Triplebar Bio

We evaluated agonist antibody discovery rates in binding-biased and unbiased libraries using Triplebar's Hyper-Throughput Screening system (HyTS). Employing a microfluidics-based paracrine discovery platform, we sorted antibody-secreting cells based on immune cell responses. Our investigation focused on identifying functional Abs and exploring the benefits of unbiased searches for novel agonists.

12:00 pm Session Break and Transition to Luncheon Presentation

12:10 LUNCHEON PRESENTATION I: Opening the Barn Door to Nkp46: Kinetic and Epitope Diversity of Optimized Immune Repertoires from Diverse Species

OmniAb

Yasmina Abdiche, PhD, Vice President, Exploratory Research, Antibody Discovery, OmniAb

Unlike traditional approaches for generating therapeutic antibodies, transgenic animals bypass the need for extensive ex-vivo engineering, including humanization, affinity maturation, and developability optimization. Divergent species like chickens further extend the epitope coverage of human targets, which is often restricted by self-tolerance in mammals. We use a model human target to compare the kinetic, affinity, and epitope diversity produced by immunizing various transgenic animals with optimized antibody repertoires on different scaffolds.

12:40 LUNCHEON PRESENTATION II: Cutting Through the Hype: Real-World Applications of AI in Antibody Discovery and Engineering

XtalPi

Alex Li, VP of Antibody Discovery, XDD, Ailux Biologics

Ailux has pioneered an innovative integrated platform that combines the best of wet lab and AI. We will explore multiple case studies that exemplify the practical applications of our AI-driven approach, from tackling GPCR targets to engineering challenging molecules, from training large language models to utilizing generative AI. Our focus is to provide a realistic and evidence-based perspective on how AI is redefining best practices for the industry.

1:10 Session Break

NOVEL DISCOVERY PLATFORMS WITH ML INTEGRATION

1:30 Chairperson's Remarks

Brandon DeKosky, PhD, Phillip and Susan Ragon Career Development Professor of Chemical Engineering, MIT Core Member, The Ragon Institute of MGH, MIT, and Harvard University

1:35 Combining Active Learning with a Rapid Synthetic Biology Platform to Design and Optimize Therapeutic Antibodies

Peyton Greenside, PhD, Co-Founder & CSO, BigHat Biosciences

BigHat Biosciences has developed novel machine learning (ML) approaches that leverage our high-speed, automated wet lab in order to rapidly and iteratively design hundreds of next-generation therapeutic antibodies each week for improved properties such as affinity, function, and developability. We'll discuss several methodological developments in multi-parameter optimization, active learning (Bayesian Optimization), and generative humanization, and highlight the functional and *in vivo* validation of our designs.

2:05 Computational Design of a Deimmunized Protease with Extended Activity *in vivo* for Degrading Immunoglobulin G

Erik Procko, PhD, Director, Discovery, Cyrus Biotechnology; Adjunct Professor, University of Illinois, Urbana

IdeS from *Streptococcus pyogenes* cleaves human IgG subclasses, severing the antigen binding domains from the Fc that mediates immune effector functions. IdeS is used clinically for desensitization of kidney transplant recipients and may have applications in autoimmunity and gene therapy, but immunogenicity prevents repeat dosing. Using computational algorithms, antigenic epitopes for CD4+ T cells and B cells were removed, while achieving high IgG proteolytic activity and specificity with improved pharmacokinetics.

2:35 Presentation to be Announced

2:50 Presentation to be Announced

ABMAX

BuzZ Sessions

3:05 Find Your Table and Meet the BuzZ Sessions Moderator

3:15 BuzZ Sessions with Refreshments

BuzZ Sessions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and

participate in active idea sharing. Please visit the BuzZ Sessions page on the conference website for a complete listing of topics and descriptions.

IN-PERSON ONLY BUZZ SESSION: Challenges Faced with Screening Biologics for Function

Elizabeth England, PhD, Associate Director, Biologics Engineering, AstraZeneca

IN-PERSON ONLY BUZZ SESSION: When will Computationally Designed Proteins Become Common in the Clinic?

Erik Procko, PhD, Director, Discovery, Cyrus Biotechnology; Adjunct Professor, University of Illinois, Urbana

IN-PERSON ONLY BUZZ SESSION: T Cell Receptors as an Emerging Modality

Govinda Sharma, PhD, Founder, Immfinity Biotechnologies

OPTIMIZING DISCOVERY SCREENING RESOLUTION AND THROUGHPUT

4:15 Strategies for Assay Miniaturization and Increased Throughput

Brandon DeKosky, PhD, Phillip and Susan Ragon Career Development Professor of Chemical Engineering, MIT Core Member, The Ragon Institute of MGH, MIT, and Harvard University

Antibody discovery has made rapid progress against simple targets like soluble ectodomains, but discovery remains difficult against challenging targets like expanded viral families and membrane proteins. Here, we will share recent case studies and unpublished data for miniaturized antibody high-throughput screening against difficult targets, including to discover functional antibodies against infectious disease antigens, and against membrane proteins.

4:45 High-Throughput Structural Modeling of Monoclonal and Multispecific Antibodies

Daniel Keri, PhD, Research Scientist, Protein Engineering and Design, Gilead Sciences

Historically, biologics discovery has primarily been an experimentally driven enterprise. Yet, the past decade has seen remarkable progress in computational protein design, structure prediction, and machine learning methods. We leverage these technologies to accelerate the biologics discovery process, as well as to design the next-generation multispecific antibodies to enable new biologies.

5:15 Profiling T Cell Receptor Cross-Reactivity via Tope-Seq: A Functional High-Throughput Screening Platform for T Cell Antigen Discovery

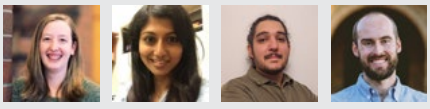
Govinda Sharma, PhD, Founder, Immfinity Biotechnologies

T cell epitope sequencing (or Tope-seq) is a high-throughput screening platform enabling rapid, *in vitro* function-based assessment of T cell receptors (TCRs) against up to a million DNA-coded peptide sequences simultaneously. Using the Tope-seq pipeline, along with our proprietary human whole proteome-coding minigene library and engineered effector/target chassis systems, we are currently applying our platform of technologies towards interrogating potential autoimmune cross-reactivities in candidate TCR therapeutics, de-risking their future clinical development.

5:45 Grand Opening Welcome Reception in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: YOUNG SCIENTIST MEET UP

Young Scientist Meet Up



Emma Altman, Senior Research Associate, Protein Sciences, Kite Pharma

Kavya Ganapathy, PhD, Postdoctoral Research Fellow, Genentech

Alexandros Karyolaimos, PhD, Researcher, Department of Biochemistry & Biophysics, Stockholm University

Sean Yamada-Hunter, PhD, Postdoctoral Research, Mackall Lab, Stanford Cancer Institute, Stanford University

7:00 Close of Day

WEDNESDAY, JANUARY 17

8:30 am Conference Registration & Morning Coffee

PLENARY FIRESIDE CHAT

9:00 Plenary Session Organizer's Remarks

Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

9:10 PLENARY FIRESIDE CHAT: Supporting and Driving Biotech: Past, Present, and Future

Innovation can refer to something new, such as an invention, or the development and introduction of new practices. Progress and challenges frequently act as the driving force behind this innovation, propelling us toward original ways of thinking and doing. The outcome can materialize as a novel product, yet it extends to novel methodologies, procedures, or modes of thought. This Fireside Chat convenes long-term supporters of PepTalk: The Protein Science and Production Week who explore the following:

- Innovations and technology development in the last 5 years
- Collaborations and strategic partnerships – advice to early-stage/ small companies
- Is there a trend toward diversification of scientists' roles, skill sets and responsibilities? Why?
- What is an unexpected market trend you are seeing?
- What excites you/what keeps you working in this industry?

9:10 Panelists:

Moderator: Jennifer Giottonini Cayer, CBO, Pulmocide; Board of Directors, UCSD Moores Cancer Center and Biocom California

Panelists:

Carter A. Mitchell, PhD, CSO, Purification & Expression, Kemp Proteins, LLC

Eric Vajda, PhD, Vice President, Preclinical R&D, OmniAb

Deborah Moore-Lai, PhD, Senior Director, Protein Development & Production, R&D Leadership, Abcam

PEPTALK PLAZA: MEET THE FIRESIDE CHAT PLENARY SPEAKERS

10:15 Meet the Fireside Chat Plenary Speakers

Stop by the PepTalk Plaza to continue the discussion and ask questions.

10:15 Coffee Break in the Exhibit Hall with Poster Viewing

TARGET AND MODALITY-BASED SCREENING

11:00 Chairperson's Remarks

Govinda Sharma, PhD, Founder, Immfinity Biotechnologies

11:05 Rapid Engineering of Soluble T Cell Receptors for Enhanced Affinity via a High-Throughput Yeast-Based Platform

Garrett Rappazzo, PhD, Scientist, Platform Technologies, Adimab

Peptide-HLA (pHLA)-targeting therapeutics can drive T cell killing of target cells based on altered intracellular protein expression. Among pHLA-targeting modalities, soluble T cell receptors (TCRs) have evolutionarily engrained advantages in peptide specificity yet require affinity maturation for therapeutic efficacy. To overcome this barrier, we developed a novel yeast-based platform that rapidly generates high-affinity TCR variants that elicit potent T cell activity *in vitro*, accelerating the development of soluble TCR-based therapeutics.

11:35 Brain Delivery of Therapeutic Proteins Using Novel Fc-Based Transport Vehicles

Padma Akkapeddi, PhD, Scientist, Antibody Discovery & Protein Engineering, Denali Therapeutics, Inc.

The blood-brain barrier (BBB) restricts the transport of large molecules between the blood and brain tissue, posing a challenge for the delivery of therapeutics to the brain. Fc-based transport vehicles (TVs) are a novel approach to brain delivery that exploit receptor-mediated transcytosis to transport biotherapeutics across the BBB. In this presentation, we will discuss the development of TVs and their potential for brain delivery of therapeutic proteins.

12:05 pm Versatile AlivaMab® Platforms Enabling Discovery and Engineering Biologics for Complex Targets and Modalities

Jane Seagal, Ph.D., Vice President, Antibody Discovery, AlivaMab Biologics
Ankita Srivastava, Ph.D., Vice President, Antibody Engineering and Protein Sciences, AlivaMab Biologics

In biologics drug discovery and engineering, success for challenging targets and advanced modalities requires experienced integration of versatile platforms and processes. This presentation will showcase AlivaMab Biologics' 'fit-for-purpose' philosophy, enabling the discovery of TCRm, human VHH, and common light chain BiSAbs, and engineering for next-generation modalities, illustrating the agility and adaptability of our comprehensive approach.

12:35 Session Break and Transition to Luncheon Presentation

12:45 LUNCHEON PRESENTATION I: A New Era in Automated Plasmid Maxi-prep: AmMag™ Quatro Solution

Rouba Najjar, MBA, Head of Product Marketing, Product Division, GenScript USA Inc

Plasmid DNA (pDNA) is an essential component of molecular biotechnology applications, such as protein expression and gene therapy. Large scale plasmid purification (maxi-prep) is labor-intensive, time consuming, and often creates a process bottleneck. GenScript has developed a new automated, large-scale, high throughput plasmid purification solution, the AmMag™ Quatro. Its scalable modular design provides scientists with an automated streamlined route to purify high-quality, transfection-grade plasmids.

1:45 Session Break

EXPERIMENTAL DESIGN TO SUPPORT ROBUST ML TRAINING DATASETS

2:00 Chairperson's Remarks

Alissa Hummer, PhD Student, Charlotte Deane Lab, Oxford Protein Informatics Group, Department of Statistics, University of Oxford

2:05 Lab-in-the-Loop ML for Accelerating Antibody Discovery, Optimization, and *de novo* Design

Nathan Frey, PhD, Senior Machine Learning Scientist, Prescient Design, a Genentech Company

Prescient Design, a Genentech accelerator, is developing novel computational tools for optimizing antibody affinity and multiple developability parameters by combining ideas from machine learning and structural biology. In this talk, I will give an overview of our lab-in-the-loop framework that consists of our novel generative modeling approaches, combined with multi-objective optimization, and active learning framework.

2:35 Iterative Active Learning Process for Rapid Generation of Robust Training Datasets

Leonard Wossnig, PhD, CTO, LabGenius Ltd.

The emergence of ML-enabled technology platforms that aim to enhance molecule performance have the potential to revolutionize the way we approach drug discovery. However, without a purpose-built tech stack that puts data quality at the heart, many are destined to fail. This talk will focus on the deep integration of predictive assays, data generation, data capturing, and data pre-processing needed to enable iterative active learning cycles for lead optimization.

3:05 Mosaic Biosciences: Engineering Proteins and Antibodies to Make Successful Drugs

Eric Furfine to be Announced, PhD, Chief Executive and Scientific Officer, Mosaic Biosciences

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

4:15 Investigating the Volume and Diversity of Data Needed for Generalizable Antibody-Antigen ΔΔG Prediction

Alissa Hummer, PhD Student, Charlotte Deane Lab, Oxford Protein Informatics Group, Department of Statistics, University of Oxford

Antibodies are an important class of medicines whose efficacy is driven by specific target binding. Given the therapeutic relevance, there have been multiple attempts to computationally predict how mutations affect binding affinity. Using experimental and synthetic data, we demonstrate that there is currently not enough experimental data available—by orders of magnitude—for accurate, generalizable prediction. We also investigate the role of diversity and suggest guidelines for robust machine learning model development.

4:45 Integrated Microfluidics and Machine Learning for High-Throughput Immunotherapeutic Drug Discovery: Deciphering Molecular Design Principles

Alon Wellner, Vice President, Biology, Co-Founder, Aureka Biotechnologies

We present an innovative system integrating microfluidics and machine learning for high-throughput immunotherapeutic drug discovery. Our approach aims to decipher molecular design principles by effectively screening and analyzing large libraries of immunotherapeutic candidates directly for their end function (e.g., T cell activation). This integrated approach holds great promise for accelerating the development of effective immunotherapeutic drugs.

5:15 Hypothesis Development through Single Cell Data Networks

Vincent A. Alessi, Lead, Product, AI, Deep Origin

We propose a cyclic approach for challenging therapeutic antibody targets, combining wet lab experiments with simulation-guided machine learning (ML). Simulations provide rapid *in silico* data, focusing wet lab experiments. ML predicts antibody-antigen binding, selecting informative cases for microfluidic validation, the results from which refine the ML model iteratively. Such integrative pipeline approaches have the potential to revolutionize antibody engineering. We share our experience hoping to guide others considering starting similar initiatives.

5:45 Close of Intelligent Antibody Discovery - Part 1 Conference

INTELLIGENT ANTIBODY DISCOVERY - PART 2

Advancing the Implementation and Use of Artificial Intelligence and Machine Learning in Biopharmaceutical Discovery

THURSDAY, JANUARY 18

7:45 am Conference Registration & Morning Coffee

8:25 Organizer's Welcome Remarks

Kent Simmons, Senior Conference Director, Cambridge Healthtech Institute

APPLICATIONS OF AI/ML IN BIOLOGICS DISCOVERY PROJECTS

8:30 Chairperson's Opening Remarks

Darcy Davidson, PhD, Structural and Computational Biologist, Genentech

8:35 FEATURED PRESENTATION: *De novo* Design of Miniprotein Ligand Scaffolds for Molecularly Targeted Therapy

Benjamin J. Hackel, PhD, Professor, Chemical Engineering & Materials Science, University of Minnesota

Hyperstable miniprotein ligands provide advantageous modularity, physiological transport, and synthesis. We have synergized design and experimental library selection to engineer a family of miniprotein binding scaffolds. Starting with proteins designed for hyperstability across three topologies, we experimentally identified the most evolvable and developable frameworks and paratope diversities, which resulted in specific, nanomolar-affinity binders to numerous targets. We leverage the resultant data in a feedback loop to design next-generation scaffolds.

9:05 A Comparative Study of Antibody Structure Prediction Methods through Molecular Dynamics Simulations

Darcy Davidson, PhD, Structural and Computational Biologist, Genentech

Computable surface properties of therapeutic proteins like antibodies can help predict biophysical properties relevant to drug formulation. Property predictions based on single states may underestimate developability risks, motivating molecular dynamics (MD) simulation. To probe whether the initial model seeding the simulation affects risk prediction, we used five ML-based structure prediction methods and compared to simulation results using experimental structures to determine an ideal workflow.

9:35 KEYNOTE PRESENTATION: Better Medicines, Created Rapidly through *de novo* Protein Design

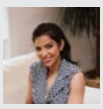
Chris Bahl, PhD, CSO and Co-Founder, AI Proteins

Miniproteins are a powerful yet underutilized therapeutic modality, with a structure that enables binding with high affinity and specificity to their targets, and that achieves remarkable stability using only the 20 canonical amino acids. By combining synthetic biology with laboratory automation, we accelerate the discovery and optimization of protein binders and create a vast toolbox of modular miniprotein domains, each with ideal drug-like properties and developability profiles.

10:05 Presentation to be Announced

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: ELECTRONIC CONNECTIONS TRAINING



Electronic Connections Training

Nandini Kashyap, Senior Director, Conferences and Social Media Strategy, Cambridge Healthtech Institute

Looking to make connections but no longer carry a paper business card with you? Join us for this event to share your electronic business card, LinkedIn profile, or to connect on the PepTalk app.

11:15 Towards Biologics by Design: Computational Optimization of Multispecific Protein Therapeutics

Norbert Furtmann, PhD, Head, Computational & High-Throughput Protein Engineering, Large Molecule Research, Sanofi

The generation of multispecific protein therapeutics necessitates the exploration of extensive design spaces, a task that cannot be entirely covered through wet lab experiments alone. By harnessing our systematically-collected and curated data assets, we have developed computational and machine learning-based optimization workflows for predicting molecular properties. We will showcase examples of how our computational pipeline assists in navigating through the vast design space of multispecific biologics.

11:45 Illuminating Antibody Diversity and Structure-Activity Relationships: A Case Study in Harnessing Transformer-Based Language Models for Therapeutic Design

Brett Averso, CTO, EVQLV, Inc.

In this case study, we describe a novel approach utilizing transformer-based language model embeddings to interpret the genetic and somatic diversity of 100 million human antibody sequences. Our robust model allows for the detailed extraction and analysis of intricate features from antibody amino acid sequences and their CDRs, facilitating promising insights into the Structure-Activity Relationship (SAR) of these molecules, and potentially shedding light on links to disease associations.

12:15 pm Session Break and Transition to Luncheon Presentation

12:25 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:25 Session Break

MODELS FOR PROTEIN STRUCTURE PREDICTION & SEQUENCE DESIGN

1:45 Chairperson's Remarks

Francis Gaudreault, PhD, Research Officer, Human Health Therapeutics, National Research Council Canada

1:50 *In silico* Evolution of Protein Binders with Deep Learning Models for Structure Prediction and Sequence Design

Brian Kuhlman, PhD, Professor, Biochemistry and Biophysics, University of North Carolina Chapel Hill

We have developed a protein design pipeline, called EvoPro, that uses iterative rounds of deep learning-based structure prediction and sequence optimization to evolve protein sequences for prespecified design goals. Initial experimental testing has focused on the creation of small, stable proteins that bind to target binding surfaces on proteins of interest. Without any experimental optimization, low nanomolar binders were designed against a PD-L1 antagonist.

2:20 Applications for RFdiffusion Open-Source Algorithm for Protein Prediction

Joseph Watson, PhD, Postdoctoral Fellow, Institute for Protein Design, University of Washington

De novo protein design seeks to learn the underlying principles of protein folding from natural proteins and to subsequently apply them to generate novel proteins with programmable functions. In this talk, I will describe the development of RFdiffusion, a generative neural network for *de novo* protein design which demonstrates state-of-the-art performance, both *in silico* and experimentally, across a broad range of therapeutically relevant design challenges.

2:50 Antibody-Antigen Structure Prediction from Deep Learning-Generated Models

Francis Gaudreault, PhD, Research Officer, Human Health Therapeutics, National Research Council Canada

The ability to correctly predict the structure of antibody-antigen complexes *in silico* would provide a lot of value for medical applications. Recent deep

learning technologies have enabled the production of antibody models with significantly better quality than traditional tools. We evaluated if such quality is sufficient for successful antibody-antigen structure prediction, using traditional molecular docking tools that normally fall short in real applications where the antibody structure is unknown.

3:20 Conditional Generation of Paired Antibody Chain Sequences through Encoder-Decoder Language Model

Simon Chu, PhD, Researcher, Biophysics Graduate Program, University of California Davis

3:50 Refreshment Break in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: SPEED NETWORKING

Speed Networking


Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute
Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

Bring yourself, and your business cards, and be prepared to share and summarize the key elements of your research in a minute. PepTalk will provide a location, timer, and fellow attendees to facilitate the introductions.

PLENARY KEYNOTE SESSION

4:35 Sponsored Plenary Introduction (Opportunity Available)

4:45 Protein and Gene Therapy Biotherapeutics: Biophysics, Simulations, and Analytical Tools to Shed Light on Biomanufacturability and Downstream Bioprocessing Opportunities

Steven M. Cramer, PhD, William Weightman Walker Professor, Isermann Department of Chemical and Biological Engineering, Rensselaer Polytechnic Institute

This talk will illustrate how a combination of biophysics, simulations, and analytical tools can be employed for a deeper understanding of the molecular basis for important biomanufacturability properties as well as the purification of both protein and gene therapy biotherapeutics from their product- and process-related impurities. In addition, the unique challenges of gene therapy bioprocessing will be discussed from the perspective of proper analytical definition of the "biological product."

5:30 Networking Reception in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: WOMEN IN SCIENCE MEET UP

Women In Science



Christa Cortesio, PhD, Director, Protein Science, Protein Biochemistry & Analytics Core, Kite Pharma

Marija Dramicanin, PhD, Head, Protein Production Facility, Walter & Eliza Hall Institute of Medical Research

Deborah Moore-Lai, PhD, Senior Director, Protein Development & Production, R&D Leadership, Abcam

CHI is proud to offer programming that honors and celebrates the advancement of diversity in the life sciences. We recognize that barriers preventing women from fully participating in the sciences are not just barriers to equality, but also critically deter scientific advancement worldwide. Our Women in Science programming invites the entire scientific community to discuss these barriers, as we believe that all voices are necessary and welcome.

6:30 Close of Day

FRIDAY, JANUARY 19

7:30 am Conference Registration

BuzZ Sessions

7:45 BuzZ Sessions with Continental Breakfast

BuzZ Sessions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the BuzZ Sessions page on the conference website for a complete listing of topics and descriptions.

IN-PERSON ONLY BUZZ SESSION: Intelligent Antibody Discovery & Engineering

Christopher R. Corbeil, PhD, Research Officer, Human Health Therapeutics, National Research Council Canada

IN-PERSON ONLY BUZZ SESSION: Applications of Molecular Dynamics for Machine Learning

Darcy Davidson, PhD, Structural and Computational Biologist, Genentech

8:45 Transition to Conference Track

ANTIBODY DESIGN & OPTIMIZATION

9:00 Chairperson's Remarks

Gilad Kaplan, PhD, Associate Director, Biologics Engineering, AstraZeneca

9:05 RESP AI Model to Accelerate the Identification of Tight-Binding Antibodies

Wei Wang, PhD, Professor, Chemistry and Biochemistry, University of California San Diego

High-affinity antibodies are often identified through directed evolution, which may require many iterations of mutagenesis and selection to find an optimal candidate. Deep learning techniques hold the potential to accelerate this process, but the existing methods cannot provide the confidence interval or uncertainty needed to assess the reliability of the predictions. We present a pipeline called RESP for efficient identification of high-affinity antibodies.

9:35 Enhancement of Antibody Thermostability and Affinity by Computational Design in the Absence of Antigen

Gilad Kaplan, PhD, Associate Director, Biologics Engineering, AstraZeneca

DeepAb, a deep learning model for predicting antibody Fv structure directly from sequence, was used to design 200 potentially stabilized variants of an anti-hen egg lysozyme (HEL) proof-of-concept antibody [FY1]. 85% of the clones exhibited increased thermal and colloidal stability. Of these, 11% showed a highly increased affinity for HEL (1.5- to 10-fold increase) while retaining the developability profile of the parental antibody.

10:05 Harnessing Large Scale Binding Data and Machine Learning to Discover and Optimize Rare Cross-Reactive Antibodies
Randolph Lopez, PhD, CTO and Co-Founder, A-Alpha-Bio

Leveraging AlphaSeq, a library-on-library method for studying protein-protein interactions, we screened a large library of synthetic antibodies to identify cross-reactive binders against human TIGIT and its mouse ortholog. Cross-reactive antibodies were further optimized for binding and bio-developability following multiple cycles of data generation, computational model training, sequence proposals, and binding validation assays. This process improved binding affinity and generated hundreds of antibody candidates with favorably predicted developability properties.

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: POST-PEPTALK CONNECTIONS

Post-PepTalk Connections


Kevin Brawley, Associate Project Manager, Production Operations & Communications, Cambridge Innovation Institute

Kent Simmons, Senior Conference Director, Cambridge Healthtech Institute

- How will our onsite app benefit your networking after the conference?
- How to view on-demand presentations to maximize your conference experience

11:15 A Machine Learning Strategy for the Identification of *In Silico* Descriptors and Prediction Models for IgG Monoclonal Antibody Developability Properties
Andrew B. Waight, PhD, Senior Director, Machine Learning, Discovery Biologics & Protein Sciences, Merck Research Labs

Prediction of biophysical properties for protein therapeutics from calculated ***in silico*** features has potential to reduce the time and cost of delivering clinical-grade material to patients. We have developed an automated machine learning workflow designed to identify the most powerful features from computationally derived physiochemical feature sets. We demonstrate the use of this workflow with medium-sized datasets of IgG molecules to generate predictive regression models for key developability endpoints.

11:45 *In silico* Improvement of Antibodies for Infectious Diseases
Reda Rawi, PhD, Staff Scientist & Co-Head, Structural Bioinformatics Core, NIH NIAID

A single administration of CIS43 can protect against malaria infection for up to 9 months. Here, we developed an *in silico* pipeline to improve the potency of CIS43 antibody variants by optimizing the binding energy to its target antigen PfCSP. Designed variants showed increased affinity and superior protective efficacy to an *in vivo* mouse challenge model. The best designed variant, antibody P3-43, showed ~10-fold improvement in protection relative to CIS43.

12:15 pm Session Break and Transition to Luncheon Presentation

12:25 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:55 Session Break

1:00 Ice Cream & Cookie Break in the Exhibit Hall with Last Chance for Poster Viewing

1:45 Chairperson's Remarks
Reda Rawi, PhD, Staff Scientist & Co-Head, Structural Bioinformatics Core, NIH NIAID

1:50 Designing Multispecific Antibodies That Maintain the Symmetrical IgG Structure Using AI and Machine Learning
Ronald Herbst, PhD, CSO, R&D, Biolojic Design Ltd.

Bispecific antibodies have emerged as attractive modalities for the development of new therapeutics but come with certain drawbacks such as fixed stoichiometry for target binding and more challenging manufacturing. Biolojic Design has developed multibodies that overcome these challenges, by using our proprietary AI technology. Multibodies have the ability to flexibly bind two different targets, while maintaining a standard IgG format. This technology enables new applications for the development of therapeutics.

2:20 An *in silico* Approach to Predicting and Optimizing Antibody Fragment Polyreactivity
Andrew C. Kruse, PhD, Professor of Biological Chemistry and Molecular Pharmacology, Harvard Medical School

Polyreactive antibodies lead to incorrect experimental results and are intractable for clinical development. We designed a set of experiments using a synthetic camelid antibody fragment ("nanobody") library to train machine learning models to assess polyreactivity from protein sequence. Our models provide quantitative scoring metrics that predict polyreactivity. We experimentally test our models' performance on three nanobody scaffolds, finding that over 90% of predicted substitutions reduced polyreactivity.

2:50 Design Novel Proteins with Desired Properties
Kathy Y. Wei, PhD, Co-Founder & CSO, 310 AI

Typically, protein engineering is labor-intensive and relies on sequential trial-and-error search. But the protein space is greater than the number of atoms in the universe. Therefore, to successfully create new designer proteins with ever-increasing complexity, it's necessary to generate to specifications, rather than search. At 310.ai, we aim to bypass trial-and-error and, instead, offer a highly parallel and coherent design solution that will impact speed, cost, and quality.

3:20 Combining Advances in Machine Learning with Experimental Automation to Build New Platforms
Daniel Smith, PhD, Head, Computation, FL83

The application of machine learning for protein drug discovery combined with automated experimental systems allows the creation of advanced platforms to accelerate drug discovery. By leveraging both digital and physical automation, large-scale, low-aleatoric noise datasets can be created quickly for training and fine-tuning machine learning models. These models, in turn, can enhance the accuracy of experimental cycles, creating symbiotic feedback to deliver drugs faster than previously possible.

3:50 PANEL DISCUSSION: Closing Panel: Model Selection and Implementation
Moderator: Reda Rawi, PhD, Staff Scientist & Co-Head, Structural Bioinformatics Core, NIH NIAID

Panelists:

Ronald Herbst, PhD, CSO, R&D, Biolojic Design Ltd.

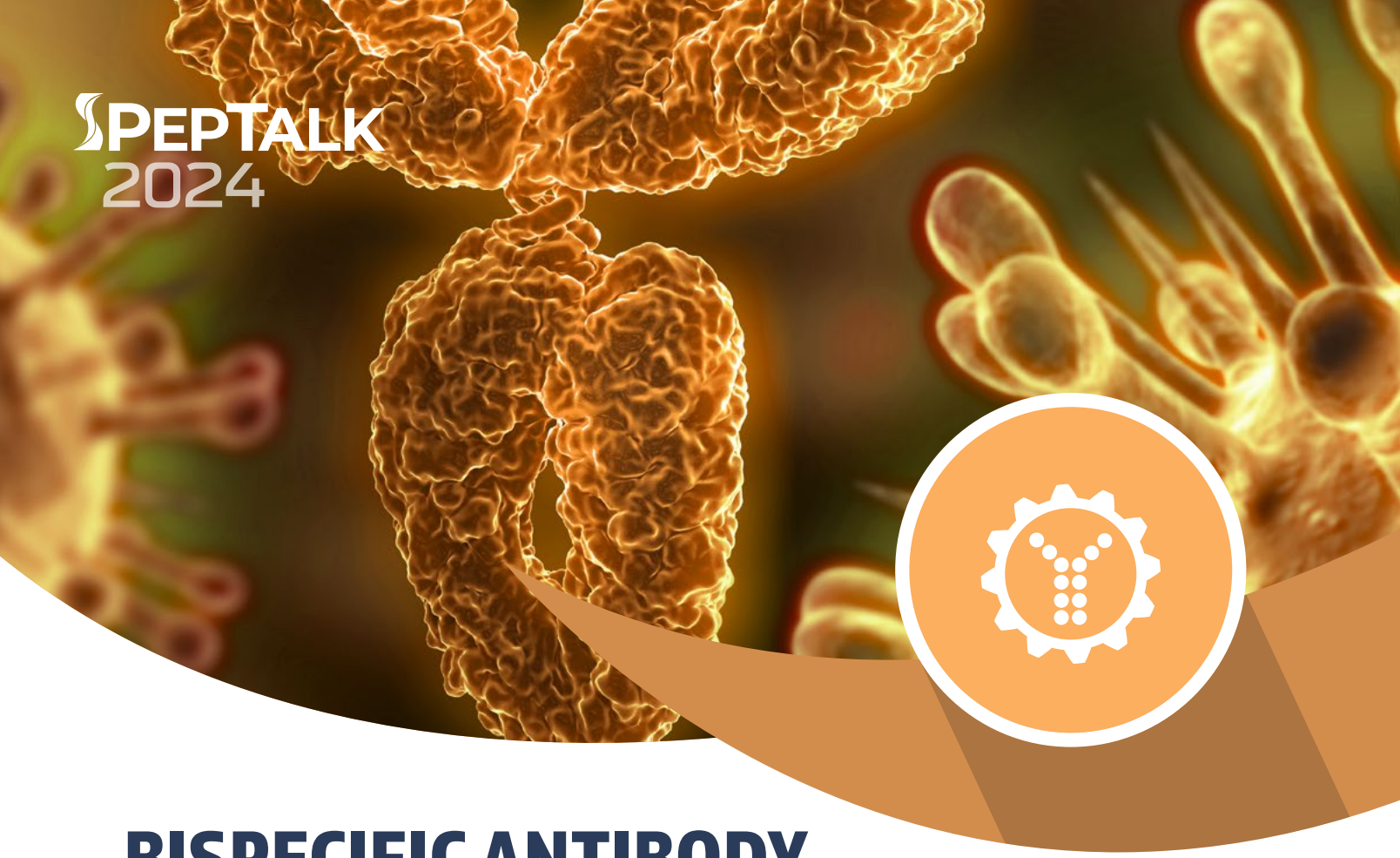
Andrew C. Kruse, PhD, Professor of Biological Chemistry and Molecular Pharmacology, Harvard Medical School

Daniel Smith, PhD, Head, Computation, FL83

Kathy Y. Wei, PhD, Co-Founder & CSO, 310 AI

4:20 Conference Wrap Up

4:30 Close of Conference



BISPECIFIC ANTIBODY DEVELOPMENT

The **Bispecific Antibody Development** pipeline reviews the fundamentals of bispecific antibody developability to help establish early in the process the parameters that define an efficacious bispecific molecule to avoid late-stage failures. More than 100 bispecific antibodies are in the clinic currently and ensuring their safety and efficacy is paramount. The Developability of Bispecific Antibodies track will showcase how platforms and engineering along with identifying favorable drug-like properties, including half-life, pk/pd, immunogenicity, stability, and manufacturability, can be considered early to optimize chances for success of multispecific drug candidates. The Safety and Efficacy of Bispecific Antibodies, ADCs and Combination Therapy track will review clinical results and milestones of emerging constructs and identify the key parameters for the success and safety of these novel formats.

JANUARY 16-17

Developability of Bispecific Antibodies

AGENDA

JANUARY 18-19

Safety & Efficacy of Bispecific Antibodies, ADCs and Combination Therapy

AGENDA

TUESDAY, JANUARY 16

7:00 am Conference Registration and Morning Coffee

8:55 Organizer's Welcome Remarks

Christina C. Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

9:00 Chairperson's Remarks

Paul Parren, PhD, CSO, Gyes; Professor, Molecular Immunology, Leiden University Medical Center

9:05 KEYNOTE PRESENTATION: Predicting Antibody Developability at the Discovery Stage

Peter M. Tessier, PhD, Albert M. Mattocks Professor, Pharmaceutical Sciences & Chemical Engineering, University of Michigan

The development, delivery, and efficacy of therapeutic antibodies are strongly influenced by three types of molecular interactions mediated by their variable regions, namely, affinity, off-target, and self-interactions. Here we report interpretable machine learning models for identifying high-affinity mAbs at the discovery stage with optimal combinations of low off-target binding and low self-association, and demonstrate that these co-optimal antibodies display drug-like *in vitro* (formulation) and *in vivo* (pharmacokinetic) properties.

9:50 Keynote Chat

Peter M. Tessier, PhD, Albert M. Mattocks Professor, Pharmaceutical Sciences & Chemical Engineering, University of Michigan

9:50 Interviewed By:

Paul Parren, PhD, CSO, Gyes; Professor, Molecular Immunology, Leiden University Medical Center

10:35 Networking Coffee Break

NOVEL FORMATS FOR DEVELOPABILITY

10:59 Chairperson's Remarks

Harald Kolmar, PhD, Professor and Head, Institute for Organic Chemistry and Biochemistry, Technische Universität Darmstadt

11:00 FEATURED PRESENTATION: Avidity Engineering for Bispecific and Multispecific Antibodies

Paul Parren, PhD, CSO, Gyes; Professor, Molecular Immunology, Leiden University Medical Center

Avidity binding, i.e.; the accumulated binding strength resulting from multiple simultaneous interactions, plays a central role in antibody biology. The manipulation of antibody avidity is therefore emerging as an important design principle for enhancing or engineering novel properties in antibody biotherapeutics. Recent advances in ways to effectively exploit the avidity space in multi-agent therapeutic antibody drug development will be discussed.

11:30 Engineering a Pure and Stable Heterodimeric IgA for the Development of Multispecific Therapeutics

Meghan M. Verstraete, PhD, Scientist, Protein Engineering, Zymeworks, Inc.

To expand the repertoire of multi-specific designs for other antibody isotypes, we present here engineering of the first heterodimeric IgA Fc with high purity, native IgA-like stability, and retained ability to bind FcαRI. This newly designed scaffold provides a first-in-class stable and manufacturable multispecific IgA platform capable of activation of neutrophils via FcαRI. A multispecific IgA platform, in turn, provides access to new biological pathways for next-generation IgA-based immunotherapies.

12:00 pm Session Break and Transition to Luncheon Presentation

12:10 LUNCHEON PRESENTATION I: S-DUAL™ PD platform: An optimized process development platform for securing higher productivity

SAMSUNG BIOLOGICS

Daniel Buckley, Director, CDO Downstream, Samsung Biologics

Bispecific antibodies (BsAbs) are vital for treating diseases with multiple targets, yet encounter challenges like instability and low yields. Samsung Biologics' S-DUAL™ platform, featuring a unique 'knobs-into-holes' design and IgG1 frame, addresses these issues. The S-DUAL™ optimized process development platform is introduced, demonstrating efficacy in targeting VEGF/HER2 antigens. S-DUAL™ achieves high expression (>8.0 g/L), a process yield over 60%, and comparable product purity, effectively overcoming critical challenges in bsAb development.

12:40 Session Break

NOVEL FORMATS FOR DEVELOPABILITY *(CONT.)*

2:00 Chairperson's Remarks

Harald Kolmar, PhD, Professor and Head, Institute for Organic Chemistry and Biochemistry, Technische Universität Darmstadt

2:05 Structure-Based Engineering of a Novel CD3ε-Targeting Antibody for Reduced Polyreactivity

Michael B. Battles, PhD, Senior Scientist II, Adimab, LLC

Using insights from the crystal structure of anti-Hu/Cy CD3 antibody ADI-26906 in complex with CD3 epsilon (CD3ε) and antibody engineering using a yeast-based platform, we have derived high-affinity CD3 antibody variants with very low polyreactivity and significantly improved biophysical developability. Comparison of these variants with CD3 antibodies in the clinic (as part of bi/multispecifics) shows that affinity for CD3ε is correlated with polyreactivity. Our engineered CD3 antibodies break this correlation.

2:35 TRYBE: An Fc-Free Antibody Format with Three Monovalent Targeting Arms and Engineered for Long *in vivo* Half-Life

Emma Dave, PhD, Principal Scientist, UCB Pharma

TrYbe is a multispecific, Fc free, therapeutic antibody format. The design consideration for this fragment-based therapeutic format will be discussed, both in terms of the functional biology, and the molecular properties. Data from multiple programs will be shared that exemplify a range of functional activities, demonstrate some beneficial properties of target engagement with respect to immune complex formation, and show consistent *in vivo* PK from albumin binding.

BuzZ Sessions

3:05 Find Your Table and Meet the BuzZ Sessions Moderator

3:15 BuzZ Sessions with Refreshments

BuzZ Sessions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the BuzZ Sessions page on the conference website for a complete listing of topics and descriptions.

IN-PERSON ONLY BUZZ SESSION: Which Formats are Most Developable

G. Jonah Rainey, PhD, Senior Director, Protein Engineering, Eli Lilly and Company

IN-PERSON ONLY BUZZ SESSION: IN-PERSON ONLY BUZZ SESSION: Enhancing Bispecific T Cell Engager Discovery, Potency, Safety, and Developability with Machine Learning and Mammalian Display

Matthew P. Greving, PhD, Vice President & Head, Machine Learning & Platform Technologies, iBio, Inc.

- Improving discovery productivity and diversity for the bispecific T cell engager's immune cell arm
- New advancements in the discovery of difficult tumor-antigen arm targets and epitopes
- T cell engager safety enhancement with ML-derived mammalian display libraries and conditional activation
- Large-scale bispecific activity and developability screening with mammalian display

4:15 Pronectins: A New Class of 14Fn3 Scaffold Linkers Designed to Prevent Loop Immunogenicity in Bispecific Constructs for Solid Tumors

Roberto Crea, PhD, Founder & President, CEO & CSO, Protelica, Inc.

A Pronectins library of 10 billion variants was designed and produced by the use of 36,000 synthetic oligonucleotides to produce loop diversity in the 3CDRs of a 14Fn3 scaffold structure. This novel process, without the use of any stochastic mutagenesis, is targeted at eliminating the occurrence of "non" human amino acids in the three CDR loops.

4:45 Enhancing Bispecific T Cell Engager Discovery, Potency, Safety, and Developability with Machine Learning and Mammalian Display

Matthew P. Greving, PhD, Vice President & Head, Machine Learning & Platform Technologies, iBio, Inc.

Bispecific anti-CD3 T cell engagers (TCEs) hold potential for cancer immunotherapy but pose challenges in balancing potency, safety, and developability. This presentation demonstrates how machine learning-driven epitope steering and mammalian-display antibody libraries can facilitate efficient discovery of diverse TCE arms. Combined, epitope-steering and mammalian-display libraries enable tuned bispecific arm pairing, improved developability, and cynomolgus monkey cross-reactivity—overcoming key obstacles in TCE development.

5:15 Charge Variant and Succinimide-Isomerization Induced & Rescued Potency of a Common Light Chain Bispecific Antibody

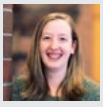
Bertie Chi, PhD, Senior Scientist, CMC Characterization & Analytical Development, Sanofi

DG motif in CDR3 can pose potential liabilities in antibodies by succinimide or iso-Asp formation, depending on the formulation pHs. This can also manifest as basic charge variant formation in accelerated or long-term stability studies. The consequence may or may not impact biological potencies. DG motif can form succinimide in acidic formulations and had reduced potency, but can be rescued by incubation at higher pHs to promote Asp/Iso-Asp formation.

5:45 Grand Opening Welcome Reception in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: YOUNG SCIENTIST MEET UP

Young Scientist Meet Up




Emma Altman, Senior Research Associate, Protein Sciences, Kite Pharma

Kavya Ganapathy, PhD, Postdoctoral Research Fellow, Genentech

Alexandros Karyolaimos, PhD, Researcher, Department of Biochemistry & Biophysics, Stockholm University

Sean Yamada-Hunter, PhD, Postdoctoral Research, Mackall Lab, Stanford Cancer Institute, Stanford University

7:00 Close of Day

WEDNESDAY, JANUARY 17

8:30 am Conference Registration & Morning Coffee

PLENARY FIRESIDE CHAT

9:00 Plenary Session Organizer's Remarks

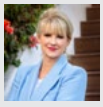
Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

9:10 PLENARY FIRESIDE CHAT: Supporting and Driving Biotech: Past, Present, and Future

Innovation can refer to something new, such as an invention, or the development and introduction of new practices. Progress and challenges frequently act as the driving force behind this innovation, propelling us toward original ways of thinking and doing. The outcome can materialize as a novel product, yet it extends to novel methodologies, procedures, or modes of thought. This Fireside Chat convenes long-term supporters of PepTalk: The Protein Science and Production Week who explore the following:

- Innovations and technology development in the last 5 years
- Collaborations and strategic partnerships – advice to early-stage/ small companies
- Is there a trend toward diversification of scientists' roles, skill sets and responsibilities? Why?
- What is an unexpected market trend you are seeing?
- What excites you/what keeps you working in this industry?

9:10 Panelists:




Moderator: Jennifer Giottonini Cayer, CBO, Pulmocide; Board of Directors, UCSD Moores Cancer Center and Biocom California

Panelists:

Carter A. Mitchell, PhD, CSO, Purification & Expression, Kemp Proteins, LLC

Eric Vajda, PhD, Vice President, Preclinical R&D, OmniAb

Deborah Moore-Lai, PhD, Senior Director, Protein Development & Production, R&D Leadership, Abcam

PEPTALK PLAZA: MEET THE FIRESIDE CHAT PLENARY SPEAKERS

10:15 Meet the Fireside Chat Plenary Speakers

Stop by the PepTalk Plaza to continue the discussion and ask questions.

10:15 Coffee Break in the Exhibit Hall with Poster Viewing

BISPECIFIC ADCs

11:00 Chairperson's Remarks

Nimish Gera, PhD, Vice President, Biologics, Mythic Therapeutics

11:05 Development of Next-Generation Bispecific and Biparatopic Protein Drug Conjugates Exploiting Novel Protein Domain Architectures

Graham Cotton, PhD, Head, Protein Therapeutics, Almac Discovery

A novel protein-drug conjugate (PDC) platform has been developed, which exploits small protein domain binders to deliver homogeneous conjugates in monospecific, biparatopic and bispecific formats. Through this innovation, differentiated PDCs have been generated which cause sustained regressions in *in vivo* cancer models against high-value targets including:

• ROR1: mono- and bispecific PDCs that exploit the co-expression pattern of this target; and

• ALPP/ALPPL2: next-generation biparatopic PDCs for the treatment of solid tumours

11:35 Combining a Biparatopic MET Antibody with a Tubulin Inhibitor for a One-Two Punch to Treat NSCLC

Thomas Nittoli, PhD, Senior Director, Therapeutic Proteins, R&D Chemistry, Regeneron Pharmaceuticals, Inc.

Lung cancers harboring MET genetic alterations respond well to selective TKIs, but benefit only 4-5% of lung cancers. We conjugated a biparatopic METxMET antibody to a cytotoxin to generate a MET ADC (METxMET-M114) that could treat ~25% of lung cancers. Overall, our findings suggest that the MET ADC, which takes advantage of the unique trafficking properties of our antibody, is a promising candidate for the treatment of MET-overexpressing tumors.

12:05 pm Introducing a Novel HipH Resin for Bispecific Antibody Purification

Tony Tomas, Dr, Field Application Scientist, Global Field Applications, Purolite, An Ecolab Company

Jetting technology is a continuous emulsification technology by which all Praesto® chromatography resins are produced. This proprietary technology results in resins with a narrow, almost uniform particle size distribution, with excellent mass transfer properties. Within Purolite's presentation, our experts will be presenting advances in Protein A chromatography including: Jetting technology, process intensification models and a novel Protein A resin designed specifically for elution of Fc-containing molecules at higher pH levels.

12:35 Session Break and Transition to Luncheon Presentation

12:45 LUNCHEON PRESENTATION: *In silico* optimization of a multimodal chromatography mAb purification step

Senthil Kumar, PhD, GoSilico Sales Specialist-Chromatography, Cytiva

In this discussion, we aim to provide reliable and reusable guidance for experimental planning and model-based process optimization for AAV full/empty particle separation, leveraging the full separation performance and straightforward scalability of AEX resins. The guiding workflow we describe for model-based process development with GoSilico™ chromatography modeling software can help process developers meet time-to-market demands.

1:15 Session Break

WHICH FORMATS ARE MOST DEVELOPABLE?

2:00 Chairperson's Remarks

Steffen H.J. Goletz, PhD, Full Professor, Deputy Head, Vice Director, Biotechnology & Biomedicine, Danish Technical University

2:05 Generation of Robust Bispecific Antibodies through Fusion of Single-Domain Antibodies on IgG Scaffolds: A Comprehensive Comparison of Formats

Steffen H.J. Goletz, PhD, Full Professor, Deputy Head, Vice Director, Biotechnology & Biomedicine, Danish Technical University

Robust bispecific antibodies through fusion of single-domain VHH and Fab into IgG scaffolds and a toolbox of complementary methods for in-depth analysis of key features, such as in-solution dual antigen binding, thermal stability, and aggregation propensity, to ensure high bsAb quality. Furthermore, novel set of *in silico* designed humanized VHH antibody phage display libraries with maximal functional diversity and CDR3 lengths from 10 to 25 aminoacids for generating fusion partners.

2:35 Manufacturability Assessment of Bispecifics in the Preclinical Space

Ronan Kelly, PhD, Director, Protein Expression & Purification, Eli Lilly & Co

The preclinical manufacturability of bispecific antibodies is a multifaceted challenge that requires careful consideration of molecule design, expression systems, purification strategies, and analytical tools. Overcoming these challenges is essential for transitioning these promising therapeutic agents from discovery-based scaffold design into clinical development. In our studies we applied combinations of both molecular and purification strategies to optimize antibody production, resulting in fit-for-platform processes for ease of manufacture at larger scales.

3:05 Accelerating Bispecifics Discovery with the Alloy Common Light Chain Fully Human Transgenic Mouse Platform

Kent Bondensgaard, SVP Head of Antibody Discovery Services, Antibody Discovery Services, Alloy Therapeutics

Alloy bispecific discovery services integrates best-in-class platforms with world class scientists to serve as an extension of your R&D team. Building on industry leading mouse platforms for fully human antibody discovery, Alloy has created Common Light Chain strains, ATX-CLC, to build bispecifics with better developability profiles by solving heavy and light chain pairing. Leveraging ATX-CLC Alloy supports bispecific discovery through format engineering and functional assessment to move candidates forward rapidly.

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

4:15 Assessing the Developability of a Next Generation of T Cell Engager Targeting CLDN6

Masaru Muraoka, PhD, Research Scientist, Discovery Biologics, Chugai Pharmaceutical Co. Ltd.

SAIL66 is a trispecific antibody composed of an anti-CLDN6 arm and an arm for T cell recruiting. SAIL66 has a high specificity for CLDN6, despite its high similarity to CLDN3, CLDN4, and CLDN9, suggesting no undesirable off-target toxicity. This presentation will describe our screening strategy, including the optimization process, for achieving acceptable developability. Clinical studies of SAIL66 are currently underway for patients with solid cancers.

4:45 Not All Bispecifics Are Created Equal

Chen Zhou, PhD, Principal Research Scientist, Biologics Drug Product Development, Abbvie Bioresearch Center

Although many different bispecific antibody formats have been used in clinical trials for various diseases, the number of approved bispecifics is still limited, partly due to the poor developability of bispecific antibodies often observed in early development. In this talk we will share the developability of a panel of commercial and advanced clinical stage bispecific molecules to provide a benchmark for the physicochemical property and developability profiles of bispecific antibodies.

5:15 PANEL DISCUSSION: Which Formats Are Most Developable?

Moderator: Steffen H.J. Goletz, PhD, Full Professor, Deputy Head, Vice Director, Biotechnology & Biomedicine, Danish Technical University

Panelists:

Masaru Muraoka, PhD, Research Scientist, Discovery Biologics, Chugai Pharmaceutical Co. Ltd.

Ronan Kelly, PhD, Director, Protein Expression & Purification, Eli Lilly & Co

5:45 Close of Developability of Bispecific Antibodies Conference

SAFETY & EFFICACY OF BISPECIFIC ANTIBODIES, ADCs AND COMBINATION THERAPY

THURSDAY, JANUARY 18

7:45 am Conference Registration & Morning Coffee

8:55 Organizer's Welcome Remarks

Christina C. Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

BISPECIFIC ANTIBODY SAFETY AND EFFICACY CHALLENGES

9:00 Chairperson's Opening Remarks

Rakesh Dixit, PhD, President & CEO, Bionavigen

9:05 KEYNOTE PRESENTATION: Tailoring Bispecifics and ADCs Drug Development to Patient and Tumor Features for Safety and Efficacy Optimization: The Clinical Perspective

Elisa Fontana, MD, PhD, Oncologist and Medical Director, Sarah Cannon Research Institute UK

Bispecific antibodies and ADCs are rapidly moving from clinical development to standard-of-care, either as monotherapy or in combination with other anticancer agents. Dose escalation clinical trial designs are shifting from tumor-agnostic approaches to more stringent criteria with pre-specified cancer types and possibly biomarker selection already in early-phase trials. Patients' drug tolerability and tumour biology are often influenced by previous lines of treatment, ad-hoc strategies for each tumor are needed.

9:35 Novel Bispecific Antibody Immunocytokines for the Recruitment of Myeloid Effector Cells in Cancer Therapy

Marjolein van Egmond, PhD, Professor, Oncology and Inflammation, Surgery/ Molecular Cell Biology and Immunology, Amsterdam UMC

Antibody-based immunotherapy is a promising strategy in cancer treatment. IgG eliminates tumor cells through NK cell-mediated ADCC and macrophage-mediated antibody-dependent phagocytosis. Neutrophils have been largely overlooked as potential effector cells because IgG ineffectively recruits neutrophils. Bispecific antibodies, which potently activate neutrophils and induce migration through FcaRI (CD89), have been developed. Coupling of TNFa activates neutrophils as effector cells, which will be discussed.

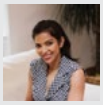
10:05 Modulating the Immune System with Bispecific Antibodies and Cytokines

Veronica Zeng, PhD, Principal Scientist, Xencor, Inc.

T cell in the tumor micro-environment requires TCR engagement, co-stimulation, and cytokines to promote activation, differentiation, and proliferation. Tumor cells lack expression of the ligands necessary to promote robust T cell activity with existing immune therapies. This presentation will describe pre-clinical data on combinations of CD28 co-stimulation, checkpoint blockade, T cell redirecting bispecifics, and cytokines to enhance anti-tumor efficacy of immune-oncology therapies.

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: ELECTRONIC CONNECTIONS TRAINING



Electronic Connections Training

Nandini Kashyap, Senior Director, Conferences and Social Media Strategy, Cambridge Healthtech Institute

Looking to make connections but no longer carry a paper business card with you? Join us for this event to share your electronic business card, LinkedIn profile, or to connect on the PepTalk app.

PRECLINICAL SAFETY AND EFFICACY OF BISPECIFIC ANTIBODIES, ADCs, AND COMBINATIONS

11:14 Chairperson's Remarks

Mark L. Chiu, PhD, CSO, Tavotek Biotherapeutics

11:15 Combination Strategies to Enhance Anti-Tumor T Cell Response

Eric Smith, PhD, Senior Director, Bispecifics, Regeneron Pharmaceuticals, Inc.

This presentation will describe preclinical data from Regeneron's new clinical approaches to enhancing anti-tumor efficacy of T cells, focusing on the combination of costimulatory bispecific antibodies with checkpoint blockade and T cell redirecting bispecifics. In addition, data from new classes of T cell targeted enhancement strategies in preclinical development will be discussed.

11:45 Enabling Improved Tolerability of Solid-Tumor-Targeting ADCs

Penelope M. Drake, PhD, Head R&D, Bioconjugates, Catalent Pharma Solutions

Our team has developed a technology to enable the development of site-specific bioconjugates made with novel linkers that are stable in the circulation. The improved efficacy and tolerability made possible by these optimized conjugates widens the therapeutic window and shows the potential for improved therapeutic treatment options.

12:15 pm Enjoy Lunch on Your Own

SAFETY AND EFFICACY CHALLENGES OF ADCs

1:45 Chairperson's Remarks

Rakesh Dixit, PhD, President & CEO, Bionavigen

1:50 KEYNOTE PRESENTATION: Recent Progress in Antibody-Drug Conjugate Therapy for Cancer

Aditya Bardia, MD, Director, Breast Cancer Research, Harvard Medical School

Triple negative breast cancer (TNBC) has relatively aggressive tumor biology, poor prognosis, and low response with standard chemotherapy. In this presentation, we will review the clinical development of novel antibody drug conjugates in triple negative breast cancer, as well as innovative combination strategies for patients with metastatic TNBC.

2:20 The Success of ADCs in the Clinic: Novelty Trap or Optimally Distinct

Anthony W. Tolcher, MD, FRCPC, FACP, CEO & Founder, NEXT Oncology

When does a new platform transition from innovation to derivation? The purpose of this presentation is to speak to other oncology "bubbles" where multiple competitors enter the field. With venture capital funding tight right now is there a flaw in defaulting to known targets and payloads which have a lower likelihood of transformative or commercial success. Using historical examples the goal of this presentation is to ensure ADCs remain innovative.

2:50 Improving the Therapeutic Index of ATACs (Amanitin-Based ADCs)

Michael Kulke, PhD, Vice President, Nonclinical Development, Oncology & Cancer Research, Heidelberg Pharma AG

Amatoxin-based ADCs (ATACs) differ from other ADCs through the use of the RNA-polymerase II inhibitor amanitin as toxic payload. Amanitin is a hydrophilic and thus biophysically unique payload. In consequence, ATACs have a distinct off-target toxicity profile compared to other approved ADCs. This can be reduced by sequence optimization of the antibody moiety. Additionally, changing the route of administration refines PK parameters leading to an improved therapeutic index.

3:20 Talk Title to be Announced
John Burke, PhD, Co-Founder, President, and CEO, Applied BioMath

3:50 Refreshment Break in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: SPEED NETWORKING

Speed Networking


Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

Bring yourself, and your business cards, and be prepared to share and summarize the key elements of your research in a minute. PepTalk will provide a location, timer, and fellow attendees to facilitate the introductions.

PLENARY KEYNOTE SESSION

4:35 Sponsored Plenary Introduction (Opportunity Available)

4:45 Protein and Gene Therapy Biotherapeutics: Biophysics, Simulations, and Analytical Tools to Shed Light on Biomanufacturability and Downstream Bioprocessing Opportunities

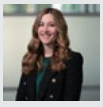
Steven M. Cramer, PhD, William Weightman Walker Professor, Isermann Department of Chemical and Biological Engineering, Rensselaer Polytechnic Institute

This talk will illustrate how a combination of biophysics, simulations, and analytical tools can be employed for a deeper understanding of the molecular basis for important biomanufacturability properties as well as the purification of both protein and gene therapy biotherapeutics from their product- and process-related impurities. In addition, the unique challenges of gene therapy bioprocessing will be discussed from the perspective of proper analytical definition of the "biological product."

5:30 Networking Reception in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: WOMEN IN SCIENCE MEET UP

Women In Science


Christa Cortesio, PhD, Director, Protein Science, Protein Biochemistry & Analytics Core, Kite Pharma

Marija Dramicanin, PhD, Head, Protein Production Facility, Walter & Eliza Hall Institute of Medical Research

Deborah Moore-Lai, PhD, Senior Director, Protein Development & Production, R&D Leadership, Abcam

CHI is proud to offer programming that honors and celebrates the advancement of diversity in the life sciences. We recognize that barriers preventing women from fully participating in the sciences are not just barriers to equality, but also critically deter scientific advancement worldwide. Our Women in Science programming invites the entire scientific community to discuss these barriers, as we believe that all voices are necessary and welcome.

6:30 Close of Day

FRIDAY, JANUARY 19

7:30 am Conference Registration

BuzZ Sessions

7:45 BuzZ Sessions with Continental Breakfast

BuzZ Sessions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the BuzZ Sessions page on the conference website for a complete listing of topics and descriptions.

IN-PERSON ONLY BUZZ SESSION: Strategies to Improve T Cell Responses to Treat Patients with Solid Tumors

Mark L. Chiu, PhD, CSO, Tavotek Biotherapeutics

- Engineering higher selectivity to solid tumor tissues
- Breaking the barriers to get into solid tumors
- Handling dysfunctional immune cells in the solid tumor microenvironment

IN-PERSON ONLY BUZZ SESSION: Challenges in Developing Immune Modulating Therapeutics for Autoimmune Diseases—Will the Opposite (Inhibition of the Activated Immune System) from an Oncology Strategy (Activation of the Immune System) Work?

Rakesh Dixit, PhD, President & CEO, Bionavigen

- To treat autoimmune disease, potential benefits in enhancing (agonism) immune checkpoint inhibitor (ICI) signaling
- Alternatively, inhibition (antagonism) of immune activation by OX-40, GITRR, and CD-137 may relieve autoimmune diseases
- Discussion on inhibitory immune checkpoint homeostasis in controlling infections and defenses against cancers
- Challenges of developing agents that promote defenses against autoreactive T cells vs. activation of cytotoxic T cells against cancers?

8:45 Transition to Conference Track

PRECLINICAL SAFETY AND EFFICACY OF BISPECIFIC ANTIBODIES, ADCs, AND COMBINATIONS *(CONT.)*

9:00 Chairperson's Remarks
Mark L. Chiu, PhD, CSO, Tavotek Biotherapeutics

9:05 1, 2 Bispecific Antibody Do; 3, 4 Look Out for More: Driving Stronger Response with Combinations of Bispecific Antibodies
Mark L. Chiu, PhD, CSO, Tavotek Biotherapeutics

Bispecific antibodies can manifest into higher specificity and stronger potency. Combination with standards of care molecules can enhance potency and efficacy.

9:35 Creating Cancer-Specific Neoantigens with Covalent Inhibitors and Targeting Them with Bispecific Antibodies
Takamitsu Hattori, PhD, Research Assistant Professor, Biochemistry and Molecular Pharmacology, NYU Grossman School of Medicine

Intracellular oncoproteins are potentially attractive targets for antibody therapy, as their mutation-containing fragments can be presented by MHC as tumor-specific neoantigens. However, recognizing minimal differences

between oncomutations and their normal counterparts is challenging. We have developed the HapImmune technology that exploits hapten-peptide conjugates generated by small-molecule covalent inhibitors as distinct neoantigens presented on MHC to enable engineered antibodies to selectively kill drug-resistant cancer cells.

10:05 Optimizing the Safety of Antibody-Drug Conjugates in Oncology: Learning from the Past to Build a Brighter Future

Paolo Tarantino, PhD, Research Fellow, Breast Oncology, Dana Farber Cancer Institute, Harvard Medical School

Antibody-drug conjugates (ADC) are progressively redefining the treatment of multiple cancer types, showing improved antitumor activity compared to conventional chemotherapy. Nonetheless, side effects remain a key concern with most novel ADCs, warranting strategies to optimize their toxicities. This talk will review the most promising strategies being pursued to improve the toxicity profile and tolerability of ADCs.

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: POST-PEPTALK CONNECTIONS

Post-PepTalk Connections


Kevin Brawley, Associate Project Manager, Production Operations & Communications, Cambridge Innovation Institute

Kent Simmons, Senior Conference Director, Cambridge Healthtech Institute

- How will our onsite app benefit your networking after the conference?
- How to view on-demand presentations to maximize your conference experience

11:15 Engineered CD47 Protects T Cells for Enhanced Antitumor Immunity

Sean Yamada-Hunter, PhD, Postdoctoral Research, Mackall Lab, Stanford Cancer Institute, Stanford University

CAR T and anti-CD47 therapy are two distinct immunotherapies that we found to be non-compatible in combination due to depletion of adoptively transferred T cells by macrophages. We engineered CD47 for selective binding to be insensitive to CD47 therapy and demonstrated that the combination of CAR T cells expressing engineered CD47 and CD47 blockade results in synergistic control of multiple solid tumors by harnessing T cell and macrophage antitumor activity.

11:45 Enjoy Lunch on your Own

1:00 pm Ice Cream & Cookie Break in the Exhibit Hall with Last Chance for Poster Viewing

BISPECIFIC ADCs: A NEW FRONTIER

1:45 Chairperson's Remarks

Rakesh Dixit, PhD, President & CEO, Bionavigen

1:50 Mitigating Toxicity with ADCs

Rakesh Dixit, PhD, President & CEO, Bionavigen

Bispecifics, ADCs, and combinations have revolutionized cancer treatment and the suffering of cancer patients. The presentation will include three key updates in the field: advances in bispecific and ADCs (including efficacy and safety), mitigation strategies to improve the efficacy and reduce toxicity (of these, two key therapeutics will be discussed), and combination strategies for specifics, targeted therapies, chemo, and ADCs.

2:20 Improving Anti-Tumor Activity with Bispecific Antibody Drug Conjugates

Frank An, PhD, Senior Director, Antibody Therapeutics, Institute for Therapeutic Innovation, Biocytogen Boston Corp.

Bispecific antibody drug conjugates (bsADCs) are emerging as a new, promising modality that may provide improved efficacy and safety in cancer therapy. Biocytogen's RenLite fully human, common light chain antibody platform allows rapid construction of bispecific antibodies of choice targeting a wide variety of tumor-associated antigens. The presentation will highlight Biocytogen's bsADC programs that demonstrate the enhanced anti-cancer activities of bsADCs in preclinical models.

2:50 Improving Anti-Tumor Activity with Bispecific Antibody Drug Conjugates

Frank Comer, PhD, Director, Tumor Targeted Delivery, Early Oncology R&D, AstraZeneca

AZD9592 is a first-in-class bispecific ADC designed to deliver a topoisomerase inhibitor payload to EGFR and cMET-expressing tumors, regardless of mutation status. AZD9592 has reduced affinity for EGFR to mitigate EGFR-driven toxicities and a cMET arm for avidity-based targeting of tumors that co-express both targets. We demonstrate that AZD9592 is active in PDX models representing a broad clinical line of sight and shows a promising safety profile.

3:20 Introduction

Jan E. Schnitzer, MD, Institute Director, Proteogenomics Research Institute for Systems Medicine

3:30 PANEL DISCUSSION: Delivering Antibodies into Solid Tumors: Improving Safety and Efficacy of Bispecific Antibodies through Proper Delivery

Moderator: Jan E. Schnitzer, MD, Institute Director, Proteogenomics Research Institute for Systems Medicine

Panelists:

Rakesh Dixit, PhD, President & CEO, Bionavigen

4:25 Conference Wrap Up

Rakesh Dixit, PhD, President & CEO, Bionavigen

4:30 Close of Conference

CHARACTERIZATION & AGGREGATION IN BIOPHARMACEUTICALS

The **Characterization & Aggregation in Biopharmaceuticals** pipeline features two back-to-back popular conferences addressing critical topics such as analytical and characterization tools for protein formulation development, aggregation, stability assessment, and impurities in biotherapeutics and vaccines. These conferences will feature case studies, new and unpublished data, interactive panel discussions, keynote talks, and many opportunities to network and make connections to discuss the timeliest issues and opportunities in biotherapeutics development.

JANUARY 16-17

Characterization of Biotherapeutics

AGENDA

JANUARY 18-19

Characterizing Protein Aggregates & Impurities

AGENDA

TUESDAY, JANUARY 16

7:00 am Conference Registration and Morning Coffee

8:55 Organizer's Welcome Remarks

Nandini Kashyap, M. Pharm, Senior Director, Conferences, and Social Media Strategy, Cambridge Innovation Institute

ADVANCED MASS SPECTROMETRY TECHNIQUES

9:00 Chairperson's Remarks

Alexander R. Ivanov, PhD, Associate Professor, Department of Chemistry & Chemical Biology, Northeastern University

9:05 LC-MS-Based Product Quality of Antibody-Based Therapeutics Direct from Cell Culture Supernatants

Juan José Bonfiglio, PhD, Science and People Lead, Mass Spectrometry, Roche, Germany

Development and production of innovative biotherapeutics demands bioprocesses that consistently yield a high-quality product. However, current methods to determine product quality do not necessarily capture the actual mix of product and related impurities in cell culture supernatant, but rather what can be captured after purification. We developed a highly-sensitive method that can be applied to the detailed characterization of cell culture supernatants from bioreactors without a falsifying pre-purification step.

9:35 A Research Journey: Over a Decade of Denaturing and Native-MS Analyses of Hydrophobic and Membrane Proteins in Amgen Therapeutic Discovery

Iain D.G. Campuzano, PhD FRSC, Scientific Director, Molecular Analytics, Amgen, Inc.

Membrane proteins and associated complexes currently comprise the majority of therapeutic targets and remain among the most challenging classes of proteins for analytical characterization. Through long-term strategic collaborations forged between industrial and academic research groups, there has been tremendous progress in advancing membrane protein mass spectrometry (MS) analytical methods and their concomitant application to Amgen therapeutic project progression.

10:05 Characterization Of Fragmentation Sites, Charge Variants, and Structural Features of Bispecific Antigen-Binding Biotherapeutic Using Separations Coupled to Mass Spectrometry

Alexander R. Ivanov, PhD, Associate Professor, Department of Chemistry & Chemical Biology, Northeastern University

Our study delves into characterization of product quality attributes associated with the Bispecific Antigen-Binding Biotherapeutic (BABB) molecule. We employed microfluidic-based capillary zone electrophoresis in conjunction with mass spectrometry (MS), to identify fragmentation/clipping sites within BABB therapeutics. We comprehensively investigated both predominant and low-abundance post-translation modifications via native MS. Lastly, we demonstrated the implementation of covalent labeling and MS, to characterize BABB's subtle conformational changes under native vs. thermally stressed conditions.

10:35 Networking Coffee Break

11:00 "Lab of the Future": End-to-End Automation of Mass Spectrometry Analysis for Biotherapeutics Characterization

Michael Poltash, PhD, Senior Scientist, Janssen Pharmaceuticals

A state-of-the-art, integrated, multi-instrument automated system was designed to execute methods involved in mass spectrometry characterization of biotherapeutics. The system includes liquid- and microplate-handling robotics and utilities, integrated LC-MS, along with data analysis software to perform sample purification, preparation, data acquisition, and data analysis as a seamless integrated unit. The results are verified and formatted for expert curation directly in the cloud.

11:30 Characterization of Forced Degraded Antibodies Using Advanced Analytics for Higher-Order Structure Assessment

Nithya Srinivasan, PhD, Principal Scientist, Amgen

Forced degradation studies are an integral part of protein therapeutics research and development. Identification of protein degradation pathways and the characterization of the higher-order structure (HOS) is critical in estimating the efficacy and safety of biotherapeutics. This talk will delve into recent advances in characterization tools for assessing HOS with a focus on case studies involving force degraded antibodies.

12:00 pm Session Break and Transition to Luncheon Presentation

12:10 LUNCHEON PRESENTATION I: Accelerating Gene Therapy Development: Analytical Technologies for Precise Characterization of Viral Vector Attributes bio-techne

Chris Heger, PhD, Director, Applications Science, Analytical Solutions Division, Bio-Techne

While gene therapies promise innovative treatments and even cures for severe diseases, a challenge in bringing new therapies to market is the lack of fit-for-purpose analytical technologies to characterize viral vector critical quality attributes. Bio-Techne offers cutting-edge automated analytical solutions to analyze multiple attributes and advance vector manufacturing workflows. In this presentation, we discuss our Simple Western and Maurice platforms to assess potency, purity, identity, capsid protein ratio, and more.

12:40 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:10 Session Break

NEW METHODS, TOOLS, AND IMAGING TECHNIQUES

1:30 Chairperson's Remarks

Xiangdan Wang, PhD, Senior Principal Scientist, BioAnalytical Sciences, Genentech, Inc.

1:35 USP Standards and Tools to Support Monoclonal Antibody Analysis Using MAM and Conventional Methods

Li Jing, PhD, Principal Scientist, USP

MS-based MAM for analytical testing of mAbs has the potential to improve efficiency and provide more detailed information on PQAs as compared to conventional methods. This presentation will overview USP reference standards and tools to support mAb characterization and analytical control strategies. Case studies, including multidimensional assessments of monitoring changes in PQAs upon forced degradation and the correlation between MAM and conventional methods, will also be discussed.

2:05 Characterization of Adeno-Associated Viruses—Strengths and Weaknesses

Andrei Hutanu, PhD, Senior Scientist, Ten23 health

Typical rAAV samples tend to be heterogenous and include a range of protein and DNA contaminants. Although the QC space of viral vectors is currently dominated by molecular biology methodology, physicochemical methods are expected to play an increasingly important role in the future. This presentation aims to highlight the benefits and drawbacks of various technologies as TEM, CGE, icIEF, DLS, SEC, thermal-shift-assays, and others for their use in formulation studies.

2:35 Peptide Mapping for Biotherapeutics Development Waters™

Caitlin Hanna, Senior Scientist, Chemistry, Waters Corporation

Reliable sample preparation is a critical factor in developing an effective peptide mapping method. This presentation will highlight Waters™ RapiZyme™ Trypsin and PeptideWorks™ Tryptic Protein Digestion Kits. RapiZyme Trypsin enables the use of a high enzyme:protein ratio and rapid 30-minute digestion while resisting autolytic degradation. Its use in the PeptideWorks Tryptic Protein Digestion Kits yields reproducible tryptic digest samples without sacrificing digestion completion or inducing high levels of peptide modifications.

BuzZ Sessions

3:05 Find Your Table and Meet the BuzZ Sessions Moderator

3:15 BuzZ Sessions with Refreshments

BuzZ Sessions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the BuzZ Sessions page on the conference website for a complete listing of topics and descriptions.

In-Person Only BuzZ Session: Understanding and Overcoming Challenges with Automation in Analytical Laboratories

Michael Poltash, PhD, Senior Scientist, Janssen Pharmaceuticals

- Should you just a full-scale automation system or automate single tasks?
- How do you future-proof your hardware for automation?
- Does automation make mistakes?

In-Person Only BuzZ Session: Leveraging LinkedIn for Scientific Advancement: Optimizing Digital Presence, Building Networks, Driving Innovation

Nandini Kashyap, Senior Director, Conferences and Social Media Strategy, Cambridge Healthtech Institute

- Strategies for Crafting an Impactful Digital Persona
- Building Global Networks and Collaborations
- Driving Innovation and Advancement through Thought Leadership

METHODS, TOOLS, AND TECHNIQUES *(CONT.)*

4:15 Application of Molecular Interaction Characterization Tools to Enable Drug Development

Xiangdan Wang, PhD, Senior Principal Scientist, BioAnalytical Sciences, Genentech, Inc.

With increasing complexity of therapeutics and challenging targets, more diversified technologies and methods are needed. In addition, there is an increasing need to understand the binding interactions that can better reflect what may happen *in vivo*. This presentation will focus on case studies that demonstrate the application of various molecular interaction characterization tools to enable drug development.

4:45 Is Your SPR/BLI Capture Reagent a Friend or Foe?

Vishal Kamat, PhD, Senior Director, Protein Sciences, Ampersand Biomedicines

5:15 Microcrystal Electron Diffraction (MicroED): A Tool for Structural Discovery

Alison Haymaker, Graduate Research Assistant, Biodesign Center for Personalized Diagnostics, Arizona State University

MicroED is a revolutionary structural biology technique. Using these microcrystals we are able to determine the structure of proteins that were previously unsolvable via X-crystallography or are too small for Cryo-EM. Using MicroED we have been able to visualize small molecules around 0.3 kDa to proteins as large as 245 kDa, along with small molecules docked onto their target proteins, and even proteins embedded in membranes.

5:45 Grand Opening Welcome Reception in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: YOUNG SCIENTIST MEET UP

Young Scientist Meet Up




Emma Altman, Senior Research Associate, Protein Sciences, Kite Pharma

Kavya Ganapathy, PhD, Postdoctoral Research Fellow, Genentech

Alexandros Karyolaimos, PhD, Researcher, Department of Biochemistry & Biophysics, Stockholm University

Sean Yamada-Hunter, PhD, Postdoctoral Research, Mackall Lab, Stanford Cancer Institute, Stanford University

7:00 Close of Day

WEDNESDAY, JANUARY 17

8:30 am Conference Registration & Morning Coffee

PLENARY FIRESIDE CHAT

9:00 Plenary Session Organizer's Remarks

Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

9:10 PLENARY FIRESIDE CHAT: Supporting and Driving Biotech: Past, Present, and Future

Innovation can refer to something new, such as an invention, or the development and introduction of new practices. Progress and challenges frequently act as the driving force behind this innovation, propelling us toward original ways of thinking and doing. The outcome can materialize as a novel product, yet it extends to novel methodologies, procedures, or modes of thought. This Fireside Chat convenes long-term supporters of PepTalk: The Protein Science and Production Week who explore the following:

- Innovations and technology development in the last 5 years
- Collaborations and strategic partnerships – advice to early-stage/ small companies
- Is there a trend toward diversification of scientists' roles, skill sets and responsibilities? Why?
- What is an unexpected market trend you are seeing?
- What excites you/what keeps you working in this industry?

9:10 Panelists:




Moderator: Jennifer Giottonini Cayer, CBO, Pulmocide; Board of Directors, UCSD Moores Cancer Center and Biocom California

Panelists:

Carter A. Mitchell, PhD, CSO, Purification & Expression, Kemp Proteins, LLC

Eric Vajda, PhD, Vice President, Preclinical R&D, OmniAb

Deborah Moore-Lai, PhD, Senior Director, Protein Development & Production, R&D Leadership, Abcam

PEPTALK PLAZA: MEET THE FIRESIDE CHAT PLENARY SPEAKERS

10:15 Meet the Fireside Chat Plenary Speakers

Stop by the PepTalk Plaza to continue the discussion and ask questions.

10:15 Coffee Break in the Exhibit Hall with Poster Viewing

CHARACTERIZATION OF BIOLOGICS

11:00 Chairperson's Remarks

Yoan Machado, PhD, Scientist, Molecular Analytics, Amgen

11:05 KEYNOTE PRESENTATION: End-to-End Implementation of Multi-Attribute Method (MAM) for Product Characterization and Control

Da Ren, PhD, Founder & CEO, BioTherapeutics Solutions

Multi-Attribute Method (MAM) has been widely used in the biopharmaceutical industry since its introduction 8 years ago. Compared to conventional analytical assays, MAM can provide site-specific information of product quality attributes (PQAs) at the amino acid level, which is crucial for process and product characterization. End-to-end implementation of MAM from development to QC testing ensures drug product quality and aligns with quality by design (QbD) principles

11:35 Automating Analytical Characterization of Next-Generation Protein Therapeutics

Miroslav Nikolov, PhD, Senior Scientist & Laboratory Head, Roche

I will present the latest advances in end-to-end automation, digitalization and data management of the protein analytics workflows in the pharma research and early development (pRED) unit of Roche, focusing on mass spectrometry analysis of complex antibody-based drug candidates. It is routinely applied to a variety of sample types and throughput, from early binder screening to clone selection and bioprocess development.

12:05 pm Complete Aggregate and Particle Characterization of Protein, Gene, and Cell Therapies

halo labs

Dikran Khachadourian, Field Application Scientist, Halo Labs

• In all biological products, distinguishing aggregated API from other particles is crucial for understanding the root cause of instability. Until now, subvisible particle characterization methods have been unreliable, slow, and difficult to use across different therapeutics. In this talk, we will discuss how Aura®, a USP 1788 compatible, low-volume, high throughput particle imaging system allows for the complete characterization and identification of subvisible particles in protein, gene, and cell therapy products.

12:35 Session Break and Transition to Luncheon Presentation

12:45 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:45 Session Break

DEVELOPABILITY AND CHARACTERIZATION FOR NOVEL BIOLOGICS

2:00 Chairperson's Remarks

Michael S. Marlow, PhD, Director Biologics CMC Research, Biotherapeutics Discovery, Boehringer Ingelheim Pharmaceuticals, Inc.

2:05 FEATURED PRESENTATION: Connecting the Lab to the Machine: A Retrospective Analysis and Prospective Evaluation

Michael S. Marlow, PhD, Director Biologics CMC Research, Biotherapeutics Discovery, Boehringer Ingelheim Pharmaceuticals, Inc.

ML/AI applications hold much promise for biotherapeutic discovery and development. However, we often encounter difficulties associated with inadequate training data to fully realize this potential. This talk will highlight solutions to various challenges we encountered during the expansion of our integrated expression, purification, and characterization platforms intended to facilitate acquisition of production and biophysical data in a consistent and structured manner to power ML models.

2:35 Lifecycle Management of Analytical Procedures for Biotherapeutics

Kevin Zen, PhD, Senior Director, IGM Biosciences

Analytical Quality-by-Design offers a systematic and robust approach to the development of analytical procedures involving all stages of the product's lifecycle. The presentation will overview FDA guidance and newer ICH guidelines on analytical control strategy including method development, validation, and lifecycle management. Special emphasis will be placed on the analytical procedures commonly used in in-process control, release and stability for biotherapeutics.

3:05 Microfluidic Modulation Spectroscopy (MMS) for Monitoring Protein Structure During Re-folding and Thermal Stress

REDSHIFTBio

David Sloan, PhD, Vice President, Applications and Product Management, RedShiftBio

Protein stability is a critical quality attribute for a new biologic drug. To investigate stability through folding and unfolding, we stressed multiple proteins thermally and with pressure and measured the changes in the protein structure and melting point (Tm) using MMS. We will also discuss a novel method for re-solubilizing and re-folding proteins using urea and pressure resulting in natively folded proteins whose structure matches that of the original unstressed protein.

3:20 Presentation to be Announced

nicoya

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

4:15 Not All Bispecifics Are Created Equal

Chen Zhou, PhD, Principal Research Scientist, Biologics Drug Product Development, Abbvie Bioresearch Center

Although many different bispecific antibody formats have been used in clinical trials for various diseases, the number of approved bispecifics is still limited, partly due to the poor developability of bispecific antibodies often observed in early development. In this talk we will share the developability of a panel of commercial and advanced clinical stage bispecific molecules, to provide a benchmark for the physicochemical property and developability profiles of bispecific antibodies.

4:45 Fc Effector Function Characterization of T Cell-Dependent Bispecifics

Zhaojun Yin, Principal Scientist, BioAnalytical Sciences gRED Development Sciences, Genentech

T cell-dependent bispecifics (TDBs) have emerged as a promising cancer immunotherapeutic modality, which redirect T cells to eliminate tumor cells by co-engaging CD3 on T cells and tumor antigen on tumor cells. The effector function characterization strategies for our TDBs will be presented herein, and case studies will be provided to evaluate the potential impact of residual effector function of Fc mutations on the efficacy and safety of TDBs.

5:15 PANEL DISCUSSION: Wrap Up Panel: Characterization for Biotherapeutics—Discussion of Topics That Are Top-of-Mind

Moderator: Alois Jungbauer, PhD, Professor & Head, Biotechnology, Institute of Bioprocess Science and Engineering, University of Natural Resources and Life Sciences (BOKU)

Panelists:

Andrei Hutanu, PhD, Senior Scientist, Ten23 health

Michael S. Marlow, PhD, Director Biologics CMC Research, Biotherapeutics Discovery, Boehringer Ingelheim Pharmaceuticals, Inc.

Zhaojun Yin, Principal Scientist, BioAnalytical Sciences gRED Development Sciences, Genentech

5:45 Close of Characterization of Biotherapeutics Conference

THURSDAY, JANUARY 18

7:45 am Conference Registration & Morning Coffee

8:25 Organizer's Welcome Remarks

Nandini Kashyap, M. Pharm, Senior Director, Conferences and Social Media Strategy, Cambridge Innovation Institute

MECHANISM AND IMPACT OF PROTEIN AGGREGATION

8:30 Chairperson's Remarks

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

8:35 Presentation to be Announced

9:05 FEATURED PRESENTATION: Frozen State Protein Aggregation and Its Impact on Biologic Process Development

Bharat Jagannathan, PhD, Principal Scientist, Attribute Sciences, Amgen Inc.

Protein aggregation is a critical quality attribute that is closely monitored during biologic candidate selection and process development. This talk will delve into the relatively rare aggregation challenges encountered during long-term storage of biologics in the frozen state. Potential mitigation strategies to control frozen aggregation will also be discussed. Finally, the implications of frozen state instability on drug substance and drug product analytical development will be addressed.

9:35 Characterization of Challenging Protein Complexes—Mixture of Soluble and Insoluble Aggregates

Xue (Snow) Yang, PhD, Senior Scientist, AbbVie, Inc.

Amyloid deposition is a key pathological hallmark across a series of neurodegenerative diseases including Alzheimer's Disease and Parkinson's Disease. However, little is known about the structure and composition of amyloid plaques. And no well-established robust methods for oligomer and fibril complexes characterization. Here, we used a suite of bioanalytical techniques to characterize the amyloid aggregate complexes which helps to understand the critical seeding and toxic species in AD.

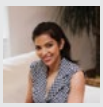
10:05 Trehalose, Sucrose and Amino Acids: Essential components of Platform Biopharma Formulations Pfanstiehl

Sudhakar Voruganti Voruganti, Dr, Director, Business Development, Pfanstiehl Inc

- Introduction of Pfanstiehl and its high quality/purity GMP components
- Essential components of a "Platform Biopharma Formulations"
- Understanding important physicochemical properties of Trehalose and Sucrose. Purity, Quality, and Consistency of Pfanstiehl's Trehalose and Sucrose
- Pfanstiehl's Biopharma Stabilization Portfolio including newly launched Amino Acids

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: ELECTRONIC CONNECTIONS TRAINING



Electronic Connections Training

Nandini Kashyap, Senior Director, Conferences and Social Media Strategy, Cambridge Healthtech Institute

Looking to make connections but no longer carry a paper business card with you? Join us for this event to share your electronic business card, LinkedIn profile, or to connect on the PepTalk app.

11:15 High Particle Numbers of Aggregated Biotherapeutics are a Key Factor for Inducing An Immunogenic Response *In Vitro*, *In Vivo*, and In The Clinic

Joseph R Cohen, Principal Scientist, Attribute Sciences, Amgen Inc.

There is concern that subvisible aggregates in biotherapeutic drug products pose a risk to patient safety. We investigated the threshold of aggregates for immune activation ***in vitro***, ***in vivo*** and clinical trials. Findings show the ability of aggregates to elicit immune responses depends on high numbers of particles. This suggests a high threshold for aggregate number to induce an immunogenic response, well beyond those found in standard biotherapeutic drug products.

11:45 Protein Aggregation Assessment for *In Vitro* Expression and *In Vivo* Serum Samples

Ray Low, PhD, Sr Dir & Head, Protein Sciences, Nutcracker Therapeutics Inc

It is extremely challenging to assess protein aggregation during ***in vitro*** expression without some form of purification. We have developed a novel method to estimate the amount of protein aggregates during the expression phase. We have also successfully used this new method to assess protein aggregation from ***in vivo*** mRNA expressed protein samples.

12:15 pm Session Break and Transition to Luncheon Presentation

12:25 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:25 Session Break

TOOLS & STRATEGIES FOR MANAGING AGGREGATES

1:45 Chairperson's Remarks

Carl Mieczkowski, PhD, Director, Allostery Consulting

1:50 Real-Time Monitoring of Protein Aggregation Using At-Line and In-Line Analytical Tools: Fantasy or Reality?

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

In recent years, there has been increasing interest in real-time monitoring of protein aggregation which has led to the development of new technologies that can be implemented in the laboratory and potentially, as a process analytical technology (PAT) during routine manufacturing. The goal of this presentation is to provide an update on these developments.

2:20 Elucidating Impacts of Enzymatic PS80 Degradants on Different Protein Aggregation Mechanisms

Caitlin V. Wood, PhD, Associate Principal Scientist, Merck & Co., Inc.

PS80 can degrade through various pathways, resulting in degradant combinations that can impact the stability of protein biologics in different ways. We investigated the correlation between specific PS80 degradation patterns through enzymatic PS80 hydrolysis and biologic product stability leveraging various analytical tools and advanced image analysis. The results indicate that different PS80 degradation profiles can have unique mechanistic impacts on protein stability.

2:50 Single-Molecule CLiC Microscopy of Protein and Oligonucleotide Interactions Including Aggregation

Sabrina Leslie, PhD, Associate Professor, Physics and Astronomy Department, The University of British Columbia

Sensitive detection and quantification of protein interactions and aggregation dynamics is an outstanding challenge. Here we present a tether-free, single-molecule microscopy platform for directly imaging the diffusion, interactions, and aggregation of molecules in nanowells. We use the CLiC (Convex Lens-induced Confinement) microscopy approach to study protein and oligonucleotide interactions over a broad range of reaction parameters (e.g., concentrations, timescales, multiple species) and investigate the steps of complex reactions like aggregation.

3:20 Uncover the secrets of your ADC with Unchained Labs

Andre Mueller, PhD, Marketing Manager Biologics Solutions, Unchained Labs

Antibody conjugates are powerful drugs – but they are also notorious: they aggregate and there's never enough sample for everything you want to do. Unchained Labs provides the right tools for this job: low volume, high throughput, integrated solutions making it easy to scope out any biologic – even ADCs. Join my talk and see for yourself how our solutions quantitate ADC and DAR, check quality, aggregation, conformational and colloidal stability, and help you optimize formulation conditions.

3:50 Refreshment Break in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: SPEED NETWORKING

Speed Networking


Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

Bring yourself, and your business cards, and be prepared to share and summarize the key elements of your research in a minute. PepTalk will provide a location, timer, and fellow attendees to facilitate the introductions.

PLENARY KEYNOTE SESSION

4:35 Sponsored Plenary Introduction (Opportunity Available)

4:45 Protein and Gene Therapy Biotherapeutics: Biophysics, Simulations, and Analytical Tools to Shed Light on Biomanufacturability and Downstream Bioprocessing Opportunities

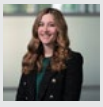
Steven M. Cramer, PhD, William Weightman Walker Professor, Isermann Department of Chemical and Biological Engineering, Rensselaer Polytechnic Institute

This talk will illustrate how a combination of biophysics, simulations, and analytical tools can be employed for a deeper understanding of the molecular basis for important biomanufacturability properties as well as the purification of both protein and gene therapy biotherapeutics from their product- and process-related impurities. In addition, the unique challenges of gene therapy bioprocessing will be discussed from the perspective of proper analytical definition of the "biological product."

5:30 Networking Reception in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: WOMEN IN SCIENCE MEET UP

Women In Science


Christa Cortesio, PhD, Director, Protein Science, Protein Biochemistry & Analytics Core, Kite Pharma

Marija Dramicanin, PhD, Head, Protein Production Facility, Walter & Eliza Hall Institute of Medical Research

Deborah Moore-Lai, PhD, Senior Director, Protein Development & Production, R&D Leadership, Abcam

CHI is proud to offer programming that honors and celebrates the advancement of diversity in the life sciences. We recognize that barriers preventing women from fully participating in the sciences are not just barriers to equality, but also critically deter scientific advancement worldwide. Our Women in Science programming invites the entire scientific community to discuss these barriers, as we believe that all voices are necessary and welcome.

6:30 Close of Day

FRIDAY, JANUARY 19

7:30 am Conference Registration

BuzZ Sessions

7:45 BuzZ Sessions with Continental Breakfast

BuzZ Sessions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the BuzZ Sessions page on the conference website for a complete listing of topics and descriptions.

Beyond Host-Cell Protein ELISA

Alois Jungbauer, PhD, Professor & Head, Biotechnology, Institute of Bioprocess Science and Engineering, University of Natural Resources and Life Sciences (BOKU)

- Understanding host-cell protein profiles with modern proteomics tools
- Are the limits state-of-the-art and which proteins are relevant?
- Fast methods for host-cell protein profiling

8:45 Transition to Conference Track

DETECTION, CHARACTERIZATION, AND CONTROL OF THE PROCESS- AND PRODUCT-RELATED IMPURITIES

9:00 Chairperson's Remarks

Abraham M. Lenhoff, PhD, AP Colburn Professor, Chemical & Biomolecular Engineering, University of Delaware

9:05 FEATURED PRESENTATION: The Role of Interactome in Host Cell Protein Composition in Downstream Processing

Alois Jungbauer, PhD, Professor & Head, Biotechnology, Institute of Bioprocess Science and Engineering, University of Natural Resources and Life Sciences (BOKU)

Protein-protein interactions may dominate coelution of protein in metal chelate chromatography and ion-exchange chromatography. Coelution of proteins cannot be solely explained by metal binding affinity using metal binding amino acid clusters at the surface of the protein. A new score to explain coelution propensity. Co-solvents during loading an elution suppress protein-protein interactions.

9:35 Host Cell Protein Analysis of AAV Gene Therapy Using LC-MS

Jonathan Bones, PhD, Principal Investigator, Characterisation and Comparability Laboratory, National Institute for Bioprocessing Research and Training (NIBRT), Ireland

Host cell protein (HCP) analysis of AAV gene therapy from both insect and

human expression systems will be presented. Semi-automated sample preparation was performed using the SP3 magnetic bead method to immobilise substrate prior to trypsin digestion. High-resolution LC-MS analysis was performed using the Vanquish Neo and Orbitrap Astral mass spectrometer. Demonstration of HCP clearance, and exploration of cleared HCPs, were evaluated using affinity-based purification using AAVx affinity chromatography.

10:05 Product and Impurity QC for Reagents used in Biopharma Manufacturing

Peter Hsueh, PhD., Marketing Product Manager, ACROBiosystems

Recombinant proteins play a pivotal role in biopharmaceutical manufacturing serving as soluble targets for screening, functional verification, and quality control. A key factor is ensuring these proteins are correctly structured to their native conformation without forming aggregates. Several case studies were explored to evaluate protein structure and aggregation, quality control measures, and analytical methods to deliver a comprehensive set of tools for biopharmaceutical manufacturing.

10:20 Presentation to be Announced

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: POST-PEPTALK CONNECTIONS

Post-PepTalk Connections


Kevin Brawley, Associate Project Manager, Production Operations & Communications, Cambridge Innovation Institute

Kent Simmons, Senior Conference Director, Cambridge Healthtech Institute

- How will our onsite app benefit your networking after the conference?
- How to view on-demand presentations to maximize your conference experience

11:15 Analysis of Bicycles: Novel Medium Molecules

Andrew Feilden, PhD, Director, Analytical Sciences, CMC, Bicycle Therapeutics plc

Bicycles are 4-10KDa fully synthetic peptides that are progressing through clinical trials. The challenges of achieving structural characterisation and identification of all impurities, as per ICH requirements, will be discussed.

11:45 Characterization and Implications of Host-Cell Protein Aggregates in Biopharmaceutical Processing

Abraham M. Lenhoff, PhD, AP Colburn Professor, Chemical & Biomolecular Engineering, University of Delaware

Host-cell proteins (HCPs) are a key class of impurity to be removed in purification of monoclonal antibodies (mAbs), with protein A chromatography (ProA) a key step. This presentation will show that most HCPs that persist beyond the ProA step do so as part of mAb-HCP aggregates, and it will describe the characteristics of the aggregates and the mechanisms of persistence and ultimately, the removal of the aggregates.

12:15 pm Session Break and Transition to Luncheon Presentation

12:25 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:55 Session Break

1:00 Ice Cream & Cookie Break in the Exhibit Hall with Last Chance for Poster Viewing

STRATEGIES FOR IMPROVING QUALITY AND STABILITY

1:45 Chairperson's Remarks

Alois Jungbauer, PhD, Professor & Head, Biotechnology, Institute of Bioprocess Science and Engineering, University of Natural Resources and Life Sciences (BOKU)

1:50 Novel Method to Rapidly Assess the Aggregation Behavior

Christoph Brandenbusch, PhD, Assistant Professor, Bioprocess Separations & Biologics Formulation Development, TU Dortmund University

Rapid and easy assessment on the aggregation propensity of biopharmaceuticals such as peptides and proteins in a given/newly developed formulation is crucial. However, even accelerated stability tests for frozen formulations still require a considerable amount of time and material. We will present a novel method based on mDSC measurements, simultaneously addressing aggregation propensity as well as solubility of the biopharmaceutical in liquid/frozen formulations.

2:20 Evolution of Commercial Antibody Formulations

Carl Mieczkowski, PhD, Director, Allostery Consulting

From 1986 to Jan. 2023, 165 commercial antibody therapeutic formulations were binned into 5 different periods and evaluated over time. We observed that average formulation pH decreased 0.5 units over time and significant trends were observed for the use of certain excipients. Average calculated pI also decreased. Reasons for the decrease in formulation pH, trends in excipient use, and lowering of pI, are explored.

2:50 Exploring Outer Membrane Vesicles: From Analysis to Therapeutic Promise

Kumkum Saxena, PhD, Vice President & Head, R&D, Versatope Therapeutics

We will present a technology platform for targeted delivery and vaccines that is based on recombinant outer membrane vesicles derived from genetically engineered probiotic bacteria with attenuated LPS for improved safety. Our leading multi-strain influenza vaccine candidate, VT-105 is highly immunogenic and protective against influenza in both ferrets and mice. The strong negative zeta potential of VT-105 ensures aggregation-free extended storage even at low temperatures.

3:20 Manufacturing Dry Powder of Interferon-Beta as Broad-Spectrum Anti-Respiratory Virus Therapeutics

Hong Seok Choi, PhD, Principal Researcher, Research Ctr, Abion Inc

ABN101 is interferon-beta with additional glycosylation chain, which leads the improvement of stability, solubility, PK profile and biological activity. With the improvement ABN101 was developed as dry powder to deliver into lungs for the treatment of respiratory viruses. Spray drying method was utilized for manufacturing rough and spherical shaped ABN101 dry powder with median diameter of around 2.5 μm. The activity of ABN101 dry powder was 80~90% (700 MIU/mg) maintained.

3:50 Enhancing Purity and Yield in Precipitation-Based Processes through Process Design

Carme Pons Royo, PhD, Postdoctoral Associate, Massachusetts Institute of Technology

Traditional precipitation processes are based on the direct addition of precipitant in a single dose, with limited control over the co-precipitation of impurities and aggregates and without considering batch-to-batch variations. Process design can modulate the co-precipitation of HCPs and aggregates through the mode and dosage timing. Additionally, novel methodologies for the continuous precipitation and crystallization of antibodies will be presented, including the addition of solid PEG.

4:20 Conference Wrap Up

4:30 Close of Conference

VECTOR DESIGN & DELIVERY

Selecting the optimal carrier system for delivery has a profound impact on the quality and characteristics of the final product. With so many versatile applications of this technology, there is an ever-increasing demand to enhance vector quality and capability. However, the vector space is not without its challenges. Some persistent issues include immunogenicity, limited cargo capacity, targeted delivery, purification, and complex regulatory considerations. Join us for the **Vector Design and Delivery** pipeline to explore innovative strategies for engineering viral and non-viral vectors with improved efficiency, scalability, and other solutions to the most challenging problems in the field.

JANUARY 16-17

Viral Vector Engineering & Scale-Up Considerations

AGENDA

JANUARY 18-19

Non-Viral Vector Engineering & Scale-Up Considerations

This conference track has been postponed.

VIRAL VECTOR ENGINEERING & SCALE-UP CONSIDERATIONS

Enhancing Design, Exploring Analytical Techniques, and Understanding Regulations

TUESDAY, JANUARY 16

7:00 am Conference Registration and Morning Coffee

8:55 Organizer's Welcome Remarks

Nikki Cerniuk, Conference Producer, Cambridge Healthtech Institute

VECTOR DESIGN AND ENGINEERING

9:00 Chairperson's Opening Remarks

Ashish Saksule, Principal Scientist & Lead, Vector Core, Vertex Pharmaceuticals, Inc.

9:05 Brave New World: A Union of AI, Random and Rational Design (Re)Shaping Viral Vector Engineering

Julia Fakhiri, PhD, Scientist, Gene Therapy Bioanalytics, Roche Diagnostics GmbH

With artificial intelligence (AI) and machine learning making headlines, a realm of boundless opportunities unfolds. Could we unleash AI's potential and merge the forces of random and guided design to engineer advanced AAV vectors? In this journey filled with possibilities and hurdles, we draw upon a wealth of AAV engineering experience, encompassing triumphs and setbacks alike.

9:35 Evolving Membrane-Associated Accessory Protein Variants for Improved Adeno-Associated Virus Production

Adam Schieferecke, PhD, Postdoctoral Scholar, California Institute for Quantitative Biosciences, University of California, Berkeley

Manufacturing sufficient Adeno-Associated Virus (AAV) to meet current and projected clinical needs is a significant hurdle to the growing gene therapy industry. Recent evidence has emerged supporting a functional role of the membrane-associated accessory protein (MAAP) in AAV production and egress. Here, I will present a directed evolution strategy our group developed to engineer novel MAAP variants that conferred increased overall production of multiple recombinant AAV serotypes.

10:05 Platform Approach for Production & Purification of Adeno-Associated Virus Vector Engineered Capsid Variants

Ashish Saksule, Principal Scientist & Lead, Vector Core, Vertex Pharmaceuticals, Inc.

In this presentation, we'll delve into a groundbreaking platform approach for the production and purification of adeno-associated virus vector engineered capsid variants. We will discuss how our innovative system transforms the landscape and optimizes the entire workflow of customized capsid variants.

10:35 Networking Coffee Break

PRODUCTION PROCESS DEVELOPMENT AND SCALING UP

11:00 Rapid, Flexible, Highly Suitable, Safe, and Cost-Effective Manufacturing of AAV Viral Vectors

Jake Connors, MS, CTO, R&D, Cirsium Biosciences

Cirsium Biosciences is a viral vector manufacturing platform developer. We develop viral vector production methods and systems using whole plants as modular, highly scalable, cost effective, and safe bioreactors. Production yields and key quality attributes including infectivity, E:F ratios, and purity are comparable to existing bioreactor-based AAV production methods. Our platform can achieve a 60-70% reduction in production costs and reduces lead time by 70% compared to competing methods.

11:30 Optimization of Upstream Approaches for Improved AAV Yield in Mammalian Cell Culture Platform

Pranav Joshi, PhD, Associate Director, Upstream Process Development, University of Pennsylvania

Enhancing AAV production in mammalian cell culture is crucial for gene therapy advancements. We will focus on optimization of upstream strategies to improve rAAV vector yield and quality. By refining upstream bioprocessing approaches, we aim to achieve higher AAV yields and better quality AAV products. These findings will provide valuable insights to the AAV bioprocessing field, paving the way for more efficient and scalable AAV production in gene therapy applications.

12:00 pm Session Break and Transition to Luncheon Presentation

12:10 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:10 Session Break

1:30 Chairperson's Remarks

Pranav Joshi, PhD, Associate Director, Upstream Process Development, University of Pennsylvania

1:35 High-Yield AAV Production across Multiple Serotypes Using Engineered Hosts

Kathy Ngo, PhD, Associate Director, Cell Engineering, CHO Plus

We present a disruptive cell engineering platform to overcome current AAV manufacturing challenges for gene therapy using a directed-evolution strategy via cell fusion, then selecting for HEK-293 cells with enhanced viral production machinery. Engineered pools and clones exhibited up to a 9-fold productivity improvement by transient transfection for AAV1, AAV2, and AAV5 (up to 10^{14} vg/mL and 10^{13} vp/mL), with a 2-fold improvement in full-to-empty ratio.

2:05 Development and Scale-Up of rVSV-SARS-CoV-2 Vaccine Process Using Single Use Bioreactor

Lizz Carey, Senior Scientist, Vaccine Process Development, Merck

Among many efforts to develop a vaccine against COVID-19, Merck developed a closed industrial-scale, single-use manufacturing process for vaccine candidate V590. For maximum virus productivity, we optimized pH and temperature during virus production in 3L bioreactors. Optimized production conditions were successfully scaled up to a 2000L bioreactor, producing a maximum virus titer of ~1.0e7 plaque forming units/mL. Additional process intensification and simplification were able to further increase virus productivity.

2:35 Leveraging the potential of AAV full/empty particle separation on anion-exchange resins by applying mechanistic modeling

cytiva

Tyler Martin, Mechanistic Modeling Specialist, Cytiva

Computer simulations are now indispensable in many industries, enabling improvements in productivity and faster innovation cycles. In biopharmaceutical processes, mechanistic modeling has shown increasing attention over the past decade, and adoption is driven by increasingly straightforward modeling workflows. This talk aims to provide an overview for a simple mechanistic modeling workflow, showcased by an industrial case study.

BuzZ Sessions

3:05 Find Your Table and Meet the BuzZ Sessions Moderator

3:15 BuzZ Sessions with Refreshments

BuzZ Sessions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the BuzZ Sessions page on the conference website for a complete listing of topics and descriptions.

IN-PERSON ONLY BUZZ SESSION: Recent Advancements with Viral Vectors

Lizz Carey, Senior Scientist, Vaccine Process Development, Merck

- Applications to gene therapy
- Emerging technologies
- Challenges and ethical considerations
- CRISPR and viral vectors

IN-PERSON ONLY BUZZ SESSION: IN-PERSON ONLY BUZZ SESSION: Strategies for Optimizing AAV Production

Kathy Ngo, PhD, Associate Director, Cell Engineering, CHO Plus

- Engineering better clones and pools
- Vector design strategies and TGE optimization
- Media and feed development for AAV production
- Case studies

PRODUCTION PROCESS DEVELOPMENT AND SCALING UP *(CONT.)*

4:15 Intensification of Downstream Manufacturing of rAAV Using Single Pass Tangential Flow Ultrafiltration

Garima Thakur, PhD, Process Development Engineer III, Viral Production Core, Regeneron Pharmaceuticals, Inc.

VIRAL VECTOR ANALYTICS

4:45 The Challenge of Preparing Viral Vectors for Physicochemical Characterization

Friederike Eilts, PhD, Chair of Bioseparation Engineering, Mechanical Engineering, Technical University of Munich

Preparation of viral vectors poses challenges in terms of stability, concentration, mono-dispersity, and purity. This study compared three protocols using Orf virus vector: steric exclusion chromatography (SXC), SXC combined with centrifugal diafiltration, and sucrose cushion ultracentrifugation. Evaluation parameters included protein removal, size distribution, infectious virus recovery, visual appearance, and electrophoretic mobility at varying pH levels. These quick and user-friendly methods offer potential solutions for efficient viral vector preparation.

5:15 Emerging Analytical Methods to Monitor Quality and Physicochemical Properties of AAV Vectors

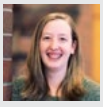
Bartek Blus, PhD, Associate Director, Gene Therapy Research, BioMarin Pharmaceutical, Inc.

With the expanding landscape of gene therapy, there has been a growing need for platform approaches to monitor quality and physicochemical properties of AAV vectors. Emerging analytical methods are often automated, require low sample volumes, and generate high-quality results for various capsid serotypes. Here, I will review recent developments in AAV analytics, highlighting high-throughput methods used to screen and guide selection of lead candidates for research and preclinical studies.

5:45 Grand Opening Welcome Reception in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: YOUNG SCIENTIST MEET UP

Young Scientist Meet Up




Emma Altman, Senior Research Associate, Protein Sciences, Kite Pharma

Kavya Ganapathy, PhD, Postdoctoral Research Fellow, Genentech

Alexandros Karyolaimos, PhD, Researcher, Department of Biochemistry & Biophysics, Stockholm University

Sean Yamada-Hunter, PhD, Postdoctoral Research, Mackall Lab, Stanford Cancer Institute, Stanford University

7:00 Close of Day

WEDNESDAY, JANUARY 17

8:30 am Conference Registration & Morning Coffee

PLENARY FIRESIDE CHAT

9:00 Plenary Session Organizer's Remarks

Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

9:10 PLENARY FIRESIDE CHAT: Supporting and Driving Biotech: Past, Present, and Future

Innovation can refer to something new, such as an invention, or the development and introduction of new practices. Progress and challenges frequently act as the driving force behind this innovation, propelling us toward original ways of thinking and doing. The outcome can materialize as a novel product, yet it extends to novel methodologies, procedures, or modes of thought. This Fireside Chat convenes long-term supporters of PepTalk: The Protein Science and Production Week who explore the following:

- Innovations and technology development in the last 5 years
- Collaborations and strategic partnerships – advice to early-stage/ small companies
- Is there a trend toward diversification of scientists' roles, skill sets and responsibilities? Why?
- What is an unexpected market trend you are seeing?
- What excites you/what keeps you working in this industry?

9:10 Panelists:




Moderator: Jennifer Giottonini Cayer, CBO, Pulmocide; Board of Directors, UCSD Moores Cancer Center and Biocom California

Panelists:

Carter A. Mitchell, PhD, CSO, Purification & Expression, Kemp Proteins, LLC

Eric Vajda, PhD, Vice President, Preclinical R&D, OmniAb

Deborah Moore-Lai, PhD, Senior Director, Protein Development & Production, R&D Leadership, Abcam

PEPTALK PLAZA: MEET THE FIRESIDE CHAT PLENARY SPEAKERS

10:15 Meet the Fireside Chat Plenary Speakers

Stop by the PepTalk Plaza to continue the discussion and ask questions.

10:15 Coffee Break in the Exhibit Hall with Poster Viewing

VIRAL VECTOR ANALYTICS

11:00 Chairperson's Remarks

Friederike Eilts, PhD, Chair of Bioseparation Engineering, Mechanical Engineering, Technical University of Munich

VIRAL VECTOR ENGINEERING & SCALE-UP CONSIDERATIONS

Enhancing Design, Exploring Analytical Techniques, and Understanding Regulations

11:05 Cell-Based Microfluidic Approach for Predicting Adeno-Associated Virus Quality Attributes

Richard Wu, PhD Candidate, Bioengineering, MIT

Bottlenecks in manufacturing strongly add to the high price tag of existing rAAV therapeutics. The current production pipeline lacks real-time monitoring tools for rAAV quality attributes. Here, we developed a microfluidic resonator that rapidly characterizes the biophysical properties of rAAV-producing cells, amenable to real-time monitoring (15 minutes for >3,000 cells). We envision a cell-based approach for monitoring rAAV product attributes with a data-driven model using biophysical properties from rAAV-producing cells.

11:35 Streamlining Potency Assay Development in Cell & Gene Therapies: From Pre-IND to BLA

Alex Santos, MS, Regulatory Scientist, Voisin Consulting Life Sciences

Potency assays in the CGT field are unique to every product and specific to the etiology of the target indication, making it challenging for regulatory bodies to provide generalized guidance and for developers to understand expectations and best practices. This PepTalk will focus on phase-appropriate matrix approaches, technical challenges & criticality in potency assay development, and the regulatory & CMC considerations developers should take into consideration.

12:05 pm Talk Title to be Announced

GYROS PROTEIN Technologies

Germana Sanna, Field Application Specialist, Sales, Gyros Protein Technologies

12:35 Session Break and Transition to Luncheon Presentation

12:45 LUNCHEON PRESENTATION I: Optimizing Harvest and Recovery for High Density Next Generation Biomanufacturing

FILTROX

Brian Bory, Business Development Manager, Life Sciences, Filtrox

Speaker II to be Announced

1:45 Session Break

NOVEL APPROACHES AND REGULATORY COMPLIANCE

2:00 Chairperson's Remarks

Sharee Adams-Hall, Senior Scientist, Pharmaceuticals, Pfizer Inc.

2:05 FEATURED PRESENTATION: Navigating CMC Regulations for Viral Vectors: A Comprehensive Guide

Mauricio S. Umana, PhD, Executive Director, Regulatory Affairs CMC, Regulatory Affairs CMC, MassBiologics

2:35 Application of SEC-MALS for Measuring Multiple CQAs for rAAV Gene Therapies

Sharee Adams-Hall, Senior Scientist, Pharmaceuticals, Pfizer Inc.

Analytics of critical quality attributes are key to developing a robust Adeno-Associated Virus (AAV) production process. Size Exclusion Chromatography with Multi-Angle Light Scattering (SEC-MALS) for AAV is high-throughput, easily implemented, amenable to GMP environment, and requires small sample volume. The study explores SEC-MALS application for process and formulation development analytics of AAVs for capsid content, transgene titer, and capsid titer. Also capsid content determination with multiple orthogonal methods is compared.

3:05 AAV titer (and more) in the blink of an eye with Stunner

UNCHAINED LABS

Ross Walton, PhD, Senior Application Scientist, Unchained Labs

Gathering analytics on AAV chews up too much sample and time. From just microliters of AAV, Stunner delivers high-throughput answers on capsid titer, empty/full ratio and aggregation. Optimize your production processes with the help of low volume analytics that give rapid results so you can always be sure of exactly what's in your sample.

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

4:15 PANEL DISCUSSION: The Synergy of Innovative Analytics, Regulatory Compliance, and Safety in Advancing Viral Vector Research and Development

Moderator: Sharee Adams-Hall, Senior Scientist, Pharmaceuticals, Pfizer Inc.

- Overlooked Regulatory Challenges and Solutions
- Analytical Techniques for Improved Safety Profiles
- Case Studies and Success Stories

Panelists:

Kei Kishimoto, PhD, CSO, Selecta Biosciences, Inc.

Amit Mathur, PhD, Senior Scientist, Genomic Medicine Unit, Sanofi

Mauricio S. Umana, PhD, Executive Director, Regulatory Affairs CMC, Regulatory Affairs CMC, MassBiologics

4:45 Mitigation of AAV Immunogenicity with ImmTOR Tolerogenic Nanoparticles

Kei Kishimoto, PhD, CSO, Selecta Biosciences, Inc.

AAV immunogenicity can adversely affect the safety and durability of gene therapy and prevent the possibility of re-dosing. We have developed tolerogenic ImmTOR nanoparticles that induce antigen-specific tolerance to co-administered antigens and have been shown to mitigate anti-drug antibodies against a fungal enzyme in Phase 3 clinical trials. Here we demonstrate the ability of ImmTOR to mitigate humoral and cellular immune responses to AAV and enable vector redosing.

5:15 Harnessing Emerging Technologies to Develop Optimal Subclonal Host Cell Line for AAV Production

Amit Mathur, PhD, Senior Scientist, Genomic Medicine Unit, Sanofi

The work presented here focuses upon the current and emerging technologies available to produce recombinant adeno-associated virus (AAV)-based viral vectors towards treatment of diseases. We will highlight automation enabled serum-free Sanofi's producer cell lines (PCLs)-based platform for production of gene therapy vectors for delivering safer therapeutics to the patients.

5:45 Close of Viral Vector Engineering & Scale-Up Considerations

JANUARY 18-19, 2024 | Inaugural

NON-VIRAL VECTOR ENGINEERING & SCALE-UP CONSIDERATIONS

Enhancing Design, Process Development, and Workflows: A Scalable Approach

VECTOR DESIGN & DELIVERY

This conference track has been postponed. Please choose an alternative conference or training seminar among those scheduled at PepTalk 2024.

PEPTALK 2024

HIGHER-THROUGHPUT BIOPRODUCTION

The demand for high-quality recombinant proteins for basic research, diagnostics, targets, and therapy continues to expand exponentially. Thus, higher-throughput techniques (HTP) in engineering hosts (CLE), developing cell lines (CLD) and optimizing cell culture for protein expression, purification and quantification expedites flexible bioproduction platforms necessary to meet these demands for both research and manufacturing pipelines. Throughout the week, the **Higher-Throughput Bioproduction** pipeline explores the newest data, innovations, and strategies to make the expression and production of these valuable proteins more efficient, effective, and trouble-free.

JANUARY 16-17

Cell Line Optimization

AGENDA

JANUARY 18-19

Recombinant Protein Expression & Production

AGENDA

TUESDAY, JANUARY 16

7:00 am Conference Registration and Morning Coffee

8:55 Organizer's Welcome Remarks

Nikki Cerniuk, Conference Producer, Cambridge Healthtech Institute

CELL LINE ENGINEERING

9:00 Chairperson's Remarks

Jonathan Diep, PhD, Principal Scientist, Cell Line Development, Amgen, Inc.

9:05 Engineering Translational Regulation for Protein Manufacturing

Peter C. Dedon, PhD, Professor, Biological Engineering, Massachusetts Institute of Technology

Using convergent technologies, we discovered an information-rich scheduling system for gene expression involving the dozens of chemical modifications of RNA in every cell—the epitranscriptome. Stress reprograms the tRNA epitranscriptome to facilitate selective translation of mRNAs critical to cell survival. We are now leveraging this discovery in a variety of applications, including protein manufacturing and cell line engineering.

9:35 MAD7 Nuclease Facilitates Cutting and Site-Specific Integration in CHO Genome

Jonathan Diep, PhD, Principal Scientist, Cell Line Development, Amgen, Inc.

Manufacturing cell lines can benefit from host cell engineering to improve performance and product quality. MAD7 is an engineered class 2 type V-A CRISPR-Cas nuclease (Cas12a/Cpf1) shown to function in a variety of systems, recently including CHO cells. MAD7 can successfully facilitate site-specific indels and knock-ins in CHO, making it a useful tool for engineering in cell line development.

10:05 KEYNOTE PRESENTATION: Engineering Out Metabolic Barriers in CHO Cells

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

Some of the greatest gains in productivity in bioprocessing have come by enhancing cell growth, viability, and resource allocation through clone selection, media screening, and process optimization. However, systems and synthetic biology now provide diverse new tools for cell and process enhancement. Here I highlight how systems biology models, machine learning, and genome editing allow us to build interpretable models and eliminate metabolic barriers to productivity in recombinant protein production.

10:35 Networking Coffee Break

11:00 Engineering Multiple Phenotypes into CHO and HEK-293 Cells to Increase mAb Productivity and AAV Productivity, Respectively

Larry Forman, Founder & CEO, CHO Plus

Our novel cell-engineering platform is based on directed evolution principles. We create engineered cells with diverse and increased gene copy numbers at the chromosomal level by homotypic cell fusions, followed by screening or selecting for desired phenotypes.This platform has been used to create: CHO cells with Qp 117 pg/cell• day for mAbs; HEK-293 cells with 9-fold higher AAV productivity, and 2-fold higher percent full; and CHO cells with 13.5-hour doubling time.

11:30 Improvements in PIK3 Alpha Kinase Production

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

Phosphoinositide 3-kinase (PI3K) is a signal kinase that affects basic cell functions such as growth, metabolism, and motility. Thus, p110a is an ideal therapeutic target for cancer treatment. Previously, Pfizer optimized production of PIK3. We have further optimized production by incorporation of their constructs into our His6-MBP-tev-target expression vector, our Tni-FNL insect line, and buffer optimization achieving a 40-fold increase in yield for p110a/p85 and a 3-fold increase in p110a.

12:00 pm Session Break and Transition to Luncheon Presentation

12:10 LUNCHEON PRESENTATION I: Novel Strategies for Unveiling Optimal Bispecific Antibody Pairings & Scale-Up Production

Jiansheng Wu, PhD, Head of Protein Sciences, VP, Protein Sciences, WuXi Biologics

Bispecific antibody production presents challenges like heterogeneity, production complexity, and stability issues, which can impact final product quality. This talk will disclose innovative strategies to address these challenges in drug development including initial small-scale high-throughput production of a vast number of bsAbs in identifying optimal pairings, as well as later stage large-scale production. Real-world case studies will showcase the successful application of these strategies.

12:40 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:10 Session Break

CELL LINE ENGINEERING *(CONT.)*

1:30 Chairperson's Remarks

Nikolai Petrovsky, PhD, Research Director, Vaxine Pty Ltd.

1:35 Chaperones: They Aren't Just for Dances Anymore

William Gillette, PhD, Principal Scientist / Deputy Director, Protein Expression Laboratory, Frederick National Laboratory for Cancer Research

Long known for their ability to enhance protein folding, the use of chaperones is becoming increasingly important as recombinant protein production projects target more complex proteins and complexes. This talk will highlight some of our labs recent work with, and modifications to, the insect cell/baculovirus platform to enhance the production of several of these challenging target proteins.

CELL LINE DEVELOPMENT

2:05 Advancing Viral Vector Production through Cell Line Development and Engineering

Tianchen Wu, PhD Candidate, Scientist II, Cell Line Development

2:35 Secrets of Secretion - Systemic Modification of the Secretory Capacity Using UNLOCK PICHIA

Iskandar Dib, Principal Scientist Process Development & Analytics, VALIDOGEN GmbH

Pichia pastoris is a highly efficient yeast system for secreted protein production. The effectiveness of entry to, and travel through, the secretory pathway constitutes a major determinant for the successful production of proteins. High efficiency can enable high-yielding economic processes for biopharma, food products and others. Using novel elements of VALIDOGEN's UNLOCK PICHIA toolbox, individual and combined engineering strategies promote improvements for the secretion of a variety of model proteins.

BuzZ Sessions

3:05 Find Your Table and Meet the BuzZ Sessions Moderator

3:15 BuzZ Sessions with Refreshments

BuzZ Sessions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To

get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the BuzZ Sessions page on the conference website for a complete listing of topics and descriptions.

IN-PERSON ONLY BUZZ SESSION: Prokaryotic Innovation

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

- E.coli has been the dominant prokaryotic recombinant expression system for 50 years.
- Improvements in use of chaperones and temperature in E.coli production.
- New expression line Vibrio Natriegens.

IN-PERSON ONLY BUZZ SESSION: IN-PERSON ONLY BUZZ SESSION: Automation in Cell Line Optimization

Vel Murugan, PhD, MBA, Associate Research Professor and Director, Biodesign Institute, Arizona State University

- Role of gene synthesis technologies
- Automation in cell engineering
- High throughput culturing environments
- Functional genomics in cell engineering and optimization

4:15 A High-Fidelity, Dual Site-Specific Integration System in CHO Cells by a Bxb1 Recombinase

Yifeng Xu, PhD, Principal Scientist, Cell Line Development Bioprocess R&D, Pfizer Inc.

Site-specific integration (SSI) via recombinase-mediated cassette exchange has shown advantages for expression of biotherapeutics. We developed a dual-site SSI system having two independent integration sites at different genomic loci, each containing a unique landing pad. The system brings a significant improvement in the efficiency of our cell line development process. The dual landing pad architecture also affords a high degree of flexibility for development of complex protein modalities.

4:45 Desirability of Virus-Free SF9 and Tni Insect Cell Lines for Human Vaccine Manufacture

Nikolai Petrovsky, PhD, Research Director, Vaxine Pty Ltd.

The baculovirus insect cell expression system (BEVS) can be adapted for large-scale manufacture of vaccine proteins and was used to produce the licensed SpikoGen COVID-19 vaccine. Insect cell lines can present various unique challenges, including adventitious viruses and lack of host cell protein assays. Nevertheless, with the right approach they can successfully produce high quality recombinant vaccine proteins at high yield and low cost of goods.

HIGH-THROUGHPUT BIOPRODUCTION

5:15 Proteomic and Transcriptomic Analysis of Cell Lines

Susan Sharfstein, PhD, Professor, Nanobioscience, Nanoscale Science and Engineering, SUNY Polytechnic Institute

In addition to producing increased levels of the protein of interest, higher productivity cell lines undergo a range of physiological changes in response to the increased productivity. In this presentation, I will discuss proteomic and transcriptomic differences between parental cell lines and DHFR-amplified progeny including changes in ribosomal proteins, energetic pathways, proteosomal activity, and tRNA biosynthetic enzymes. In addition, transcription factor alterations were seen, potentially altering transcription rates.

5:45 Grand Opening Welcome Reception in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: YOUNG SCIENTIST MEET UP

Young Scientist Meet Up




Emma Altman, Senior Research Associate, Protein Sciences, Kite Pharma

Kavya Ganapathy, PhD, Postdoctoral Research Fellow, Genentech

Alexandros Karyolaimos, PhD, Researcher, Department of Biochemistry & Biophysics, Stockholm University

Sean Yamada-Hunter, PhD, Postdoctoral Research, Mackall Lab, Stanford Cancer Institute, Stanford University

7:00 Close of Day

WEDNESDAY, JANUARY 17

8:30 am Conference Registration & Morning Coffee

PLENARY FIRESIDE CHAT

9:00 Plenary Session Organizer's Remarks

Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

9:10 PLENARY FIRESIDE CHAT: Supporting and Driving Biotech: Past, Present, and Future

Innovation can refer to something new, such as an invention, or the development and introduction of new practices. Progress and challenges frequently act as the driving force behind this innovation, propelling us toward original ways of thinking and doing. The outcome can materialize as a novel product, yet it extends to novel methodologies, procedures, or modes of thought. This Fireside Chat convenes long-term supporters of PepTalk: The Protein Science and Production Week who explore the following:

- Innovations and technology development in the last 5 years
- Collaborations and strategic partnerships – advice to early-stage/ small companies
- Is there a trend toward diversification of scientists' roles, skill sets and responsibilities? Why?
- What is an unexpected market trend you are seeing?
- What excites you/what keeps you working in this industry?

9:10 Panelists:




Moderator: Jennifer Giottonini Cayer, CBO, Pulmocide; Board of Directors, UCSD Moores Cancer Center and Biocom California

Panelists:

Carter A. Mitchell, PhD, CSO, Purification & Expression, Kemp Proteins, LLC

Eric Vajda, PhD, Vice President, Preclinical R&D, OmniAb

Deborah Moore-Lai, PhD, Senior Director, Protein Development & Production, R&D Leadership, Abcam

PEPTALK PLAZA: MEET THE FIRESIDE CHAT PLENARY SPEAKERS

10:15 Meet the Fireside Chat Plenary Speakers

Stop by the PepTalk Plaza to continue the discussion and ask questions.

10:15 Coffee Break in the Exhibit Hall with Poster Viewing

HIGH-THROUGHPUT BIOPRODUCTION

11:00 Chairperson's Remarks

Susan Sharfstein, PhD, Professor, Nanobioscience, Nanoscale Science and Engineering, SUNY Polytechnic Institute

11:05 Genome-Scale Production of Expression Ready Clones and Distribution

Vel Murugan, PhD, MBA, Associate Research Professor and Director, Biodesign Institute, Arizona State University

The DNASU Plasmid Repository is a global, non-profit organization that facilitates scientific sharing, supporting a growing collection of over 560,000 high-quality plasmids with genes from more than 1,350 organisms in over 750 vector backbones. DNASU provides a central location for researchers to deposit their plasmids upon publication, increasing accessibility and accelerating downstream research. Our human collection contains >18,000 unique ORFs in multiple backbone vectors like pDONR221, pLenti 6.3, and pANT7-cGST.

11:35 Utilizing a Streamlined Automated Workflow to QC Baculovirus Expression

Andrea Partridge, PhD, Senior Scientist, Protein & Structural Chemistry, Merck & Co., Inc.

Challenges exist with the Baculovirus expression system including time and effort to generate, screen, and store large numbers of viruses. To address this we have developed a streamlined process to QC new viral constructs by incorporating off-the-shelf automation platforms, screening miniaturization techniques, and data management platforms. This workflow accelerates viral generation through an improved screening funnel and reduces the total number of viral samples that need to be managed.

12:05 pm Sponsored Presentation *(Opportunity Available)*

12:35 Session Break and Transition to Luncheon Presentation

12:45 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:45 Session Break

CHARACTERIZATION, SCREENING, AND SAFETY CONSIDERATIONS

2:00 Presentation to be Announced

2:05 Impact of Sf-Rhabdoviral Contaminants on Biosafety in the Baculovirus-Insect Cell System

Donald L. Jarvis, PhD, Professor, Molecular Biology, University of Wyoming

The insect cell lines widely used as hosts in the baculovirus-insect cell system are contaminated with adventitous viruses. We assessed the infectivity of Sf-rhabdoviruses for mammalian cell lines and immunocompromised mice to determine their impact on the biosafety profile of this biologics manufacturing platform.

2:35 Strategies for Characterizing High Performance CHO Cell Lines for Biotherapeutic Production

Luke Nelson, Senior Scientist, R&D, Merck

The screening of many random clones that takes place during traditional CHO cell line development offers a wealth of information on the molecular basis of both "good" and "bad" production cell lines. In this presentation I will review studies using genomics, transcriptomics, and morphological profiling to characterize high performance CHO clones and discuss how these lessons can be applied to cell line engineering and clone selection.

3:05 Sponsored Presentation *(Opportunity Available)*

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

4:15 Optimizing Early Candidate Screening and Accelerating Cell Line Development

Zorica Dragic, PhD, Director, Cell Line Screening and Development, Novartis Pharma AG

4:45 Comprehensive Glycoproteomic Characterization of Different Host Cell Lines and Biotherapeutics

Qiong Wang, PhD, Senior Scientist, Mammalian Expression, Pfizer

Glycoproteomic analysis of CHO host cell lines commonly utilized in biopharmaceutical settings is reported with intracellular and secreted glycoproteins examined. Ontogeny analysis revealed key differences, such as general metabolic and biosynthetic pathways, and glycoproteins that are problematic contaminants in bioproduction. Site-specific glycosylation comparisons of recombinant proteins secreted from CHO and HEK cells are also presented to reveal the importance of cell line choice best suited for a particular bioproduction application.

5:15 Harnessing Emerging Technologies to Develop Optimal Subclonal Host Cell Line for AAV Production

Amit Mathur, PhD, Senior Scientist, Genomic Medicine Unit, Sanofi

The work presented here focuses upon the current and emerging technologies available to produce recombinant adeno-associated virus (AAV)-based viral vectors towards treatment of diseases. We will highlight automation enabled serum-free Sanofi's producer cell lines (PCLs)-based platform for production of gene therapy vectors for delivering safer therapeutics to the patients.

5:45 Close of Cell Line Optimization Conference

THURSDAY, JANUARY 18

7:45 am Conference Registration & Morning Coffee

8:25 Organizer's Welcome Remarks

Mary Ann Brown, Executive Director, Conferences, Team Lead, PepTalk, Cambridge Healthtech Institute

UNDERSTAND YOUR HOST AND KNOW YOUR RECOMBINANT PROTEIN

8:30 Chairperson's Opening Remarks

Christa Cortesio, PhD, Director, Protein Science, Protein Biochemistry & Analytics Core, Kite Pharma

8:35 FEATURED YOUNG SCIENTIST: Identifying Drivers of Cellular Productivity Using HRP-Based Proximity Labeling

Frances Maureen Rocamora, PhD, Project Scientist, Pediatrics, University of California, San Diego

Identifying essential molecular mechanisms involved in protein secretion can inform rational strategies for cellular engineering and recombinant protein production. Here, we used biotinylation by antibody recognition to investigate the host cell secretory machinery supporting the synthesis and secretion of a monoclonal antibody, rituximab, in a panel of CHO cells. We aim to identify the cellular processes and candidate components of the secretory machinery that significantly impact recombinant protein productivity.

9:05 *Pichia pastoris*: The Ideal Eukaryotic Expression System for Heterologous Protein Synthesis

Angela Gelli, PhD, Professor, Department of Pharmacology, School of Medicine, University of California, Davis

Pichia pastoris yeast is a highly useful eukaryotic protein expression system due to its low cost, genetic tractability, rapid gene expression, and scalability. We developed and optimized a protocol in which we can routinely generate recombinant metalloproteases that are pure and proteolytically active for downstream applications. By altering the feeding regime, through implementation of non-fermentable and non-repressing carbon source during the methanol induction phase, we maximized growth and protein production.

9:35 Protein Production from HEK293 Cell Line-Derived Stable Pools with High Protein Quality and Quantity to Support Discovery Research

Songyu Wang, PhD, Senior Scientist, Protein Technologies Group, Amgen

We present a robust method for expressing proteins in human embryonic kidney 293 (HEK293)-derived stable pools, leading to recombinant protein products with much less clipped species compared to those expressed in CHO cells. The protocol is also applicable to HEK293S GnTI- (N-acetylglucosaminyltransferase I–negative) and Expi293F GnTI- suspension cells, facilitating production of high yields of proteins with less complex glycans for use in structural biology projects.

10:05 HIGH-SPEED IDENTIFICATION OF SUPERIOR ESETEC® PRODUCTION STRAINS WACKER

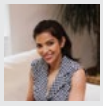
Philipp Schmid, Dr., Process Development, Wacker Biotech

Finding the right strain-plasmid combination for soluble recombinant protein production in *E. coli* can be challenging and time-consuming. To accelerate this laborious task, we developed a multi-stage combinatorial screening workflow that allows automated parallel cloning, transformation, and screening of up to 900 ESETEC® single clones per target protein. Productivity of the clones is assessed from sub-milliliter batch cultivation to liter-scale fermentation and allows rapid identification of superior ESETEC® production strains.

10:20 Presentation to be Announced

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: ELECTRONIC CONNECTIONS TRAINING



Electronic Connections Training

Nandini Kashyap, Senior Director, Conferences and Social Media Strategy, Cambridge Healthtech Institute

Looking to make connections but no longer carry a paper business card with you? Join us for this event to share your electronic business card, LinkedIn profile, or to connect on the PepTalk app.

EXPRESSION AND PRODUCTION OF UNIQUE PROTEINS

11:15 Immunogen and Screening Protein Productions to Develop a Specific and Sensitive Antibody for Viral Coat Protein Detection

Christa Cortesio, PhD, Director, Protein Science, Protein Biochemistry & Analytics Core, Kite Pharma

Introduction of chimeric antigen receptor (CAR)-encoding DNA into primary human T cells via viral transduction is a critical step in CAR T manufacturing. Characterization of infective viral particles is important to ensure a robust process. Here, we describe the design and production of a recombinant viral envelope protein to generate and screen for sensitive and specific detection antibodies, allowing additional characterization of viral particles.

11:45 Fluorescent Protein Production, Purification, and Coupling to Microspheres

Marija Dramicanin, PhD, Head, Protein Production Facility, Walter & Eliza Hall Institute of Medical Research

Fluorescent proteins (FPs) are essential in biological research, but their wide excitation range causes issues in traditional cytometry due to spectral overlap. Full-spectrum flow cytometers simplify analysis by removing the need for frequent filter changes. Producing FPs in *Escherichia coli*, purifying, and coupling them to microspheres offers a cost-effective, convenient method with long-term storage capability and easy multi-color analysis. This simplifies experiments involving multiple FPs or protein-coupled microspheres.

12:15 pm Session Break and Transition to Luncheon Presentation

12:25 LUNCHEON PRESENTATION I: Discover the ProteoAnalyzer System: Automated Protein Analysis that is Parallel to None Agilent

Kyle Luttgeharm, PhD, Product Manager, DGG - Integrated Genomics Division, Agilent Technologies

Chris Wenz, R&D Scientist, DGG - Integrated Genomics Division, Agilent Technologies

Parallel capillary electrophoresis is a powerful technique for automated protein analysis. The ProteoAnalyzer system is a novel instrument that uses this technique to overcome the limitations of traditional methods. It features 12 capillaries, validated reagents, and automated maintenance, enabling you to obtain high quality data for various protein sample types. Join our seminar to learn how the ProteoAnalyzer system can transform your protein analysis workflow.

12:55 LUNCHEON PRESENTATION: Corynex® : Microbial production platform for GLP-1 related peptides AJINOMOTO

Hayato Nagano, PhD, Researcher, Biopharma Solutions Group, Research Institute for Bioscience Products & Fine Chemicals, Ajinomoto Co., Inc.

Ajinomoto Bio-Pharma Services as a fully integrated CDMO offers a broad range of innovative platform technologies and end-to-end solutions for biopharmaceutical development and manufacturing. In this presentation, we will introduce our CDMO capabilities and highlight the Corynex® protein and

peptide expression platform technology, including its application towards the highly productive, scalable and sustainable manufacture of GLP-1 related peptides and VHHs.

1:25 Session Break

EXPRESSION AND PRODUCTION OF DIFFICULT-TO-EXPRESS PROTEINS

1:45 Chairperson's Remarks

Robert M. Hughes, PhD, Associate Professor, Chemistry, East Carolina University

1:50 *In vitro* Glycosylation of Recombinantly Expressed Membrane Proteins

Gabriel A. Cook, PhD, Assistant Professor, Department of Chemistry, Oklahoma State University

Glycoproteins take part in nearly every biological process and make up a large percentage of the proteome. We are specifically interested in the properties of membrane glycoproteins, which are key components in a number of different disease states. Our experiments demonstrate that recombinantly expressed full-length membrane proteins that contain an N-glycosylation consensus sequence can be glycosylated by N-glycosyltransferase, even in the presence of membrane mimetic environments.

2:20 Going to the Source: Purification from the Native Host to Obtain Difficult-to-Produce Proteins and to Gain Novel Biological Insights

Rhys Grinter, PhD, Lab Head, Molecular Physiology of Microbial Pathogens Laboratory, Monash University

Recombinant expression has revolutionised protein production. However, many proteins cannot be expressed in available systems. This is especially true for membrane proteins and complex enzymes. An alternative strategy is the purification of these proteins directly from their host organism by the genetic introduction of affinity tags. Yields from this purification strategy are compatible with modern structural and biochemical characterisation—and preservation of the host context provides new biological insights.

2:50 Structural Interrogation of Vaccine-Induced Humoral Responses to the Lassa Virus Glycoprotein

Hailee Perrett, PhD, Research Associate, Scripps Research Institute

The LASV glycoprotein complex (GPC) mediates viral entry and is the sole target of neutralizing antibodies. LASV vaccine design is complicated by the metastability of the GPC. We describe the development of prefusion-stabilized, trimeric GPC ectodomains. Further, we define the polyclonal antibody response post-vaccination, demonstrating the immunodominance of off-target epitopes and emphasizing the need for further GPC engineering.

3:20 Immobilized Enzymes as Benchtop Reagents for Biochemists? Two Case Studies

Robert M. Hughes, PhD, Associate Professor, Chemistry, East Carolina University

Biochemists have long used enzyme immobilization as a route to robust and reusable biocatalysts. However, the scope of enzymatic activities successfully recapitulated in immobilized form has remained relatively narrow, limiting potential applications. The advent of orthogonal protein and peptide coupling methodologies presents a broadly applicable solution to this problem. We will describe our approach to recapitulating the activities of TEV protease and cAMP-dependent protein kinase (PKA) in immobilized form.

3:50 Refreshment Break in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: SPEED NETWORKING

Speed Networking


Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

Christina Lingham, Executive Director, Conferences and Fellow, Cambridge Healthtech Institute

Bring yourself, and your business cards, and be prepared to share and summarize the key elements of your research in a minute. PepTalk will provide a location, timer, and fellow attendees to facilitate the introductions.

PLENARY KEYNOTE SESSION

4:35 Sponsored Plenary Introduction (Opportunity Available)

4:45 Protein and Gene Therapy Biotherapeutics: Biophysics, Simulations, and Analytical Tools to Shed Light on Biomanufacturability and Downstream Bioprocessing Opportunities

Steven M. Cramer, PhD, William Weightman Walker Professor, Isermann Department of Chemical and Biological Engineering, Rensselaer Polytechnic Institute

This talk will illustrate how a combination of biophysics, simulations, and analytical tools can be employed for a deeper understanding of the molecular basis for important biomanufacturability properties as well as the purification of both protein and gene therapy biotherapeutics from their product- and process-related impurities. In addition, the unique challenges of gene therapy bioprocessing will be discussed from the perspective of proper analytical definition of the "biological product."

5:30 Networking Reception in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: WOMEN IN SCIENCE MEET UP

Women In Science



Christa Cortesio, PhD, Director, Protein Science, Protein Biochemistry & Analytics Core, Kite Pharma

Marija Dramicanin, PhD, Head, Protein Production Facility, Walter & Eliza Hall Institute of Medical Research

Deborah Moore-Lai, PhD, Senior Director, Protein Development & Production, R&D Leadership, Abcam

CHI is proud to offer programming that honors and celebrates the advancement of diversity in the life sciences. We recognize that barriers preventing women from fully participating in the sciences are not just barriers to equality, but also critically deter scientific advancement worldwide. Our Women in Science programming invites the entire scientific community to discuss these barriers, as we believe that all voices are necessary and welcome.

6:30 Close of Day

FRIDAY, JANUARY 19

7:30 am Conference Registration

BuzZ Sessions

7:45 BuzZ Sessions with Continental Breakfast

BuzZ Sessions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the BuzZ Sessions page on the conference website for a complete listing of topics and descriptions.

IN-PERSON ONLY BUZZ SESSION: Common Issues with Transient Protein Production

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

Henry C. Chiou, PhD, Senior Director General Manager, Biosciences, Thermo Fisher Scientific

- What are the current challenges to transient protein production?
- How do we optimize the whole protein expression workflow process?
- How can we maintain volumetric yields while scaling transient expression up or down?
- What cell line(s) should we use and when?
- What parameters can impact the quality or physical attributes of transiently produced proteins?

IN-PERSON ONLY BUZZ SESSION: Protein Interest Group (PIG) – Online Community of Protein Scientists

Oleg Brodsky, Senior Principal Scientist, Structural Biology & Protein Sciences, Pfizer Inc.

- What is the Protein Interest Group (PIG), and what it isn't
- How do we share our knowledge and experiences pre-competitively, aside from published manuscripts
- Logistics, topics covered, group remit
- How to become a member

8:45 Transition to Conference Track

MEETING DEMANDS WITH HIGHER-THROUGHPUT BIOPRODUCTION

9:00 Chairperson's Remarks

John Dresios, PhD, Executive Director, Biological Innovations Center; Leidos Technical Fellow & Solutions Architect, Applied Science Division, Leidos Innovations Center, Leidos, Inc.

9:05 Maximizing Effectiveness of Protein Expression Screening for Drug Discovery

Inna Zilberleyb, Scientist IV, Biomolecular Resources, Genentech, Inc.

Recombinant protein production is an integral part of drug discovery. As therapeutic targets become more challenging, we evolve our methods to triage protein variants more efficiently, while reducing cost and shortening timelines. We have developed a multi-host mid-scale expression and screening platform to supplement our existing small-scale high-throughput expression analysis. The semi-automated workflow is integrated with robotic liquid handlers and provides sufficient quantities of proteins for biochemical and structural screening.

9:25 SPOC: An Advanced Proteomic Platform for Ultra-High-Throughput Production and Kinetic Analysis of Functional Protein Arrays

Chidozie Victor Agu, PhD, Manager, Bioassay Development, INanoBio, Inc.

Sensor-Integrated Proteome on Chip (SPOC) technology enables real-time, high-throughput kinetic analysis of biomolecular interactions. By automating *in situ* production and capture-purification of fully-folded functional protein arrays on biosensors, SPOC can simultaneously analyze 1000 unique proteins on single SPR sensor, providing quantitative, qualitative, and kinetic information for all targets. SPOC finds application in drug discovery for off-target binding screening, serology and antigen identification for vaccine development, and biomarker discovery for diagnostics.

9:45 An Integrated *in vivo* & *in vitro* Bacterial Protein Production Platform for Next-Generation Site-Specific Antibody Drug Conjugates

Jacquelyn Blake-Hedges, PhD, Scientist, Protein Biochemistry, Sutro Biopharma

Sutro Biopharma's XpressCF+ cell-free protein synthesis (CFPS) system is a powerful platform to produce antibodies containing non-natural amino acids that facilitates homogenous site-specific conjugation of ADCs. A novel hybrid IgG production process has been developed in which light chains, pre-fabricated in *E. coli*, are added to CFPS reactions to produce full-length antibodies. This integrated process increases CFPS titers and enables the production of high DAR and dually conjugated ADCs.

10:05 Innovation in mAbs purification using affinity chromatography resins based on proprietary rProtein A

Simona Serban, Dr, Global Application Director, Life Sciences Division, Sunresin New Materials Co. Ltd

Using a multidisciplinary approach involving biologists, biochemists and polymer chemists, we created a new approach to the development of a new rProtein A for affinity chromatography resins. The impact of different steps in the expression, production and purification of rProtein A is followed by a study on the effect of the rProtein A coupling chemistry on agarose and methacrylic porous beads and comparative test performance in mAb chromatographic purification processes.

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

PEPTALK PLAZA: POST-PEPTALK CONNECTIONS

Post-PepTalk Connections


Kevin Brawley, Associate Project Manager, Production Operations & Communications, Cambridge Innovation Institute

Kent Simmons, Senior Conference Director, Cambridge Healthtech Institute

- How will our onsite app benefit your networking after the conference?
- How to view on-demand presentations to maximize your conference experience

11:15 Development of a High-Yield CHO-Cell Free Protein Expression System

John Dresios, PhD, Executive Director, Biological Innovations Center; Leidos Technical Fellow & Solutions Architect, Applied Science Division, Leidos Innovations Center, Leidos, Inc.

Mammalian cell-free protein synthesis systems hold promise as platforms for rapid generation of proteins with complex posttranslational modifications (PTMs). However, current approaches suffer from low protein yields, variable expression levels, and insufficient PTMs. We describe Leidos' approach

combining novel mRNA engineering and biochemical technologies for the development of CHO cell-free systems enabling rapid, on-demand, high-yield production of various protein classes using plug-and-play chassis systems with optimized molecular components.

11:35 Streamlining Cell-Free Protein Expression Systems for Low-Cost On-Demand Medical Diagnostics and the Production of Personalized Magistral Biotherapeutics

Bradley C. Bundy, PhD, Associate Professor, Faith & Learning Fellow, Chemical Engineering, Brigham Young University

In vitro "Cell-Free" Protein Synthesis systems hold disruptive potential within the protein pharmaceutical and medical diagnostics industries. Recent engineering advancements have paved the way for the on-demand production of biotherapeutics at the point-of-care. This capability is vital in facilitating magistral and personalized treatments, disrupting the way we approach healthcare. Furthermore, notable progress has been made in the development of "cell-free" at-home colorimetric biosensors, opening up new possibilities for personalized cancer treatment.

11:55 Automated Model-Based Optimization of Difficult-to-Express Protein Expression in a Robotic Facility

Niels Jonas Krausch, PhD, Postdoc, Bioprocess Engineering, Technische University Berlin

The KIWI-biolab enables efficient recombinant bioprocess development and optimization on a robotic platform with fully automatic orchestration of parallel bioreactor systems of different scales, analytical instruments, and a mobile laboratory robot. Based on FAIR data principles it allows self-controlled parallel fed-batch cultivations, integrated sample analysis, and mathematical model-based parameter calibration and CQA optimisation. The power of the platform is demonstrated by industrially relevant recombinant processes including Fabs, elastins, and hydrogenase.

12:15 pm Session Break and Transition to Luncheon Presentation

12:25 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:55 Session Break

1:00 Ice Cream & Cookie Break in the Exhibit Hall with Last Chance for Poster Viewing

OPTIMIZING WORKFLOWS IN BIOPRODUCTION LABS

1:45 Chairperson's Remarks

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

1:50 Managing Parallel Protein Production Workflows in a Matrixed Organization

Oleg Brodsky, Senior Principal Scientist, Structural Biology & Protein Sciences, Pfizer Inc.

The Structural Biology and Protein Sciences group plays a key role within Pfizer's oncology research organization, supporting and enabling early-stage small-molecule drug discovery efforts. Operating at the interface of discovery technologies and medicinal chemistry, the group generates recombinant proteins for hit identification, lead optimization, biochemical assay development, and structure-based drug design campaigns. Successful process development and workflow optimization strategies will be highlighted in this presentation.

2:10 Strategies for Task Prioritization, Maximum Productivity, and Career Development

Christa Cortesio, PhD, Director, Protein Science, Protein Biochemistry & Analytics Core, Kite Pharma

Protein production and biochemistry teams encounter different challenges associated with supporting chimeric antigen receptor (CAR) T cell therapy development depending on the program stage. Effective and concurrent support of discovery research through clinical development requires different activities, careful planning, and effective task prioritization. These activities offer career development opportunities for individual team members, which must be properly balanced with meeting ambitious productivity goals.

2:30 CRDMOs Management: Experience From Targeted LNP (tLNP) Platform

QC Yong, Antibody CMC, Associate Director, Capstan Therapeutics

Targeted lipid nanoparticles (tLNP), which allows delivery of payloads to selected populations of cells through targeting moieties, is one of the most promising therapeutic concepts of the near future. Due to the complexity of tLNPs as a drug product, it is very challenging to manage multiple CDMOs/CROs to develop and manufacture multiple intermediates, drug substance, and the eventual drug product. This talk will share some experiences in management of CDMOs/CROs.

2:50 Navigating Data Management Challenges in High-Throughput Expression Labs

Andrea Partridge, PhD, Senior Scientist, Protein & Structural Chemistry, Merck & Co., Inc.

A common issue in high throughput expression labs is data management. Typical work streams require managing multiple types of data across systems incapable of crosstalk. Tracking all of these data streams usually requires heavy IT support, increases the burden on scientists, and severely limits the ability to mine the data to identify trends. An interesting question follows: Is higher throughput better if it leads to a data management crisis?

3:10 IN-PERSON ONLY: Workflow Think Tanks: Collaboration on Reducing Costs, Challenges, and Opportunities

Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

Join a Think Tank group to share and experience and hear what others have learned:
1) Workflow vs. technology development?
2) Scale-up: when and how to go from research to manufacturing?
3) Doing more with less: how do you test new methods and workflows without blowing up your annual budget?
4) Keeping staff motivated and engaged?
5) Tearing down silos: how do you foster cross-functional collaborations to innovate and improve?

3:55 PANEL DISCUSSION: Bioproduction Lab Challenges: Methodologies, Strategies, and the Art of Managing Multiple Projects

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

Research laboratories provide crucial support to drug discovery efforts. As we would expect, there are numerous challenges in the effective operation of these critically needed facilities. This panel discussion will focus on the concepts, technologies, and strategies necessary to meet the ever-increasing need for biotherapeutics.

- Prioritizing projects or asking the right questions
- Total workflow efficiency
- Engaging and developing team members
- The importance of tech development to long-term success

Panelists:
Oleg Brodsky, Senior Principal Scientist, Structural Biology & Protein Sciences, Pfizer Inc.
Christa Cortesio, PhD, Director, Protein Science, Protein Biochemistry & Analytics Core, Kite Pharma
Andrea Partridge, PhD, Senior Scientist, Protein & Structural Chemistry, Merck & Co., Inc.
QC Yong, Antibody CMC, Associate Director, Capstan Therapeutics

4:30 Close of Conference

PRESENT A POSTER AND SAVE $50!

Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions. To secure an onsite poster board and/or ensure your poster is included in the conference materials, your full submission must be received, and your registration paid in full by December 1, 2023.

LEARN MORE

Reasons you should present your research poster at this conference:

- Your research will be seen by our international delegation, representing leaders from top pharmaceutical, biotech, academic and government institutions
- Discuss your research and collaborate with other attendees
- Your poster will be published in our conference materials
- Receive $50 off your registration

CAMBRIDGE HEALTHTECH INSTITUTE IS PROUD TO SUPPORT AND RECOGNIZE THE SCIENTISTS OF TOMORROW!

Full-time graduate students and PhD candidates qualify for the student rate. Students are encouraged to present a research poster.

- Receive a poster presentation slot and a savings off your registration fee
- Present your research poster to an international delegation representing leaders from top pharmaceutical, biotech, academic and government institutions
- Network with potential employers and contacts to further your research and form collaborations

MEDIA SPONSORS

SPONSORING ORGANIZATIONS:

ANTIBODY SOCIETY

CAS 华人抗体协会 CHINESE ANTIBODY SOCIETY

OFFICIAL PUBLICATION:

Bio·IT World

LEAD SPONSORING PUBLICATIONS:

GEN Genetic Engineering & Biotechnology News

The Scientist EXPLORING LIFE, INSPIRING INNOVATION

SPONSORING PUBLICATIONS:

American Pharmaceutical Review

DDN EXPLORING DRUG DISCOVERY AND DEVELOPMENT

Pharmaceutical Outsourcing

WEB PARTNERS:

Gene Therapy Net .com

BIG4BIO

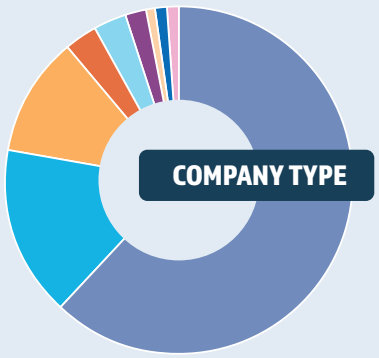
Biocompare The Buyer's Guide for Life Scientists

labcompare The Buyer's Guide for Laboratory Equipment

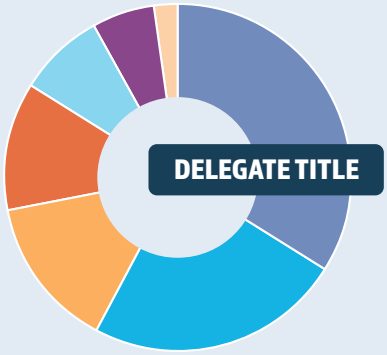
PepTalk 2023 EXHIBITORS

- 3M Health Care Business
- 908 Devices Inc
- Absolute Biotech
- Abterra Biosciences
- Acrobiosystems
- Ajinomoto Bio Pharma Svcs
- Applied BioMath LLC
- Biocytogen Boston Corp
- Biointron Biological USA Inc
- Biosynth Intl Inc
- Biotage US
- Bon Opus Biosciences LLC
- Bruker Scientific LLC
- Chemglass Life Sciences
- Constant Systems Ltd
- Coriolis Pharma Research GmbH
- Correlia Biosystems
- Creative Biolabs
- Cytiva
- ExcellGene Inc
- Fida Biosystems ApS
- Fluidic Analytics
- FyoniBio
- Gator Bio Inc
- GenScript USA Inc
- Gyros Protein Technologies
- Harbour BioMed
- Hauptman Woodward Medical Research Institute
- ImmunoPrecise Antibodies
- Immuto Scientific
- Infors HT USA Inc
- Kaneka Americas Holding Inc
- KBI Biopharma
- Kemp Proteins a Six 02 Bioservices Co
- Kuhner Shaker Inc
- KYinno
- Mimotopes Pty Ltd
- MOBILion Systems Inc
- Molecular Devices LLC
- OmniAb
- Pace Analytical Life Sciences
- Pall Life Sciences
- PBS Biotech Inc
- Pfanstiehl Inc
- Polysciences Inc
- Prestige Biologics Co Ltd
- Protein BioSolutions Inc
- ProteoGenix
- Purolite Ltd
- Rapid Novor Inc
- RedShiftBio
- Refeyn Ltd
- Revvity Signals
- RheoSense Inc
- Sanyou Biopharmaceuticals Co Ltd
- SCIEX
- Shanghai Model Organisms Ctr Inc
- Synbio Technologies
- TA Instruments
- Triplebar Bio
- Unchained Labs
- Wheeler Bio
- WuXi AppTec Sales Discovery
- WuXi Biologics
- Yokogawa Fluid Imaging Technologies Inc

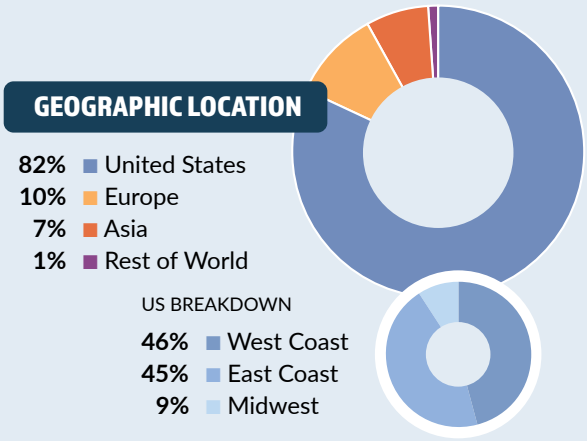
2023 ATTENDEE DEMOGRAPHICS



62% Biotech
16% Pharma
11% Academic
3% Government
3% Healthcare
2% Societies
1% Services
1% CRO
1% Other



34% Scientist/ Technologist
24% Sales & Marketing
14% Director
8% Executive
6% Manager
2% Professor
2% Assistant



82% United States
10% Europe
7% Asia
1% Rest of World

US BREAKDOWN

46% West Coast
45% East Coast
9% Midwest

FOR INFORMATION REGARDING SPONSORSHIP AVAILABILITY, 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

HOTEL & TRAVEL

Conference Venue and Hotel:
Hilton San Diego Bayfront
1 Park Boulevard
San Diego, CA 92101

Discounted Room Rate: $286 s/d
includes complimentary Wi-Fi

Discounted Room Rate Cut-off Date: December 19, 2023

VISIT THE TRAVEL PAGE CHI-PepTalk.com
to make your hotel reservations and for additional information

SAVE $100 off the Conference Registration by reserving your Hotel Room with the Hilton San Diego Bayfront!

Your reservation must be made under the Peptalk Room block for a minimum of 4 nights. Must be reserved by December 19, 2023. Only one discount applicable per hotel room.

Can't Make it to San Diego?

Connect from anywhere.
Join via our robust virtual platform and access these dynamic features.

- INTUITIVE INTERFACE
- COMPANY BRANDING (LOGO)
- DOWNLOADS
- LIVE CHAT
- LIVE SESSIONS
- RECORDED SESSIONS
- POSTER SESSIONS
- PANEL DISCUSSIONS

23rd Annual

PEPTALK 2024

January 16-19, 2024 | San Diego, CA | HILTON SAN DIEGO BAYFRONT AND ONLINE

STANDARD PACKAGE

(Includes access to ALL conferences and training seminars (4 days) & networking events. Plus, on-demand access. You are allowed to move between conference tracks to attend presentations taking place at the same time.)

	COMMERCIAL	ACADEMIC, GOVERNMENT, HOSPITAL-AFFILIATED
ADVANCE REGISTRATION RATES UNTIL DECEMBER 8	$3,099	$1,499
STANDARD PRICING AFTER DECEMBER 8 AND ONSITE	$3,299	$1,599

BASIC PACKAGE

(Includes access to ONE conference or training seminar (2 days) & networking events. Plus, on-demand access. You are allowed to move between conference tracks to attend presentations taking place at the same time.)

	COMMERCIAL	ACADEMIC, GOVERNMENT, HOSPITAL-AFFILIATED
ADVANCE REGISTRATION RATES UNTIL DECEMBER 8	$2,049	$1,049
STANDARD PRICING AFTER DECEMBER 8 AND ONSITE	$2,249	$1,149

POST-EVENT ON-DEMAND ONLY OPTIONS

Includes post-event recorded access to ALL conference programs. Does not include access to live Q&A or networking.

	COMMERCIAL	ACADEMIC, GOVERNMENT, HOSPITAL-AFFILIATED
ADVANCE REGISTRATION RATES UNTIL DECEMBER 8	$2,634	$1,274
STANDARD PRICING AFTER DECEMBER 8 AND ONSITE	$2,804	$1,359

CONFERENCE DISCOUNTS*

GROUP DISCOUNTS ARE AVAILABLE
Have your colleagues or team attend PepTalk: The Protein Science and Production Week In-Person or Virtually. Purchase a full-price registration, and participants from the same organization will receive a 20% discount.

For more information on group discounts contact Uma Patel at 781-972-5447.

ALUMNI DISCOUNT–SAVE 20%: CHI appreciates your participation at our 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 December 1, 2023.
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 content in various marketing materials and products.

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

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!

Please refer to the Registration Code below:

Cambridge HEALTHTECH Institute
A Division of Cambridge Innovation Institute

250 First Avenue, Suite 300
Needham, MA 02494
Healthtech.com
Fax: 781-972-5425