24th Annual

PepTalk

The Protein Science and Production Week

January 13-16, 2025 | San Diego, CA + Virtual
Hilton San Diego Bayfront

ADVANCE SAVINGS!
REGISTER BY DECEMBER 6
SAVE UP TO $200

2025 PROGRAMS

- PROTEIN EXPRESSION
- HIGHER THROUGHPUT
- DEVELOPABILITY AND CHARACTERIZATION
- TARGETED THERAPIES - NEW
- ANTIBODY ENGINEERING

PLENARY SESSIONS

Rethinking Transgene Design for Protein Expression

JARROD SHILTS, PHD,
R&D Lead Scientist, ExpressionEdits Ltd.

FIRESIDE CHAT

Navigating the Professional Landscape: Strategic Pathways to Biotech Success

Delve into the intricate career journeys of protein scientists and how strategic collaborations influence success in biotech.

Includes Access to
BioLogic SUMMIT 2025
AI/ML for Biologic Drug Development

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CHI-PepTalk.com

Organized by Cambridge Healthtech Institute

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ABOUT THE EVENT

Join us at PepTalk, the premier conference dedicated to advancing biotherapeutic discovery and development. With over two decades of experience, PepTalk provides comprehensive programming and innovative solutions that bridge biotherapeutic research and practical application. Throughout the week, precise and dedicated pipelines offer symposia, conference tracks, and training seminars focused on protein expression, production platforms, lab automation for higher throughput, analytical methods including developability and characterization, antibody discovery and development, and new this year, targeted therapies and drug delivery systems. Learn from expert speakers, engage with a devoted community, and gain valuable tools to propel your research forward.

CONFERENCE PROGRAMS feature keynote presentations, case studies, and new unpublished data from influential leaders in academia and industry.

SYMPOSIA align with the overarching pipeline theme, are led by esteemed researchers and thought leaders, and will offer an invaluable opportunity to delve into technical nuances often overlooked, and feature interactive discussions, panel talks, and podium presentations.

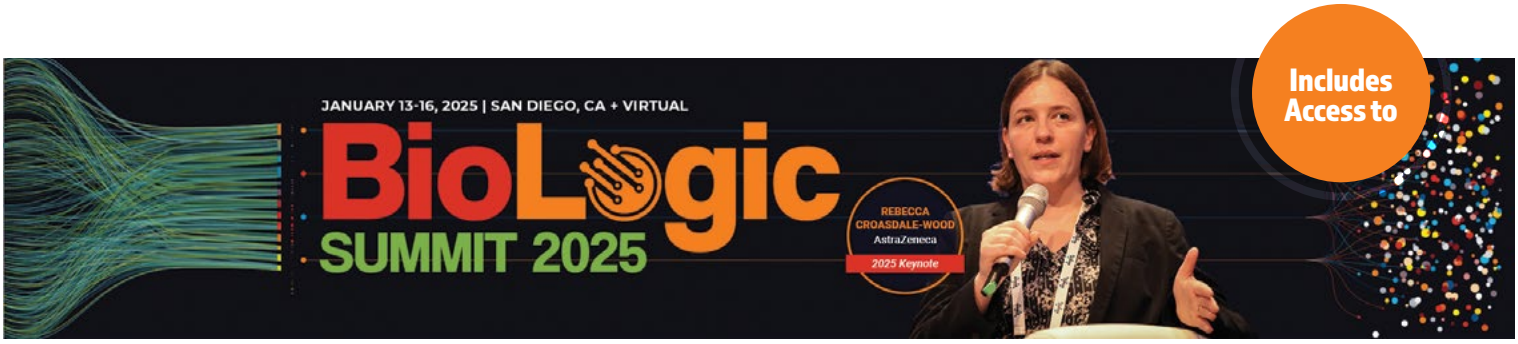
TRAINING SEMINARS offer focused instruction in topics related to your field using a mix of lecture and interactive discussion formats and are led by experienced instructors. These may be combined with conferences to customize your week at PepTalk.

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.



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PepTalk

January 13-16, 2025
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CONFERENCE PROGRAMS

click title to view program

PROTEIN EXPRESSION

SYMPOSIUM: (Re)Discovering Protein Expression Platforms

- Recombinant Protein Production - Part 1
- Recombinant Protein Production - Part 2

HIGHER THROUGHPUT

SYMPOSIUM: Predictive Protein Production

- Automation in Protein Sciences
- Cutting-Edge Tools for Purification and Quality Assurance

DEVELOPABILITY AND CHARACTERIZATION

SYMPOSIUM: ML and Predictive Methods in Analytical Development

- Methods for Developability Analysis
- Characterization for Novel Biotherapeutics

TARGETED THERAPIES NEW

SYMPOSIUM: Vectors for Targeted Delivery

- Targeted Radioligand Therapies
- Next-Generation Protein Degradation

ANTIBODY ENGINEERING

SYMPOSIUM: Bispecific Engineering & Therapeutics

TRAINING SEMINAR: Introduction to Antibody Engineering

TRAINING SEMINAR: Antibody Drug Discovery

#CHIPepTalk

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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.

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PepTalk

The Protein Science and Production Week

2025 PROGRAMS

	JANUARY 13 | SYMPOSIA	JANUARY 14-15	JANUARY 15-16
PROTEIN EXPRESSION	(Re)Discovering Protein Expression Platforms	Recombinant Protein Production - Part 1	Recombinant Protein Production - Part 2
HIGHER THROUGHPUT	Predictive Protein Production	Automation in Protein Sciences	Cutting-Edge Tools for Purification and Quality Assurance
DEVELOPABILITY AND CHARACTERIZATION	ML and Predictive Methods in Analytical Development	Methods for Developability Analysis	Characterization for Novel Biotherapeutics
TARGETED THERAPIES - NEW	Vectors for Targeted Delivery	Targeted Radioligand Therapies	Next-Generation Protein Degradation
ANTIBODY ENGINEERING	Bispecific Engineering & Therapeutics	TRAINING SEMINAR Introduction to Antibody Engineering	TRAINING SEMINAR Antibody Drug Discovery

TS TRAINING SEMINARS

TUESDAY - WEDNESDAY

- Introduction to Antibody Engineering
- Advanced Purification of Engineered Biologics and Research Protein Tools
- Bridging the Gap from R&D to Bioprocessing

WEDNESDAY - THURSDAY

- Antibody Drug Discovery: From Target to Lead

PLENARY SESSIONS

KEYNOTE SPEAKER:

Wednesday, January 15, 11:45 AM – 12:30 PM

Rethinking Transgene Design for Protein Expression

JARROD SHILTS, PHD,
R&D Lead Scientist, ExpressionEdits Ltd.

FIRESIDE CHAT:

Wednesday, January 15, 1:55 – 2:30 PM

Navigating the Professional Landscape: Strategic Pathways to Biotech Success

Delve into the intricate career journeys of protein scientists and how strategic collaborations influence success in biotech.

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IN-PERSON ONLY

PepTalk

Training SEMINARS

By Cambridge Healthtech Institute

TUESDAY, JANUARY 14, 2025 8:30 AM - 6:30 PM
WEDNESDAY, JANUARY 15, 2025 8:30 AM - 11:00 AM

TS5B: Introduction to Antibody Engineering

Instructors:

Andrew R.M. Bradbury, MD, PhD, CSO, Specifica, an IQVIA business

James D. Marks, MD, PhD

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.

TS6B: 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.

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.

TS7B: Bridging the Gap from R&D to Bioprocessing

Instructors:

Carissa L. Young, PhD, Senior Director, Development Asset Lead, Biogen

Marieke Koedood Zhao, PhD, Independent Consultant, Bioprocess Development

Do you seek to better understand end-to-end operations in drug development; gain clarity of biotech-pharma functions, cross-functional teams, and phase-appropriate analytics; and improve quantitative go/no-go decisions in order to accelerate therapies to patients?

This 1.5 day course will focus on discovery & drug development processes and operations—providing an overview of the drug pipeline and key milestones towards IND filings, detailed assessments of cross-functional strategies, and in-depth learnings in R&D spanning therapeutic candidate selection, developability assessments, risks & mitigations, and analytical & process development considerations for regulatory submissions.

This interactive course is designed for scientists and engineers in discovery, nonclinical development, and CMC, with a desire to increase the probability of success of therapeutic candidates across multiple modalities (biologics, small molecules, cell and gene therapies). Instructors will share best practices, key pitfalls, translational guidelines, data-driven strategies, and regulatory considerations through case studies, course materials, and supplemental information.

WEDNESDAY, JANUARY 15, 2025 3:15 PM - 5:50 PM
THURSDAY, JANUARY 16, 2025 8:15 AM - 4:15 PM

TS5C: 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.

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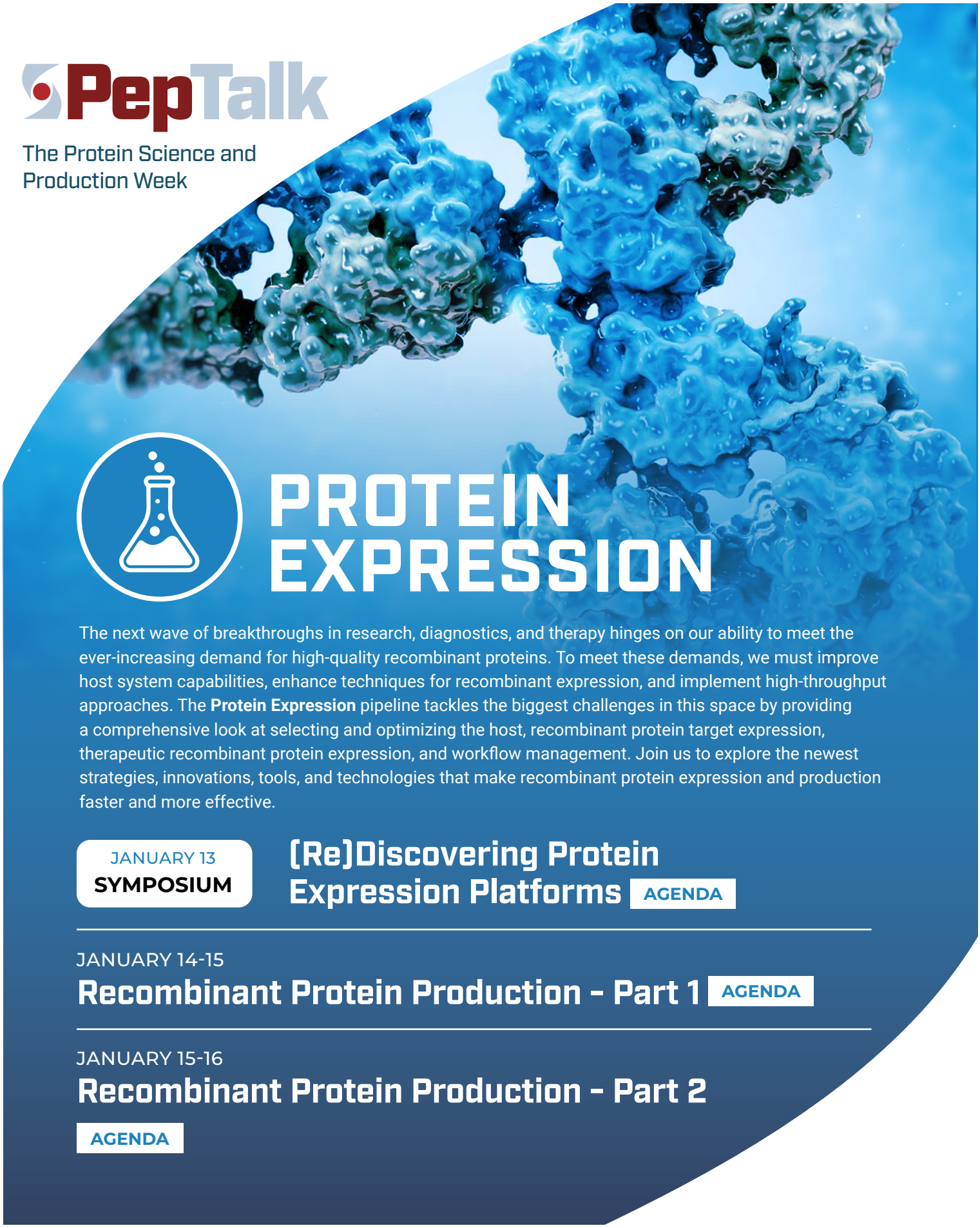
The Protein Science and Production Week



PROTEIN EXPRESSION

The next wave of breakthroughs in research, diagnostics, and therapy hinges on our ability to meet the ever-increasing demand for high-quality recombinant proteins. To meet these demands, we must improve host system capabilities, enhance techniques for recombinant expression, and implement high-throughput approaches. The **Protein Expression** pipeline tackles the biggest challenges in this space by providing a comprehensive look at selecting and optimizing the host, recombinant protein target expression, therapeutic recombinant protein expression, and workflow management. Join us to explore the newest strategies, innovations, tools, and technologies that make recombinant protein expression and production faster and more effective.

JANUARY 13
SYMPOSIUM

[Re]Discovering Protein Expression Platforms

AGENDA

JANUARY 14-15

Recombinant Protein Production - Part 1

AGENDA

JANUARY 15-16

Recombinant Protein Production - Part 2

AGENDA

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MONDAY, JANUARY 13

8:00 am Registration and Morning Coffee

8:50 Organizer's Welcome Remarks

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

THE HOST SELECTION PROCESS: SCIENCE OR ART?

8:55 Chairperson's Remarks

Edward Kraft, PhD, Senior Director, Small Molecule Discovery, Leash Bio

9:00 Cellular Protein Manufacturing Machines: How to Decide Which Path is Best for Your Favorite (or Dreaded) Protein

Carter Mitchell, CSO, Purification & Expression, Kemp Proteins

The developments in protein purification have largely remained stagnant with a major focus on recombinant production to boost titer and simplify the purification process. While boosting titer for certain protein classes is a viable solution, some classes have post translational modification or challenging maturation processes that can result in non-active, partially active, and/or highly heterogeneous protein. How do you choose whether recombinant or native source is the proper starting point? When choosing recombinant systems, what insight is needed to set-up a process for success? We will discuss relevant information, how to use bioinformatics and ML tools to make informed decisions, and situations when reverting to old-school methods can outperform the current state-of-the-art.

9:30 Optimal Expression Host Selection for Protein Production across the Proteome

Edward Kraft, PhD, Senior Director, Small Molecule Discovery, Leash Bio

Selecting optimal expression systems capable of reliably producing assay-ready proteins is formidable. Key considerations including efficiency, protein localization, disulfide bonding, glycosylation, organism source, team dynamics, and downstream assay prerequisites are examined. Presently, no single expression system can consistently deliver proteins of requisite quantity and quality for downstream assays. The discussion concludes with insights into the critical need for high-quality data to properly train and validate advanced ML and AI models.

10:00 It Is Obvious Which Recombinant Protein Expression to Use, Or Isn't It?

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

While many proteins are indeed best expressed in a specific expression system, researchers should remain vigilant and keep an open mind. Case studies will be presented that illustrate how the initial and 'obvious' choice of *E. coli*, insect, or mammalian (and *Vibrio natriegens*) expression system was inappropriate.

10:30 Beyond Limits: Moss-Based Technology for Advanced Protein Production

Andreas Schaaf, CSO & Managing Director, Research & Development, eleva GmbH

The development of next-generation pharmaceuticals requires more adaptable expression systems to manufacture complex and demanding proteins. To address the shortcomings of current production methods, we have created a transformative expression system based on moss. This cutting-edge technology has now advanced to a pre-commercial phase, successfully producing a second product that failed in conventional systems. The unique features of this system will be illustrated using the example of the production of recombinant factor H (CPV-104).

11:00 Networking Coffee Break

APPLYING AUTOMATION TO ENHANCE EXPRESSION & PRODUCTION

11:15 The Development of a High-Throughput Small-Scale Intracellular Expression Testing Platform for Non-Antibody Proteins

Christine L. Kugel, Principal Scientific Researcher, Biomolecular Resources, Genentech, Inc.

The drug discovery landscape is ever-evolving and constantly demands ways to produce difficult-to-express proteins in a fast and efficient manner. In our department, Biomolecular Research at Genentech, we have implemented several expression platforms to enable speedy and robust expression screening for structural and biochemical studies. This presentation will highlight some of the key challenges which we face when expressing a large amount of diverse intracellular and membrane proteins.

11:45 End-to-End Automated Cell Culture Seed Production Platform

Daniel Poole, PhD, Senior Scientist, Biologics HTP Expression Sciences, Johnson & Johnson Innovative Medicine

Transient mammalian cell transfection is a gold-standard method for production of various large-molecule modalities in the drug discovery setting. However, production of high-quality cell culture seed with =99% viability is typically a labor-intensive and hard-to-automate process, especially when 10-100L of culture is needed. Here, we describe our end-to-end automated cell culture platform to prepare, maintain, and deliver large volumes of high-quality cell culture.

12:15 pm LUNCHEON PRESENTATION: Innovative Engineering and Production Strategies for Fab, ScFv & VHH

Jiansheng Wu, Vice President, Protein Sciences, WuXi Biologics USA LLC

Antibody fragments such as Fab, ScFv, and VHH are transforming antibody drug development, serving as both independent therapeutics and key components in bispecific antibodies. However, producing and engineering these fragments comes with unique challenges including low yields, impurities, aggregation and stability issues. This talk will showcase cutting-edge solutions to these obstacles, offering insights into molecular engineering, high-titer CHO expression systems, and targeted purification techniques specifically designed for Fab, ScFv, and VHH.

12:45 Session Break

DISCOVERING & DEVELOPING HOST CAPACITY

1:30 Chairperson's Remarks

Jan-Willem de Gier, PhD, Professor, Biochemistry and Biophysics, Stockholm University

1:35 (Re)Discovering CHO—Opening New Potential through Further Cell Engineering

Bjørn Voldborg, MSc, Head, National Biologics Facility, DTU Bioengineering, Technical University of Denmark

Through gene-specific cell engineering, we have demonstrated the power of engineered CHO cells, (geCHO) enabling rapid production of bespoke glycoforms of therapeutic proteins. With this platform, we have produced and screened multiple therapeutic drug candidates (vaccines and enzymes) *in vitro* and *in vivo* to determine the optimal glycoform. Robust and efficient targeted engineering can be used to address specific challenges like contaminating HCP's, unwanted product activity, and more.

2:05 Advancements in Manufacturing: Leveraging *Drosophila* S2 Cells for Consistent, High-Quality Protein Production

Max Søgaard, PhD, Senior Vice President, R&D and Technology, ExpreS2ion Biotechnologies

Since its establishment in 1972, *Drosophila melanogaster* S2 has been invaluable in academia for its ease of handling and versatile protein expression. While viral methods can reduce cell viability, the ExpreS^2 system ensures high viability, enhancing product homogeneity and batch consistency crucial for API manufacturing. ExpreS2ion Biotechnologies has advanced S2 cell use for clinical testing of malaria vaccines, and recently achieved Phase III clinical validation during testing of a COVID-19 vaccine.

2:35 Glycoengineering and mAb Production in the Fungus Thermothelomyces heterothallica C1

Anne Huuskonen, Senior Scientist, Industrial Biotechnology & Food Solutions, VTT Tech Research Center of Finland

This study explores the potential of the fungus Thermothelomyces heterothallica C1 as an alternative cost-efficient platform for monoclonal antibody (mAb) production. We have engineered the glycosylation pathways of C1 to produce human-like N-glycans with good productivity and product quality. Production levels over 9 g/l of secreted mAb with desired glycan profile have been obtained.

3:05 Corynex® : Microbial Production Platform Suitable for Peptides and VHHs

Hayato Nagano, PhD, Researcher, Research Institute Bioscience Products & Fine Chem, 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, antibody mimetics including VHH and ancillary materials.

3:35 Networking Refreshment Break

4:00 (Re)Discovering Pichia – Overcoming Cellular Limitations… and Common Prejudices

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

Key bottlenecks in the *Pichia pastoris* expression system can be overcome utilizing VALIDOGEN's comprehensive UNLOCK PICHIA toolbox, addressing challenges at every stage from translation and transcription to protein folding and secretion. In addition, contrary to the common belief that methanol is necessary for optimal performance VALIDOGEN's exclusive AOX1 promoter variants enable highly efficient methanol-free processes. Through innovative approaches production times can be significantly shortened, further enhancing process efficiency and maximizing productivity.

4:30 Solving Protein Expression Challenges with a Multicellular Platform: Transgenic *Drosophila melanogaster*

Matt Anderson-Baron, PhD, CoFounder & CEO, Future Fields

The expansive genetic toolkit for *Drosophila melanogaster* allows for stable expression of bioactive proteins. Illustrated through multiple case studies, we will discuss genetic strategies on optimizing protein expression, including tissue-specific and inducible expression. This novel approach has the potential to overcome recombinant protein expression difficulties associated with conventional systems.

5:00 Investigation of Yeast Strain Variants for Higher Recombinant Protein Production via High-Throughput Screening

Thibault Mayor, PhD, Professor, Michael Smith Laboratories, Biochemistry & Molecular Biology, University of British Columbia

Saccharomyces cerevisiae is commonly used for recombinant protein production but often yields low levels compared to other systems. To identify bottlenecks, we screened a genomic library of 4,000 mutant strains and ~1,000 isolates from diverse environments for higher laccase production. Gene ontology analysis highlighted processes like vesicle trafficking, vacuolar degradation, and metabolism. Deleting certain genes increased protein production in our lab strain, offering new bioengineering strategies.

5:30 Sequential Customization of Expression Hosts for Enhanced Recombinant Protein Production

Jan-Willem de Gier, PhD, Professor, Biochemistry and Biophysics, Stockholm University

Producing a recombinant protein involves selecting an appropriate expression host and optimizing the production process. Ideally, the expression host is customized for the production of a recombinant protein. However, currently no generic platforms exist for customizing expression hosts. Therefore, we have developed for *E. coli* the EcCustom platform, which enables sequential customization for the production of any recombinant protein. The EcCustom concept can be applied to any expression host.

6:00 Close of Symposium

TUESDAY, JANUARY 14

7:30 am Registration and Morning Coffee

8:30 Organizer's Welcome Remarks

Nikki Cerniuk, Conference Producer, Cambridge Healthtech Institute

PERFECTING MEMBRANE PROTEIN PRODUCTION

8:35 Chairperson's Opening Remarks

Timothy K. Craig, PhD, Lab Head Protein Sciences, Pfizer Inc.

8:40 Overcoming the Hurdles of Expressing Challenging Membrane Proteins: GPCRs and Ion Channels

Alexander Alexandrov, PhD, Associate Director, Abilita Biosciences

Low expression levels and instability of GPCRs and ion channels hinder protein-based screening and antibody discovery efforts. At Abilita Therapeutics, we leverage advanced protein engineering and directed-evolution EMP technology to significantly enhance the yield and thermostability of multispan membrane proteins. This results in availability of highly expressed and stable GPCRs and ion channels, enabling the effective isolation of novel therapeutic antibodies through both *in vivo* and *in vitro* approaches.

9:10 High-Throughput Membrane Protein Production Supporting Drug Discovery

Timothy K. Craig, PhD, Lab Head Protein Sciences, Pfizer Inc.

Integral membrane proteins are a class of highly druggable targets that are difficult to access in recombinant systems in amounts and quality sufficient for binding-first methods such as DNA Encoded Library (DEL) and ASMS for hit finding, and then for follow-up of hits. In this talk, I will review strategies and approaches for accessing these targets using membrane mimetics including SMALPs and other forms.

9:40 KEYNOTE PRESENTATION: Cell-Free Systems for the Production of Glycoproteins

Matthew DeLisa, PhD, Director, Cornell Institute of Biotechnology, Cornell University

Cell-free systems offer a promising platform for producing complex glycoproteins. By bypassing the limitations of living cells, we can achieve precise control over glycosylation patterns and accelerate protein production. This approach holds significant potential for the development of therapeutic glycoproteins.

10:10 From Screening to Large-Scale Purification: Versatility of Strep-TactinXT Magnetic Beads

Philipp Henning, PhD, Team Lead, Research and Development, IBA Lifesciences

MagStrep beads address the evolving laborious and time-consuming change challenges in protein purification by enabling a rapid and efficient purification process that also makes automation and scalability feasible. With their high binding capacity and specificity, these beads ensure superior purity and yield. MagStrep Beads are a cutting-edge solution, providing unmatched efficiency, convenience, and performance in protein purification.

10:25 Characterizing Membrane Protein in Near-Native Conditions Using the NativeMP Copolymer Suite

Jan Kubicek, CSO & Co Founder, Protein Production, Cube Biotech GmbH

Membrane proteins are target of most current drugs. Despite their relevance, their study lags behind soluble proteins due to their challenging purification. I will introduce our NativeMP copolymers whose solubilization efficiency rivals state-of-the-art detergents. Moreover, they provide superior stabilization, as the proteins remain in a native environment. Copolymers are fully compatible with electron cryo-EM & I will provide examples of how to optimize samples for this work. I also show how we have successfully measured the binding of known ligands and raised antibodies.

10:40 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

OPTIMIZING THE PRODUCTION OF DIFFICULT-TO-EXPRESS PROTEIN TARGETS

11:20 Human Focal Adhesion Proteins: Expression and Purification

Petra Fromme, PhD, Paul V. Galvin Professor, Chemistry & Biochemistry, Arizona State University

This study focuses on human focal adhesion proteins, investigating their expression and purification. We aim to elucidate the role of these proteins in cellular adhesion and signaling. Through a combination of molecular biology techniques, we successfully purified recombinant focal adhesion proteins. Our findings provide a foundation for further research into the structure, function, and potential therapeutic applications of these essential components.

11:50 Optimizing the Production of Difficult-to-Express Protein Targets

Prashant Pradhan, PhD, Postdoctoral Researcher, Molecular Biology, UT Southwestern Medical Center

Many proteins are difficult to produce in recombinant systems due to factors such as insolubility, instability, and low yield. This presentation will discuss strategies to optimize the expression of challenging protein targets.

12:20 pm Enjoy Lunch on Your Own

1:30 Refreshment Break in the Exhibit Hall with Poster Viewing

2:00 Chairperson's Remarks

Bjørn Voldborg, MSc, Head, National Biologics Facility, DTU Bioengineering, Technical University of Denmark

2:05 Using Top-Down Proteomics to Better Understand Recombinant RAS Modifications for Compound Targeting

Grace Scheidemantle, PhD, Scientist 1, Cancer Research Technology Program, Frederick National Lab for Cancer Research

RAS proteins are the most frequently mutated in human cancer. The role of post-translational modifications (PTMs) in RAS-dependent signaling is not fully understood. Top-down analysis of intact and modified RAS protein forms (proteoforms) provides a level of molecular detail unachievable by other proteomic methods. Previously, The NCI RAS Initiative developed—and here, we further optimized a novel top-down assay to understand cysteine reactivity and localization of PTMs on RAS proteoforms.

2:35 Expression of SARS-CoV-2 Protein NendoU and Its Mutants

Manashi Sonowal, Researcher, Biochemistry, Arizona State University

NendoU, a SARS-CoV-2 protein, plays a critical role in viral replication and evasion of host immune response. This presentation will explore the expression and characterization of wild-type and mutant NendoU proteins. Understanding the NendoU protein will aid in developing mitigation strategies and therapeutic interventions against the virus.

3:05 Beyond Expi293: A Next-Gen 293-Based Expression System Enabling Production of a Wider Variety of Proteins in an Easily Automatable Format

Jonathan Zmuda, Director Cell, Cell Biology, Thermo Fisher Scientific Inc

While much progress has been made in the field of transient protein expression in recent years, challenges still remain in producing sufficient amounts of proteins that express at low levels, or not at all, in existing expression systems. Here, we introduce the next generation of 293-based protein expression systems designed to address the expanding needs of scientists from milliliter to multi-liter scales. This advanced system features:

1) a new 293 cell line paired with optimized reagents to achieve significantly higher recombinant protein yields, 2) the capability to express a broader range of proteins, including those that are typically difficult to express in existing 293 platforms, 3) reagents tailored for automated, high-throughput workflows, and 4) streamlined, automation-friendly protocols that reduce the number of steps and increase the number of transfections possible each week.

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

BuzZ Sessions

4:15 BuzZ Sessions

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.

BuzZ Table 1: Getting the Math Right: Adding and Subtracting Post-Translational Modifications (PTMs) to Recombinant Proteins

Christopher Cooper, PhD, Director and Head of Protein Sciences, CHARM Therapeutics

- Choosing an appropriate QC method for your budget
- Moving on from biotin. Upcoming alternative protein labelling technologies
- Challenges in addition of site-specific PTMs (e.g. phosphorylation) and protein PTMs (e.g. ubiquitin, SUMO)
- Advances in (de)glycosylation and its analysis

BuzZ Table 2: Improving Membrane Protein Yield and Quality

Neha Bhat, PhD, Sr Scientist, Biologics Discovery, Johnson & Johnson Innovative Medicine

- Advancements in detergents and nanodisc technologies
- Emerging techniques to overcome instability
- High-throughput screening and process automation approaches
- Overcoming glycosylation and post-translational challenges
- Case studies and practical challenges

OPTIMIZING THE PRODUCTION OF DIFFICULT-TO-EXPRESS PROTEIN TARGETS *(CONT.)*

5:00 Innovations in the Purification, Antigen Expression, and Labeling of HIV-1 Gag Viral-Like Particles (VLPs) for Native Membrane Protein Display

Neha Bhat, PhD, Sr Scientist, Biologics Discovery, Johnson & Johnson Innovative Medicine

We have developed a reproducible and scalable platform for production and purification of HIV-1 Gag VLPs to display "difficult to express" proteins in their native lipid environment and their native conformation. To enhance antigen expression, we have optimized cell lines and identified peptides that increase antigen expression in the membrane. Further, we have developed methods to site-specifically conjugate biotin molecules on VLPs without affecting antigen expression, conformation, size or purity.

ADVANCEMENTS IN TOOLS AND TECHNIQUES FOR TARGET EXPRESSION

5:30 *In vivo* Biotinylation of Recombinant Proteins in Different Expression Systems

Christopher Cooper, PhD, Director and Head of Protein Sciences, CHARM Therapeutics

The coenzyme biotin binds to streptavidin with high affinity, and is exploited in screening and assay formats commonly used in drug discovery. Proteins can be selectively post-translationally biotinylated using the BirA biotin ligase. Co-expressing with BirA *in vivo* may lead to advantages, including reduced processing times and more complete modification. We discuss intracellular co-expression of BirA in *E. coli*, and intracellular and secreted co-expression in insect cells and mammalian cells.

6:00 Latest Capabilities of Cell-Free Protein Synthesis

Vincent Noireaux, PhD, Professor, Synthetic Biology and Biological Physics, University of Minnesota

Cell-free transcription-translation (TXTL) is a rapidly expanding technology that offers a broad range of applications. TXTL is characterized by a fast experimental turnover enabling the synthesis of proteins from DNAs encoding single genes to DNAs encoding tens of genes. I will present the last capabilities of an all-*E. coli* TXTL system.

6:30 Networking Reception in the Exhibit Hall with Poster Viewing

THE PLAZA: YOUNG SCIENTIST MEET-UP

Young Scientist Meet-Up

Su Hyun Kim, PhD, Postdoctoral Researcher, University of California-San Diego

Grace Scheidemantle, PhD, Scientist 1, Cancer Research Technology Program, Frederick National Lab for Cancer Research

7:30 Close of Day

WEDNESDAY, JANUARY 15

7:44 am Registration and Morning Coffee

WOMEN IN SCIENCE – COFFEE AND CONVERSATIONS

WOMEN IN SCIENCE – COFFEE AND CONVERSATIONS

Christa Cortesio, PhD, Director, Protein Biochemistry & Analytics Core, Kite, A Gilead Company

Bushra Husain, PhD, Director of Assay, Profiling and Pharmacology, AstraZeneca

Deborah Moore-Lai, PhD, Vice President, Protein Sciences, ProFound Therapeutics

ADVANCEMENTS IN TOOLS AND TECHNIQUES FOR TARGET EXPRESSION

8:15 Chairperson's Remarks

Christopher Cooper, PhD, Director and Head of Protein Sciences, CHARM Therapeutics

8:20 Compact Programmable Control of Protein Secretion in Mammalian Cells

Alex Elias Vlahos, PhD, Postdoctoral Researcher, Synthetic Biology, Stanford University

Synthetic biology offers the potential to control intercellular signals such as secreted proteins in biomedicine. In this talk, I will highlight compRELEASE, a platform to control the secretion or expression of any protein of interest using endogenous 14-3-3 proteins and proteases in mammalian cells. Furthermore, the compRELEASE platform enables the compact control of multiple proteins, while minimizing the overall genetic payload—and is compatible with pre-existing synthetic protein circuits.

8:50 Recombinant Protein Tools—Supporting Small Molecule Lead Discovery and Optimization Efforts

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

The Structural Biology and Protein Sciences group supports Pfizer's oncology research organization early-stage small molecule drug discovery efforts generating recombinant proteins for hit identification and lead optimization cycles. Addressing the challenges of resource constraints and aggressive timelines, the group utilizes optimized protein production processes to support the projects in its research portfolio. This presentation will highlight some of the successful strategies utilized to generate high-quality, fit-for-purpose recombinant protein tools.

9:20 Improvements in Large-Scale Production of Tobacco Etch Virus Protease

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

Tobacco etch virus (TEV) protease is the workhorse of protein expression. TEV-protease is remarkable in its sequence specificity, and its ability to cleave fusion tag proteins. We report work on large-scale production of TEV-protease using different promotors, media, fusion tags, and expression platforms. How our pgl plus bacteria negates post-translational modification (gluconylation and phosphogluconylation), and mollifies deleterious effects on Ni^{2+}-affinity. Our new protocols increase production yields to 400-500 mg/L TEV-protease.

9:50 Self-Removing Affinity Tag for Improved Production Yields

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

This study introduces a novel self-removing affinity tag for enhanced protein production. The tag facilitates efficient purification while minimizing downstream processing steps. We demonstrate its effectiveness in various expression systems and protein targets, resulting in significantly higher yields compared to traditional affinity tags. Our findings provide a valuable tool for researchers seeking to optimize protein production and purification processes.

10:20 High Throughput Signal Peptide Engineering to Enhance Protein Biologics Development andProduction

AVENUE BIOSCIENCES

Tero-Pekka Alastalo, CEO, Avenue Biosciences Inc

Signal peptides play a crucial role in regulating protein biosynthesis and expression. Despite existing in hundreds of thousands and expressing notable diversity, signal peptides have largely gone unexplored in commercial protein engineering. We present technological advances and case examples in signal peptide engineering: A method with an unparalleled coverage of >5,500 naturally occurring and synthetic signal peptides that can be simultaneously tested in biological systems.

10:50 Booth Crawl with Bagels and Coffee in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

PLENARY SESSION

11:35 Plenary Keynote Introduction *(Sponsorship Opportunity Available)*

11:45 Rethinking Transgene Design for Protein Expression

Jarrod Shilts, PhD, R&D Lead Scientist, ExpressionEdits Ltd.

If you compare a typical human gene to the transgenes used to manufacture proteins, they have markedly different structures despite being foundational to the biotechnology industry. At ExpressionEdits, we have revised the paradigm for how a mammalian transgene should look by re-introducing introns back into the cDNA sequence. We have trained an AI model of "genetic syntax" to learn how to combine coding and non-coding DNA to improve protein expression.

12:30 pm Enjoy Lunch on Your Own

1:10 Refreshment Break in the Exhibit Hall with Poster Viewing

PLENARY FIRESIDE CHAT

1:45 Plenary Fireside Chat Introduction *(Sponsorship Opportunity Available)*

1:55 Navigating the Professional Landscape: Strategic Pathways to Biotech Success

Moderator: Deborah Moore-Lai, PhD, Vice President, Protein Sciences, ProFound Therapeutics

Panelists:

Emma Altman, Senior Research Associate, Protein Sciences, Kite, a Gilead Company

Henry C. Chiou, PhD, Senior Director General Manager, Biosciences, Thermo Fisher Scientific (Recently Retired)

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

QC Yong, PhD, Associate Director, Antibody CMC, Capstan Therapeutics

2:30 Close of Recombinant Protein Production – Part 1 Conference

2:30 Refreshment Break in the Exhibit Hall with Poster Viewing

WEDNESDAY, JANUARY 15

11:00 am Registration Open

PLENARY SESSION

11:35 Plenary Keynote Introduction *(Sponsorship Opportunity Available)*

11:45 Rethinking Transgene Design for Protein Expression

Jarrod Shilts, PhD, R&D Lead Scientist, ExpressionEdits Ltd.

If you compare a typical human gene to the transgenes used to manufacture proteins, they have markedly different structures despite being foundational to the biotechnology industry. At ExpressionEdits, we have revised the paradigm for how a mammalian transgene should look by re-introducing introns back into the cDNA sequence. We have trained an AI model of "genetic syntax" to learn how to combine coding and non-coding DNA to improve protein expression.

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

QC Yong, PhD, Associate Director, Antibody CMC, Capstan Therapeutics

2:30 Refreshment Break in the Exhibit Hall with Poster Viewing

ACCELERATING ANTIBODY PRODUCTION

3:15 Chairperson's Opening Remarks

Jakub Tomala, PhD, Postdoctoral Fellow, Biomedical Engineering & Spangler Lab, Johns Hopkins University

3:20 Genome-Wide CRISPR/Cas9 Screening Unveils a Novel Target ATF7IP–SETDB1 Complex for Enhancing Difficult-to-Express Protein Production

Su Hyun Kim, PhD, Postdoctoral Researcher, University of California-San Diego

Emerging novel biotherapeutics, which are typically difficult-to-express, require improvements for high-yield production. In this study, we conducted a genome-wide fluorescence-activated cell sorting (FACS)–based CRISPR knockout screening in bispecific antibody (bsAb)–producing Chinese hamster ovary (CHO) cells. The screening identified ATF7IP and SETDB1 genes, which are binding partners for H3K9me3-mediated transcriptional repression. Knockout of the ATF7IP-SETDB1 complex enhanced bsAb productivity by 2.7-fold and monoclonal Ab productivity by 3.9-fold without affecting product quality.

3:50 FEATURED PRESENTATION: Method for Producing Multispecific Antigen-Binding Molecules with Additional Disulfide Bond

Priyanka Chichili, PhD, Principal Scientist, Chugai Pharmabody Research

LINC-Ig has an extra disulfide bond between the CH1 domains of the heavy chains and brings the Fab domains closer to avoid non-specific crosslinking of cells by the Fab domains. Efficient formation of the disulfide bond of LINC-Ig was a challenge. Here we present the methods we developed to promote the LINC formation.

4:20 Investigation of the Effect of Protein Glycation in Immunotherapy for GBM

Hamzeh Rahimi, PhD, Scientist, City of Hope National Medical Center

This study explores the effects of protein glycation on immunotherapy for glioblastoma multiforme (GBM). We investigate how glycation, a common post-translational modification, influences immune cell function, tumor microenvironment, and treatment response. Our findings provide insights into the potential role of glycation in cancer immunotherapy and may inform future therapeutic strategies.

4:50 IL-2/Anti-IL-2 Antibody Fusion Proteins: Production and Purification

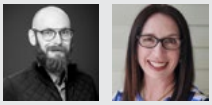
Jakub Tomala, PhD, Postdoctoral Fellow, Biomedical Engineering & Spangler Lab, Johns Hopkins University

Cytokine/antibody fusion proteins (termed immunocytokines) assemble intramolecularly to bias cytokine signaling behavior through multi-layered structural and molecular effects, and overcome common issues of free cytokines when used as therapeutics. Immunocytokines require special considerations with respect to their production to avoid oligomerization and/or aggregation. This modular approach, based on interleukin-2 (IL-2), can be extended to any cytokine of interest for a broad range of biomedical applications.

5:50 Close of Day

MENTORING MEET-UP

Creating and Fostering a Productive and Effective Mentor-Mentee Relationship



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

Deborah Moore-Lai, PhD, Vice President, Protein Sciences, ProFound Therapeutics

THURSDAY, JANUARY 16

7:15 am Registration Open

BuzZ Sessions

7:30 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.

BuzZ Table 1: Therapeutic Protein Production: Innovations and Best Practices

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

- Construct design and misfolding prevention
- Leveraging machine learning and data optimization
- Cell-free systems for complex protein synthesis

BuzZ Table 2: Common Issues with 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 (Recently Retired)

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

ENHANCING THERAPEUTIC PROTEIN PRODUCTION BEYOND ANTIBODIES

9:15 Chairperson's Remarks

Su Hyun Kim, PhD, Postdoctoral Researcher, University of California-San Diego

9:20 The Fungus Thermothelomyces Heterothallica C1 as a Robust Production Platform for Therapeutic and Vaccine Proteins

Anne Huuskonen, Senior Scientist, Industrial Biotechnology & Food Solutions, VTT Tech Research Center of Finland

Thermothelomyces heterothallica C1 is a well-known industrial enzyme production host able to reach 120 g/l enzyme levels in a 6-7-day process. We have developed the C1 technology suitable for low-cost manufacturing of therapeutic and vaccine proteins including virus-like particles (VLPs), nanoparticles, and individual antigens. Production levels ranging from several hundreds of mg/l to 20 g/l of secreted protein have been obtained.

9:50 Immobilized Enzyme-Based Strategies for Recombinant Protein Production

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

Fusion proteins (MBP, GST, etc.) are frequently used in recombinant protein production pipelines to improve soluble yields of target proteins. The removal of fusion proteins is typically accomplished enzymatically. While this can be highly efficient, removal of these enzymes post-fusion removal can complicate target protein purification. Enzyme immobilization represents one potential solution to this problem. Here we present strategies for the incorporation of immobilized enzymes into recombinant protein production workflows.

10:20 Coffee Break in the Exhibit Hall with Poster Viewing

LINKEDIN SKILLS WORKSHOP

LINKEDIN SKILLS WORKSHOP

Jonathan Frampton, PhD, Vice President, Business Development, ProteoNic BV

11:15 Small-Scale Covalent Fragment Screening Coupled to High-Throughput Protein Purification to Pre-Screen for Cysteine Reactivity

Yasmin A Kadry, PhD, Investigator, Protein & Cellular & Structural Sciences, GSK

We have developed a screening method to identify reactive cysteines in recombinant proteins that is coupled to a high-throughput protein expression and purification platform. Proteins purified in 96-well plates are pre-screened against representative covalent fragments to detect the presence of reactive cysteines. Proteins identified with reactive cysteines are prioritized for scaled-up reagent production and more comprehensive screening, optimizing both reagent utilization and screening resources.

11:30 Advancements in VLP Technology: From Pandemic Countermeasures to Broad-Spectrum Applications in Vaccine Development

Max Søgaard, PhD, Senior Vice President, R&D and Technology, ExpreS2ion Biotechnologies

Recent pandemics have accelerated vaccine development, highlighting the importance of recombinant Virus-Like Particles (VLPs) for strong, durable immune responses. Scalable, high-yield VLP manufacture and the VLP dose-sparing effect significantly reduce cost-of-goods, crucial for global vaccine manufacturing. ExpreS2ion Biotechnologies developed a VLP-based COVID-19 vaccine, which was recently validated in Phase III clinical trials, and is now applying VLP technology to HER2 positive breast cancer demonstrating the breadth of VLP applications.

12:00 pm In-Cell NMR Observation of Biomolecules Inside Living Cells Using Advanced Stable Isotope Labeling Achieved by Cell-Free Protein Synthesis

Takanori Kigawa, PhD, Senior Scientist, RIKEN Center for Biosystems Dynamics Research

In-cell NMR spectroscopy is a potential method to investigate the behavior of therapeutic proteins and their targets at atomic resolution in living cells. We used in-cell NMR combined with site-specific 19F-labeling, enabled by cell-free protein synthesis, to explore the membrane-associated states of the Ras protein in living cells. This approach allowed us to characterize the conformational states of Ras depending on its nucleotide-bound states and oncogenic mutations.

12:30 Enjoy Lunch on Your Own

1:10 Ice Cream & Cookie Break in the Exhibit Hall with Last Chance for Poster Viewing

LABORATORY WORKFLOW INNOVATIONS: POWERING PRODUCTIVITY

2:00 Chairperson's Remarks

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

2:05 Critical Tools and Practices to Promote Data Integrity in a Protein Production Core

Christa Cortesio, PhD, Director, Protein Biochemistry & Analytics Core, Kite, A Gilead Company

Protein-biochemistry-related support of chimeric antigen receptor (CAR) T cell therapy programs from early development through commercialization requires effective project management, nimble business practices, and

excellent cross-functional communication. This is facilitated by several tools, including a laboratory information management system (LIMS), SMART goal setting practices, and an environment that properly balances individual and teamwork-oriented tasks.

2:30 Advancing HT Functional Assays for the Profiling of Multispecific Antibodies

Bushra Husain, PhD, Director of Assay, Profiling and Pharmacology, AstraZeneca

With the increase in complexity of novel modality biologics comes a growing challenge in the design of antibody screening cascades that effectively inform on lead candidates with superior potency and translatability. In this study we will showcase how robust functional assays using primary cells can be miniaturized and run in high throughput to provide early insights into what makes a potent multispecific drug.

2:55 Self-Driving Laboratories to Autonomously Navigate the Protein Fitness Landscape

Jacob Rapp, PhD, Research Scientist, Biochemistry, University of Wisconsin

Protein engineering is a highly iterative process, with multiple rounds of hypothesis-driven experimentation leading to better hypotheses in subsequent rounds on an overall trajectory toward a fitness optimum. Our Self-Driving Autonomous Machines for Protein Landscape Exploration (SAMPLE) platform automates the hypothesis, experiment, and data interpretation steps in a closed, autonomous loop, enabling researchers to focus on the overall experimental design rather than the lengthy iteration process, accelerating progress.

3:20 FEATURED PANEL DISCUSSION: Higher-Throughput Protein Production Challenges: Methodologies, Strategies, and the Art of Managing Multiple Projects

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

Protein expression/production 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 focuses on the concepts, technologies, and strategies necessary to meet the ever-increasing need for biotherapeutics.

- Know your protein
- Strategies on managing multiple “top priority” projects
- Total workflow efficiency
- The importance of tech development to long-term success
- Troubleshooting strategies

Panelists:

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

Christa Cortesio, PhD, Director, Protein Biochemistry & Analytics Core, Kite, A Gilead Company

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

Edward Kraft, PhD, Senior Director, Small Molecule Discovery, Leash Bio

Jacob Rapp, PhD, Research Scientist, Biochemistry, University of Wisconsin

Bjørn Voldborg, MSc, Head, National Biologics Facility, DTU Bioengineering, Technical University of Denmark

4:15 Close of Conference

PepTalk

The Protein Science and Production Week

HIGHER THROUGHPUT

The need for high-quality proteins for basic research, diagnostics, and therapy is growing exponentially. Protein discovery and development scientists continue to expand the repertoire of proteins available by leveraging workflows, automation, high-throughput screening, real-time monitoring, purification strategies, quality control, and data sciences. During the Higher Throughput pipeline we bring together leaders from across biopharmaceutical process development to discuss challenges, showcase innovations, and share technical solutions. Attend to learn more.

JANUARY 13
SYMPOSIUM

Predictive Protein Production AGENDA

JANUARY 14-15

Automation in Protein Sciences AGENDA

JANUARY 15-16

Cutting-Edge Tools for Purification and Quality Assurance AGENDA

REGISTER EARLY & SAVE!

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MONDAY, JANUARY 13

8:00 am Registration and Morning Coffee

8:50 Organizer's Welcome Remarks

Lynn Brainard, Conference Producer, Cambridge Innovation Institute

DRIVING HIGH-THROUGHPUT AND CELL-FREE INNOVATIONS FOR THE FUTURE

8:55 Chairperson's Remarks

Matthew Coleman, PhD, Senior Scientist & Group Leader, Biosciences and Biotechnology Division, Lawrence Livermore National Laboratory

9:00 Innovative Start-Up Showcase: SPOC Proteomics High-Plex Cell-Free Expression Methods for Affinity Screening and Biological Validation of Antibody-Based Therapeutics

Lydia Gushgari, PhD, Chief of Staff, SPOC Proteomics

Sensor-integrated proteome on chip (SPOC) is the world's first highly multiplexed kinetic proteomic biosensor. Our unique cell-free production combined with simultaneous capture-purification onto biosensors enables up to 1000 unique proteins per chip, reducing costs by 10x from traditional recombinant protein workflows. Using real-time SPR screening, we offer qualitative, quantitative, and kinetic data for thousands of proteins simultaneously to support drug discovery, biomarker discovery, vaccine development, plasma proteomics, and diagnostics.

9:30 Discussion Collaborative Impact: Innovators & Users in Action

Moderator: Lydia Gushgari, PhD, Chief of Staff, SPOC Proteomics

Panelists:

Astrid Musnier, PhD, CoFounder & Head, Biology, MAbSilico SAS

10:00 Generating and Measuring Protein-Antibody Interactions in Cell-Free Lysate Reaction Systems

Matthew Coleman, PhD, Senior Scientist & Group Leader, Biosciences and Biotechnology Division, Lawrence Livermore National Laboratory

Cell-free protein synthesis (CFPS) systems are versatile and can facilitate swift turnaround in design, production, and characterization of antibodies. We use CFPS combined with microfluidic systems for producing computationally designed proteins and affinity reagents for validating specific protein and peptide interactions without any purification. This approach utilizes microfluidics combined with fluorescent correlation spectroscopy, for screening interaction kinetics in real-time.

10:30 Unlocking the Power of Machine Learning for Codon Optimization and Predictable Protein Expression

Rita Cruz, Head, Molecular Biology, Ingenza Ltd

The choice of codons significantly impacts recombinant protein expression in engineered organisms. The most common codon optimization strategies are rather simplistic, unreliable and inefficient. This presentation will introduce codABLE™, a groundbreaking machine-learning algorithm that aligns natural codon usage patterns with gene expression levels to create gene designs that are highly compatible with the production host. The integration of codABLE™ with expertise in diverse biomanufacturing hosts enables rapid and reliable development of the protein production process.

10:45 Presentation to be Announced

11:00 Networking Coffee Break

11:15 Cell-Free Expression of Antibodies and Antibody Fragments from Veterinary Species and Their Application in Downstream Assays

Erika Orban, PhD, Principal Scientist, Protein Therapeutics & Biochemistry & Cell Enginering, Zoetis Inc.

The production of antibodies is a time-consuming process. Cell-free protein synthesis (CFPS) offers a faster solution for protein expression, therefore its applicability with antibodies and antibody fragments was investigated. In the present study we focused on the expression of functional single-chain antibody fragments, and how the method could be used in a high-throughput assay format. Here we report on different CFPS methods and their applicability in downstream assays.

11:45 High-Throughput Protein Expression Screening of Cell-Surface Protein Ectodomains

Anita Ghosh, PhD, Senior Scientist, Antigen Production, Institute for Protein Innovation

Cell-surface receptors pose challenges in expression and purification due to low levels, misfolding, and instability. We introduce a high-throughput ELISA fluorescence approach to rapidly assess multiple recombinant constructs. Utilizing small-scale expression, enzymatic biotinylation, and C-terminal His-tag capture, this approach efficiently prioritizes constructs for large-scale production. Testing truncation constructs across various protein families demonstrated its effectiveness, significantly saving time in identifying optimal candidates for downstream applications.

12:15 pm Enjoy Lunch on Your Own

12:45 Session Break

ENGINEERING THE FUTURE: STREAMLINING PROTEIN PRODUCTION

2:00 Chairperson's Remarks

Nathan E. Lewis, PhD, GRA Eminent Scholar and Professor, Center for Molecular Medicine Complex, Department of Biochemistry and Molecular Biology, University of Georgia

2:05 Unlocking Next-Generation Protein Manufacturing Using Systems Engineering

Romel Menacho-Melgar, PhD, CEO, Roke Biotechnologies

We introduce a systems engineering approach to protein expression in *E. coli*, leveraging standard two-stage expression bioprocesses across various scales, from microtiter plates to instrumented bioreactors. This approach facilitates the engineering of strains that operate beyond traditional growth-associated constraints, allowing for the application of advanced tools such as dynamic control over host proteins. We have used this to enhance the production of difficult-to-express proteins and genetically program downstream purification steps.

2:35 High-Throughput Bacterial Protein Production in an Academic Lab

Stacey Gerben, PhD, Collaborative Manager, Institute for Protein Design, University of Washington

The talk will focus on advances in optimizing small-scale, high-throughput protein production in an academic setting in the Institute of Protein Design (IPD) at the University of Washington. It will highlight a versatile approach that accommodates varying levels of automation, ensuring compatibility with available resources as well as recent work maturing and standardizing the method across different labs and buildings within the IPD.

3:05 Rebuilding Expression System and Its Applications for Research & Development of Biologics

Takashi Ebihara, COO, GeneFrontier Corporation

PUREfrex is our unique, rebuilt, cell-free protein expression system. It's easy to customize for various applications, and useful for high-throughput screening of various kinds of biologics, difficult-to-express proteins, or novel modalities having the synergy with the AI/ML platform.

3:20 Optimized Workflow for Targeted Therapeutic Delivery Using Viral and Non-viral Vectors

Speaker to be Announced, Azenta Life Sciences

We present a streamlined end-to-end workflow designed to maximize transduction efficiency for gene delivery. This workflow incorporates three key solutions: 1) optimization of long polyA regions in mRNA for enhanced LNP encapsulation and efficient delivery; 2) production of high-titer lentiviral vectors (LV) at 10^9 TU/ml, tailored for difficult-to-transduce cells and high-throughput LV packaging in 96-well plates suitable for CRISPR screening; and 3) generation of synthetic oligo libraries for adeno-associated virus (AAV) production, paired with long-read viral sequencing for capsid engineering. Together, these innovations provide powerful tools that can accelerate progress in cell therapy, gene therapy, and immuno-oncology applications.

3:35 Networking Refreshment Break

4:00 Using Systems Approaches to Study and Engineering Protein Secretion in Mammalian Cells

Nathan E. Lewis, PhD, GRA Eminent Scholar and Professor, Center for Molecular Medicine Complex, Department of Biochemistry and Molecular Biology, University of Georgia

4:30 Solid-state Storage of Cell-free Systems

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

5:00 PANEL DISCUSSION: Revolutionizing Protein Production Through Engineering and Innovation

Moderator: Nathan E. Lewis, PhD, GRA Eminent Scholar and Professor, Center for Molecular Medicine Complex, Department of Biochemistry and Molecular Biology, University of Georgia

Dive into the forefront of protein production innovation with this expert-led panel discussion. From systems engineering approaches that enhance microbial expression and streamline purification to cutting-edge advancements in high-throughput, cell-free, and mammalian protein production, to unveiling transformative technologies reshaping the field. Explore practical solutions and research aimed at reducing costs, increasing scalability, and unlocking the full potential of proteins for biologics and beyond.

Panelists:

Stacey Gerben, PhD, Collaborative Manager, Institute for Protein Design, University of Washington

Romel Menacho-Melgar, PhD, CEO, Roke Biotechnologies

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

5:30 Close of Symposium

TUESDAY, JANUARY 14

7:30 am Registration and Morning Coffee

8:30 Organizer's Welcome Remarks

Lynn Brainard, Conference Producer, Cambridge Innovation Institute

RAPID RESULTS WITH BREAKTHROUGH HIGH-THROUGHPUT SCREENING AND ANALYSIS

8:35 Chairperson's Remarks

James D. Love, PhD, Vice President, Automation & Process Optimization, Novo Nordisk AS

8:40 High-Throughput Experimentation with AI to Engineer Protein Function Under Programmable Constraints

Alejandro Chavez, MD, PhD, Associate Professor, Department of Pediatrics, University of California San Diego

Designing proteins with desired functionality is a fundamental challenge of protein engineering. I'll be sharing our team's progress towards combining high-throughput experimental assays and deep probabilistic modeling to engineer proteins with user-defined properties.

9:10 Microplate-Based High-Throughput System for Antibody Interaction and Thermostability Analysis

Ryo Matsunaga, PhD, Assistant Professor, Department of Bioengineering, School of Engineering, The University of Tokyo

Antibody development involves complex characterization steps, which are time-consuming and limited by low-throughput assays. This presentation introduces microplate-based high-throughput systems for expressing and analyzing recombinant antibodies. Utilizing nanopore sequencing, surface plasmon resonance (SPR) for interaction analysis, and differential scanning fluorimetry (DSF) for thermal stability analysis, these systems enable efficient evaluation of antibody affinity, specificity, and stability, accelerating data-driven antibody design. Examples of antibody design using this system will be presented.

9:40 Automated, High-Throughput Manufacturing and Screening of CAR T Cells

Sean Yoder, Research Automation Core Lead & Senior Manager, Cell Biology Research, Kite, a Gilead Company

Chimeric antigen receptor (CAR) T cells have transformed cancer treatment in the clinic, making a significant impact in the treatment of B cell malignancies. As we search for the next therapy, the need to screen large, architecturally diverse CAR libraries requires a robust high-throughput manufacturing process. Here we describe a novel high-throughput CAR T cell manufacturing and screening process for the identification of tumor-specific antigen CAR T cells.

10:10 Introducing the New Mini-Scale AmMag Quatro Mini-1100 and Scalable Maxi-1400 for Automated Plasmid Purification

Rouba Najjar, Head of MKT and BD, Product Divisions, CPBU, GenScript USA Inc.

GenScript introduces the new AmMag Quatro Mini-1100, an advanced system for high-throughput mini-prep plasmid purification, processing up to 192 samples per run with low endotoxin levels ideal for transfection-grade plasmids. Complementing this innovation, the AmMag Quatro Maxi-1400 supports maxi-preps with volumes up to 200 mL. Together, these systems streamline workflows, reduce hands-on time, and deliver scalable, high-quality solutions for modern research needs.

10:40 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

11:20 Accelerating High-Throughput Production through Functional Assessments of Bispecifics

Kristoff Homan, PhD, Senior Principal Scientist, Discovery Biotherapeutics, Bristol-Myers Squibb Company

Bispecific discovery can be accelerated through implementation of an efficient bispecific production platform. Through generating fit-for-purpose bispecifics ready for high-throughput functional assessments, timelines from target identification through lead optimization can be accelerated. Case studies from preclinical programs demonstrate the ability to rapidly identify preferred therapeutic formats and optimize bispecifics as well as efficiently interrogate large bispecific sequence spaces though leveraging sampling methods.

11:50 PANEL DISCUSSION: Turbocharging Therapeutic Development: Optimizing High-Throughput and Screening for Advanced Protein Therapies

Moderator: James D. Love, PhD, Vice President, Automation & Process Optimization, Novo Nordisk AS

This panel discussion will dive into advancements in protein expression and high-throughput screening, focusing on innovations that are accelerating the development of protein therapeutics. Learn from these experts as they share their strategies for implementing automation tools to shorten research through development timelines.

Panelists:

Alejandro Chavez, MD, PhD, Associate Professor, Department of Pediatrics, University of California San Diego

Kristoff Homan, PhD, Senior Principal Scientist, Discovery Biotherapeutics, Bristol-Myers Squibb Company

Ryo Matsunaga, PhD, Assistant Professor, Department of Bioengineering, School of Engineering, The University of Tokyo

Rouba Najjar, Head of MKT and BD, Product Divisions, CPBU, GenScript USA Inc.

Sean Yoder, Research Automation Core Lead & Senior Manager, Cell Biology Research, Kite, a Gilead Company

12:30 pm Session Break

12:40 Luncheon Presentation to be Announced

1:30 Refreshment Break in the Exhibit Hall with Poster Viewing

OPTIMIZING PROTEIN EXPRESSION BY HARNESSING AUTOMATION FOR STREAMLINED PROCESSES

2:00 Chairperson's Remarks

Iman Farasat, PhD, Director, High Throughput Expression, Johnson & Johnson Innovative Medicine

2:05 Better, Faster, Stronger, Smarter: Transforming Drug Discovery with Cutting-Edge Automation

Daniel Yoo, Scientific Associate Director, Large Molecule Discovery & Research Data Science, Amgen, Inc.

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

2:35 Automation in Biologics Production & Characterization: Then, Now, and Future

Iman Farasat, PhD, Director, High Throughput Expression, Johnson & Johnson Innovative Medicine

The complexity of mammalian cell culture and the heterogeneity of large-molecule products have historically limited the application of robotic automation platforms in production and characterization to mainly either early stages for small-quantity, stage-gate quality material, or later stages for industrializing specific task accomplishments. Here, we reveal our next-generation automation strategy to bridge the gap and prepare large quantities of high-quality material, solving an essential need for more complex biologics modalities.

3:05 Custom Additives: Unlocking New Potential in Protein Production

nuclera

Michael Chen, CEO & Co Founder, Nuclera UK

Accelerating Protein Production: The eProtein Discovery™ system enables rapid, automated screening and production of difficult-to-express proteins, resulting in soluble, functional proteins within just 48 hours. Case Studies: Real-world examples showcasing the successful expression of challenging proteins, such as transcription factors, through cell-free protein synthesis (CFPS). From Cell-Free to Cells: Demonstrating how cell-free expression insights can be applied to cell-based systems, enabling scalable protein production from microgram/sub-milligram to milligram quantities of functional proteins.

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

BuzZ Sessions

4:15 BuzZ Sessions

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.

BuzZ Table 3: Balancing High-Throughput Expression with Data Capture/Analysis

James Kostas, Senior Scientist, Protein and Structural Chemistry, Merck

BuzZ Table 4: Challenges in High-Throughput Production Platforms

Kristoff Homan, PhD, Senior Principal Scientist, Discovery Biotherapeutics, Bristol-Myers Squibb Company

- HT production approaches
- Incorporating AI/ML predictions into workflows
- Challenges with emerging modalities
- Functional assessment of molecules

BuzZ Table 5: LIMS Level-Up

Emma Altman, Senior Research Associate, Protein Sciences, Kite, a Gilead Company

Nicole Cannon, Protein Sciences, Kite Pharma

- Tips, but no tricks, for starting a LIMS
- Data management pitfalls & solutions
- Limitations - where to draw the line?
- Reckless encouragement

OPTIMIZING PROTEIN EXPRESSION BY HARNESSING AUTOMATION FOR STREAMLINED PROCESSES *(CONT.)*

5:00 Developing High-Throughput Small-Scale Secreted Protein Expression Screening Platform

Sairupa Paduchuri, Scientist 3, Biomolecular Research, Genentech, Inc.

Recombinant protein expression and production is a critical step in drug discovery—and secreted proteins have been a rich source of therapeutics and drug targets. To support growing demand for these proteins, we developed methods to triage protein expression constructs effectively by automating processes, increasing capacity, and reducing costs. This presentation focuses on small-scale high-throughput secreted protein expression platform and the crucial collaboration between different sub-groups to provide efficient results.

5:30 Coupling HT Expression with Automated Gene-to-Structure Data Acquisition and Analysis to Accelerate the Design-Make-Test-Analyze (DMTA) Cycle

James Kostas, Senior Scientist, Protein and Structural Chemistry, Merck

The production of highly purified, well-characterized protein reagents for structural biology generates large and diverse datasets, spread throughout various instruments, notebooks, and databases. In our group, we have developed an optimized HT expression workflow that utilizes digitized, mineable data wherever possible. This, coupled with data centralization and visualization through various dashboards, enables us to more accurately predict protein behavior based on construct design.

6:00 Purification Strategy Development Based on a Comprehensive HTP Screening Tool for Multispecific Molecules

Jane (Yongjing) Guo, PhD, Senior Principal Scientist & Lab Head, Large Molecules Research, Sanofi

Multispecific antibodies (msAbs) present unique protein production challenges due to product-related impurities. Combined purification-enabling mutations (PEMs) and charge-pair mutations (CPMs) at Sanofi have been shown to enforce the correct chain pairing of msAbs and their productivity. This combination could accommodate a wide range of production scales including medium- to high-throughput purification workflows for msAb.

6:30 Networking Reception in the Exhibit Hall with Poster Viewing

THE PLAZA: YOUNG SCIENTIST MEET-UP

Young Scientist Meet-Up

Su Hyun Kim, PhD, Postdoctoral Researcher, University of California-San Diego

Grace Scheidemantle, PhD, Scientist 1, Cancer Research Technology Program, Frederick National Lab for Cancer Research

7:30 Close of Day

WEDNESDAY, JANUARY 15

7:44 am Registration and Morning Coffee

WOMEN IN SCIENCE – COFFEE AND CONVERSATIONS

WOMEN IN SCIENCE – COFFEE AND CONVERSATIONS

Christa Cortesio, PhD, Director, Protein Biochemistry & Analytics Core, Kite, A Gilead Company
Bushra Husain, PhD, Director of Assay, Profiling and Pharmacology, AstraZeneca
Deborah Moore-Lai, PhD, Vice President, Protein Sciences, ProFound Therapeutics

DATA AT THE SPEED OF DISCOVERY: REAL-TIME MONITORING AND ANALYTICAL BREAKTHROUGHS

8:15 Chairperson's Remarks
Christopher Wassif, PhD, Director, Molecular Engineering & Antibody Technologies, AstraZeneca

8:20 KEYNOTE PRESENTATION: Automation and AI for Protein Engineering and Analysis
James D. Love, PhD, Vice President, Automation & Process Optimization, Novo Nordisk AS

AI and GenAI require large amounts of high quality data for training models; for example, the successes of AlphaFold were only possible due to tens of thousands of experimentally derived structures. Automation is an optimal way of generating large, consistent data sets and this presentation will focus on the techniques and approaches that are in use to achieve these goals, and additionally how AI is aiding in this task.

8:50 From Zero to 60B: Building DEL Infrastructure for Machine Learning
Ben Miller, Head, Operations, Leash Bio

Accurately predicting interactions between small molecules and proteins is an unsolved problem that will require large datasets with excellent fidelity. At Leash, we're building infrastructure to design, execute, and analyze DNA Encoded Chemical Library data at-scale with a small team. During this talk we will present some of the problems and solutions we've developed over the past year that allow us to rapidly visualize billions of data points.

9:20 Exploring a Deep Screening Platform & High-Throughput Processes to Improve AI Capabilities
Christopher Wassif, PhD, Director, Molecular Engineering & Antibody Technologies, AstraZeneca

This presentation will focus on the convergence of a new high-throughput antibody discovery platform capable of screening 100s of millions of antibodies with machine learning to accelerate the full discovery process. This work is resulting in the identification of high affinity, developable modalities fit for therapeutic use in accelerated time frames while generating significant amounts of data—further refining our algorithms and models.

9:50 Managing Attention: Applying Large Language Models to Discover Function Protein Insights
Gowri Nayar, Research Scientist, Biomedical Data Science, Russ Altman Lab, Stanford University

Protein language models (PLMs) generate vast, high-dimensional data encapsulated in attention matrices, presenting challenges in storage and analysis. We develop abstractions of PLM outputs to extract functional protein insights while managing data complexity. By focusing on key attention patterns, we reduce storage needs and computational overhead without losing critical details. This approach enhances scalability, enabling efficient and precise protein function prediction and annotation, even for large and unannotated datasets.

10:20 Unleashing the Power of Automation for High Throughput Antibody Synthesis
Richard Altman, Field Application Scientist, Life Solutions, Thermo Fisher Scientific

The discovery and optimization of antibodies, through traditional or AI-assisted methods, necessitates rapid and reliable data generation. Here we introduce a high-throughput platform for synthesizing monoclonal antibodies. Our platform seamlessly integrates DNA normalization, transfection, antibody purification, and buffer exchange within our MES, ensuring traceability throughout the entire workflow.

10:50 Booth Crawl with Bagels and Coffee in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

PLENARY SESSION

11:35 Plenary Keynote Introduction *(Sponsorship Opportunity Available)*

11:45 Rethinking Transgene Design for Protein Expression
Jarrod Shilts, PhD, R&D Lead Scientist, ExpressionEdits Ltd.

If you compare a typical human gene to the transgenes used to manufacture proteins, they have markedly different structures despite being foundational to the biotechnology industry. At ExpressionEdits, we have revised the paradigm for how a mammalian transgene should look by re-introducing introns back into the cDNA sequence. We have trained an AI model of "genetic syntax" to learn how to combine coding and non-coding DNA to improve protein expression.

12:30 pm Enjoy Lunch on Your Own

1:10 Refreshment Break in the Exhibit Hall with Poster Viewing

PLENARY FIRESIDE CHAT

1:45 Plenary Fireside Chat Introduction *(Sponsorship Opportunity Available)*

1:55 Navigating the Professional Landscape: Strategic Pathways to Biotech Success

Moderator: Deborah Moore-Lai, PhD, Vice President, Protein Sciences, ProFound Therapeutics
Panelists:
Emma Altman, Senior Research Associate, Protein Sciences, Kite, a Gilead Company
Henry C. Chiou, PhD, Senior Director General Manager, Biosciences, Thermo Fisher Scientific (Recently Retired)
Frances Maureen Rocamora, PhD, Assistant Project Scientist, Pediatrics, University of California, San Diego
QC Yong, PhD, Associate Director, Antibody CMC, Capstan Therapeutics

2:30 Close of Automation in Protein Sciences Conference

2:30 Refreshment Break in the Exhibit Hall with Poster Viewing

WEDNESDAY, JANUARY 15

11:00 am Registration Open

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2:30 Refreshment Break in the Exhibit Hall with Poster Viewing

NEXT-GEN STRATEGIES AND BREAKTHROUGH TECHNOLOGIES FOR BIOTHERAPEUTICS

3:15 Chairperson's Remarks

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

3:20 Strategies for High-Throughput Purification of Complex Multispecifics

Jeremy King, PhD, Senior Principal Scientist, Amgen, Inc.

Multispecific purification presents unique challenges due to the complexity of the molecules involved and the large number of potential binder combinations. During lead selection, it is common to test hundreds to thousands of multispecific antibodies, requiring rapid purification of high-quality material. To meet these material demands, we have developed one-step purification methods of multispecific antibodies using newer capture resins.

3:50 The Columnless Continual Purification System

Tadayoshi Kawasaki, PhD, Director, DRK Bioprocess Technology Consulting, Technical Advisor of Noritake Co., Ltd.

This innovative system allows continuous capture of antibody proteins directly from cell culture fluid without any clarification. Its principle is based on an in-line mixer that accelerates the binding reaction between IgG and Protein A resin, and a hydrocyclone that separates the antibody-bound resin from the culture medium. This technology does not even use a chromatography column, thus shortening the steps and reducing the footprint of the antibody manufacturing.

4:20 Chromatography Modeling Trends—A Key Driver for Smarter and Faster Process Development

Vlatko Stojanoski, Bioprocessing Resin Sales Specialist, Cytiva

The Cytiva Protein Select resin and tag provide affinity purification, traceless tag cleavage, and tag removal, all in one step. This presentation explores the possibilities for recombinant protein purification with this new resin and tag system. We also demonstrate its efficiency, resolution, and scalability.

4:50 A Magnetic Bead for Rapid Purification of Difficult Targets without Tags

Sabat Gonzalez-Serrano, Graduate Fellow, Chemical & Biomolecular Engineering, Ohio State University

Magnetic bead protein affinity purification provides a fast and efficient method for isolating proteins. Despite its advantages, recombinant tags may pose a significant challenge for some proteins' native structure and/or biological activity, potentially limiting the screening of promising therapeutic candidates. To address this, we have developed a magnetic bead platform that facilitates tagless affinity purification. This innovative technology aims to help accelerate and expedite protein research and drug discovery.

5:20 Creation of a Versatile Automated Two-Step Purification System with Increased Throughput Capacity for Preclinical mAb Material Generation

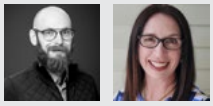
Anthony S. Ransdell, Senior Principal Scientist, Biotechnology Discovery Research, Eli Lilly and Company

Our studies highlight the development of an adaptable purification system designed to optimize the balance among throughput, chromatographic flexibility, and total product yields. By integrating a 150 mL Superloop into an ÄKTA FPLC system for automated two-step tandem purifications, we managed to process various cell culture supernatant volumes ranging from 0.1 to 2 liters, achieving purification yields as high as 2 grams.

5:50 Close of Day

MENTORING MEET-UP

Creating and Fostering a Productive and Effective Mentor-Mentee Relationship



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

Deborah Moore-Lai, PhD, Vice President, Protein Sciences, ProFound Therapeutics

THURSDAY, JANUARY 16

7:15 am Registration Open

BuzZ Sessions

7:30 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.

BuzZ Table 3: Towards Wholly *de novo* Proteins

Cole A. DeForest, PhD, Weyerhaeuser Endowed Professor and Associate Chair, Department of Chemical Engineering, University of Washington

- Computational protein design
- Non-canonical amino acid incorporation via genetic code expansion
- Engineered cell lines and non-traditional expression hosts

BuzZ Table 4: Special Challenges in Routine Protein Production

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

- When you needed the protein yesterday - high pressure production
- How things change when this protein may be headed for the clinic
- Out of left field - strange things that proteins do, and what to do back

ADVANCING HIGH-THROUGHPUT SOLUTIONS FOR TACKLING COMPLEX PROTEINS

8:15 Chairperson's Remarks

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

8:20 Rational and Combinatorial Design of Peptides for ss-mRNA/ds-mRNA Separation and Purification

Pankaj Karande, PhD, Associate Professor, Chemical & Biological Engineering, Rensselaer Polytechnic Institute

A generalizable, scalable, and efficient purification platform is critical for the success of mRNA therapeutics. Our goal in this work is to develop downstream bioseparation strategies to separate dsRNA impurities from ssmRNA. We designed peptide ligands that are selective towards dsRNA and coupled these peptides to filtration membranes to demonstrate the feasibility of purifying labile ss-mRNA from dsRNA at high yield and purity in a scalable fashion.

8:50 One-Step Purification and Functionalization of Bioactive Proteins

Cole A. DeForest, PhD, Weyerhaeuser Endowed Professor and Associate Chair, Department of Chemical Engineering, University of Washington

Site-specific installation of non-natural functionality onto proteins has enabled countless applications in biotechnology, chemical biology, and biomaterials science. In this presentation, I will discuss our recent efforts taking advantage of split inteins and bacterial transpeptidases to simultaneously terminally functionalize and purify homogeneous protein populations in a single step.

9:20 Open-Source Milligram-Scale, Four-Channel, Automated-Protein Purification System

John E. Pak, PhD, Senior Scientist & Group Leader, Protein Sciences, Chan Zuckerberg Biohub

We present an open-source chromatography platform for parallel protein purification at milligram scales. This device can purify up to four proteins and access eight buffers through a network of software-driven valves. It is controlled via Python scripting or a user-friendly graphical interface. We have released a detailed hardware build guide and open-sourced the control software, enabling others to create customized purification instruments.

9:50 POSTER PRESENTATION Development of Semi-Automated Magnetic Bead Purification Platform for Multi-Milligram Material Generation

Joanne Chen, Senior Scientist, Protein Therapeutics, Denali Therapeutics Inc

We developed a semi-automated magnetic bead purification platform integrating the MagWash module with a Tecan liquid handler. This system processes up to 8 samples (50 mL each) in parallel, producing multi-milligram quantities of purified proteins with minimal manual effort. It delivers protein quality comparable to conventional methods with consistent reproducibility and scalability, paving the way for full automation and higher throughput to address increasing demands in protein production.

10:20 Coffee Break in the Exhibit Hall with Poster Viewing

LINKEDIN SKILLS WORKSHOP

LINKEDIN SKILLS WORKSHOP

Jonathan Frampton, PhD, Vice President, Business Development, ProteoNic BV

11:00 Production of Native Recombinant Proteins Using a Novel Split Intein Affinity Technology

Robert I. Clifford, Senior Scientist, AstraZeneca

In this work, we showed the development and utility of a split intein-based expression and purification system. The findings in this work show that a novel split intein-based affinity technology can be an effective capture strategy that can potentially provide a scalable platform for the purification of any expressed protein, which could change the way we produce novel recombinant proteins in both academic and industrial settings.

UNLEASHING QUALITY ASSURANCE FOR OPTIMAL PURIFICATION, PERFORMANCE, AND YIELD

11:30 Post-Translational Modifications Detected by Intact Mass and MS2: Case Studies Illuminating the Vital Role of QC in Protein Reagent Production

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

The vital role of protein QC is well established. By incorporating precise intact mass determination and MS2 analysis, a protein production lab can have valuable tools at their disposal. Case studies will be presented which illustrate how the detection of post-translational modifications have fundamentally altered projects.

12:00 pm What Does It Take for a Successful Impurity Isolation—Exploring the Tools, Tactics, and Techniques

Kevin Crossley, Scientist, Synthetic Group, Amgen, Inc.

Impurity isolation is a critical aspect of pharmaceutical development. Potential drug candidates are perpetually evolving, with optimizations in synthetic routes leading to new impurities that require characterization before downstream processing. Separations scientists are tasked with resolving these impurities at analytical-scale and finding conditions that are scalable and amenable to the stability of the impurity. Tools, tactics, and purification techniques that help overcome these challenges will be discussed.

12:30 Enjoy Lunch on Your Own

1:10 Ice Cream & Cookie Break in the Exhibit Hall with Last Chance for Poster Viewing

LABORATORY WORKFLOW INNOVATIONS: POWERING PRODUCTIVITY

2:00 Chairperson's Remarks

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

2:05 Critical Tools and Practices to Promote Data Integrity in a Protein Production Core

Christa Cortesio, PhD, Director, Protein Biochemistry & Analytics Core, Kite, A Gilead Company

Protein-biochemistry-related support of chimeric antigen receptor (CAR) T cell therapy programs from early development through commercialization requires effective project management, nimble business practices, and excellent cross-functional communication. This is facilitated by several tools, including a laboratory information management system (LIMS), SMART goal setting practices, and an environment that properly balances individual and teamwork-oriented tasks.

2:30 Advancing HT Functional Assays for the Profiling of Multispecific Antibodies

Bushra Husain, PhD, Director of Assay, Profiling and Pharmacology, AstraZeneca

With the increase in complexity of novel modality biologics comes a growing challenge in the design of antibody screening cascades that effectively inform on lead candidates with superior potency and translatability. In this study we will showcase how robust functional assays using primary cells can be miniaturized and run in high throughput to provide early insights into what makes a potent multispecific drug.

2:55 Self-Driving Laboratories to Autonomously Navigate the Protein Fitness Landscape

Jacob Rapp, PhD, Research Scientist, Biochemistry, University of Wisconsin

Protein engineering is a highly iterative process, with multiple rounds of hypothesis-driven experimentation leading to better hypotheses in subsequent rounds on an overall trajectory toward a fitness optimum. Our Self-Driving Autonomous Machines for Protein Landscape Exploration (SAMPLE) platform automates the hypothesis, experiment, and data interpretation steps in a closed, autonomous loop, enabling researchers to focus on the overall experimental design rather than the lengthy iteration process, accelerating progress.

3:20 FEATURED PANEL DISCUSSION: Higher-Throughput Protein Production Challenges: Methodologies, Strategies, and the Art of Managing Multiple Projects

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

Protein expression/production 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 focuses on the concepts, technologies, and strategies necessary to meet the ever-increasing need for biotherapeutics.

- Know your protein
- Strategies on managing multiple "top priority" projects
- Total workflow efficiency
- The importance of tech development to long-term success
- Troubleshooting strategies

Panelists:

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

Christa Cortesio, PhD, Director, Protein Biochemistry & Analytics Core, Kite, A Gilead Company

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

Edward Kraft, PhD, Senior Director, Small Molecule Discovery, Leash Bio

Jacob Rapp, PhD, Research Scientist, Biochemistry, University of Wisconsin

Bjørn Voldborg, MSc, Head, National Biologics Facility, DTU Bioengineering, Technical University of Denmark

4:15 Close of Conference

PepTalk

The Protein Science and Production Week

DEVELOPABILITY AND CHARACTERIZATION

The **Developability & Characterization** pipeline brings together three cutting-edge programs exploring advancements in predicting, analyzing, and optimizing critical quality attributes across diverse biotherapeutic modalities. Attendees will gain insights into leveraging ML tools to model developability parameters, applying analytical techniques to guide lead molecule development, formulation, and biomanufacturing, and tailoring characterization approaches to a variety of biologic drug formats. Industry and academic experts will showcase recent experiences, research, and pressing issues through case studies, unpublished data, interactive panel discussions, and keynote presentations. In these sessions, we will explore the current state-of-the-art in biotherapeutics characterization, compare the applicability of different strategies across drug classes, and encourage attendees to consider novel approaches in their R&D programs.

JANUARY 13
SYMPOSIUM

ML and Predictive Methods

AGENDA

JANUARY 14-15

Methods for Developability Analysis

AGENDA

JANUARY 15-16

Characterization for Novel Biotherapeutics

AGENDA

REGISTER EARLY & SAVE!

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MONDAY, JANUARY 13

8:00 am Registration and Morning Coffee

8:50 Organizer's Welcome Remarks

Govinda Sharma, PhD, Conference Producer, Cambridge Healthtech Institute

DATA-DRIVEN PREDICTION IN ANALYTICAL DEVELOPMENT

8:55 Chairperson's Remarks

Kyle A. Barlow, PhD, Senior Scientist, Computational Biology, Adimab LLC

9:00 High-Throughput Developability Strategies to Support the Modern Pipeline and ML Models

Gilad Kaplan, PhD, Director, Biologics Engineering, AstraZeneca

Early developability screens are used to predict the downstream biophysical characteristics and manufacturability of candidate drug biologics. To realize the full potential of early developability screens, a fully automatable, predictive, and high-throughput developability screen is needed. We present our data-driven approach to increasing the throughput of the early developability phase to accommodate a growing pipeline and generate the data needed to construct *in silico* developability prediction models.

9:30 The Determinants of Aggregation in Small Protein Domains

Cydney M. Martell, PhD Candidate, Department of Pharmacology, Northwestern University

Predicting protein aggregation remains difficult, limiting their use for biotechnology and therapeutic applications. We aim to design aggregation-resistance by collecting and learning from large, experimentally validated datasets. I quantified aggregation after thermal and pH stress for thousands of small protein domains using mass spectrometry. I'm developing machine learning models to predict aggregation from protein features. Through iterative experiments and design, I will refine my model to achieve unprecedented aggregation-resistance.

10:00 Developability Assessment in Early Therapeutic Antibody Discovery by Integrating Machine Learning and High-Throughput Bioanalytical Assays

Dalton Markrush, Scientist, Global Bioanalytics, Alloy Therapeutics

Selection of highly developable leads is crucial for clinical translation and requires accurate developability assessments benchmarked against the clinical landscape. Combining large *in vitro* datasets with *in silico* tools, we have developed integrated wet lab and dry lab workflows that enable rational selection of both assays and candidates. The resulting developability pipeline enables efficient identification of highly developable leads with consideration of specific downstream risks.

10:30 Developability Profiles of Antibodies Discovered from Specifica's Generation 3 VHH, Fab, and scFv Libraries

Frank Erasmus, Director, Bioinformatics, Specifica, an IQVIA business

This presentation provides an overview of the developability profiles of antibodies discovered from Specifica's Generation 3 VHH, Fab, and scFv libraries, selected using phage and yeast display. Antibodies are assessed as VHH/VHH-Fc or IgG, with many exhibiting strong affinities and specificities to their targets. Data show that a large panel of leads perform comparably to the late-stage or clinically approved antibodies from which they are derived in terms of developability. Metrics such as self-interaction, aggregation, polyspecificity/polyreactivity, hydrophobicity, and thermal stability support the conclusion that drug-like antibodies can be selected directly without requiring further optimization.

11:00 Networking Coffee Break

11:15 High-Concentration Developability Approaches and Considerations

Jonathan Zarzar, Senior Principal Scientist and Group Leader, Pharmaceutical Development, Genentech, Inc.

The increase in biologics administered subcutaneously has required higher protein concentrations and highlighted liabilities such as protein aggregation, precipitation, and high viscosity. Identifying optimal high-concentration formulations that limit these liabilities can be slow and costly, and often prevent therapeutics from moving rapidly into the clinic/market. Here, we present advances that have been made in understanding high-concentration protein behavior as well as interesting case studies.

11:45 Machine Learning Methods for Integrated Developability Predictions in Early-Stage Antibody Discovery

Kyle A. Barlow, PhD, Senior Scientist, Computational Biology, Adimab LLC

Initial antibody discovery generates molecules with a wide range of biophysical characteristics that can be used to predict developability, presenting an opportunity to filter or improve their properties. We present machine learning models for developability predictions of properties such as hydrophobicity, chemical stability, and viscosity, and explain how they are deployed to obtain actionable information. We describe the generation and benchmarking of the models and associated experimental input training data.

12:15 pm LUNCHEON PRESENTATION: Unlocking the Future of Antibody Developability with High-Throughput Data and AI Modeling

Speaker to be Announced, Ginkgo BioWorks Inc

Antibody developability is critical for therapeutic discovery, requiring high-quality data and advanced analytics to optimize candidates. At Ginkgo Bioworks, we've scaled developability workflows to high-throughput, generating robust datasets for biophysical and functional characterization. Our AI team leverages over a decade of expertise to build predictive models for antibody developability, offering end-to-end or modular solutions. Join us to learn how Ginkgo is participating in the revolution in biologics with flexible, innovative approaches.

12:45 Session Break

SIMULATION AND STRUCTURE-BASED APPROACHES FOR BIOTHERAPEUTIC DEVELOPMENT

2:00 Chairperson's Remarks

Salvador Ventura, PhD, Full Professor, Biochemistry and Molecular Biology, Autonomous University of Barcelona

2:05 Aggrescan4D: Structure-Informed Analysis of pH-Dependent Protein Aggregation

Salvador Ventura, PhD, Full Professor, Biochemistry and Molecular Biology, Autonomous University of Barcelona

Protein aggregation impacts industrial protein production and formulation. Aggrescan3D (A3D) was developed to aid in understanding and engineering aggregation in globular proteins. It has become one of the most popular structure-based predictors for aggregation studies and protein redesign. Here, we present Aggrescan4D (A4D), which largely extends A3D's functionality by incorporating pH-dependent aggregation prediction and an evolutionarily informed automatic mutation protocol to engineer protein solubility.

2:35 Computational Design of Membrane Protein Stability, Recognition, and *de novo* TM Regulatory Adaptors

Marco Mravic, PhD, Assistant Professor, Department of Integrative Structural and Computational Biology, Scripps Research Institute

CURATED DATA AND DATABASES IN PREDICTING DEVELOPABILITY

3:05 Chairperson's Remarks

Salvador Ventura, PhD, Full Professor, Biochemistry and Molecular Biology, Autonomous University of Barcelona

3:10 Development of Clinically Relevant Specifications for Biologics

Siddarth Prabhu, Process Development Scientist, Attribute Sciences, Amgen

Biological relevance tools are essential to gain knowledge about attribute impact which can be used to inform clinically relevant specifications. A new data science method called the Clinical Impact of Attributes (CIA) approach will be shared that uses clinical trial information to justify clinically safe specifications. CIA analyzes clinical studies to determine if any correlations exists between attribute levels exposed in patients and the development of adverse events.

3:40 Networking Refreshment Break

4:00 Leveraging a Database of Therapeutic Antibodies to Design Novel Therapeutics with De-Risked Developability Profiles

Oliver Turnbull, PhD Candidate, Department of Statistics, University of Oxford

Approved therapeutic antibodies provide valuable insights into which biophysical properties can be considered safe from a developability perspective, aiding the design of biotherapeutics with de-risked developability profiles. I will present our work on building a database of therapeutic antibodies (TheraSAbDab), using this to develop a predictive tool for developability risk (Therapeutic Antibody Profiler 2), and finally our generative machine learning model (p-IgGen) for creating developability-conditioned *in silico* screening libraries.

4:30 It's Going to Take a Village: Standardizing Analytics for Better Machine Learning

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

Effective machine learning (ML) relies on high-quality data and standardized analysis procedures. We will explore the critical need for a collaborative, community-driven approach to standardizing ML analytics and contemplate strategies for producing better data. By establishing best practices and shared resources, development groups across the industry will be empowered to efficiently integrate different data types and leverage the full toolbox of ML techniques, ensuring reproducibility, interpretability, and robust model performance.

5:00 Checking Your Peptides in Databases: Complexities and Quirks

Christopher Southan, PhD, Honorary Professor, Deanery of Biomedical Sciences, University of Edinburgh

Public databases of sequences and bioactivity data, including from patent extractions, are a crucial but overlooked resource for peptide researchers. Because natural endogenous or designed therapeutic peptides fall between the formal representations of small-molecule cheminformatics and protein-sequence bioinformatics, they have database representational challenges that make them difficult to find. This presentation will review various sources of peptide entries in PubChem and offer searching tips.

5:30 Close of Symposium

TUESDAY, JANUARY 14

7:30 am Registration and Morning Coffee

8:30 Organizer's Welcome Remarks

Govinda Sharma, PhD, Conference Producer, Cambridge Healthtech Institute

HIGH-THROUGHPUT ANALYTICAL DEVELOPMENT

8:35 Chairperson's Remarks

Ben Niu, PhD, Principal Scientist, Discovery Biotherapeutics, Bristol-Myers Squibb Company

8:40 High-Throughput and Automation in Characterizing Novel Modalities and Beyond

Ben Niu, PhD, Principal Scientist, Discovery Biotherapeutics, Bristol-Myers Squibb Company

The emergence of diverse biotherapeutic modalities, ranging from monoclonal antibodies (mAbs) to multispecific biologics and antibody-drug conjugates (ADCs), has revolutionized drug discovery. In this presentation, I will demonstrate how we integrate high-throughput techniques and automated processes to accelerate the characterization of novel biotherapeutics. By leveraging advanced analytical platforms, automation technologies, and data-driven approaches, we can efficiently assess quality attributes, deepen product understanding, and streamline the development of transformative new medicines.

9:10 Simultaneous Optimization of Antibody Specificity, Potency, and Pharmacokinetics through Charge Engineering

Mark C. Julian, PhD, Principal Scientist, Biologics Drug Discovery, Biogen

Successful antibody therapeutics are dependent on a myriad of properties including potency, specificity, and pharmacokinetics. This work highlights their interplay via an affinity optimization campaign targeting species cross-reactivity. Antibodies with improved cross-reactivity showed high levels of off-target polyreactivity. These trade-offs were overcome in a subsequent yeast display campaign, which provided mutations for further pharmacokinetic engineering. By integrating these mutations into the variable region, we were able to prolong antibody half-life.

9:40 High-Throughput Intact Mass QC: Aiming to Match High-Throughput Protein Production through Automated Data Processing with ProteinMetrics Byosphere

Xinbi Li, PhD, Associate Principal Scientist, Biologics Engineering, AstraZeneca

The demand for high-throughput intact analysis has steadily increased with implementation of high-throughput expression and purification. Analyzing proteins at the intact level offers a fast and straightforward characterization approach for QC. Implementing ProteinMetrics workflow can accelerate data processing to around 1 minute/sample, resulting in a throughput of more than 3000 samples/week. The software takes protein sequences as input, calculates theoretical molecular weight, and automatically annotates peaks in the spectrum.

10:10 Polysorbate Degradation Challenges and Risk Mitigation Strategies

Pfanstiehl

Sudhakar Voruganti, Director, Business Development, Pfanstiehl Inc

PS80 is a non-ionic surfactant routinely used in biotherapeutic formulations. PS80 prevents protein aggregates and protects proteins from denaturation from various stresses. However, there are challenges associated with PS80 as it is prone to degradation via oxidative or hydrolytic pathways. There are several root causes for PS80 degradation via oxidative pathway including transition metal contamination such as Fe and Cu. In this presentation we will discuss about mitigating risks with PS80 degradation using Pfanstiehl high purity, low endotoxin, low metal excipients.

10:40 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

11:20 High-Throughput Screening of Therapeutic Antibody Viscosity Using a Protein Large Language-Based Machine Learning Approach

Krishna D. Bharadwaj Anapindi, Senior Scientist, Biology, Gilead Sciences Inc.

Subcutaneous administration of biologics necessitates high-concentration formulations, often leading to increased viscosity, complicating development and administration. This study introduces a multimodal feature-based machine learning workflow for predicting antibody viscosity. By integrating diverse data types—sequence, structural, physiochemical, and language model embeddings—the workflow learns from physiochemical and protein evolutionary rules. This approach aims to streamline high-concentration biologic development, enhancing therapeutic efficacy and patient compliance.

11:50 Implementing High-Throughput Developability Analytics to Drive Biotherapeutic Engineering

Andrew K. Urick, PhD, Principal Scientist, Protein Engineering, Boehringer Ingelheim Pharmaceuticals, Inc.

Biotherapeutic engineering campaigns require high-throughput assays to design proteins with favorable developability and functional properties. Implementing these assays in an early research context requires a harmonization of production, purification, and analytical techniques to rapidly generate the proper data to drive project decisions. I will describe our strategy for implementing high-throughput analytics in our engineering workflows with focus on sample consumption, throughput, and maximization of analytical diversity.

12:20 pm Enjoy Lunch on Your Own

1:30 Refreshment Break in the Exhibit Hall with Poster Viewing

AGGREGATION, STABILITY, AND FORMULATION

2:00 Chairperson's Remarks

Michael Poltash, PhD, Principal Scientist, Cell Engineering and Analytical Sciences, Janssen Pharmaceuticals

2:05 Manufacturability Assessments for Therapeutic Antibodies Reveal Liabilities Unique to Immunoglobulin Subclass

Charles G. Starr, PhD, Senior Scientist, Developability and Preformulation Sciences, Sanofi

Biotherapeutic manufacturing processes subject proteins to a variety of potentially destabilizing conditions, including but not limited to shifts in temperature, pH, and chemical environment, and interfacial stress. We present a manufacturability suite of scale-down methods that can be used to identify liabilities and prioritize candidates when transitioning from research to development. Our development and benchmarking of these methods reveals liabilities unique to each IgG subclass and light chain isotype.

2:35 Weighing in the Biophysical Characterization Power: From Discovery to In-Depth Understanding to Biologics Product

Jing Song, Associate Principal Scientist, Analytical Enabling Capabilities, AR&D, Merck & Co., Inc.

Two case studies covering biophysical characterization of protein solutions will be presented. First, water proton nuclear magnetic resonance (wNMR) was employed as a noninvasive, *in situ* method to assess aggregation propensity of a high-concentration drug product, Dupixent®, directly in primary containers. Second, a Reciprocal Injection Device (RID) was introduced to accelerate screening of concentration-dependent protein stability and interfacial interactions of formulations under intensified stress conditions within prefilled syringes.

3:05 Advancements in the Separation, Detection, and Characterization of Biotherapeutic Peptides (e.g.; Insulin and GLP-1 Receptor Agonists) Waters™

Bill Warren, Consultant Product Manager, Bioseparations, Waters Corp

Parker Lee, Sales Application Chemist II, Waters | Wyatt Technology

Advances in the characterization of GLP-1 and other therapeutic peptides, such as insulin analogs, using MaxPeak Premier columns (125 Å, 250 Å) have enhanced insights into aggregation profiles, monomeric and oligomeric states, and self-association pathways. SEC-MALS with an 18-angle DAWN™ detector provided molecular mass precision for each peak, while additional mass spectrometry studies validated composition, enhancing peak identification. This multi-platform approach provides accurate identity, stability, and oligomeric stoichiometry analyses to this rapidly growing area of therapeutic peptides.

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

BuzZ Sessions

4:15 BuzZ Sessions

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 BREAKOUT: BuzZ Table 7: AI and ML in Biotherapeutic Process Development and Manufacturing: Hype vs. Reality

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

BuzZ Table 6: Building the End-to-End Workflow in Analytical Development: Current and Future Technologies

Kevin Zen, PhD, Senior Director, IGM Biosciences

- High throughput analytics for developability workflow
- Immunogenicity prediction and *ex vivo* assays to assess immunogenicity
- Aggregation prediction and analytical technologies to assess aggregation propensity
- PTM prediction and analytical tools to assess molecular liability
- Balance between biological function and biophysical stability

5:00 Novel Approaches for Drug Product-Oriented mAb Developability Assessment Combining Biophysical Characterization and Benchmarking to Commercial Products

Kristian Le Vay, Expert Scientist, Scientific Research & Technology Collaborations, Coriolis Pharma Research GmbH

Our drug-product-oriented mAb developability assessment combines biophysical characterization and benchmarking to commercial mAbs to identify lead candidates with favorable properties. Novel methods, such as unfolding reversibility by Modulated Scanning Fluorimetry (MSF), chemical denaturation and refolding, and the concentration dependency of Tm (ΔTm) provide valuable insights when selecting the most promising candidates for mAb development. This approach reduces risk in drug development and identifies pathways for stable drug products.

5:30 PANEL DISCUSSION: Change the Molecule or Fix it Later? How to Choose the Right Tool for the Job when Addressing Liabilities

Moderator: Jonathan Zarzar, Senior Principal Scientist and Group Leader, Pharmaceutical Development, Genentech, Inc.

Panelists:

Danny Chou, PhD, President and Founder, Compassion BioSolution, LLC

Mark C. Julian, PhD, Principal Scientist, Biologics Drug Discovery, Biogen

Kristian Le Vay, Expert Scientist, Scientific Research & Technology Collaborations, Coriolis Pharma Research GmbH

Rahul Misra, PhD, Scientist, Biophysics and Process Analytical Technology, Sanofi

Charles G. Starr, PhD, Senior Scientist, Developability and Preformulation Sciences, Sanofi

6:30 Networking Reception in the Exhibit Hall with Poster Viewing

THE PLAZA: YOUNG SCIENTIST MEET-UP

Young Scientist Meet-Up

Su Hyun Kim, PhD, Postdoctoral Researcher, University of California-San Diego

Grace Scheidemantle, PhD, Scientist 1, Cancer Research Technology Program, Frederick National Lab for Cancer Research

7:30 Close of Day

WEDNESDAY, JANUARY 15

7:44 am Registration and Morning Coffee

WOMEN IN SCIENCE – COFFEE AND CONVERSATIONS

WOMEN IN SCIENCE – COFFEE AND CONVERSATIONS

Christa Cortesio, PhD, Director, Protein Biochemistry & Analytics Core, Kite, A Gilead Company

Bushra Husain, PhD, Director of Assay, Profiling and Pharmacology, AstraZeneca

Deborah Moore-Lai, PhD, Vice President, Protein Sciences, ProFound Therapeutics

PROCESS DEVELOPMENT AND ANALYTICS

8:15 Chairperson's Remarks

Umer Hassan, PhD, Assistant Professor, Electrical & Computer Engineering, Rutgers University

8:20 Nano-DSF Technology as a Preliminary Decision-Making Tool for Long Term Stability Evaluation of Vaccine Formulations

Rahul Misra, PhD, Scientist, Biophysics and Process Analytical Technology, Sanofi

8:50 Development of mRNA Precipitation-Based Processes through Process Design

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

Process design is challenging when one operation's outcome significantly impacts the next. In precipitation-based processes, the 3D structure of precipitates plays a crucial role in recovery and dissolution. This presentation introduces new high-throughput methods to screen and characterize precipitates and precipitation conditions. Furthermore, we will also present our integrated and continuous manufacturing process for mRNA production and purification. Additionally, prediction models for process development will be discussed.

9:20 Development and Qualification of Analytical Methods to Support Low-Concentration Drug Product in-Use Studies

Adithi Bhargava, Scientist, Late-Stage Pharmaceutical Development, Genentech, Inc.

The emergence of highly potent therapeutics with low expected clinical doses creates a challenge for analytical characterization of simulated drug product in-use samples. Sample characterization for protein concentration, size variants, charge variants, and potency often necessitates additional analytical method development to improve sensitivity and ensure compatibility with in-use samples. Here we report the development and qualification of reliable in-use methods to characterize simulated in-use samples during drug product development.

9:50 Autonomous Bioanalytical Single-Cell Imaging Device for Advanced Biomanufacturing Applications

Umer Hassan, PhD, Assistant Professor, Electrical & Computer Engineering, Rutgers University

Single-cell characterization is one of the most critical measurements—being utilized in medical diagnostics, cellular therapeutics, and biomanufacturing applications. Different cellular-therapies-based biomanufacturing assays require single-cell monitoring while determining cellular potency, viability, and activity. Single-cell measurements serve as QC in many biomanufacturing processes. Here, I will present our recently 3D-printed, autonomous bioanalytical imaging and characterization setup based on florescence microscopy, capable of imaging cells at point-of-care.

10:20 Sponsored Presentation *(Opportunity Available)*

10:50 Booth Crawl with Bagels and Coffee in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

PLENARY SESSION

11:35 Plenary Keynote Introduction *(Sponsorship Opportunity Available)*

11:45 Rethinking Transgene Design for Protein Expression

Jarrod Shilts, PhD, R&D Lead Scientist, ExpressionEdits Ltd.

If you compare a typical human gene to the transgenes used to manufacture proteins, they have markedly different structures despite being foundational to the biotechnology industry. At ExpressionEdits, we have revised the paradigm for how a mammalian transgene should look by re-introducing introns back into the cDNA sequence. We have trained an AI model of "genetic syntax" to learn how to combine coding and non-coding DNA to improve protein expression.

12:30 pm Enjoy Lunch on Your Own

1:10 Refreshment Break in the Exhibit Hall with Poster Viewing

PLENARY FIRESIDE CHAT

1:45 Plenary Fireside Chat Introduction *(Sponsorship Opportunity Available)*

1:55 Navigating the Professional Landscape: Strategic Pathways to Biotech Success

Moderator: Deborah Moore-Lai, PhD, Vice President, Protein Sciences, ProFound Therapeutics

Panelists:

Emma Altman, Senior Research Associate, Protein Sciences, Kite, a Gilead Company

Henry C. Chiou, PhD, Senior Director General Manager, Biosciences, Thermo Fisher Scientific (Recently Retired)

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

QC Yong, PhD, Associate Director, Antibody CMC, Capstan Therapeutics

2:30 Close of Methods for Developability Analysis Conference

2:30 Refreshment Break in the Exhibit Hall with Poster Viewing

WEDNESDAY, JANUARY 15

11:00 am Registration Open

PLENARY SESSION

11:35 Plenary Keynote Introduction *(Sponsorship Opportunity Available)*

11:45 Rethinking Transgene Design for Protein Expression

Jarrod Shilts, PhD, R&D Lead Scientist, ExpressionEdits Ltd.

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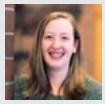

Moderator: Deborah Moore-Lai, PhD, Vice President, Protein Sciences, ProFound Therapeutics

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QC Yong, PhD, Associate Director, Antibody CMC, Capstan Therapeutics

2:30 Refreshment Break in the Exhibit Hall with Poster Viewing

BI AND MULTISPECIFIC BIOLOGICS

3:15 Chairperson's Remarks

Peter Pavlik, PhD, Senior Director, Protein Engineering, Aptevo Therapeutics

3:20 Parallelization of Paratope Optimization and Antibody Format Screening for Efficient Characterization and Development of Multispecific T Cell Engagers

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

Understanding the interplay of antibody geometry with optimal paratope affinity, valency, and target epitope is critical to identifying lead multispecifics. The increased complexity and number of paratopes involved necessitates robust protein engineering strategies, empirical format screening, and biophysical characterization to overcome challenges in the design process and evaluation of multispecific antibodies. Here we present a workflow for parallel paratope optimization and high throughput antibody format screening to decrease inefficiencies.

3:50 Modular Multispecific Biotherapeutics: Rapid Therapeutic Design with the ADAPTIR Platform

Peter Pavlik, PhD, Senior Director, Protein Engineering, Aptevo Therapeutics

Employing modular biotherapeutics is an effective method for maintaining pipeline productivity, particularly for smaller companies. The ADAPTIR and ADAPTIR-FLEX platform technologies allow for rapid development of novel multispecific biotherapeutics. This talk will outline isolation, characterization, and optimization of binding domains and their incorporation into our platforms to accelerate the process of drug discovery and development. I will be highlighting our clinical, Mipletamig (APVO436) and ALG.APV-527, as well as preclinical, assets.

4:20 Advancing a New Class of Proprietary Tumor-Activated T Cell Engagers.

Aude Segaliny, PhD, Senior Director, Head of Research & Preclinical Pharmacology, Amberstone Biosciences

Although T Cell Engagers (TCEs) are potent therapeutic agents, their application in solid tumors has been limited by a narrow therapeutic window. Our Tumor Microenvironment Activated Therapeutics (T-MATE™) Platform addresses this challenge by utilizing tumor acidity as a safety switch. T-MATEs undergo a pH-dependent conformational change that allows them to retain high activity in the acidic pH typical of the tumor microenvironment while exhibiting minimal activity at physiological pH.

4:50 Unravelling the Mechanism of Aggregation in Next-Gen Multispecific Antibodies

Michael Poltash, PhD, Principal Scientist, Cell Engineering and Analytical Sciences, Janssen Pharmaceuticals

Multispecific antibodies mark the next generation of antibody based biotherapeutics. With new technologies evolving, new challenges and new solutions have been quickly introduced. Engineered cysteines were recently developed to enhance the stability of multispecific antibodies; however, expression of these "stapled" molecules results in high levels of aggregation in bioreactors. Here, we describe a multifaceted approach to fully characterize the underlying mechanism of aggregation in multispecific antibodies.

5:20 Close of Day

MENTORING MEET-UP

Creating and Fostering a Productive and Effective Mentor-Mentee Relationship

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

Deborah Moore-Lai, PhD, Vice President, Protein Sciences, ProFound Therapeutics

THURSDAY, JANUARY 16

7:15 am Registration Open

BuzZ Sessions

7:30 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.

BuzZ Table 5: Multiple Challenges for Multispecific Antibodies
Meghan M. Verstraete, PhD, Scientist, Protein Engineering, Zymeworks, Inc.

BuzZ Table 7: Challenges in Intracellular Delivery of Proteins/Peptides
Joseph Pazzi, Director, Formulation, reThink64 Bionetworks

- What Proteins/Peptides with intracellular targets are on the market?
- What are current approaches for penetrating the cell membrane?
- Pros and cons of current approaches like CCPs, nanodiscs, LNPs, pcAAVs?
- What are the major challenges in cell membrane penetration and tissue localization?

CHARACTERIZATION OF ADCs AND NOVEL FORMATS

8:15 Chairperson's Remarks
Jianzhong Wen, PhD, Principal Scientist, Group Leader, Merck & Co., Inc.

8:20 Bioanalytical Strategies to Characterize ADC *in vitro/in vivo* Stability and Pharmacokinetics
Jianzhong Wen, PhD, Principal Scientist, Group Leader, Merck & Co., Inc.

A comprehensive understanding of ADCs' *in vitro* and *in vivo* stability and PK is vital for design and selection. In this presentation, I will share case studies highlighting the use of various immunoassays and advanced mass spectrometry techniques to evaluate linker stability, biotransformation, and PK.

8:50 Stability Characterization and Rapid Formulation Development of an ADC—Is It Possible to "Re-Engineer a Good Formulation in a Week?"
Danny Chou, PhD, President and Founder, Compassion BioSolution, LLC

The focus of this presentation is to describe a case study where the stability "sweet spot" of a "biosimilar" ADC was identified in the amount of time that is generally considered impossible. The results may challenge the current paradigm for ADC "developabilty" assessment, including suitable analytical strategy, as well as formulation development.

9:20 KEYNOTE PRESENTATION: Overview of the History and Progress of Botulinum Neurotoxins Therapy
Sathya Venkataramani, PhD, Director, Protein Science, Abbvie

The exponential growth of Botulinum Neurotoxins (BoNTs) for medical and aesthetic applications over the last few decades has led to a marked increase in the number of available BoNT products. As the popularity of neurotoxins increases, so are the challenges with respect to molecular architecture, intrinsic properties, pharmacological activity and manufacturing. This keynote is focused on tracing the birth and progress of neurotoxins, current challenges, and future opportunities.

10:20 Coffee Break in the Exhibit Hall with Poster Viewing

LINKEDIN SKILLS WORKSHOP

LINKEDIN SKILLS WORKSHOP
Jonathan Frampton, PhD, Vice President, Business Development, ProteoNic BV

CHARACTERIZATION OF ADCs AND NOVEL FORMATS *(CONT.)*

10:50 Chairperson's Remarks
Jianzhong Wen, PhD, Principal Scientist, Group Leader, Merck & Co., Inc.

10:55 Affinity and Developability Optimization of an HIV Biotherapeutic and a Cross-Species Reactive TIGIT Antibody using AlphaBind
Randolph Lopez, PhD, CTO and Co-Founder, A-Alpha-Bio

This talk will focus on two case studies of molecular characterization and unique developability challenges. First, in an HIV biotherapeutic with enhanced cross-reactivity across diverse strains. Second, in a novel anti-TIGIT antibody with optimized species cross-reactivity and manufacturability. By integrating advanced molecular modeling and biophysical validation, we demonstrate how AlphaBind enables rapid, precise optimization of complextherapeutics. This approach highlights innovative strategies for characterizing next-generation biotherapeutics using tailored approaches.

NANOPARTICLES AND VIRUSES

11:25 Chairperson's Remarks
Michael S. Marlow, PhD, Director, Biologics CMC Research, Biotherapeutics Discovery, Boehringer Ingelheim Pharmaceuticals, Inc.

11:30 Characterizing Novel Drug Routers and their Emergent Networks
Joseph Pazzi, Director, Formulation, reThink64 Bionetworks

Given the drawbacks of drug carriers (lipid nanoparticles, viruses, etc.), we have developed a novel macromolecular assembly called a Drug Router which engages the biophysics of tubule formation for delivery. This talk will discuss both the comparable molecular characterization to nanoparticles, but also the Router's more tailored analysis for its contrasting components. As Routers function by forming tubule networks, we also discuss the unique characterization of these secondary, emergent architectures.

12:00 pm Recent Developments at NIST on Particle-Based Reference Materials to Facilitate Biotherapeutic Advancement
Kurt D. Benkstein, PhD, Research Chemist, Biomolecular Measurement Division, NIST

Particle metrology, including size determination and quantification, is critical for advancing the biopharmaceutical industry. Particles in biotherapeutics can be either desired pharmaceutical agents (e.g., lipid nanoparticles, virus-like particles) or impurities (e.g., protein aggregates, extrinsic materials). NIST is developing a suite of reference materials to enable and enhance quantitative measurement of both the desired and the unwanted particulate materials. This presentation showcases recent NIST reference material developments to improve biotherapeutic particle measurements.

12:30 Session Break

12:40 LUNCHEON PRESENTATION: A Novel icIEF Fractionation and SPR-Based Workflow for Correlating Charge Structure to Bispecific Antibody Function
Sriram Kumaraswamy, Sr. VP Product & Marketing, Product & Marketing, Nicoya Lifesciences

Charge variant characterization can be complex and time-consuming. We present a streamlined workflow using icIEF-based fractionation and Digital SPR for binding kinetics analysis of Mosunetuzumab (a bispecific antibody) and a biosimilar. icIEF enabled charge heterogeneity analysis, while Digital SPR revealed reduced binding for the acidic biosimilar fraction. This workflow helps identify critical charge species that can impact binding potency.

1:10 Ice Cream & Cookie Break in the Exhibit Hall with Last Chance for Poster Viewing

NANOPARTICLES AND VIRUSES *(CONT.)*

2:00 Chairperson's Remarks

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

2:05 Characterization of Lentiviral Vectors Applied to Biomanufacturing

Aziza Manceur, PhD, Research Officer, National Research Council of Canada

Lentiviral vectors (LV) are used for cell and gene therapy applications. Since 2017, nine lifesaving LV-based therapies have been approved for commercialization. Despite this progress, a few bottlenecks remain in terms of LV biomanufacturing. Here, we will propose solutions to improve LV yields, decrease costs, and streamline the biomanufacturing process. Notably, characterizing the LV particles during the production and purification process is key to improving the overall LV recovery.

2:35 Single-Particle and Single-Cell Microscopy to Advance Our Understanding, Development, and Quality Control of mRNA-LNP Vaccines and Therapeutics

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

I will present CLiC (Convex Lens-induced Confinement), a single-particle imaging platform that measures the size, mRNA payload, and dynamic properties of nanoparticles in controlled, cell-like conditions (ACS Nano 2024 & 2021). This technique enables the study of particle behavior during manufacturing and in living cells. Our goal is to correlate these measurements with clinical results, advancing the understanding and optimization of vaccine effectiveness from the microscopic to the clinical scale.

3:05 PANEL DISCUSSION: What Can We Learn from Each Other? Translating Solutions for Improved Developability across Modalities, Formats, and Applications

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

Panelists:

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

Ben Niu, PhD, Principal Scientist, Discovery Biotherapeutics, Bristol-Myers Squibb Company

Michael Poltash, PhD, Principal Scientist, Cell Engineering and Analytical Sciences, Janssen Pharmaceuticals

Jianzhong Wen, PhD, Principal Scientist, Group Leader, Merck & Co., Inc.

4:05 Session Wrap-Up

4:15 Close of Conference

REGISTER EARLY & SAVE!
TABLE OF CONTENTS

PepTalk

The Protein Science and Production Week

TARGETED THERAPIES

The NEW Targeted Therapies pipeline explores the frontiers of targeted therapies and drug delivery systems, offering an integrated approach to advancing these transformative technologies. Discussions will delve into the engineering of safe and effective vectors to optimize delivery of therapeutic payloads such as mRNA, cell therapies, and gene therapies; insights into the promising realm of targeted radioligand therapies, which leverage the specificity of targeted molecules combined with the potency of radioisotopes for precise cancer cell elimination, as well as next-generation protein degradation approaches, which hold the potential to combat previously "undruggable" targets. Attendees will explore fundamental principles, optimization strategies, innovative targeting mechanisms, computational approaches, and clinical translation strategies, encouraging them to push the boundaries of biomedical research and clinical applications.

JANUARY 13
SYMPOSIUM

Vectors for Targeted Delivery AGENDA

JANUARY 14-15

Targeted Radioligand Therapies AGENDA

JANUARY 15-16

Next-Generation Protein Degradation

AGENDA

MONDAY, JANUARY 13

8:00 am Registration and Morning Coffee

8:50 Organizer's Welcome Remarks

Nikki Cerniuk, Conference Producer, Cambridge Healthtech Institute

ENGINEERING VIRAL AND NON-VIRAL VECTORS

8:55 Chairperson's Opening Remarks

Jay Sarkar, PhD, CoFounder, reThink64 Bionetworks

9:00 Discovery of a New Class of Cell-Penetrating Peptides by Novel Phage Display Platform

Jinsha Liu, PhD, Senior Scientist, Tentarix Biotherapeutics

A novel phage display platform, NNJA, was developed for targeted and cytosolic delivery. This innovative approach involves engineering a lysosomal cathepsin substrate into phage PIII, which displays a unique random sequence at its N-terminus. By selectively eliminating lysosomal-trapped peptide-phage, NNJA enables peptide-phage that escapes lysosomes to advance to the next round. Proof-of-concept studies demonstrated efficient cytosolic siRNA delivery by NNJA peptides, leading to significant gene silencing across various cell types.

9:30 Conjugation of Antibodies to Lipid Nanoparticles for Enhanced Target Localization

QC Yong, PhD, Associate Director, Antibody CMC, Capstan Therapeutics

Antibody-conjugated lipid nanoparticles (LNPs) are developed to enhance targeted drug delivery. By coupling antibodies to LNPs, we aim to improve therapeutic efficacy and reduce off-target side effects through precise localization to target cells.

10:00 Bioreversible Anionic Bioconjugation for Intracellular Protein Delivery

Azmain Alamgir, Research Scientist, Biochemical Engineering, Cornell University

Intracellular protein delivery is challenging due to cellular barriers. We developed a novel bioconjugation method to introduce anionic groups onto proteins, enhancing their encapsulation in lipid nanoparticles. This approach enables efficient intracellular protein delivery with potential for broad therapeutic applications.

10:30 Networking Coffee Break

PAYLOAD AND PACKAGING OPTIMIZATION

11:15 Quantitation and Integrity Evaluation of RNA Genome in Lentiviral Vector by Direct RT-ddPCR

Zhiyong He, PhD, Biologist, R&D, NIST

Lentiviral vectors (LV) are powerful tools for cell and gene therapies. We have developed a direct reverse transcription digital droplet PCR (RT-ddPCR) approach without RNA extraction and purification for estimation of LV titer and genome integrity. The advantage of direct RT-ddPCR is to avoid the RNA extraction and handling. Our results showed that direct RT-ddPCR resulted in the equivalent titers determined by RNA extraction followed by RT-ddPCR.

11:45 Molecular Exclusion Limits for Diffusion Across a Porous Capsid

Ekaterina Selivanovitch, PhD, Postdoctoral Researcher, Cornell Smith School of Chemical and Biomolecular Engineering, Cornell University

We investigated the size limitations for molecules diffusing through a porous protein capsid. By encapsulating enzymes and varying the size of substrates, we determined the effective pore size and identified factors influencing molecular transport across the capsid.

12:15 pm Enjoy Lunch on Your Own

12:45 Session Break

NOVEL AND NEXT-GEN VECTOR CONSTRUCTS

2:00 Chairperson's Remarks

QC Yong, PhD, Associate Director, Antibody CMC, Capstan Therapeutics

2:05 Optimization of Biocompatibility for a Hydrophilic Biological Molecule Encapsulation System

Nathaniel Nucci, PhD, Associate Professor, Biological and Biomedical Sciences, Rowan University

Reverse micelle (RM) encapsulation has long been an attractive mechanism for biological delivery, yet an RM-based platform has yet to show generalized success for biocompatible encapsulation and delivery of drugs. We use RMs to encapsulate proteins for structure/function study. Recently, we have worked to leverage what works well for structural studies toward development of a biocompatible platform for protein encapsulation and delivery. Our most recent developments will be presented.

2:35 Versatile Cell/Tissue-Specific Delivery of AAV9 with No Capsids Engineered at All

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

Development of AAV vectors with defined tissue tropism usually employs capsid engineering, often by inserting targeting peptides into capsid loops. However, engineered capsids with unique tissue tropism often show poor physicochemical properties that raise concerns in transduction efficiency, manufacturability, and safety. We have developed a method that can grant receptor-specific tissue tropism to natural and unmodified AAV9 capsids, which was used to achieve enhanced brain delivery of AAV9 in mice.

3:05 Networking Refreshment Break

4:00 Harnessing Exosomes for Delivery of Therapeutic Proteins and Nucleic Acids

Pranav Sharma, PhD, Founder & CSO, R&D, Xosomix

Exosomes are transportation vesicles that cross the blood-brain barrier (BBB) to carry biomolecules to specific cellular targets, including the brain. While exosomes have an innate capability to heal defective cells and tissues, loading them with difficult-to-deliver drugs such as impermeable small molecules, antibodies, proteins, and nucleic acids acts as a force multiplier. We harness the targeting capability of exosomes to mediate efficient delivery of therapeutic biomolecules to neurons and synapses.

4:30 KEYNOTE PRESENTATION: Novel Drug Router Constructs for Large-Molecule Delivery

Jay Sarkar, PhD, CoFounder, reThink64 Bionetworks

The limited uptake of nanoparticle carriers for large molecule delivery has restricted the applications of new drug modalities like RNAs, DNA, and peptides. Instead of relying on uptake, our novel Drug Router constructs grow network connections to the cells, then channel large drug cargoes into their cytoplasm. Here, we present their unique properties and their utility in delivering a variety of drug modalities and to a variety of cells/tissues.

5:00 PANEL DISCUSSION: Breaking Barriers: Next-Generation Vectors for Protein Therapeutics

Moderator: QC Yong, PhD, Associate Director, Antibody CMC, Capstan Therapeutics

Panelists:

Zhiyong He, PhD, Biologist, R&D, NIST

Jay Sarkar, PhD, CoFounder, reThink64 Bionetworks

Pranav Sharma, PhD, Founder & CSO, R&D, Xosomix

5:30 Close of Symposium

TUESDAY, JANUARY 14

7:30 am Registration and Morning Coffee

8:30 Organizer's Welcome Remarks

Mimi Langley, Executive Director, Conferences, Cambridge Healthtech Institute

CLINICAL TRIALS, DOSIMETRY, AND COMBINATION STRATEGIES

8:35 Chairperson's Remarks

Shaemus Gleason, Executive Vice President, Clarity Pharmaceuticals

8:40 KEYNOTE PRESENTATION: Advancing Radiopharmaceuticals: Clinical Trials and Infrastructure for Therapeutic Success

Mary Jessel, PhD, Senior Vice President, Global Medical Affairs, Telix Pharmaceuticals

This presentation will cover clinical trial design and infrastructure, supply chain challenges, and future developments in radiotherapy, personalized dosimetry, and AI.

9:10 Commercial Considerations for the Development of Radiopharmaceuticals

Roland Turck, MD, Managing Partner, TurckBio

Radiopharmaceuticals are creating more interest than ever. To live up to their blockbuster promise, RPs have to be clearly better than competing conventional therapies, particularly ADCs. A framework to systematically assess how RPs can compete will be introduced. RPs will compete in early lines of therapy, implying that they will be used in combination—requiring thinking differently about clinical development. Imaging tracers can support development but add complexity.

9:40 The New Precision Therapies with Precision Diagnostics to Select Patients and Monitor Responses: Convergence of *in vivo* and *in vitro*

Arshad Ahmed, Founder & CEO, Zaylan Associates

This presentation explores the synergy between precision therapies and diagnostics, and discusses how advanced diagnostics enable patient selection for innovative treatments. The talk will highlight the convergence of *in vivo* and *in vitro* techniques,, particularly in the emerging area of Radioligand Therapies (RLT) where we see need for incorporating "liquid biopsy" approaches to complement imaging. We will examine case studies showcasing successful applications of this approach and consider future directions.

10:10 Attend Concurrent Tracks

10:40 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

11:20 Impact of Treatment Sequence, Radioisotope, and Tumor Immunogenicity on Anti-Tumor Immunity Following Combined Treatment with a Radiopharmaceutical and Immune Checkpoint Blockade

Zachary S. Morris, PhD, MD, Department Chair and Endowed Professor of Human Oncology, University of Wisconsin Madison

Radiopharmaceutical therapy (RPT) enhances tumor response to immune checkpoint inhibitors (ICI) in preclinical models. Here, we present results of preclinical investigation of the effects of treatment sequence, radioisotope properties, and tumor immunogenicity on the therapeutic interactions between RPT and ICIs in syngeneic murine tumor models.

11:50 Enhancing Efficacy of Immune Checkpoint Blockade with Targeted Radionuclide Therapies

Ravi B. Patel, MD, Assistant Professor and Physician, Radiation Oncology, University of Pittsburgh

The development of immune checkpoint blockades has revolutionized treatment paradigms for metastatic cancer. However, despite gains in tumor response and survival many patients eventually develop resistance to immunotherapy treatments. One strategy to enhance efficacy of immunotherapy is through the use of targeted radionuclide therapy which can deliver immunomodulatory radiation to metastatic sites. We will highlight current results and future directions on the development of combination immunotherapy and radionuclide therapy treatments.

12:20 pm Enjoy Lunch on Your Own

1:30 Refreshment Break in the Exhibit Hall with Poster Viewing

SUPPLY CHAIN AND QC CONSIDERATIONS

2:00 Chairperson's Remarks

Zachary S. Morris, PhD, MD, Department Chair and Endowed Professor of Human Oncology, University of Wisconsin Madison

2:05 Selecting Scalable Supply Chains for Radiopharmaceutical Manufacturing

Shaemus Gleason, Executive Vice President, Clarity Pharmaceuticals

Scalability issues have impeded several radiopharmaceutical launches in both diagnostic and therapeutic applications. Historical challenges with scalability have resulted in a lack of investment in certain isotopes and disruptions in patient care for others. To mitigate these issues in the future, it is crucial to select supply chains that inherently provide scalability. How can we ensure scalability in future radiopharmaceutical supply chains to avoid past pitfalls?

2:35 Quality-Control Considerations for Regulatory Approval

Eugene Borrelli, Senior Director, Quality Assurance, OranoMed

When designing production and quality-control processes during clinical supply, it's important to consider how these processes will be communicated to regulators and inspectors as the drug moves into the approval process. Early planning for validation and verification studies and documentation of the decisions made can be instrumental in educating these parties and can help make the approval process move smoothly.

3:05 POSTER HIGHLIGHT: Combining Advanced Peptide Screening Methods to Identify Peptide Candidates for Peptide Radionuclide Conjugates Development

Weiliang Timo Xu, PhD, Assoc Dir Bus Dev, Zonsen Peplib Biotech

We have developed an advanced peptide discovery platform that identifies peptide candidates for peptide radionuclide conjugates (RDCs). This platform combines Peptide Information Compression Technology (PICT), Disulfide-Rich Peptides (DRPs) phage display, animal toxin, nano macrocyclic, and virtual peptide libraries. It rapidly identifies potent peptide hits with antibody-like affinity (sub-nM to pM), enhanced serum stability (hours to days), and bi-functional capabilities, optimized to bind multiple receptor targets within 6 months.

3:25 Refreshment Break in the Exhibit Hall with Poster Viewing

4:15 BuzZ Sessions

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.

Buzz Table 8: Challenges in the Production and Distribution of Short-Lived Radiopharmaceuticals
Arshad Ahmed, Founder & CEO, Zaylan Associates

- Time constraints from production, QC to delivery
- Pros and cons of decentralized production
- The need for specialized production facilities and highly-skilled personnel
- Regulatory compliance
- Supply chain logistics
- Waste management

PRE-TARGETED RADIOIMMUNOTHERAPIES

5:00 DOTA Ligand–Bound Radionuclide-Based Pretargeted Radioimmunotherapy
Sarah M. Cheal, PhD, Assistant Professor, Biological Chemistry in Radiology, Cornell University

We utilize 1,4,7,10-tetraazacyclododecane-N, N', N", N'"-tetraacetic acid (DOTA) radiohapten capture to obtain high therapeutic indices during pre-targeted radioimmunotherapy (PRIT). This strategy, known as DOTA-PRIT, involves using anti-tumor antigen/anti-(DOTA) radiohapten bispecific antibodies (BsAb) and DOTA-radiohaptens for therapy with lutetium-177 (^{177}Lu) and actinium-225 (^{225}Ac). Recently, we introduced the SADA (Self-Assembling Dis-Assembling) BsAb platform, and a Phase 1 trial of GD2-SADA + [^{177}Lu]Lu-DOTA in GD2-expressing solid tumors is underway (NCT05130255).

5:30 Pre-Targeted Radioimmunotherapy with Self-Assembling and Disassembling [SADA] Bispecific Fusion Proteins: Preclinical Evidence for Treatment of Solid and Hematological Malignancies
Brian Santich, Senior Director of Research, Y-mAbs Therapeutics Inc.

We present the latest findings from preclinical studies on self-assembling and disassembling (SADA) bispecific fusion proteins directed against solid and hematological tumors that overexpress the GD2 glycolipid (GD2-SADA) and CD38 glycoprotein (CD38-SADA), respectively. Our studies support a two-step approach to pretargeted radioimmunotherapy, clinical development of which is now underway with GD2-SADA and Lutetium-177 (Lu-177)-DOTA (NCT05130255) and CD38-SADA and Lu-177-DOTA (NCT05994157).

6:00 PreTarg-it Radioimmunotherapy with Bispecific Antibodies
Michael Thiele, PhD, Founder & CSO, Biology Research, OncoOne R&D GmbH

Radioimmunotherapy targets cancer cells using antibodies but is limited by radiation exposure to healthy tissues. The modular theranostic PreTarg-it system uses tumor-penetrating bispecific antibodies and radionuclide-labeled chelators fused to the HSG hapten. Pilot studies with the bispecific antibody ON105 targeting oxMIF and the 177Lu-labeled DOTA-di-HSG hapten (IMP288) showed significant tumor regression in colorectal and pancreatic cancer mouse models, indicating potential for treating challenging solid tumors and late-stage malignancies.

6:30 Networking Reception in the Exhibit Hall with Poster Viewing

THE PLAZA: YOUNG SCIENTIST MEET-UP

Young Scientist Meet-Up

Su Hyun Kim, PhD, Postdoctoral Researcher, University of California-San Diego
Grace Scheidemantle, PhD, Scientist 1, Cancer Research Technology Program, Frederick National Lab for Cancer Research

7:30 Close of Day

WEDNESDAY, JANUARY 15

7:44 am Registration and Morning Coffee

WOMEN IN SCIENCE – COFFEE AND CONVERSATIONS

WOMEN IN SCIENCE – COFFEE AND CONVERSATIONS

Christa Cortesio, PhD, Director, Protein Biochemistry & Analytics Core, Kite, A Gilead Company
Bushra Husain, PhD, Director of Assay, Profiling and Pharmacology, AstraZeneca
Deborah Moore-Lai, PhD, Vice President, Protein Sciences, ProFound Therapeutics

NOVEL TARGETING MECHANISMS AND EMERGING TARGETS

8:15 Chairperson's Remarks
Mary Jessel, PhD, Senior Vice President, Global Medical Affairs, Telix Pharmaceuticals

8:20 Expanding Targeted Radioligand Therapy to HER2-Expressing Breast Cancer Using Affibody Molecules as Targeting Vectors
Fredrik Frejd, PhD, CSO, Affibody AB

Breast cancer is a major cause of cancer-related death among women; molecular radiotherapy may improve the outcomes. HER2 is an important oncogenic driver in a large subset of breast cancers. Affibody-based HER2-specific clinical imaging has demonstrated pharmacological access to the target in women with metastatic disease. Incorporating the same targeting vector with a biodistribution-modulating albumin binder, ABY-271, is in advanced preclinical development for targeted radioligand therapy.

8:50 Single-Domain Antibody-Based Radiopharmaceuticals for Novel Cancer Stroma Targets
Herman Steen, PhD, CEO, Cortalix

Single-domain antibodies (nanobodies), selected by means of synthetic libraries, have a number of advantages for development into radiopharmaceuticals. Due to their small size, they penetrate deeper into target tissue, they have a simpler structure, and they are much more stable, easier to functionalize, faster, and cheaper to make. Here, Cortalix presents the selection of single-domain antibodies for novel radiopharmaceutical targets for fibrosis and fibrotic cancers, such as colon cancer.

9:20 Dendrimer Nanoparticles (DEP) Enable Targeted Precision Delivery and Customized Biodistribution for Cancer Radiotheranostics
Jeremy Paull, Vice President, Development & Regulatory Affairs, Starpharma Holdings Ltd.

DEP dendrimer nanoparticles are a versatile, clinically validated platform that enables targeted and precision delivery and customized biodistribution profiles for cancer radiotheranostics, and can be tailored in size to address shortcomings of small molecule and large antibody targeting. The biodistribution and efficacy of targeted DEP dendrimer radiotheranostics show a favorable biodistribution profile, with rapid blood clearance and significant tumor accumulation, coupled with anticancer activity in models of human disease.

9:50 Glypican-3 as Radiotheranostics Target for Hepatocellular Carcinoma and Neuroendocrine Prostate Cancer

Woonghee Lee, PhD, Postdoctoral Fellow, Molecular Imaging Branch, National Cancer Institute, National Institutes of Health

Glypican-3 (GPC3) is a membrane-associated proteoglycan that is significantly upregulated in hepatocellular carcinoma (HCC)—the most common type of liver cancer—and in neuroendocrine prostate cancer (NEPC), a rare but lethal subtype for which there are few treatments. Because HCC- and NEPC-selective imaging is critical for diagnosis, monitoring treatment response, and surveillance—and novel therapies are needed to improve outcomes—GPC3 represents a promising radiotheranostics target.

10:20 CD24-Targeted Radiotheranostics for Hepatocellular Carcinoma

Hima Makala, Research Scientist, Molecular Imaging and Therapy, NCI, NIH

When patients with hepatocellular carcinoma (HCC)—the most common type of liver cancer—are treated with embolization or radiotherapy, often clinicians cannot distinguish non-viable from viable/residual/recurrent disease with conventional CT/MRI imaging. While positron emission tomography (PET) imaging with 18F-fluorodeoxyglucose is used for other cancers, it is taken up in just 50% of HCC. CD24 is overexpressed in HCC and represents a promising radiopharmaceutical target for the imaging and treatment of HCC.

10:50 Booth Crawl with Bagels and Coffee in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

PLENARY SESSION

11:35 Plenary Keynote Introduction *(Sponsorship Opportunity Available)*

11:45 Rethinking Transgene Design for Protein Expression

Jarrod Shilts, PhD, R&D Lead Scientist, ExpressionEdits Ltd.

If you compare a typical human gene to the transgenes used to manufacture proteins, they have markedly different structures despite being foundational to the biotechnology industry. At ExpressionEdits, we have revised the paradigm for how a mammalian transgene should look by re-introducing introns back into the cDNA sequence. We have trained an AI model of "genetic syntax" to learn how to combine coding and non-coding DNA to improve protein expression.

12:30 pm Enjoy Lunch on Your Own

1:10 Refreshment Break in the Exhibit Hall with Poster Viewing

PLENARY FIRESIDE CHAT

1:45 Plenary Fireside Chat Introduction *(Sponsorship Opportunity Available)*

1:55 Navigating the Professional Landscape: Strategic Pathways to Biotech Success

Moderator: Deborah Moore-Lai, PhD, Vice President, Protein Sciences, ProFound Therapeutics

Panelists:

Emma Altman, Senior Research Associate, Protein Sciences, Kite, a Gilead Company

Henry C. Chiou, PhD, Senior Director General Manager, Biosciences, Thermo Fisher Scientific (Recently Retired)

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

QC Yong, PhD, Associate Director, Antibody CMC, Capstan Therapeutics

2:30 Close of Targeted Radioligand Therapies Conference

2:30 Refreshment Break in the Exhibit Hall with Poster Viewing

WEDNESDAY, JANUARY 15

11:00 am Registration Open

PLENARY SESSION

11:35 Plenary Keynote Introduction *(Sponsorship Opportunity Available)*

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QC Yong, PhD, Associate Director, Antibody CMC, Capstan Therapeutics

2:30 Refreshment Break in the Exhibit Hall with Poster Viewing

STRATEGIES FOR SAFETY AND TARGETED DELIVERY

3:15 Chairperson's Opening Remarks

H. Ümit Kaniskan, PhD, Associate Professor, Laboratory of Dr. Jian Jin, Pharmacological Sciences, Icahn School of Medicine at Mt. Sinai

3:20 Engineering Bispecific Antibody-Based Degraders for Improved Targeting and Affinity

Andy Goodrich, PhD, Associate Director, Biologics, Epibiologics

Eliminating extracellular proteins is a compelling therapeutic modality. EpiTACs are bispecific antibodies in which one arm binds a target and the other arm leverages an EpiAtlas of tissue-enriched degrading receptors comprised of transmembrane ligases, cytokine/chemokine receptors, and internalizing receptors resulting in selective degradation of membrane and soluble proteins. EpiTACs elicit robust *in vitro* and *in vivo* activity in a target-, tissue-, and disease-specific manner for a broad range of indications.

3:50 KEYNOTE PRESENTATION: Optimizing Payloads for Efficient Delivery of Degrader Antibody Conjugates (DACs)

Jin Wang, PhD, Director, Biochemistry and Molecular Pharmacology, Baylor College of Medicine

Antibody-drug conjugates (ADCs) have garnered significant attention in the pharmaceutical industry. However, current ADCs are constrained by a limited repertoire of payloads, primarily owing to stringent potency requirements. Targeted protein degraders, characterized by their catalytic nature, present a promising alternative as mechanism-based, highly potent payloads. This discussion will focus on strategies for optimizing payloads for efficient delivery of degrader antibody conjugates, potentially expanding the scope of ADC technology.

INCREASING SELECTIVITY AND EXPANDING THE LIGASE TOOLBOX

4:20 A Versatile Toolbox for Developing New E3 Ligase-Based Degraders

Dongwen Lyu, PhD, Associate Director, Target Discovery Core, University of Texas San Antonio Health Science Center

Targeted protein degradation (TPD) using proteolysis-targeting chimeras (PROTACs) and molecular glue degraders (MGDs) is an emerging strategy to develop novel therapies for cancer and beyond. A key challenge in TPD is the limited availability of ligandable E3 ligases, with current studies mainly using CRBN and VHL. The TPD community aims to expand the E3 ligase landscape. Here, we offer a versatile toolbox for developing new E3 ligase-based degraders.

4:50 Unveiling Nature's Arsenal: Discovery and Characterization of Novel E3 Ligases

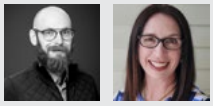
Hailong Zhang, PhD, CEO, Blueray Biopharma Co. Ltd.

E3 ubiquitin ligases are master regulators of protein homeostasis, orchestrating diverse cellular processes. Despite their critical role, our understanding of the E3 ligase landscape remains limited. This talk will present our efforts in identifying and characterizing novel E3 ligases using cutting-edge proteomic and biochemical approaches. By elucidating the substrate specificity and regulatory mechanisms of these enzymes, we aim to uncover new therapeutic opportunities for diseases driven by protein dysfunction.

5:50 Close of Day

MENTORING MEET-UP

Creating and Fostering a Productive and Effective Mentor-Mentee Relationship



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

Deborah Moore-Lai, PhD, Vice President, Protein Sciences, ProFound Therapeutics

THURSDAY, JANUARY 16

7:15 am Registration Open

BuzZ Sessions

7:30 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.

BuzZ Table 6: Multispecific Antibody Design and Production Strategies for Maximizing Target and Tissue Selectivity

Andy Goodrich, PhD, Associate Director, Biologics, Epibiologics

- Protein design and degrader selection strategies to enhance tissue selectivity
- Antibody developability assessments to ensure specificity and drug-like properties
- Multispecific protein production and purification from screening through manufacturing

EXPANDING THERAPEUTIC APPLICATIONS AND NOVEL APPROACHES

9:15 Chairperson's Remarks

Lei Xie, PhD, Professor, Computer Science & Biochemistry & Biology, City University of New York

9:20 Targeted Protein Degradation Systems to Enhance WNT Signaling

Sungjin Lee, PhD, Associate Director, R&D, Surrozen Inc

This study explores the potential of targeted protein degradation (TPD) systems to enhance Wnt signaling. A novel fusion protein, SWEETS, was engineered to selectively degrade E3 ubiquitin ligases, leading to increased Wnt activity. This approach demonstrates the feasibility of tissue-specific modulation of Wnt signaling, opening up possibilities for new therapeutic strategies.

9:50 Advancing Digital Twins for PROTAC Drug Discovery for Incurable Diseases

Lei Xie, PhD, Professor, Computer Science & Biochemistry & Biology, City University of New York

In seeking effective and safe PROTAC therapeutics for currently incurable diseases, the conventional one-drug-one-gene reductionist approach is insufficient. We advocate for a shift to systems pharmacology, utilizing rich data from patient and perturbation omics. Our recent efforts include predicting genome-wide PROTAC targets, cell type-specific phenotype screening, and using transfer learning to link disease models and human physiology. This AI-powered systems pharmacology approach shows promise in drug discovery.

10:20 Coffee Break in the Exhibit Hall with Poster Viewing

LINKEDIN SKILLS WORKSHOP

LINKEDIN SKILLS WORKSHOP

Jonathan Frampton, PhD, Vice President, Business Development, ProteoNic BV

11:00 Light-Inducible Protein Degradation in Bacteria

Nathan Tague, PhD, Founder, SynsoryBio

We engineered LOVdeg, a light-responsive protein tag that can be appended to a protein of interest for inducible degradation in *Escherichia coli* using blue light. We demonstrate the modularity of LOVdeg and pair it with other optogenetic systems for enhanced performance. Our results introduce a valuable tool for bacterial synthetic biology and exemplify the design of a dynamic degradation tag that interfaces with endogenous proteasome machinery.

11:30 CYpHER: Catalytic Extracellular TPD for Potent Degradation of CNS and Oncology Targets

Zachary R. Crook, PhD, Senior Research Scientist, Ben Towne Center, Seattle Children's Hospital

Extracellular targeted protein degradation (eTPD) is making rapid strides in targeting disease-associated proteins that are otherwise insufficiently inhibited by conventional drugs. We developed CYpHER, a catalytic eTPD technology that uses pH-engineered molecules that bind both target and transferrin receptor (TfR), driving target uptake and endosomal release. TfR also permits CNS access, and we are developing potent, durable molecules for targeting neurological conditions poorly served by existing strategies.

12:00 pm Single-Domain Antibody-Based Protein Degrader for Synucleinopathies and Tauopathies

Yixiang Jiang, PhD, Research Scientist, New York University

Synucleinopathies and tauopathies, characterized by a-synuclein or tau protein accumulation, lack effective treatments. Antibody therapies targeting these proteins aim to inhibit aggregation and enhance degradation, but face various challenges. Leveraging protein degradation technologies, we developed single-domain antibody-based degraders with excellent brain and neuronal uptake as well as improved capacity for a-synuclein or tau degradation, by increasing their proteasomal or lysosomal degradation. These strategies hold promise for treating synucleinopathies and tauopathies.

12:30 Enjoy Lunch on Your Own

1:10 Ice Cream & Cookie Break in the Exhibit Hall with Last Chance for Poster Viewing

EXPANDING THERAPEUTIC APPLICATIONS AND NOVEL APPROACHES *(CONT.)*

2:00 Chairperson's Remarks

Jin Wang, PhD, Director, Biochemistry and Molecular Pharmacology, Baylor College of Medicine

2:05 New Technologies for Advancing the Targeted Protein Degradation

H. Ümit Kaniskan, PhD, Associate Professor, Laboratory of Dr. Jian Jin, Pharmacological Sciences, Icahn School of Medicine at Mt. Sinai

The Jian Jin Laboratory at Icahn School of Medicine at Mount Sinai is a leader in discovering novel degraders targeting oncogenic proteins and developing new technologies for advancing the targeted protein degradation field. Our lab's progress in recent years advancing the targeted protein degradation, exemplified by Bridged PROTACs, TF-PROTACs, TeloTAC, Methyl-PROTAC, Z-PROTAC, and KEAP1-recruiting PROTACs, as well as additional approaches, will be discussed.

POWERFUL ASSAYS FOR HIGH-THROUGHPUT PROTEIN DEGRADATION

2:35 Analytical Ultracentrifugation Is a New Dynamic Platform Technology for Targeted Protein Degradation

Judith Ronau, PhD, Senior Scientist, AbbVie Inc.

Our group at AbbVie has joined forces with BioAnalysis, LLC to develop a powerful new platform assay that utilizes analytical ultracentrifugation to probe degrader-induced ternary complex formation more deeply, while addressing knowledge gaps in ternary complexes. We hope to share practical applications of this method/case studies with an audience that is interested in targeted protein degradation and next-generation degradation.

3:05 Revolutionizing TPD Hit Discovery: Ultra-High-Throughput DEL Phenotypic Assays for Detection of Protein Degradation and Transcriptomic Analysis

Daniel G. Sipes, MS, Senior Vice President, Technology, Plexium

Plexium harnesses a differentiated platform of proprietary technologies and approaches to establish a robust and diverse portfolio of monovalent targeted protein degrader therapeutics. Our cell-based uHTS platform leverages multiple assay formats including reporter, multiplexed immunofluorescence, transcriptomic, and phenotypic readouts resulting in identification of novel monovalent degraders, neosubstrates, and unprecedented E3 ligases. Microfluidic bead-based DNA encoded libraries enables interrogation of chemical space with advanced assays at a scale not otherwise practical.

3:35 Developing Robust Assays for Protein Degradation Studies

Ralph Mazitschek, PhD, Assistant Professor, Harvard Medical School; Co-Director of the Chemical Biology Platform, Center for Systems Biology, Massachusetts General Hospital

Developing robust assays for protein degradation studies is crucial for advancing drug discovery and understanding cellular mechanisms. This work focuses on designing reliable, sensitive, and high-throughput assays to monitor protein degradation dynamics. By integrating advanced detection methods and optimizing assay conditions, these tools enable precise quantification of degradation rates, contributing to the evaluation of therapeutic candidates and enhancing our knowledge of proteostasis regulation in health and disease.

4:05 Session Wrap-Up

4:15 Close of Conference

REGISTER EARLY & SAVE!
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PepTalk

The Protein Science and Production Week

ANTIBODY ENGINEERING

Antibody therapies have been approved for the treatment of cancer, immune disorders, metabolic, cardiovascular, and infectious diseases. PepTalk's **Antibody Engineering** pipeline offers a forum for protein scientists who are working to discover and develop differentiated biotherapeutics for additional unmet medical needs quickly and efficiently. These programs explore smarter and higher throughput screening methods, novel discovery platforms, strategies for dealing with challenging targets and modalities, creative engineering approaches for improving the precision and efficacy of therapeutic antibodies and the increasing role of machine learning and AI in discovery and engineering. Join us to explore the important advances in this dynamic field.

JANUARY 13
SYMPOSIUM

Bispecific Engineering & Therapeutics

AGENDA

JANUARY 14-15: **TRAINING SEMINAR**

Introduction to Antibody Engineering

AGENDA

JANUARY 15-16: **TRAINING SEMINAR**

Antibody Drug Discovery

AGENDA

REGISTER EARLY & SAVE!

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MONDAY, JANUARY 13

8:00 am Registration and Morning Coffee

8:50 Organizer's Welcome Remarks

Nikki Cerniuk, Conference Producer, Cambridge Healthtech Institute

OPTIMIZING AND ENGINEERING BI- AND MULTISPECIFICS

8:55 Chairperson's Opening Remarks

Danielle Dettling, CSO and Co-Founder, Fury Biosciences LLC

9:00 Improving Expression and Stability of Immunocytokine Therapeutics

Davis Goodnight, PhD, Scientist II, A-Alpha Bio

The development of immunocytokine therapeutics is hindered by challenges with expression and stability. In this talk, we discussed using computational remodeling tools to create stable cytokine variants and high-throughput measurements to improve their functional expression. The resulting immunocytokines showed improved developability and elicited an anti-tumor response with limited toxicity in a mouse syngeneic tumor model.

9:30 Designing Tumor-Selective Multispecific Antibodies for the Treatment of Solid Tumors

Danielle Dettling, CSO and Co-Founder, Fury Biosciences LLC

The immunosuppressive tumor microenvironment in solid cancers has long been documented to be highly dysregulated, contributing broadly to tumor survival. Numerous cell surface markers and enzymatic activities have been correlated with poor disease outcomes. We take an unbiased approach to the discovery of novel cell surface markers and enzymatic activities that can be leveraged to design and build tumor selective multispecific immunotherapies.

10:00 KEYNOTE PRESENTATION: Directed Assembly of Bispecific Antibody by Electrostatic Steering—Development of Platform and Application to Therapeutic Antibodies

Hitoshi Katada, PhD, Head, Biologics Engineering, Chugai Pharmaceutical Co. Ltd.

To address chain pairing when expressing bispecific antibodies, we have established FAST-Ig technology which promotes correct heavy- and light-chain assembly through electrostatic steering. In this presentation, development and application of FAST-Ig platforms including structural insight using two therapeutic antibodies will be introduced.

10:30 Holistic Process Development for Bispecific Antibodies—Tools and Digital Solutions

Alexi Cabatingan, Chromatography Resin Specialist Resin Specialist, Sales, Cytiva
Senthil Kumar, GoSilico Sales Specialist, Chromatography, Cytiva

Developing purification protocols for bispecific antibodies present extra challenges compared to conventional therapeutic monoclonal antibodies (mAbs). Strategies for efficient capture and polishing are discussed already in antibody engineering. The best combination of available resins and methods needs to provide sufficient separation of product and process related impurities. In this talk, we explore different purification strategies and see how *in silico* chromatography process development can streamline experimental PD work and simultaneously improve process understanding.

11:00 Networking Coffee Break

11:15 Engineering Solutions for Homogeneous Production of Asymmetric Bispecific Antibodies with the DuetMab Platform

John D. Bagert, PhD, Associate Director, Biologics Engineering, AstraZeneca

Asymmetric monovalent bispecific IgGs are becoming a leading biotherapeutic format, however, correct chain pairing remains a production challenge. Building on our clinically validated DuetMab platform, we present engineering solutions for streamlining the manufacturing of correctly assembled bispecific antibodies. We introduce novel electrostatic steering mutations and interchain disulfide engineering to facilitate orthogonal-chain pairing between heavy and light chains. We show the versatility of this platform for a diverse set of bsIgGs.

11:45 Trop2-Targeted CD28 Bispecific Antibodies Enhance T Cell Activation and Tumor Cell Killing

Yoon Kyung Kim, PhD, Scientist, Cell Biology, Xencor

T cell activation is initiated by TCR/CD3 binding to peptide-MHC and enhanced by co-stimulatory receptor engagement. Since solid tumors lack these ligands, we developed a bispecific antibody that bridges Trop2, an emerging target overexpressed on various solid tumors, to the CD28 co-stimulatory receptor on T cells. This presentation highlights preclinical data on Trop2-targeted CD28 co-stimulation combined with CD3 bispecific antibodies, aiming to prolong T cell survival and boost anti-tumor responses.

12:15 pm LUNCHEON PRESENTATION: Multifaceted AlivaMab® Platforms for the Discovery and Engineering of Novel Biologic Therapeutics

Jane Seagal, VP Antibody Discovery, Antibody Discovery, AlivaMab Biologics LLC

Efficient biologic therapeutic discovery and engineering relies on diverse, high-quality antibody libraries. Here we highlight the agility of AlivaMab Biologics and Ablexis platforms supported by a collection of AlivaMab® Mouse strains enabling the development of novel modalities, including fully human single-domain antibodies, a unique approach to CLC discovery, and TCRm antibodies. Our platforms consistently deliver molecules with the key attributes required for successful drug development.

12:45 Session Break

2:00 Chairperson's Remarks

Nick Till, PhD, Postdoctoral Fellow, Chemistry, Stanford University

2:05 Accelerating Lead ID: Navigating the bsAb ADC Discovery Landscape to Accelerate Drug Candidate Nomination

Nicholas Marshall, PhD, Head of Protein Sciences, Invenra Inc.

The potency and multi-target specificity advantages of bispecific antibody drug conjugates (bsAb ADC) differentiate them from traditional antibody therapeutics. The complexity of engineering bsAb ADC drugs is significant, and years may be spent optimizing for both efficacy and manufacturability. Using the B-Body bispecific platform, Invenra is able to validate target pairs and evaluate drug candidates simultaneously in a framework with proven manufacturability, thereby shortening the lead ID phase.

HARNESSING THE POWER OF CONDITIONAL ACTIVATION AND INDUCED PROXIMITY

2:35 Tailoring Multispecifics for Context-Dependent Efficacy

Matthew Lundberg, PhD, Associate Director, Protein Engineering, Tentarix Biotherapeutics Inc.

Multispecific antibodies hold immense therapeutic potential. However, their efficacy can be hindered by non-specific activation. This talk will explore strategies to engineer multispecifics for context-dependent activation, enhancing therapeutic index and minimizing off-target effects. By incorporating specific molecular triggers or cellular context cues, we aim to optimize multispecific antibodies for targeted and effective disease intervention.

3:05 Finding the Needle in the Bispecific Antibody Haystack with a Versatile Toolbox

Stefan Schmidt, PhD, CEO, evitria AG

Bispecific antibodies are currently the fastest growing segment of the antibody market. Selecting the antibody for binding is no longer sufficient as other parameters such as avidity, geometry, flexibility or spatial distance of the binders have a huge impact on the biological function. Therefore, a huge variety of formats has been developed. In this presentation we describe the manufacturing and comparison of a range of different versions and discuss properties and advantages of these antibodies.

3:35 Networking Refreshment Break

4:00 HCAb Harbour Mice®: Advancing Multi-Specific Antibodies, CAR-T, ADC, and mRNA-LNP Therapeutics

Joe JiuQiao Zhao, Head, External Innovation, Nona Biosciences

HCAb Harbour Mice® is a fully human immunoglobulin transgenic mouse platform that produces fully human heavy chain-only antibodies (HCAb). This presentation will explore the genesis and evolution of HCAb Harbour Mice®, highlighting the application of fully human VHH in bispecific and multi-specific antibodies, CAR-T therapies, ADCs, and mRNA-LNP therapeutics.

4:30 Trogocytosis-Targeting Chimeras (TrogoTACs) for Targeted Protein Transfer

Nick Till, PhD, Postdoctoral Fellow, Chemistry, Stanford University

Herein we disclose the development of bispecific molecules (TrogoTACs) capable of inducing contact-dependent protein transfer between cells by redirecting trogocytosis in a targeted fashion. To accomplish this goal, chimeric antibody–small molecule conjugates were designed with specificity to cell surface proteins with mutually exclusive expression on donor and acceptor cell types. The protein transfer process is rapid, requires cell-cell contact, and depends on expression of the receptors targeted by the TrogoTAC.

EXPANDING THERAPEUTIC APPLICATIONS BEYOND ONCOLOGY

5:00 Generation of Multispecific WNT Mimetics for Tissue Regeneration

Hui Chen, PhD, Associate Director, Protein Sciences, Surrozen

WNTs regulate myriad biological processes of stem cell function, tissue homeostasis, and injury repair in adults. However, it is very challenging to develop WNT molecules into therapeutic molecules due to their hydrophobic properties. We described a platform for potent, selective WNT surrogate generation by multivalent binding to WNT receptors. Recently, we further explored a cell-targeting system (BRidged Activation by Intra/intermolecular Division) for cell-specific targeting.

5:30 Dual Antibody Inhibition of KLK5 and KLK7 for Netherton Syndrome and Atopic Dermatitis

Cecilia Chiu, PhD, Scientist IV, Genentech, Inc.

Serine proteases kallikreins KLK5 and KLK7 are critical for maintaining skin barrier function. Excessive KLK activities can lead to Netherton syndrome and atopic dermatitis. Our study demonstrated that combined treatment with inhibitory anti-mKLK5 and anti-mKLK7 antibodies improves skin integrity and reduces inflammation in mouse NS and AD models. We further generated a humanized bispecific aKLK5/7 inhibitory antibody, presenting a promising therapy for clinical development in NS and other inflammatory dermatoses.

6:01 Close of Symposium

TUESDAY, JANUARY 14, 2025 8:30 AM - 6:30 PM | WEDNESDAY, JANUARY 15, 2025 8:30 AM - 11:00 AM

INTRODUCTION TO ANTIBODY ENGINEERING

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.

Instructors:
Andrew R.M. Bradbury, MD, PhD, CSO, Specifica, Inc., a Q2 Solutions Company

James D. Marks, MD, PhD

WEDNESDAY, JANUARY 15, 2025 3:15 PM - 5:50 PM | THURSDAY, JANUARY 16, 2025 8:15 AM - 4:15 PM

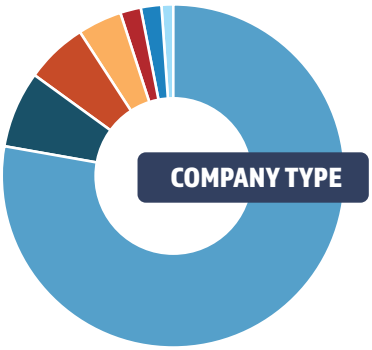
ANTIBODY DRUG DISCOVERY: FROM TARGET TO LEAD

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.

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

Cambridge Healthtech Institute Training Seminars offer real-life case studies, problems encountered and solutions applied, and extensive coverage of the basic science underlying each topic. Experienced Training Seminar instructors offer a mix of formal lectures, interactive discussions, and activities to help attendees maximize their learning experiences. These immersive trainings will be of value to scientists from industry and academic research groups who are entering new fields–and to those working in supporting roles that will benefit from an in-depth briefing on a specific aspect of the industry.

2024 ATTENDEE DEMOGRAPHICS

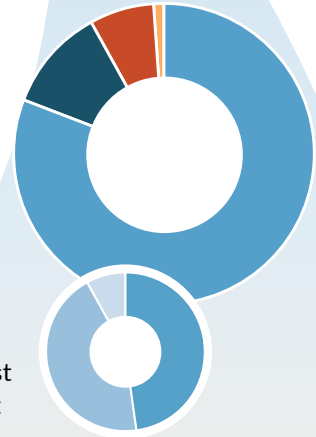


78% Biotech
7% Commercial
6% Academic
4% Services
2% Healthcare
2% CRO
1% Other

31% Sales & Marketing
28% Scientist/ Technologist
16% Executive
14% Director
7% Manager
2% Professor
2% Assistant

GEOGRAPHIC LOCATION

81% United States
11% Europe
7% Asia
1% Rest of World



US BREAKDOWN

48% West Coast
44% East Coast
8% Midwest

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- Ajinomoto Co Inc
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Conference Venue and Hotel:
Hilton San Diego Bayfront
1 Park Boulevard
San Diego, CA 92101

Discounted Room Rate: $296 s/d
includes complimentary Wi-Fi

Discounted Room Rate Cut-off Date: December 16, 2024

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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/BioLogic Room block for a minimum of 4 nights. Must be reserved by December 16, 2024. Only one discount applicable per hotel room.

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(Includes access to ALL conferences, training seminars, and symposia (4 days), and networking events. Plus, on-demand access. You are allowed to move between conference tracks to attend presentations taking place at the same time.)

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1 Symposium	$999	$599

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