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- Enhancing Antibody Binding and Specificity
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- Next-Generation Cancer Immunotherapies
- Antibody-Drug Conjugates
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FORMULATION & STABILITY
- Optimizing Biologics Formulation Development
- Lyophilization and Emerging Drying Technologies
- Protein Aggregation and Emerging Analytical Tools

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- Engineering Genes, Vectors, Constructs and Clones
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- Applying Expression Platforms

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- Detection and Characterization of Particulates and Impurities
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CONFERENCE-AT-A-GLANCE

	PART A		PART B		PART C	
	SUNDAY	MONDAY	TUESDAY AM	TUESDAY PM	WEDNESDAY	THURSDAY	FRIDAY
PIPELINE 1 Protein Engineering & Development	PRE-CONFERENCE SHORT COURSES*	Recombinant Protein Therapeutics		Enhancing Antibody Binding and Specificity; Membrane Proteins		Emerging Technologies for Antibody Discovery and Engineering	
PIPELINE 2 Antibody Therapeutics		Next-Generation Cancer Immunotherapies		Antibody-Drug Conjugates		Bispecific Antibody Therapeutics	
PIPELINE 3 Formulation & Stability		Optimizing Biologics Formulation Development		Lyophilization and Emerging Drying Technologies		Protein Aggregation and Emerging Analytical Tools	
PIPELINE 4 Expression & Production		Engineering Genes, Vectors, Constructs and Clones		Recombinant Protein Expression; Membrane Proteins; CHO Cell Culture		Applying Expression Platforms	
PIPELINE 5 Analytics & Impurities		Characterization of Biotherapeutics		Detection and Characterization of Particulates and Impurities		Extractables and Leachables	
PIPELINE 6 Process Technologies & Purification		Single-Use Technologies and Continuous Processing		Protein Purification and Recovery; Membrane Proteins		Higher-Throughput Protein Purification	
Short Courses*				Dinner Short Courses			
Cambridge Healthtech Training SEMINARS		Introduction to Bioprocessing; Introduction to Extractables and Leachables and Packaging		Introduction to Formulation			

*Separate Registration Required

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ABOUT PEPTALK

PepTalk: The Protein Science Week is one of the largest gatherings of protein science researchers in the world. It offers an array of education, innovation and networking programs, and provides many opportunities to scientists.

PepTalk is an annual gathering where industry experts from around the world convene to share case studies, unpublished data, breakthroughs and solutions that support and enhance research, and to gain new perspectives on the evolution of biologics.

Attend this Event to:
- Network with over 1300+ attendees from over 30 countries
- Hear unpublished data and case studies from industry leaders
- Create your own agenda – Premium Package allows access to all conferences for one price!
- Showcase your research by presenting a scientific poster
- Participate in the popular BuzZ Session Roundtable Discussions
- View over 150 scientific posters
- Build your own schedule using the event mobile app
- Visit over 100 companies in the exhibit hall
- Take advantage of student fellowships available for grad students and Ph.D. candidates

IT'S A WRAP:
PEPTALK 2016 CLOSING PLENARY PANEL DISCUSSION

Friday, January 22, 12:00 pm

Protein therapeutics is one of the fastest-growing global markets, driven by increasing adoption of protein- over non-protein drugs, growing funding for protein engineering and reduced drug discovery timelines and costs. As the science improves, so does the complexity of the R&D organization: it really does "take a village" to bring next-generation therapies to market and patients who need them. Ensuring product quality plus speed to market requires collective insights from experts working across the stages of protein science R&D – as embodied by panelists representing each PepTalk Pipeline topic.

PANELISTS

Randall Brezski, Ph.D.
Scientist, Antibody Engineering, Genentech, Inc.

Rakesh Dixit, Ph.D.
DABT, Vice President, Research & Development; Global Head, Biologics Safety Assessment, Medimmune

Thomas Laue, Ph.D.
Professor, Biochemistry and Molecular Biology; Director, Biomolecular Interaction Technologies Center (BITC), University of New Hampshire

Dominic Esposito, Ph.D.
Director, Protein Expression Laboratory, Frederick National Laboratory for Cancer Research, Leidos Biomedical Research, Inc.

Marisa K. Joubert, Ph.D.
Senior Scientist, Process Development, Amgen, Inc.

Jonas V. Schaefer, Ph.D.
Head, High-Throughput Laboratory, University of Zurich

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DINNER SHORT COURSES*

Sunday, January 17 • 5pm – 8pm

SC1: How to Set Up Collaborations between Academia and Industrial Biotech Companies
Not all academic and industrial organizations and scientists are aware of the possibilities and pitfalls of industrial-academic collaboration. By sharing our opinions and experiences, we hope to contribute to successful interactions between the biotech industry and the knowledge base of academic science. Any academic-industrial collaboration should start by acknowledging the different primary objectives of the partners. We discuss four different modes of collaboration between academia and industry: consulting, contract research, bilateral partnerships and public-private partnerships (PPPs).
Instructors:
- *Bernhard O. Palsson, Ph.D., Galletti Professor of Bioengineering, Professor of Pediatrics, and the Principal Investigator, Systems Biology Research Group, Bioengineering, University of California, San Diego*
- *Andrew Fosberry, Ph.D., Manager, Expression and Fermentation Sciences, GlaxoSmithKline*

SC2: Next-Generation Sequencing of Antibody Libraries: Bridging Experimental and Bioinformatic Methods
Next-generation sequencing of antibody repertoires provides a quantitative approach to measuring the diversity and distribution of antibody libraries. This course enables researchers to design, perform and analyze antibody NGS studies. Practical details of antibody NGS with an emphasis on *in vivo* libraries and the Illumina MiSeq platform are emphasized. Experimental sample preparation strategies that ensure the acquisition of high-quality NGS datasets are highlighted. Bioinformatics processing considerations and examples are also presented.
Instructor:
- *Tarik Khan, Ph.D., Postdoctoral Fellow, Department of Biosystems Science and Engineering, ETH Zurich*

SC3: A Rational Approach to Formulation Development of Biologic Therapeutics
The course offers a forum on how to develop sound formulations for biologic drugs. Case studies are presented to demonstrate how to incorporate QbD concepts to assess critical material attributes, design multivariate experiments, how to obtain representative data and how to analyze data in order to propose robust formulation for bulk drug substance or final drug product in the context of designated container closure systems. The course utilizes real-world examples and interactive discussion.
Instructor:
- *Kevin Zen, Ph.D., Senior Director, Biologics Development, Allgenesis Biotherapeutics*

SC4: Insect Cell Expression Systems: Cutting-Edge Advances for Enhancing Protein Production
We first introduce the baculovirus-insect cell system and share an overview of our experience expressing many proteins in it, together with information on high throughput. We include practical tips that facilitate your setup and use of this system for recombinant protein production. Finally, we present our latest research on host protein processing and efforts to engineer host pathways in insect cell systems. We will adjust the level of this course to participants' experience.
Instructors:
- *Dominic Esposito, Ph.D., Director, Protein Expression Laboratory, Frederick National Laboratory for Cancer Research, Leidos Biomedical Research, Inc.*
- *Donald Jarvis, Ph.D., Professor, Molecular Biology, University of Wyoming; President, GlycoBac, LLC*

SC5: Accelerated Stability Testing of Biologics
This short course aims to guide the researcher in designing studies for accelerated stability testing of biologics. The course begins with basic underlying concepts governing protein drug product stability, and focuses on design principles for measuring stress and accelerated stability testing of not only the protein of interest, but also of excipients and primary packaging components. Strategies to handle complexities arising from their interactions will also be discussed.
Instructors:
- *Jan Jezek, Ph.D., CSO, Development, Arecor Ltd.*
- *Vishal C. Nashine, Ph.D., Senior Research Investigator, Drug Product Science & Technology, Bristol-Myers Squibb Co.*

SC6: DNA Matters: Applications for High-Throughput Rational Design
As our understanding of gene sequence data increases, so does the ability to design and improve genes, pathways, genomes and organisms using synthetic biology techniques. This revolution in biology demands large quantities of custom, high-quality, synthetic DNA constructs and rationally designed libraries produced through high-throughput, high-capacity manufacturing processes. We present innovative technologies allowing high-throughput production of long, clonal, sequence-perfect DNA, and discuss diverse applications for synthetic DNA and rationally designed libraries across industry and academia.
Instructors:
- *Devin Leake, Ph.D., Vice President, R&D and Operations, Gen9, Inc.*
- *William Finlay, Ph.D., Director, Global Biotherapeutic Technologies, Pfizer, Inc.*

Tuesday, January 19 • 5:45pm – 8:45pm

SC7: Targeting of GPCRs with Monoclonal Antibodies
While GPCRs are important therapeutic targets, it has been challenging to discover therapeutically relevant antibodies against them. This course examines different steps along the anti-GPCR antibody discovery pathway and highlights various approaches to accomplishing each step. The topics covered include: antibody discovery, including methods to generate antibodies and antigen preparation; assays to measure antibody binding; *in vitro* assays to measure functional activity of the antibody; and review of promising GPCR targets and antibodies in the clinic.
Instructor:
- *Barbara Swanson, Ph.D., Director, Research, Sorrento Therapeutics, Inc.*

SC8: Designing Antibodies for Function and Low Risk of Immunogenicity
For antibody therapeutics, a variety of *in silico*, *in vitro* and *in vivo* immunogenicity selection/testing technologies are available and these can be used at various stages during antibody development from discovery through to lead optimization. This workshop provides an introduction to antibody immunogenicity, assessment of the technologies available for lead selection, rational sequence design through engineering and how these tools can be integrated with optimizing antibodies for desired function.
Instructors:
- *Tim D. Jones, Ph.D., Vice President, Biology, Abzena plc*
- *Christopher Thanos, Ph.D., Senior Director, Biotherapeutics Discovery Research, Halozyme Therapeutics, Inc.*

SC9: Lyophilization Formulation Development and Process Optimization
Nearly half of all marketed protein therapeutics are freeze-dried (lyophilized). Therefore, successful marketing of protein therapeutics requires the ability to develop this dosage form properly and efficiently. This dinner course will describe the basics of lyophilization, with a focus on how protein can be damaged during the freezing and drying steps. A tutorial on developing freeze-dried formulations will be given, followed by a discussion on cycle optimization. It is critical that the cycle and formulation be developed in tandem. Freeze-drying can be an expensive process, so the efficiency of the cycle and maintaining the integrity of the final formulation is paramount.
Instructor:
- *Mark Manning, Ph.D., CSO, Legacy BioDesign LLC*

SC10: Transient Protein Production in Mammalian Cells
This short course introduces both the fundamental concepts and technologies needed to establish transient protein production in mammalian cells. This allows for the rapid generation, purification and characterization of milligram-to-gram quantities of secreted or intracellular recombinant proteins for therapeutic, functional and structural studies. The course combines instruction and case studies in an interactive environment.
Instructors:
- *Richard Altman, MS, Research Scientist, Discovery Research, Alexion Pharmaceuticals*
- *Henry C. Chiou, Ph.D., Associate Director, Cell Biology, Life Science Solutions, Thermo Fisher Scientific*
- *Dominic Esposito, Ph.D., Director, Protein Expression Laboratory, Frederick National Laboratory for Cancer Research, Leidos Biomedical Research, Inc.*

SC11: Protein Aggregation: Mechanism, Characterization and Consequences
Protein aggregation is recognized by regulatory agencies and industry as a key quality attribute of biotherapeutic products. Various aggregates hold the potential for adversely impacting production and patients. This in-depth workshop reviews origins and consequences of aggregation in biotherapeutics, and then examines strategies for predicting and quantifying it. It benefits scientists engaged in development, production, analytical characterization and approval of biotherapeutics and who require a good working knowledge of aggregation.
Instructors:
- *Thomas Laue, Ph.D., Professor, Biochemistry and Molecular Biology; Director, Biomolecular Interaction Technologies Center (BITC), University of New Hampshire*
- *David F. Nicoli, Ph.D., Vice President, R&D, Particle Sizing Systems, LLC*

SC12: Improved Methods for Binder Screening and Validation
A robust pipeline for the high-throughput generation of affinity reagents enables many scientific projects and novel applications. To optimize the pipeline's throughput, we have developed a streamlined process, consisting of parallel Ribosome Display selections and various semi-automated high-throughput screenings. Also including aspects of target acquisition to binder validation while decreasing its time and cost requirements, we perform simultaneous selections against 94 targets and screen and validate several thousand binders in parallel for their characteristics.
Instructors:
- *Jonas V. Schaefer, Ph.D., Head, High-Throughput Laboratory, Biochemistry, University of Zurich*
- *Fridtjof Lund-Johansen, Ph.D., Group Leader, Immunology, Oslo University Hospital*

**Separate registration required*

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Cambridge Healthtech
Training SEMINARS*

JANUARY 18-19, 2016
DAY 1 8:30 AM - 5:30 PM | DAY 2 8:30 AM - 12:30 PM

TS1: Introduction to Bioprocessing

Instructors:
Sheila G. Magil, Ph.D., Senior Consultant, BioProcess Technology Consultants, Inc.
Frank J. Riske, Ph.D., Senior Consultant, BioProcess Technology Consultants

CHI's Introduction to Bioprocessing training seminar offers a comprehensive survey of the steps needed to produce today's complex biopharmaceuticals, from early development through commercial. The seminar begins with a brief introduction to biologic drugs and the aspects of protein science that drive the intricate progression of analytical and process steps that follows. We then step through the stages of bioprocessing, beginning with the development of cell lines and ending at scaling up for commercial production. The seminar also explores emerging process technologies, facility design considerations and the regulatory and quality standards that govern our industry throughout development. The important roles of analytical methods at all stages of development as well as formulation and stability assessments in developing and gaining approval for a biopharmaceutical are also examined. This 1.5-day class is directed to attendees working in any aspect of industry, including scientific, technical, business, marketing or support functions, who would benefit from a detailed overview of this field.

Instructor Biographies:

Sheila Magil has over 20 years of experience in quality and analytical method development for biologics, peptides and small molecules. Her expertise includes quality assurance, protein and peptide biochemistry and analytical development. She was formerly Senior Manager of Analytical Development and Quality Control at Biomeasure, Inc., and previously held positions at Waratah Pharma, Alkermes, Bion and HHMI at Massachusetts General Hospital. Dr. Magil has implemented quality systems and has managed external analytical and QC activities for multiple biopharmaceutical products. Dr. Magil holds a Ph.D. in Biochemistry from the University of Minnesota.

Frank J. Riske, Ph.D., Senior Consultant at BioProcess Technology Consultants has over 25 years of experience in the biopharmaceutical industry. Prior to joining BioProcess Technology Consultants, Dr. Riske was Senior Director in the Late Phase Process Development Group at Genzyme, a Sanofi company. Before Genzyme, Dr. Riske held positions at Epic Therapeutics, Repligen and Hoffmann-LaRoche. Dr. Riske has extensive experience in the development of downstream processes for cytokines, proteins and virus from plasma, *E. coli*, *Pichia* and mammalian systems and in the development and manufacture of novel drug delivery systems. Dr. Riske received his BS in Biology from Fairfield University, Ph.D. in Biochemistry and Microbiology from Rutgers University and completed a postdoctoral position at Hoffmann-LaRoche.

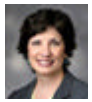
TS2: Introduction to Extractables and Leachables and Packaging

Instructor:
Diane Paskiet, MS, Director of Scientific Affairs, West Pharmaceuticals

Chemical substances can be leached into biologics from various components used in the manufacture, storage or delivery of a therapeutic product, leading to a negative impact on the product and potential for an undesirable effect on the patient. This training seminar provides a background on regulatory expectations for materials and components in contact with biologics and the unique applications to biologic delivery systems. Sources of leachables will be realized by understanding components of delivery systems as related to the physical and chemical requirements for various delivery systems. Attendees will be shown how to design studies to understand material chemistry through extractable studies and correlation to potential leachables. These learnings will put into perspective the current regulations and provide a means to develop best practices to manage extractables and leachables issues by applying science and risk-based approaches for assessing extractables and acquiring appropriate information to support regulatory submissions. Over the 1.5 days, the following topics will be addressed:

- Regulatory Expectations for Container Closure and Delivery Systems
- Overview of Materials Used to Manufacture, Store and Deliver Biologics
- Designing Studies to Qualify Materials for Intended Use
- Controlled Extractables Testing (CES)
- Leachables Studies
- Case Studies

Instructor Biography:



Ms. Paskiet has over 20 years of experience in polymer analysis relating to product failures, deformulation and migration studies. She has served as a project advisor in support of qualification studies associated with container closure systems for IND and NDA filings. Her current responsibilities include coordination of studies for technical support and R&D. Previous to this role she was in charge of site operations for West-Monarch Analytical Laboratories.

JANUARY 19-20, 2016
DAY 1 2:00 PM - 5:30 PM | DAY 2 8:30 AM - 5:00 PM

TS3: Introduction to Biologics Formulation and Delivery

Instructor:
Timothy Kelly, Ph.D., Vice President, Biopharmaceutical Development, KBI Biopharma, Inc.

The course focuses on strategies to plan and execute preformulation and formulation development studies for biologics, which require co-optimization of multiple physical, chemical and conformational stability attributes while operating under accelerated timelines to deliver the drug to the clinic.
The course begins with an overview of biophysical and biochemical properties of proteins. A typical development workflow (including statistical analysis and DOE elements) will be outlined to demonstrate the core elements employed during protein formulation. The course concludes with real-world examples from formulation development projects for liquid and lyophilized products.

Topics include:
- Basics of protein biochemistry, with focus on folding mechanism, stability and structural hierarchy
- Degradation pathways relevant to biologics shelf life
- Biophysical and analytical characterization tools
- Typical workflow for biologics formulation development projects
- Introduction to common delivery devices

Instructor Biography:

Tim Kelly has over 20 years of experience in protein and nucleic acid characterization. In his role at KBI Biopharma, Tim is responsible for analytical development, formulation development and quality control. Prior to joining KBI Biopharma, Tim held the position of Director of Quality Control for Diosynth Biotechnology, where he was responsible for method validation, in-process control, release and stability of clinical and commercial biopharmaceutical products. Tim's experience also includes the analytical development, formulation development, characterization and/or production of more than 200 clinical and commercial protein therapeutics, including monoclonal antibodies, enzymes, cytokines, fusion proteins, PEGylated proteins, protein vaccines and peptides. Tim has led the successful formulation development of over 95 clinical and commercial biopharmaceutical products, including liquid and lyophilized dosage forms for intravenous and subcutaneous administration, at protein concentrations ranging from 10μg/mL to 200mg/mL. Tim earned his Ph.D. in Molecular Genetics & Biochemistry from Georgia State University.

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Recombinant Protein Therapeutics

Fusion Proteins and Beyond

Cambridge Healthtech Institute's Recombinant Protein Therapeutics conference explores the customizable functionality of fusion protein therapeutics, which possess advantages over antibody-based therapies by combining modular building blocks that can reach targets not accessible to antibodies. Additional advantages include lower patient dosing, reduced production costs and improved product homogeneity. This meeting explores the varying constructs and "designs" of fusion protein molecules, and discloses how these proteins are being engineered to form more efficacious therapeutics that offer specificity with enhanced stability and longer half-life.

SUNDAY, JANUARY 17

4:00-5:30 pm Registration

5:00-8:00 Dinner Short Courses *See page 4 for details*

MONDAY, JANUARY 18

7:30 am Conference Registration and Morning Coffee

DELIVERY INNOVATIONS

9:00 Chairperson's Opening Remarks
Stefan Schmidt, Ph.D., MBA, Vice President, Process Science and Production, Rentschler Biotechnology

KEYNOTE PRESENTATION

9:10 Blood-Brain Barrier Penetrating IgG-Fusion Proteins for the Treatment of Lysosomal Storage Disorders
Ruben Boado, Ph.D., Vice President, R&D, ArmaGen, Inc.
Lysosomal enzymes, such as iduronase (IDUA) and sulfatases, are large molecule drugs that do not cross the blood-brain barrier (BBB). The BBB-penetration of enzyme therapeutics is enabled by re-engineering the recombinant enzyme as IgG fusion proteins, wherein the IgG transport domain targets a specific endogenous receptor-mediated transporter within the BBB, such as the human insulin receptor (HIR). First-in-human clinical trials are in progress.

9:50 Drug Delivery and Immunotherapy Enabled by a Tumor-Targeting Peptide-Fc Fusion
Jennifer Cochran, Ph.D., The Hitachi America Associate Professor, Bioengineering, and Chemical Engineering Director, Graduate Studies, Stanford University
I will discuss an engineered peptide-Fc fusion protein that we have adapted for targeted delivery of chemotherapeutic agents, as well as recruitment of immune cell effector functions to tumors. The co-administration of peptide-Fc fusion and an immune stimulating cytokine results in significant control of tumor growth in melanoma and colon carcinoma models, which is further enhanced by combination with checkpoint blockade inhibitors.

10:20 Coffee Break

OVERCOMING DISEASE

▸ **FEATURED PRESENTATION**

10:45 Next-Generation FVIII Fusion Protein Incorporating Both XTEN Insertions and von Willebrand Factor
Robert Peters, Ph.D., Vice President, Hematology Research, Biogen

11:15 Development of Luspatercept as a Therapeutic for Anemia Caused by Ineffective Erythropoiesis
Ravindra Kumar, Ph.D., CSO, Acceleron Pharma, Inc.
Several members of the TGF superfamily such as activins, GDF11 regulate gene transcription thru Smad2/3 phosphorylation. Increased Smad2/3 phosphorylation has been observed in diseases of anemia caused by ineffective erythropoiesis such as thalassemia and myelodysplastic syndrome (MDS). We have developed luspatercept (ACE-536) as a trap for selective ligands responsible for Smad2/3 activation. Murine ortholog of ACE-536 (RAP-536) has been shown to enhance differentiation of late stage erythroblasts and attenuate ineffective erythropoiesis. We will show the effect of RAP-536 treatment to correct anemia in murine model of thalassemia and MDS.

11:45 Development of Physiocrine-Based Therapeutics
Andrew Cubitt, Ph.D., Vice President, Intellectual Property, aTyr Pharma, Inc.
Physiocrines are extracellular signaling regions of tRNA synthetases, enzymes that catalyze a key step in protein synthesis, and act as endogenous modulators of the immune system. Physiocrines offer the opportunity to modulate biological pathways through naturally occurring mechanisms that provide advantages including reduced side effects. Our product, Resokine IV, is in Phase I clinical trials, and is a therapeutic for rare disorders where a patient's immune system is imbalanced.

12:15 pm Sponsored Presentation *(Opportunity Available)*

12:45 Session Break

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

TARGETING CANCER

2:00 Chairperson's Remarks
Céline Monnet, Ph.D., Senior Scientist, Molecular Design Unit, Innovation Department, LFB Biotechnologies

2:05 Targeting MUC16-Positive Malignancies with the Novel TRAIL-Based Cancer Therapeutic Meso64-TR3
Dirk Spitzer, Ph.D., Instructor, Surgery, Washington University School of Medicine
We recently redesigned the way the soluble TNF superfamily member TRAIL can be produced from mammalian cells by creating a head-to-tail fusion protein (trimer), designated TR3. This new drug platform has great potential as a cancer therapeutic due to its extensibility with the goal of creating tumor-targeted TR3 analogs in a stoichiometrically controlled fashion. Here, we will present our latest data on the second generation, MUC16 (CA125)-targeted biologic Meso64-TR3.

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2:35 Potential Role of LEC/Antibody Fusion Protein in the Immunotherapy of Cancer
Alan L. Epstein, M.D., Ph.D., Professor, Pathology, University of Southern California Keck School of Medicine
A novel fusion protein consisting of the human chemokine LEC and a human antibody that targets degenerative regions of tumors has been found to be an effective reagent for the immunotherapy of cancer. Used with inhibitors of tumor-induced immunosuppression, experimental tumors show dramatic regression after IV treatment. Due to its broad applicability and unique mechanism of action, this reagent has high potential in enhancing current immunotherapy approaches and vaccine technology.

3:05 Engaging Innate and Adaptive Immunity Using Cancer-Reactive Immunocytokines
Paul M. Sondel, M.D., Ph.D., Professor, Pediatrics, Hematology & Oncology, University of Wisconsin, Madison
Ideal cancer therapy should be tumor-specific, eradicate primary tumors and metastases and prevent recurrence. Our research team has used tumor-reactive mAbs linked to IL2 (immunocytokines) as an initial platform to induce innate and adaptive anti-tumor effects. Effective preclinical approaches have moved into clinical testing. We are now testing immunotherapies in combination; our goal is to identify and refine combinations of "off the shelf" immunotherapies that can eliminate cancer.

3:35 Sponsored Presentation *(Opportunity Available)*

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

INNOVATIVE ENGINEERING

4:30 Affibody-Based C5 Inhibitors for Targeting the Terminal Complement Pathway
Patrik Strömberg, Ph.D., MBA, Senior Director and Head, Biomedical Science & Portfolio Innovation, Swedish Orphan Biovitrum AB (SOBI)
Complement inhibitors against C5 have been developed utilizing the innovative Affibody scaffold for protein targeting. In order to optimize and "tailor" the PK/PD properties for leads in different applications, various fusion protein and protein engineering approaches were tested. In this talk, data from several fusion proteins and PEGylated molecules will be described.

5:00 Proinsulin-Transferrin Fusion Protein as a Long-Lasting and Liver-Targeted Insulin Analog
Wei-Chiang Shen, Ph.D., John A. Biles Professor, Pharmacology & Pharmaceutical Sciences, University of Southern California
Liver-specific insulin action is important in insulin therapy due to physiological relevance. A fusion protein (ProINS-Tf) consisting of proinsulin (ProINS) and transferrin (Tf) was prepared. The liver-targeted effect is due to: Tf receptor-mediated endocytosis, intracellular activation of ProINS-Tf, and long retention of the activated form in hepatocytes. In Type 1 diabetes mice, ProINS-Tf demonstrated: a long-lasting glucose lowering effect, no peripheral insulin action, and no severe hypoglycemia at high doses.

5:45 BuzZ Session A
Join your peers and colleagues for interactive roundtable discussions.
Please see page 55 for additional information.

6:30-7:45 Welcome Reception in the Exhibit Hall with Poster Viewing

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7:45 Close of Day

TUESDAY, JANUARY 19

8:00 am Conference Registration and Morning Coffee

IMPROVING PROPERTIES AND STRATEGIES

8:30 Chairperson's Remarks
Wei-Chiang Shen, Ph.D., John A. Biles Professor, Pharmacology & Pharmaceutical Sciences, University of Southern California

8:35 Fc Engineering to Increase Half-Life and Reduce Effector Functions
Céline Monnet, Ph.D., Senior Scientist, Molecular Design Unit, Innovation Department, LFB Biotechnologies
Using random mutagenesis and phage display technologies, we have isolated several Fc variants of human IgG1 with improved affinity for the neonatal Fc receptor (FcRn). These Fc variants allow for increased serum persistence in human FcRn-transgenic mice. Their binding capacities to complement and FcgRs are variably affected. The variant with the longest half-life proved devoid of effector functions and could be used to improve therapeutic Fc fusion proteins.

9:05 Affibody-Based Ligand-Trap that Blocks IL-17 with Unparalleled *in vivo* Potency and Long Plasma Half-Life
Joachim Feldwisch, Ph.D., Director, Preclinical Development, Affibody AB
Il-17 is a potent inducer of tissue inflammation involved in auto-inflammatory disease. Here we describe the engineering of a ligand trap fusion protein designed to block IL-17 mediated pathology. The ligand trap is based on two small Affibody scaffold domains for IL-17 inhibition, and an albumin binding domain for extended plasma half-life supporting once monthly dosing. The fusion protein has unparalleled potency with complete blocking of the dimeric interleukin.

9:35 Sponsored Presentation *(Opportunity Available)*

9:50 Coffee Break in the Exhibit Hall with Poster Viewing

11:00 Targeting Therapeutics with an Antibody Specific to Damaged Arthritic Cartilage
Ahuva Nissim, Ph.D., Reader, Antibody and Therapeutic Engineering, Biochemical Pharmacology, Queen Mary University
Our study demonstrates an antibody that binds specifically to arthritic cartilage enhanced therapeutic efficacy of murine tumor necrosis factor receptor 2-Fc (mTNFR2-Fc, a mouse version of Etanercept) and viral-IL-10 (vIL-10). Our platform technology is novel and combines several approaches to achieve what no existing treatment can do: a drug can be injected systemically, localize specifically to arthritic joints, remain there and release its therapeutic payload in response to disease activity.

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11:30 Manufacturing Recombinant Protein Therapeutics under Cost Constraints
Stefan Schmidt, Ph.D., MBA, Vice President, Process Science and Production, Rentschler Biotechnology
Biologicals represent the fastest growing segment in the drug pipeline, which puts pressure on economical manufacturing. Here I demonstrate how to solve challenges by applying disposables, using modular concepts, scaling up of perfusion processes, replacing costly affinity resins and reducing the number of steps in platform processes. With examples from fusion proteins to biosimilars, the case studies highlight successful process design, optimization strategies, and critical manufacturing parameters.

Sponsored by novozymes

12:00 pm Veltis® Technology: Engineered Albumins for Optimized Serum Half-Life Extension
Darrell Sleep, Director, Novozymes Biopharma R&D
Short circulatory half-life represents a major obstacle for many protein and peptide-based therapeutics, resulting in increased dosing with the consequent risk of side effects and reduced patient compliance. The half-life of therapeutic can be significantly improved by conjugation or fusion to albumin, improved half-life is a result of increased size and recycling via the neonatal Fc receptor (FcRn). We will describe rationally engineered albumins with increased FcRn affinity, and their application to improve the pharmacokinetic properties of therapeutic candidates, along with a new transgenic rodent model to aid the preclinical development of albumin-based drugs.

12:30 Session Break

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

1:45 Close of Conference

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Enhancing Antibody Binding and Specificity

Scientific Strategies for Measuring and Engineering Target-Specific Binding and Specificity for Next-Generation Antibody Therapeutics

As the industry expands its repertoire of antibody-drug products into new therapeutic areas, product formats and protein constructs, the control of antibody/antigen targeting, binding and specificity will take on a new level of importance for researchers in this field. The Enhancing Antibody Binding and Specificity conference presents innovative approaches to the modulation of binding activity, mechanism of action and difficult target challenges such as transmembrane proteins and intracellular targeting.

TUESDAY, JANUARY 19

1:00 pm Conference Registration

2:00 Chairperson's Opening Remarks
Yasmina Abdiche, Ph.D., Research Fellow; Head, Bioanalytics Group, Rinat-Pfizer

KEYNOTE PRESENTATION

2:05 New Methods and Antibody Formats for Achieving Exceptional Specificity
Shohei Koide, Ph.D., Professor, Biochemistry and Molecular Biology, University of Chicago
Creating affinity reagents that discriminate subtle chemical differences, such as post-translational modifications, remains a major challenge, although the problem of achieving high affinity is essentially solved. We have engineered antibody and non-antibody reagents with high specificity, including those that cleanly discriminate the difference of a methyl group, arguably the smallest difference in protein antigens. A surprising mechanism underlying their exquisite specificity led to new antibody formats suitable for achieving exceptional specificity.

STRATEGIES AND TECHNOLOGIES FOR EPITOPE MAPPING

2:45 Strategies and Applications for Epitope Mapping
Caroline Colley, Ph.D., Senior Scientist, Antibody Discovery and Protein Engineering, MedImmune
There are a variety of epitope mapping methods with a range of different applications in antibody discovery. These range from low-resolution approaches, such as competition assays, which enable selection of antibodies recognizing different regions of the target, through to high-resolution X-ray crystallography, which can contribute to defining mechanism of action. This talk outlines epitope mapping approaches at MedImmune, and using case studies, highlights their application for drug discovery.

3:15 Refreshment Break in the Exhibit Hall with Poster Awards

4:00 Sponsored Presentation *(Opportunity Available)*

4:30 Advances in the Analytical Methods Used to Characterize the Epitopes of Monoclonal Antibodies
Yasmina Abdiche, Ph.D., Research Fellow; Head, Bioanalytics Group, Rinat-Pfizer
This talk will focus on high throughput biosensor methods aimed at characterizing epitopes of monoclonal antibodies in the context of drug discovery. Data will be corroborated by orthogonal analytical techniques.

5:00 Epitope Diversity Evaluation in the Early Screening Funnel
Alexander Ivanov, Ph.D., Senior Scientist, AbbVie Bioresearch Center
Generation of large and diverse pools of biologic molecules may be critical to improve success in Biologic drug discovery. Properly designed high throughput screening at a very early stage could be important to secure competitive advantage. The talk will provide case study examples and review of the role and use of emerging and existing technologies for early epitope diversity screening that could help in selecting a drug candidate, save time and resources on assay development, enrich institutional knowledge and potentially inform intellectual property considerations.

5:30-5:45 Short Course Registration

5:45-8:45 Dinner Short Courses *See page 4 for details*

WEDNESDAY, JANUARY 20

8:00 am Conference Registration and Morning Coffee

ENGINEERING ANTIBODY BINDING AND SPECIFICITY

8:30 Chairperson's Remarks
Tilman Schlothauer, Ph.D., Senior Scientist, Biochemical and Analytical Research, Large Molecule Research, Roche Pharma Research and Early Development (pRED), Roche Innovation Center Penzberg

8:35 Biologic and Antibody Approaches to Undruggable Intracellular Targets
David A. Scheinberg, M.D., Ph.D., Vincent Astor Chair, and Chairman, Molecular Pharmacology Program, Sloan Kettering Institute
Most proteins and oncogenic drivers are not druggable currently with small molecules. MHC presentation of peptide fragments of these critical proteins on the cell surface allows recognition and killing of target cells by TCR's on T cells after vaccination or by use of TCR mimic antibodies. Several examples with multiple formats showing selectivity and cytotoxicity to several cancer cell types will be demonstrated.

9:05 Targeting Cell Surface Antigens with a Novel Therapeutic Antibody Concept
Paul W.H.I. Parren, Ph.D., Senior Vice President and Scientific Director, Genmab
IgG molecules can form ordered hexamers upon binding to membrane-bound antigens. We developed a novel therapeutic antibody platform inspired by this natural mechanism. By introducing specific mutations in the Fc domain, we developed the HexaBody technology, a novel antibody format that shows enhanced hexamerization upon target binding on a cell surface, while remaining fully monomeric in solution. This presentation describes therapeutic applications of HexaBody for the treatment of cancer.

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Enhancing Antibody Binding and Specificity

Scientific Strategies for Measuring and Engineering Target-Specific Binding and Specificity for Next-Generation Antibody Therapeutics

Sponsored by SCHRÖDINGER. BIOLOGICS

9:35 Computational Advances in Antibody Design: Toward Improved Optimization and Selection
David Pearlman, Ph.D., Senior Principal Scientist, Schrödinger
Recent computational advances hold significant promise both for improved prediction of antibody structure from sequence, and for the ability to precisely calculate physically relevant properties such as affinity and stability. When combined with additional theoretical approaches to identify liabilities, we can use these tools to variously optimize a lead antibody candidate and triage among multiple potential leads.

10:05 Coffee Break in the Exhibit Hall with Poster Viewing

10:50 Novel Insights of Engineering Non-Antigen Contact Regions of Factor VIII Mimetic Bispecific Anti-Factor IXa/Factor X IgG Antibody
Yuri Teranishi, Researcher, Antibody Engineering Group, Discovery Research, Chugai Pharmaceutical Co., Ltd.
ACE910 is a humanized anti-factors IXa and X bispecific IgG4 antibody that places two factors into proximity and mimics factor VIII function for the treatment of hemophilia A. We have evaluated the effect of modification of non-antigen contacting regions on the biological activity of FVIII mimetic bispecific antibody. Some novel insights from this study unique to our bispecific antibody will be presented.

11:20 Antibody Engineering for Enhanced Ph-Dependent FcRn Interaction
Tilman Schlothauer, Ph.D., Senior Scientist, Biochemical and Analytical Research, Large Molecule Research, Roche Pharma Research and Early Development (pRED), Roche Innovation Center Penzberg
The human Fc receptor neonatal (FcRn) is responsible for endosomal antibody transport and mediation of antibody half-life. Many approaches of IgG engineering have been tested in the past to increase the binding affinity to FcRn. A possible pitfall of such approaches is the isolated view only at the Fc domain. We observed by the application of several FcRn interaction analyses and antibody engineerings that an antibody needs to be considered as a whole molecule for appropriate pH dependent FcRn engineering.

11:50 Insights into the Molecular Basis of a Bispecific Antibody's Target Selectivity
Yariv Mazor, Ph.D., Scientist, Antibody Discovery and Protein Engineering, MedImmune, LLC
Dual targeting is thought to enhance biological efficacy, limit escape mechanisms, and increase target selectivity via a strong avidity effect mediated by concurrent binding to both antigens on the surface of the same cell. However, factors that regulate the extent of target selectivity are not well understood. We show that dual targeting alone is not sufficient to promote efficient target selectivity, and report the substantial roles played by the affinity of the individual arms, overall avidity and valence.

12:20 pm Sponsored Presentation *(Opportunity Available)*

12:50 Session Break

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

DISCOVERY AND DEVELOPMENT OF ANTIBODIES FOR MEMBRANE PROTEIN TARGETS

2:00 Chairperson's Remarks
Caroline Colley, Ph.D., Senior Scientist, Antibody Discovery and Protein Engineering, MedImmune

2:05 Antibody Discovery Against GPCRs Using Yeast Antibody Display Technology
Abhishek Datta, Ph.D., Scientist II, Drug Discovery, Biogen
G-protein coupled receptors (GPCRs) are membrane proteins that are important drug targets. The development of therapeutic antibodies against them has been challenging. We have employed multiple strategies to identify antibodies against a Class A GPCR. Here we present selection strategies that have enabled identification of antibodies using the Adimab yeast antibody discovery and optimization platform. Functional characterization of these antibodies and their potential use as a therapeutic in immunological disorders will be discussed.

2:35 Engineering Ion Channels for Structural Studies and Ligand Discovery
Susmith Mukund, Senior Research Associate, Genentech, Inc.

3:05 Antibody-Mediated Blockade of Human Orai1 Inhibits T Cell Activation *in vitro* and *in vivo*
Stefan Zahn, Ph.D., Principal Scientist, Antibody Technology, Novo Nordisk A/S
Ion channels are widely expressed on cells and tightly regulate the flow of ions between the extracellular and the intracellular environment. Dysregulation has been linked to pain, epilepsy and even autoimmune inflammatory diseases. We will present our recent work on targeting T cell-specific ion channels like CRAC by antibodies inhibiting T cell activation *in vivo* and *in vitro*.

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

4:30 Targeting Tumor Selective Cell Surface Antigens Using Designer Antibodies
Madan Katragadda, Ph.D., Senior Principal Scientist, Pfizer, Inc.
Potent novel means of therapeutic intervention utilizing immune cell retargeting and antibody-drug conjugates necessitates tumor selective targets owing to their extremely high potent nature. Several strategies have evolved in the past decade to selectively target tumors by either exploiting antigens, antigen complexes and glycoepitopes that are selectively overexpressed on tumor cells relative to the normal cells or simultaneously targeting two or more antigens using antibody engineering techniques. Examples describing these strategies are presented.

5:00 Challenges in Generating Antibodies to Integral Membrane Proteins
Ramkrishna (Ramu) Sadhukhan, Senior Group Leader, AbbVie Bioresearch Center Center
Developing therapeutic antibodies against integral membrane proteins is difficult, as GPCRs and ion channels are often expressed at low levels on cell surface and are unstable when purified. Poor quality membrane protein immunogens has led to limited success in generating antibodies that bind native cell surface molecules and remains a bottleneck for membrane protein target validation and monoclonal antibody-based therapeutics. Here, we present antigen preparation and antibody generation against multispanner proteins.

5:45 BuzZ Session B
Join your peers and colleagues for interactive roundtable discussions.
Please see page 55 for additional information.

6:30-7:30 Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Conference

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Emerging Technologies for Antibody Discovery and Engineering

Cutting-Edge Technologies to Enable the Discovery of Novel Biotherapeutic Targets and Well-Behaved Biotherapeutics

As large pharma continues its integration of biologic drugs into its product portfolios and discovery operations, it is imperative that industry companies identify truly novel drug targets for unmet medical needs – and that the biotherapeutics against these are selected and engineered to minimize development risk. The Emerging Technologies for Antibody Discovery and Engineering conference offers a forum for showcasing the current state of the art for research methodologies that will support the discovery and development of next-generation biotherapeutics.

THURSDAY, JANUARY 21

7:45 am Conference Registration and Morning Coffee

8:15 Chairperson's Opening Remarks
Randall Brezski, Ph.D., Scientist, Antibody Engineering, Genentech, Inc.

KEYNOTE PRESENTATION

8:20 Integrated Computational Design and High-Throughput Screening
Philip M. Kim, Ph.D., Associate Professor, Computational and Integrative Biology, University of Toronto
I will present our advances in combining computational and experimental techniques to develop novel inhibitors. We have developed an integrated pipeline that first computationally designs large libraries of potential inhibitors and can then screen these for either cellular phenotype or high affinity binding. I will showcase this pipeline on two example applications, first for developing inhibitors to protein-protein interactions and second for developing novel high-affinity biologics.

EMERGING SELECTION METHODOLOGIES

9:00 Screening for Blood-Brain Barrier Targeting Antibodies
Eric Shusta, Ph.D., Professor, Chemical and Biological Engineering, University of Wisconsin
The blood-brain barrier presents a substantial obstacle to brain drug delivery. To help address this issue, we have recently developed a variety of antibody screening paradigms specifically designed with the blood-brain barrier in mind. New screening paradigms and resultant antibodies that have preference for the brain vasculature will be discussed.

9:30 Targeting Influenza A: Discovery and Structural Analysis of a Human-Derived Broadly Neutralizing Anti-HA Antibody
Patrick Lupardus, Ph.D., Scientist, Structural Biology, Genentech, Inc.
Influenza A results in millions of infections worldwide each year and represents a significant pandemic threat. Using a technique to enrich and isolate antigen-targeted plasmablasts from vaccinated healthy donors, we discovered an anti-hemagglutinin (HA) antibody that neutralizes all clinically relevant Influenza A strains and is efficacious in preclinical models of infection. Structural analysis identified the stalk region of HA as the epitope and provides a molecular mechanism for virus neutralization.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

11:00 B Cell Selection for Antibody Discovery
Partha Chowdhury, Ph.D., Principal Scientist, MedImmune
Despite being a useful platform for antibody discovery, the main bottleneck of the hybridoma technology has been the low number of specific hits that are typically obtained. This necessitates large number of fusions and deep mining of clones for assuring success. This presentation will be about a new process improvement approach showcasing how B cell population can be fractionated to ensure a large increase in the quantity and quality of hybridoma generation.

11:30 Engineering a Protease Inhibitor Scaffold for Alternative Functions
Henry Maun, Ph.D., Principal Scientific Researcher, Early Discovery Biochemistry, Genentech, Inc.
Sponsored by PALL Life Sciences

12:00 pm Session Break

12:15 Presentation to be Announced
Sponsored by AbCellera

1:15 Ice Cream Break in the Exhibit Hall with Poster Viewing

ANTIBODY DISCOVERY LIBRARIES

2:00 Chairperson's Remarks
Partha Chowdhury, Ph.D., Principal Scientist, MedImmune

2:05 High-Throughput Sequencing of B Cell VH:VL Pairs and Proteomic Methods for the Discovery of Human mAbs in Serum
Gregory C. Ippolito, Ph.D., Research Assistant Professor, Molecular Biosciences, The University of Texas at Austin
The Georgiou Group has developed and patented technologies for the extensive molecular analysis of human antibody responses. These techniques allow for the direct comparison of protein-level serum antibody repertoires to DNA-level repertoires in circulating peripheral blood B cells. Their utility for the discovery of native serum antibodies shall be discussed.

2:35 Novel Phage Display Library from Naïve Rabbit Antibody Repertoires
Christoph Rader, Ph.D., Associate Professor, Cancer Biology and Molecular Therapeutics, The Scripps Research Institute
Owing to their high affinities and specificities, rabbit mAbs have demonstrated value and potential as basic, diagnostic, and therapeutic reagents. We generated and validated a large naïve rabbit antibody repertoire represented by a phage display library encompassing >10 billion independent antibodies. Rabbit mAbs selected from this library against a panel of human antigens revealed high affinity, specificity, and diversity, as well as therapeutic utility as components of CAR-engineered T cells.

3:05 Creating Focused Mutant Libraries for Protein Engineering
Nels Thorsteinson, Scientific Services Manager, Biologics, Chemical Computing Group
Sponsored by CHEMICAL COMPUTING GROUP
Protein engineering plays a pivotal role in modulating the function, activity and physical properties of biologics. However, the efficient search and evaluation of an excessively large sequence design space is challenging. Here we have developed a computational approach which predicts mutation probabilities for given residue sites in specified sequences. In assessing the probabilities at given residue sites, the sequence search space can be efficiently sampled to design and produce focused mutant libraries.

Emerging Technologies for Antibody Discovery and Engineering

Cutting-Edge Technologies to Enable the Discovery of Novel Biotherapeutic Targets and Well-Behaved Biotherapeutics

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

4:15 Antibodies from Immunotherapy Treated Cancer Patients
Mark Branum, Ph.D., Director, Theraclone Sciences
Theraclone utilizes its proprietary I-STAR human B-cell technology platform to discover novel targets and antibodies. The memory B cell repertoires of several cancer patients with clinical responses immunotherapy were interrogated. Antibodies from these patients were sequenced, expressed and and characterized for tumor reactivity.

4:45 Next Generation Sequencing (NGS) in mRNA Display Selections
Ginger Chao Rakestraw, Ph.D., Senior Research Investigator II, Bristol-Myers Squibb
Applications of NGS with mRNA display selection will be discussed. This will include methods to recover low-abundance sequences from a diverse population and additional methods for rapid optimization of antibodies and other polypeptides.

5:15 A Pipeline to Select Human Antibodies *in vivo* Against Defined Cancer Targets
Fortunato Ferrara, Ph.D., Research Assistant Professor, Experimental Therapeutics, University of New Mexico
We have developed an *in vitro* approach that combines the advantage of phage display selection with yeast display cell sorting, to discover hundreds of recombinant human antibodies against different targets, including cancer biomarkers. For immune-based cancer detection and treatment, antibodies recognizing targets in their native state are required. For this reason, we have introduced *in vivo* screening to our pipeline to isolate effective candidates for cancer detection.

5:45 Close of Day

6:00-7:00 Reception in the Tiki Pavilion

FRIDAY, JANUARY 22

8:00 am Conference Registration and Morning Coffee

OPTIMIZING ANTIBODY DISCOVERY AND ENGINEERING

8:30 Chairperson's Remarks
Mohammad Tabrizi, Ph.D., Head, Director & Senior Fellow, Merck Research Laboratories

8:35 Screening Antibodies for Conformational and Colloidal Stability
Mark Brader, Ph.D., Biopharmaceutical Industry Consultant, Formulation Development; Former Principal Scientist, Biogen
A major challenge to more efficient mAb developability engineering and formulation optimization is decision-making and risk assessment from accelerated stability data and measurements of physicochemical properties. The design of optimally stable protein pharmaceuticals must take into account degradation via conformational and colloidal mechanisms, recognizing that in high concentration formulations colloidal effects become more pronounced. Insights into conformational and colloidal stability aspects from rapid screening and stability data are presented.

9:05 Translational Research Models for Improved Antibody Discovery
Mohammad Tabrizi, Ph.D., Head, Director & Senior Fellow, Merck Research Laboratories

9:35 Regulation of Antibody Class Switch Recombination
Ali Zarrin, Ph.D., Scientist, Immunology, Genentech, Inc.
Preceding antibody constant regions are switch (S) regions varying in length and repeat density that are targets of activation-induced cytidine deaminase. We asked how participating S regions influence each other to orchestrate rearrangements at the IgH locus by engineering mice in which the weakest S region, S , is replaced with prominent recombination hotspot Sμ. Our studies provide novel insights into the regulation and genetic manipulation of antibody isotype switching.

10:05 Coffee Break with a Poster Pavilion

11:00 A Computational-Experimental Pipeline for Biologic Design
Samuel Coulbourn Flores, Ph.D., Assistant Professor, Cell and Molecular Biology, Uppsala University
Predicting the effect of substitution mutations on affinity and specificity is key to designing biologics *in silico*. I present ZEMu, a novel multiscale method which focuses computer resources on the region around the mutation site. With ZEMu, we produce a short list of mutations with high probability of substantially improving affinity, leading to a considerable reduction in the experimental effort. I discuss ongoing development of cancer and autoimmune disease therapies.

11:30 A Comprehensive System to Manage GSK's Antibody Discovery Processes
Trevor Wattam, Ph.D., Manager, Biopharm Discovery Group, Biopharm Discovery Group, GlaxoSmithKline
GSK's large-molecule research programs are based on a unique platform of antibody discovery technologies. To support and integrate the different screening, engineering and production processes, we have implemented a comprehensive R&D workflow system called the GSK's Antibody Discovery Database (ADD). We will present how the ADD makes GSK's lead discovery process more efficient, with use cases from GSK's yeast and phage display as well as hybridoma and humanization processes.

12:00 pm IT'S A WRAP: PEPTALK 2016 CLOSING PLENARY PANEL DISCUSSION ***See page 2 for details***

1:15 Close of Conference

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Next-Generation Cancer Immunotherapies

New Targets and Pathways, Immunotherapy Combinations, Translational Strategies and Intellectual Property Updates to Support Entry into the Surging Cancer Immunotherapy Space

Strong clinical successes with antibodies against checkpoint targets have spawned a surge of interest from across the industry in the development of antibody immunotherapeutics and related treatment combinations. The challenges facing those now entering the field include establishing clinical proof of concept, product differentiation, selection of patient responders and the identification of effective treatment combinations. The Next-Generation Cancer Immunotherapies conference presents innovative approaches to checkpoint inhibition, protein engineering strategies to improve the efficacy of immunotherapies and the application of bispecific antibody platforms to immunotherapy target pairs.

SUNDAY, JANUARY 17

4:00-5:30 pm Registration

5:00-8:00 Dinner Short Courses *See page 4 for details*

MONDAY, JANUARY 18

7:30 am Conference Registration and Morning Coffee

9:00 Chairperson's Opening Remarks
Robert Mabry, Ph.D., Director, Protein Sciences and Antibody Technology, Jounce Therapeutics

KEYNOTE PRESENTATION

9:10 The Current State of Science in Immunotherapy: A Review of Pembrolizumab and Other Checkpoint Inhibitors
Michael Rosenzweig, DVM, Ph.D., Executive Director, Immuno-oncology, Merck Research Laboratories
Cancer immunotherapy has been revolutionized by the recent clinical successes of checkpoint blockades. Pembrolizumab, a checkpoint inhibitor, is an investigational, selective, humanized, monoclonal anti-PD-1 antibody designed to block the interaction of PD-1 on T-cells with its ligands to reactivate anti-tumor immunity. Pembrolizumab is being evaluated across more than 30 types of cancers, as monotherapy and in combination, and we are exploring different tumor characteristics such as PD-L1 expression as predictors of responsiveness.

PROTEIN ENGINEERING STRATEGIES FOR TARGETED IMMUNOTHERAPIES

9:50 Conformation of the Human Immunoglobulin G2 Hinge Imparts Superagonistic Properties to Immunostimulatory Anticancer Antibodies
Ann White, Ph.D., Senior Research Fellow, Cancer Sciences Unit, Southampton University
Monoclonal antibodies designed to stimulate anti-tumour immunity by engaging stimulatory receptors, such as CD40, 4-1BB and CD28, on immune cells generally require Fc receptor mediated cross-linking for activity. We demonstrate that human IgG2 is uniquely agonistic independent of Fc R interaction due to a structurally constrained conformation achieved through hinge region disulphide rearrangment. This allows the engineering of reagents with defined therapeutic activity regardless of Fc R expression levels in the local microenvironment.

10:20 Coffee Break

10:45 Modulation of *in vivo* Dynamics of Antibodies
E. Sally Ward, Ph.D., Professor, Molecular and Cellular Medicine, Texas A&M Health Science Center
FcRn-IgG interactions can be engineered to modulate the *in vivo* dynamics of antibodies and their target antigens. This is being combined with the use of fluorescence microscopy to inform the subcellular trafficking behavior of the engineered proteins. The presentation will cover recent developments on these topics.

11:15 *In vivo* Efficacy of a Bispecific Antibody Targeting EGFR and CTLA-4
Mihriban Tuna, Ph.D., Vice President, Discovery, F-star GmbH & F-star Biotechnology Ltd.
A bispecific antibody was generated by engineering the constant region against EGFR and combining with the variable domain of CTLA-4. The ensuing EGFR/CTLA-4 bispecific showed efficacy in an *in vivo* model compared to either EGFR or CTLA-4 alone. Efficacy of the bispecific in the mouse model did not correlate with Treg depletion, suggestive of a novel biology.

11:45 Preclinical Evaluation of an Agonist Antibody Targeting ICOS
Robert Mabry, Ph.D., Director, Protein Sciences and Antibody Technology, Jounce Therapeutics
Jounce is developing an agonistic antibody to the co-stimulatory molecule ICOS. Preclinical studies demonstrate that anti-ICOS agonistic antibodies are efficacious in syngeneic tumor models, with enhanced efficacy observed in combination with PD-1 inhibition.

12:15 pm Sponsored Presentation *(Opportunity Available)*

12:45 Session Break

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

DEVELOPMENT OF BISPECIFIC ANTIBODIES FOR CANCER IMMUNOTHERAPY

2:00 Chairperson's Remarks
Shyra Gardai, Ph.D., Principal Scientist, Preclinical Research, Seattle Genetics

2:05 Case Study: Development Challenges of BiTE® Antibodies for Cancer Immunotherapy
Richard Smith, Ph.D., Director, Research, Protein Technologies, Amgen, Inc.
Bispecific T-cell Engager (BiTE®) antibody constructs enable specific targeting of cytotoxic T cells to tumors. Following clinical validation of this approach with the recently approved BLINCYTO™ (blinatumomab) we are advancing the platform with a discovery engine that integrates the identification of new targets with the development of BiTE® antibody constructs with improved pharmacokinetic properties.

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Next-Generation Cancer Immunotherapies

New Targets and Pathways, Immunotherapy Combinations, Translational Strategies and Intellectual Property Updates to Support Entry into the Surging Cancer Immunotherapy Space

Sponsored by freeslate

2:35 Anti-CD20/CD3 T Cell Dependent Bispecific Antibody (TDB) as Potential Therapy for B Cell Malignancies
Laura Sun, Ph.D., Principal Research Associate, Translational Oncology, Genentech, Inc.
The preclinical development of a B cell targeting anti-CD20/CD3 T cell dependent bispecific antibody (CD20-TDB) will be described. CD20-TDB is highly active in killing B cells *in vitro* and *in vivo* as demonstrated in multiple murine models. In cynomolgus monkeys, CD20-TDB potently depletes B cells in peripheral blood and lymphoid tissues while demonstrating PK properties similar to those of conventional monoclonal antibodies.

3:05 Next-Generation Bispecific Immunomodulatory Antibodies for Tumor Directed Immune Activation
Peter Ellmark, Ph.D., Principal Scientist, Research, Alligator Bioscience AB
Increasing the response rate while minimizing toxicity can be achieved by combining agents towards different immune modulatory targets and by directing the immune activation to the tumor. Intratumoral administration is currently evaluated in the clinic with a CD40 agonistic antibody (ADC-1013). In addition, bispecific antibodies targeting two different immunomodulating receptors provides new opportunities to increase the effect and direct the immune system to the tumor.

3:35 Sponsored Presentation *(Opportunity Available)*

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

4:30 Chemically-Generated Immunomodulatory Bispecific Antibodies
Yanwen Fu, Ph.D., Associate Director, Antibody Technologies and Chemical Biology, Sorrento Therapeutics
Bispecific antibodies (BsAbs) capable of engaging cytotoxic T lymphocytes for tumor cell lysis are emerging as a new option for cancer treatment. Sorrento has developed a robust platform to generate BsAbs through hetero-dimerization of two chemically-modified half antibodies. Using this approach, we synthesized a variety of immunomodulatory bispecific IgGs and F(ab)2. Results from BsAb assembly, biophysical characterization and effector-cell mediated cytoxicity assays will be presented.

INTELLECTUAL PROPERTY ISSUES FOR CANCER IMMUNOTHERAPY

5:00 Intellectual Property Review of Major Immunotherapy Targets: Non-Composition of Matter Approaches to Developing Unique IP in Cancer Immunotherapy
Konstantin M. Linnik, Ph.D., Partner, Intellectual Property, Nutter, McClennen & Fish, LLP
Immuncology IP is crowded – the number of drugs in R&D far exceeds the number of targets. Navigating the IP around major targets is critical but, more importantly, every drug developer faces challenges in protecting its own intellectual property. What are the patenting approaches that allow entry into this crowded IP space, while preserving the broadest scope of protection?

5:45 BuzZ Session A
Join your peers and colleagues for interactive roundtable discussions.
Please see page 55 for additional information.

6:30-7:45 Welcome Reception in the Exhibit Hall with Poster Viewing

7:45 Close of Day

TUESDAY, JANUARY 19

8:00 am Conference Registration and Morning Coffee

NEXT-GENERATION STRATEGIES FOR TARGETING CHECKPOINT INHIBITORS

8:30 Chairperson's Remarks
Peter Ellmark, Ph.D., Principal Scientist, Research, Alligator Bioscience AB

8:35 Clinical Updates for Novel Targets and Pathways
Bernard A. Fox, Ph.D., Harder Family Chair and Chief, Laboratory of Molecular and Tumor Immunology, Earle A. Chiles Research Institute, Providence Cancer Center
Clinical success of novel immunotherapies in tumors other than melanoma is fueling a sea change, and observations of a strong T cell infiltrate being a good prognostic factor, independent of tumor stage, are providing insight into the mechanisms responsible. We are performing assessments of gene signatures to guide an evaluation of the tumor with multispectral imaging and objective assessment tools. This information will be used to guide treatment decisions.

9:05 Characterization and *In Vivo* Evaluation of Blocking Antibodies Against GARP, a Novel Immune Checkpoint Target
Bas van der Woning, Ph.D., Principal Scientist, arGEN-X
GARP is required for TGF-β activation from Tregs. We have identified anti-GARP antibodies which inhibit active TGF-β production from human Tregs. Using a model of xenogeneic graft-versus-host disease induced by transplantation of human PBMCs in NSG mice, we show that blocking antibodies against hGARP inhibit the immune suppressive function of human Tregs *in vivo*. mAbs against GARP that inhibit human Treg function may therefore represent new immunotherapeutic approaches for the treatment of cancer.

9:35 Sponsored Presentation *(Opportunity Available)*

9:50 Coffee Break in the Exhibit Hall with Poster Viewing

11:00 Proxinium, an Anti-EpCam-PE40 Targeted Protein Therapeutic (TPT) Mediates Direct Anti-Tumor Efficacy and Induces Anti-Tumor Immune Responses
Gregory Adams, Ph.D., Chief Development Officer, Viventia Bio
TPTs mediate direct tumor killing and offer the ability to activate anti-tumor immunity. In early phase clinical studies, intratumoral injection of Proxinium mediated impressive effects directly on injected tumors and indirectly on uninjected tumors, suggesting the generation of an anti-tumor immune response. Clinical trial results and preclinical studies will be presented both examining the mechanisms underlying the indirect anti-tumor effect and evaluating the potential of combining Proxinium with checkpoint inhibitors.

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Next-Generation Cancer Immunotherapies

New Targets and Pathways, Immunotherapy Combinations, Translational Strategies and Intellectual Property Updates to Support Entry into the Surging Cancer Immunotherapy Space

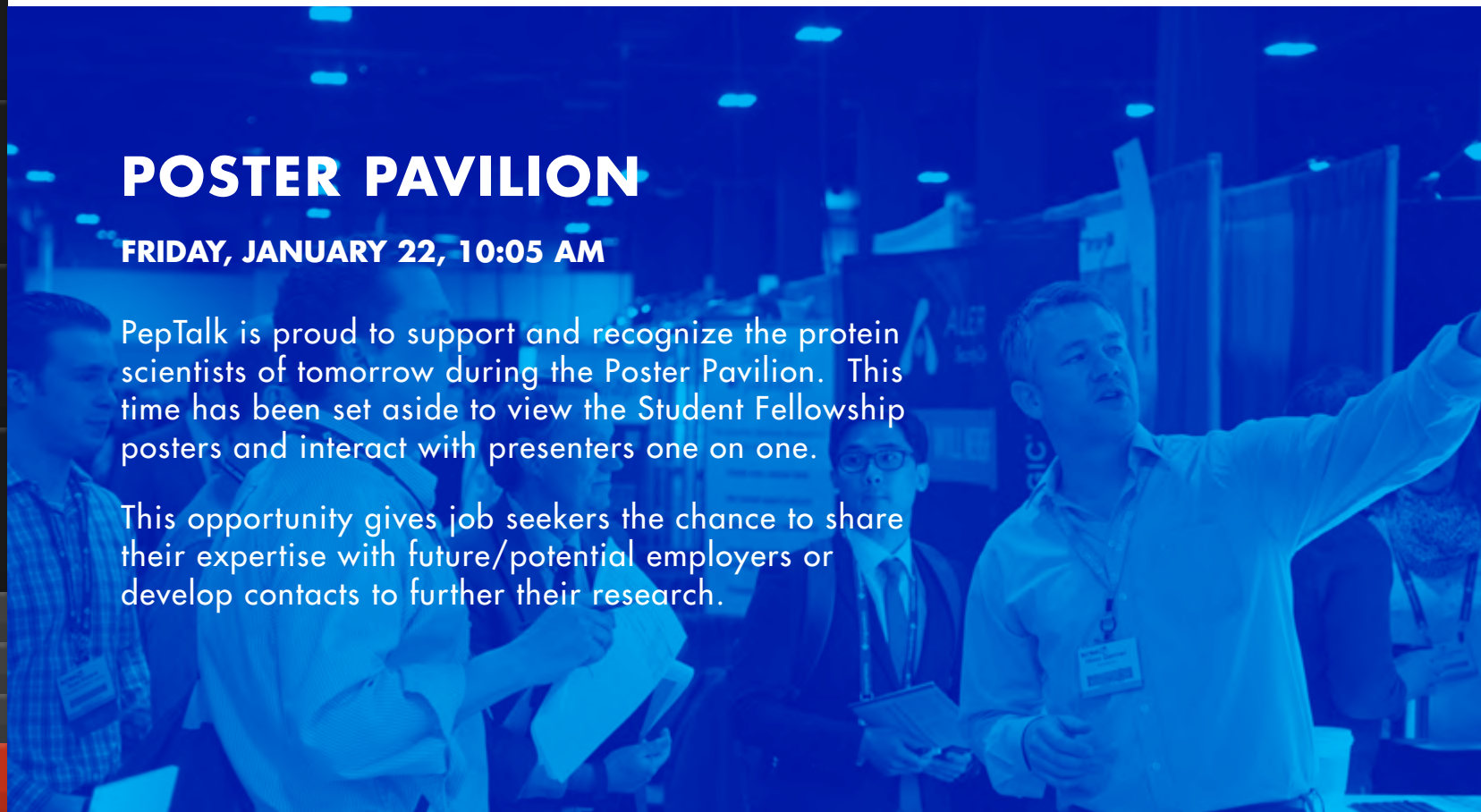
11:30 A Sugar Engineered Non-Fucosylated Anti-CD40 Antibody, SEA-CD40, with Enhanced Immune Stimulatory Activity Alone and in Combination with Immune Checkpoint Inhibitors
Shyra J. Gardai, Ph.D., Principal Scientist, Immunology, Seattle Genetics
SEA-CD40 is a novel first-in-class therapeutic antibody using Seattle Genetics' proprietary sugar-engineered antibody (SEA) technology. Preclinically, SEA-CD40 mediates enhanced CD40 signaling to antigen-presenting cells resulting in robust APC activation and expansion of tumor-associated antigen specific T-cells. While SEA-CD40 drives immune activation as a single agent, it also demonstrates substantial combinatorial activity with immune checkpoint inhibitors preclinically.

12:00 pm Sponsored Presentation *(Opportunity Available)*

12:30 Session Break

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

1:45 Close of Conference



POSTER PAVILION

FRIDAY, JANUARY 22, 10:05 AM

PepTalk is proud to support and recognize the protein scientists of tomorrow during the Poster Pavilion. This time has been set aside to view the Student Fellowship posters and interact with presenters one on one.

This opportunity gives job seekers the chance to share their expertise with future/potential employers or develop contacts to further their research.

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Antibody-Drug Conjugates

Engineering for Clinical Success

ADCs have reached an exciting point in development where engineering success has led to more than 30 ADCs in clinical trials, with more on the way. Cambridge Healthtech Institute's Antibody-Drug Conjugates conference reveals the engineering that has brought about today's revolution, and examines how to design safe and effective ADCs. In addition, strategies for advancing ADCs to the clinic will be discussed along with considerations for clinical trial design. Analyzing ADCs to explore conjugation, stability, payloads and tumor penetration will also be addressed in this leading ADC event.

TUESDAY, JANUARY 19

1:00 pm Conference Registration

DEVELOPING EFFICACIOUS ADCs

2:00 Chairperson's Opening Remarks
Aaron K. Sato, Ph.D., Vice President, Research, Sutro Biopharma, Inc.

KEYNOTE PRESENTATION

2:05 Antibody Drug Conjugates – Past, Present and Future
Nancy Whiting, Pharm.D., BCOP, Vice President & Head, Medical Affairs, Seattle Genetics
With more than 30 ADCs in clinical testing and 2 FDA-approved products, ADCs have the potential to be a significant part of the cancer therapy armamentarium. This talk will review the history of ADCs, emerging clinical data with existing ADCs and future innovations designed to enhance clinical activity of ADCs.

2:45 Translatability of Nonclinical Safety Findings of ADCs
Mary J. Hinrichs, Ph.D., Principal Toxicologist, Biologics Safety Assessment, MedImmune
Because therapeutic index is a major hurdle to ADC development, there is considerable effort to understand the relationship between ADC properties and safety in order to engineer second generation ADCs with better therapeutic index. In this presentation I will discuss: the translatability of traditional nonclinical safety studies to clinical toxicity, the relationship between normal tissue expression and on/off target toxicity, and engineering factors that impact safety of ADCs.

3:15 Refreshment Break in the Exhibit Hall with Poster Awards

4:00 Sponsored Presentation *(Opportunity Available)*

ADCs IN THE CLINIC

4:30 Molecular Integrity of Antibody-Drug Conjugates: Applying Preclinical Learnings to the Clinic
Brooke Rock, Ph.D., Senior Scientist, Pharmacokinetics and Drug Metabolism, Amgen, Inc.
Characterizing the mechanisms of ADC instability and release of the cytotoxin are germane in the design of the next generation of ADCs. The metabolism and disposition of ADCs, especially in regards to non-cleavable cytotoxins, are not fully understood. Understanding the mechanism behind release of the cytotoxin moiety and the chemistry that influences this release is important in both the efficacy of the ADC as well as toxicity profile.

5:00 The Role of Brentuximab Vedotin in Treatment of Hodgkin Lymphoma and in Prevention of Relapse Post High-Dose Therapy and Autologous Stem Cell Transplant
Auayporn P. Nademanee, M.D., Jan & Mace Siegel Professor, Hematology & Hematopoietic Cell Transplantation, Associate Clinical Director, Hematology & Hematopoietic Cell Transplantation, and Director, Matched Unrelated Donor (MUD) Program, City of Hope
Brentuximab vedotin (BV) consists of an anti-CD 30 antibody conjugated by a protease-cleavable linker to microtubule-disrupting agent, monomethyl auristatin E. In a pivotal Phase II trial, BV induced 75% response rate, 34% complete remission rate in patients with Hodgkin lymphoma (HL) who had relapsed after high-dose therapy and autologous stem cell transplant (Auto-SCT). The results show that giving BV post auto-SCT improved PFS in patients who were at risk for relapse.

5:30-5:45 Short Course Registration

5:45-8:45 Dinner Short Courses *See page 4 for details*

WEDNESDAY, JANUARY 20

8:00 am Conference Registration and Morning Coffee

ENGINEERING ADCs

8:30 Chairperson's Remarks
Mary J. Hinrichs, Ph.D., Principal Toxicologist, Biologics Safety Assessment, MedImmune

8:35 Impact of Disulfide Linker Variation on Antibody-Drug Conjugate *in vitro* and *in vivo* Properties
Peter Dragovich, Ph.D., Principal Scientist, Medicinal Chemistry, Genentech, Inc., a member of the Roche Group
ADCs are a growing class of anti-cancer therapeutic agents that are comprised of an antibody attached to a cytotoxic payload via a linking moiety. We previously disclosed the design of a new ADC linker that is directly attached to a mAb cysteine residue via a disulfide bond. Several structural modifications of this disulfide linker will be described along with the associated impacts on ADC cell-culture potency, pharmacokinetics, and xenograft efficacy.

9:05 The Application of Site-Specific Conjugation Technology to Create Novel Bispecifics, Pegylated Biologics and Peptide Conjugates
Aaron K. Sato, Ph.D., Vice President, Research, Sutro Biopharma, Inc.
Using Xpress CF+, hundreds of non-natural amino acid antibody variants are made within a day. Using fast, quantitative conjugation chemistries, e.g. Click Chemistry, antibodies are conjugated within hours. The variants are selected based on expression, cell binding, conjugation efficiency, and cell killing. This technology has also been applied to other therapeutic modalities, e.g. peptides and proteins. Case studies will be presented in this talk.

Antibody-Drug Conjugates

Engineering for Clinical Success

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9:35 An Integrated Approach to Managing Immunogenicity Risk and Drug Immune Modulation

Sponsored by PROIMMUNE www.proimmune.com

Jeremy Fry, D.Phil., Director, Sales, ProImmune

Immunogenicity is one of the most complex issues to address in drug design and development. I will provide an overview of the best tools to mitigate immunogenicity risk, including Mass Spectrometry antigen presentation assays; DC-T and T cell proliferation assays for biologic lead selection/optimization; HLA-peptide binding assays to characterize individual epitopes as well as undiluted whole blood cytokine storm assays.

10:05 Coffee Break in the Exhibit Hall with Poster Viewing

10:50 Site-Specific Conjugations for Well-Defined and Stable ADCs

Changshou Gao, Ph.D., Fellow, R&D, Antibody Discovery & Protein Engineering, MedImmune

11:20 Sweet Delivery of the Bitter – Using Carbohydrate-Targeting Antibodies for Tumor-Specific Delivery of Cytotoxic Drugs

Felix Hart, MSc, Scientist, Bioassays & Nonclinical Studies, Glycotope GmbH

ADCs have great potential to deliver cytotoxic agents to cancer cells. For three novel glyco-optimized antibodies, carbohydrates on the surface of cancer cells represent promising targets for the specific delivery of cytotoxic drugs for cancer therapy. Tumor specificity and Fc-mediated effector functions were shown by immunohistochemistry and antibody-dependent cellular cytotoxicity, respectively. Next, as a prerequisite for intracellular drug delivery, target internalization upon antibody binding and lysosomal localization were confirmed.

11:50 Innovative Payload Platform Powers ADC Development

Ravi J. Chari, Ph.D., Executive Director, Chemistry, ImmunoGen, Inc.

12:20 pm Linkers with High Drug Loads and Precisely Controlled Chemical Structure based on XTEN™

Sponsored by AMUNIX™

Volker Schellenberger, Ph.D., President and CEO, Amunix

Since 2006, Amunix has been developing precision engineered protein polymers trademarked as XTEN™ for use in half-life extension and drug delivery. Precisely customized, highly soluble XTEN structures can be produced in large quantities over a wide size range (5 to >100kDa) and with precisely controlled drug conjugation sites. XTEN can provide half-life in addition to its action as a drug linker. This allows the utilization of peptides and antibody fragments in addition to IgGs for tumor targeting.

12:50 Session Break

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

CONQUERING CANCER WITH ADCs

2:00 Chairperson's Remarks

Peter Dragovich, Ph.D., Principal Scientist, Medicinal Chemistry, Genentech, Inc., a member of the Roche Group

2:05 Therapy of Advanced Solid Cancers with Sacituzumab Govitecan (IMMU-132), a Novel ADC Targeting Trop-2

David M. Goldenberg, M.D., Professor and President, Garden State Cancer Center and Chairman, Chief Scientific & Chief Patent Officer, Immunomedics, Inc.

IMMU-132 comprises a high ratio of SN-38, the active metabolite of the anti-topoisomerase-1 inhibitor, irinotecan, conjugated with a proprietary linker to a humanized anti-Trop-2 antibody. Trop-2 is expressed at a high level by a large number of epithelial cancers, with low expression by normal tissues. Repeated frequently, high objective responses by RECIST1.1 criteria have been achieved in patients with triple-negative breast cancer, non-small-cell and small-cell lung cancers.

2:35 ADCs Targeting Embryonic and Pluripotent Stem Cell Markers as Novel Therapeutics for Metastatic Cancers

Michael Schopperle, Ph.D., CEO, CureMeta

New research suggests that metastatic and aggressive cancers may be caused by reprogrammed cancer stem cells with embryonic and pluripotent characteristics. We have developed several antibodies which are specific for embryonic stem cells markers and have made several ADCs as novel therapeutics for metastatic cancers. Our studies show that our new ADCs are specific for and highly efficient at killing pluripotent cancer stem cells.

3:05 XMT-1522: A Novel Anti-HER2 ADC for the Treatment of Low HER2-Expressing Tumors and Combination with Trastuzumab-Based Regimens in HER2-Driven Tumors

Natasha Bodyak, Ph.D., Senior Director, Biology, Mersana Therapeutics, Inc.

There is a need for more potent anti-HER2 ADCs to maximize benefits. XMT-1522 is an anti-HER2 ADC that uses a novel, human anti-HER2 antibody optimized for cytotoxic payload delivery, and is non-competitive with trastuzumab or pertuzumab for HER2 binding. This presentation will highlight pre-clinical data demonstrating potent anti-tumor activities of XMT-1522 as a single agent in low HER2-expressing tumors and in combination with trastuzumab and pertuzumab in HER2-driven tumors.

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

INNOVATIVE ENGINEERING

4:30 Probody Therapeutics and the Target Landscape for Drug Conjugates

Jonathan Terrett, Ph.D., Vice President, Oncology Discovery, CytomX Therapeutics, Inc.

CytomX's Probody Drug Conjugates (PDC) Platform is a novel and differentiated approach for developing highly targeted antibody therapeutics. Probodies are designed to expand the therapeutic window by focusing antibody efficacy directly to diseased tissues. PDCs are activated selectively in the TME, leading to improved PK and toxicity profiles. PDCs can target proteins not suitable for ADC development. *In vivo* efficacy and safety studies demonstrate an improved therapeutic index.

5:00 Stable and Efficacious Site Specific ADCs of Un-Modified Antibodies

Sean Hu, Ph.D., Senior Vice President, R&D, Dophen Biomed

Site-Specific ADCs are made in a one-pot reaction directly from un-modified mABs using engineered transglutaminase. Such ADCs are as stable as their parent mABs in blood circulation with toxins remaining 100% attached for 21 days after injection. They are 4 to 8 times more efficacious in xenograft models than their counterparts of random conjugation via lysine residues. This platform works directly for any intact IgG1, IgG2, or IgG4.

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5:45 BuzZ Session B
Join your peers and colleagues for interactive roundtable discussions.
Please see page 55 for additional information.

6:30-7:30 Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Conference

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Bispecific Antibody Therapeutics

Engineering Multispecificity

Creating bioactive molecules that are multivalent and multifunctional offers the promise of more effective therapies. Empowered antibodies bind to at least two molecular targets simultaneously, thereby delivering a highly potent therapeutic, particularly for cancer. The Bispecific Antibody Therapeutics meeting explores the challenges of engineering multispecificity to ensure stability and efficacy, and reviews the numerous forms of multispecific antibodies in development, including next-generation antibody formats. Case studies highlight safety issues, along with preclinical and clinical data.

THURSDAY, JANUARY 21

7:45 am Conference Registration and Morning Coffee

STRATEGIES FOR DEVELOPING BISPECIFICS

8:15 Chairperson's Opening Remarks
Robert Mabry, Ph.D., Director, Protein Sciences and Antibody Technology, Jounce Therapeutics

KEYNOTE PRESENTATION

8:20 Advancement in Novel Bispecific Biotherapeutics: Challenges and Opportunities
Rakesh Dixit, Ph.D., DABT, Vice President, Research & Development, and Global Head, Biologics Safety Assessment, MedImmune
Advancement in protein engineering has revolutionized the development of bipspecific biologics. There are more than 50 different formats/platforms through which multiple targets or functions can be modulated with one molecule. Despite overcoming many protein engineering challenges, there are newer CMC, manufacturing PK, immunogenicity, safety, efficacy challenges in the preclinical and clinical development. The presentation will provide a start-of-art overview of bispecific antibodies with opportunities to overcome challenges.

9:00 Bispecific Antibodies: Strategies, Considerations and Challenges
Christoph Spiess, Ph.D., Senior Scientist, Antibody Engineering, Genentech, Inc., a member of the Roche Group
Bispecific antibodies are moving mainstream as therapeutics with currently two bispecific antibodies approved and about 30 in clinical development. The presentation will discuss novel approaches to produce bispecific antibodies in a single cell as well as strategies to screen for the best bispecific antibody. This includes considerations for designing bispecifics to match the proposed mechanism of action and intended clinical application.

9:30 Facile Generation of Common Light Chain Bispecific Antibodies
Paul Widboom, Ph.D., Senior Scientist, Antibody Engineering, Adimab LLC
A variety of bispecific constructs benefit from the use of a single variable light region pairing with multiple heavy regions. This talk will demonstrate the facile engineering of multiple VHs that pair with a single light chain. A panel of bispecific antibodies are generated to bind to each target with high affinity and exhibit favorable biophysical properties similar to traditional therapeutic antibodies.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

11:00 Updates on BiTE® Technology and Development Programs
Matthias Klinger, Ph.D., Principal Scientist, BiTE Immunology, Amgen Research Munich GmbH
BiTE® antibody constructs have reached the market with the recent conditional approval of blinatumomab for the treatment of Philadelphia chromosome-negative relapsed or refractory acute lymphoblastic leukemia by the U.S. Food and Drug Administration. This presentation will provide an update on further progress of blinatumomab as well as of other BiTE® antibody constructs in early clinical development. Additionally, the evolution of the BiTE® technology will be discussed.

11:30 Engineering Next-Generation Biotherapeutics: Developability & Manufacturability
Christopher Smith, Ph.D., Senior Scientific Consultant, Biologics, Genedata
Next-gen biotherapeutics, specifically bi- and multispecifics, alternative scaffolds, and ADCs, provide many advantages over traditional IgG-based molecules. As highly engineered molecules they pose new design, cloning, expression, purification, and analytics challenges. Our workflow platform automates the engineering, production, and testing of large panels of these candidate molecules. We demonstrate the platform's capability to explore the huge combinatorial space of novel molecule-specific designs, its high-throughput capability, and its built-in tools for developability and manufacturability assessments.

12:00 pm Session Break

12:15 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Ice Cream Break in the Exhibit Hall with Poster Viewing

ENGINEERING BISPECIFICS

2:00 Chairperson's Remarks
James Ernst, Ph.D., Senior Scientist, Protein Therapeutics, Genentech, Inc., a member of the Roche Group

2:05 CrossMAb Vh-Vl
Jörg Thomas Regula, Ph.D., Head, Functional Characterization, Large Molecule Research, Roche Pharma Research & Early Development
The CrossMAb technology can be used to generate a bispecific antibody from two independent parental antibodies by immunoglobulin domain exchange. The three different CrossMAb designs were named for their exchanged domains: CH1-CL, Vh-Vl and Fab. The CrossMAb CH1-CL was used for the Ang2-VEGF CrossMAb. Additional modifications renders the CrossMAb Vh-Vl to a suitable alternative. The CrossMAb technology enables several bispecific molecules with 1+1, 2+1 or 2+2 binding sites.

2:35 Bispecific FynomAbs: Novel Modes of Action through Tailored Architecture
Isabella Attinger-Toller, Ph.D., Director, Pharmacology, in vivo Pharmacology, Covagen AG, one of the Janssen Pharmaceutical Companies of J&J
Covagen develops bispecific FynomAbs by fusing its Fynomer binding proteins to antibodies resulting in multi-specific therapeutics with novel modes-of-action and enhanced efficacy. FynomAbs have optimal biophysical and pharmacokinetic properties, making them attractive as drug candidates. Here we present the discovery and development of COVA322, a clinical-stage bispecific TNF/IL-17A inhibitor for the treatment of inflammatory diseases. Furthermore, FynomAbs with tailored anti-tumor activities will be presented.

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Bispecific Antibody Therapeutics

Engineering Multispecificity

3:05 Sponsored Presentation *(Opportunity Available)*

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

4:15 Optimization and Application of an Fc-Containing Bispecific Platform
Gregory L. Moore, Ph.D., Senior Scientist, Protein Engineering, Xencor, Inc.
Xencor has developed a new platform for long-lived and easy-to-manufacture bispecific antibodies. We have applied it to rapidly produce CD3 bispecific antibodies targeting CD123 for AML, CD20 for B cell malignancies, and CD38 for multiple myeloma. Each antibody is shown to be potently active in non-human primate studies, and GMP manufacturing is straightforward with yields over 2 g/L. Application to multiple formats and target combinations will be discussed.

4:45 The DuoBody Technology: A Versatile Platform for Bispecific Antibody Discovery and Development
Paul W.H.I. Parren, Ph.D., Senior Vice President & Scientific Director, Genmab BV
The DuoBody platform is based on the convenient post-production method of controlled Fab-arm exchange which yields bispecific antibodies that retain the time-honored molecular structure and quality attributes of therapeutic IgGs. The process is proven to be highly robust with linear scalability from bench to manufacturing scale. This presentation will highlight recent advances in the application of the DuoBody technology for randomized library generation and screening of large antibody panels.

5:15 Development of Bispecific AffiMab Antibody Engineered Using Affibody Molecule for Target Therapy
Kyu-Tae Kim, Ph.D., Director, ADDs Program, AbClon
Antibodies are functionalized using Affibody Molecules to create bispecific AffiMabs. AffiMab is an innovative bispecific antibody generated from a genetic link between therapeutic antibody and Affibody molecule. AffiMab efficiently targets two disease proteins simultaneously and it contains full human IgG functions with increased specificities. ADA-zIL6 is an AffiMab simultaneously targeting the IL-6 and TNF. ADA-zIL6 blocks combined IL-6 and TNF-triggered serum amyloid A secretion *in vivo*.

5:45 Close of Day

6:00-7:00 Reception in the Tiki Pavilion

FRIDAY, JANUARY 22

8:00 am Conference Registration and Morning Coffee

CONQUERING DISEASE WITH BISPECIFICS

8:30 Chairperson's Remarks
Paul Widboom, Ph.D., Senior Scientist, Antibody Engineering, Adimab LLC

8:35 Preclinical Development of the Tribody Tb535, a 5T4 Targeting Bispecific T-Cell Engager
Nico Mertens, Ph.D., Vice President and Head, Antibody Research, R&D, Biotecnol Ltd.
Tribodies use the natural heterodimerization present in a Fab molecule to create trivalent or trispecific recombinant antibody fragment fusion proteins. Biotecnol used its Tribody platform to create Tb535, a fully humanized bispecific antibody fragment which binds bivalently to the oncofoetal glycoprotein 5T4 and monovalent to the T-cell activating CD3 cluster. Tb535 is a highly stable molecule with excellent manufacturability properties and is highly active against a wide range of carcinomas.

9:05 A Novel Tissue-Specific Agonist of the FGF21 Pathway for the Treatment of Type 2 Diabetes
James Ernst, Ph.D., Senior Scientist, Protein Therapeutics, Genentech, Inc., a member of the Roche Group
Type 2 diabetes is a large and growing healthcare problem throughout the world. Activation of the FGF21 pathway has been shown to improve several features of type 2 diabetes in mice and humans. We have discovered a novel bispecific antibody that mimics the function and metabolic effects of FGF21. Treatment with this antibody improves glycemic and lipid profiles in mouse disease models, and reduces weight in mice and non-human primates.

9:35 Getting TRAIL Back on Track: RG7386, A Novel Bispecific FAP-DR5 Antibody for the Treatment of Cancer
Oliver Krieter, M.D., Senior Translational Medicine Leader, pRED Innovation Center Penzberg, Roche
Activation of the extrinsic apoptotic pathway by TRAIL is dependent on clustering of death receptors (DR) on the surface of cells. However, current TRAIL-based strategies have proven ineffective in clustering DRs, hence in extrinsic pathway activation and failed to demonstrate robust activity in clinical trials. RG7386 is a novel bispecific FAP-DR5 antibody, binding with high affinity to fibroblast activation protein (FAP) and with low affinity to DR5.

10:05 Coffee Break with a Poster Pavilion

ANALYTICAL TOOLS AND PLATFORM TECHNOLOGIES

11:00 Modular mAb2 Technology Enables Rapid Assessment of Bispecific Modality
Mateusz Wydro, Ph.D., Senior Scientist, Tumor Biology & Protein Sciences, F-star Biotechnology
One of the bottlenecks of bispecific approach is the lengthy process of generating stable molecules with sufficient quality and quantity to enable functional assessment and *in vivo* PoC studies. F-star's proprietary modular antibody technology addresses this limitation by a robust "plug and play" process so multiple modalities can be produced and assessed in parallel; this makes it possible to pick the best candidates efficiently and confidently.

11:30 The BEAT Bispecific Antibody Technology: An Industry-Applicable Platform for the Development of Highly Potent Biologics
Greg Elson, Ph.D., Vice President, Biologics Manufacturing, Glenmark Pharmaceuticals
Glenmark Pharmaceutical`s BEAT® format is a robust and versatile bispecific heavy chain hetero-dimerization technology based on a unique concept of bio-mimicry. Several T cell recruiting bispecific antibodies against different cancers are currently under evaluation, with GBR 1302 being Glenmark's most advanced development candidate. This BEAT® antibody potently re-directs T cells to HER2 positive cancer cells and demonstrates strong tumour cell lysis activity. Bioprocess and preclinical biological data will be presented.

12:00 pm IT'S A WRAP: PEPTALK 2016 CLOSING PLENARY PANEL DISCUSSION ***See page 2 for details***

1:15 Close of Conference

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Optimizing Biologics Formulation Development

Formulation Strategies for Different Stages of Development, New Product Formats, Device/Delivery Systems and Emerging Analytical Methods

Each year, the PepTalk Optimizing Biologics Formulation Development meeting brings together an international audience of analytical and formulation scientists from leading industry companies to hear solutions to the most significant challenges in their field. For 2016, the conference focuses on formulation strategies in early and pre-commercial development, the challenges of new molecule and product formats, emerging technologies to support the speed and quality of formulation development, formulation issues for device and packaging systems and problem solving for the challenges in the day-to-day work of protein formulators.

SUNDAY, JANUARY 17

4:00-5:30 pm Registration

5:00-8:00 Dinner Short Courses *See page 4 for details*

MONDAY, JANUARY 18

7:30 am Conference Registration and Morning Coffee

9:00 Chairperson's Opening Remarks
Tarik Khan, Ph.D., Postdoctoral Fellow, Late-Stage Pharmaceutical and Processing Development, F. Hoffmann-La Roche Ltd.

KEYNOTE PRESENTATIONS

9:10 Formulation Strategies in an Era of Accelerating Timelines and Novel Biotherapeutic Modalities
Ping Y. Yeh, Ph.D., Executive Director, Drug Product Formulation Technologies, Process Development, Amgen, Inc.
The advancement of bio-therapeutics to treat unmet medical needs has been progressively expanded to new disease targets. The "biology first and modality second" R&D strategy has been successfully applied to probe human biology, resulting in the engineering of novel protein modalities, many of which bring significant challenges to protein formulation and delivery. In this presentation, formulation strategy and technology considerations that bridge discovery and commercialization will be discussed.

9:45 Probing the Interface of Protein Stability Analysis, Formulation Development and Biosimilarity Assessments
David B. Volkin, Takeru and Aya Higuchi Distinguished Professor, Pharmaceutical Chemistry, The University of Kansas School of Pharmacy
This presentation describes the challenges and opportunities of performing fingerprint analysis of various protein analysis data sets (e.g., higher-order structure, potency, pharmaceutical stability) and applying the results to formulation development and biosimilarity assessment. Topics include mathematical approaches to evaluate combined data sets from analysis of protein stability; applying these tools to a case study comparison of model, well-defined IgG1-Fc glycoforms; and potential future applications to full-length mAbs and complex biomolecules.

10:20 Coffee Break

ANALYTICAL METHODS AND TECHNOLOGIES FOR FORMULATION DEVELOPMENT

10:45 Structure-Based Formulation Effects on Endotoxin Quantification
Tarik Khan, Ph.D., Postdoctoral Fellow, Late-Stage Pharmaceutical and Processing Development, F. Hoffmann-La Roche Ltd.
Parental pharmaceuticals must be monitored for the presence of toxic endotoxins, as they present a serious health hazard. The Limulus Amebocyte Lysate (LAL) assay has become the gold standard for analyzing drug product, but has recently been shown to loose sensitivity to controlled spike-ins in the presence of certain formulation buffers and surfactants. This talk will explore supramolecular endotoxin structure changes based on formulation conditions and their correlated LAL effects.

11:15 Biophysical Characterization of Peptide and Protein Formulations
Per-Olof Wahlund, Ph.D., Senior Scientist, Biophysics Screening & Characterization Novo Nordisk
Development of pharmaceutical formulations of peptides/proteins is a delicate balance between optimising pharmacological action, safety and stability. Extensive biophysical characterization is required to develop a stable formulation, by combining different biophysical methods it is possible to make a more complete interpretation and to generate crucial information regarding the peptide´s/protein´s solubility, self-association, and interactions with excipients. Illustrating case studies will be presented.

11:45 Integration of High Throughput Formulation Screening into Drug Product Development Process
Vladimir Razinkov, Ph.D., Principal Scientist, Product Formulation Technologies, Amgen, Inc.
High throughput methods provide both speed and efficiency during selection of optimal formulation stability for biopharmaceutical product. It is critical to choose the right methods which are specific to modality and stage of development. High throughput screening methods are not only about fewer resources and faster processes. It is also about information-rich and comparable data suitable for statistical analysis allowing robust characterization and long term prediction of critical stability properties.

12:15 pm Case Stories of Protein and Peptide Stabilization Achieved by Co-Formulations with Recombinant Human Serum Albumin Derived from Baker's Yeast *Sponsored by* novozymes
Jens Thostrup Bukrinski, Ph.D., Senior Scientist, Novozymes A/S, Biopharma R&D
An important property of albumin is the inherent ability to stabilize colloidal systems and albumin thus has a long history of use as a drug stabilizer. The mechanisms involved in the stabilization are multiple and dependent on the degradation pathway of the specific drug. One well-known mechanism is when albumin is used to coat hydrophobic and hydrophilic surfaces in packaging materials and process equipment preventing surface-induced aggregation and drug depletion. Mechanisms of stabilization for other degradation pathways are less well understood. New data indicating at least two different mechanisms is presented here. In some cases surface-exposed hydrophobic patches on albumin interact with problematic drug moieties forming a drug-albumin complex less prone to aggregate. In other cases, an excluded volume effect is observed and no drug-albumin complex observed.

12:45 Session Break

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Optimizing Biologics Formulation Development

Formulation Strategies for Different Stages of Development, New Product Formats, Device/Delivery Systems and Emerging Analytical Methods

1:00 Luncheon Presentation I: A Novel Automated System for Buffer Exchange and Concentration of Biopharmaceuticals

Sponsored by freeslate

Russell Burge, Ph.D., Applications Scientist, Freeslate Inc.

Protein formulation preparation requires either dilution or buffer exchange of a protein solution into multiple formulation buffers. Traditional approaches for buffer exchange include dialysis, desalting columns, and centrifugal UF/DF devices. While these are all relatively simple and easy, they are also manual, and specifically dialysis and desalting columns do not allow for protein concentration. Recently, Freeslate has developed a novel automated system for efficient buffer exchange and concentration of biopharmaceuticals. In this talk, we describe this system and its application to protein formulation preparation.

1:30 Luncheon Presentation II *(Sponsorship Opportunity Available)*

FORMULATION SOLUTIONS FOR NOVEL BIOTHERAPEUTICS

2:00 Chairperson's Remarks

Valentyn Antochshuk, Ph.D., Principal Scientist, Bioprocess Development, Merck

2:05 Characterization of Stability and Small Molecule Related Species in Antibody Drug Conjugates

Colin Medley, Ph.D., Scientist, Genentech, Inc.

Antibody drug conjugates (ADCs) are complex therapeutic agents combining the specific targeting properties of antibodies and highly potent cytotoxic small molecule. One critical quality attribute of ADCs is the purity and stability of the active drug on the ADC, which is difficult to access once the drug is conjugated to the antibody. This talk will highlight some of ways we're evaluating the small molecule portion of ADCs.

2:35 Factors Impacting the Stability of Multi-Domain Fusion Proteins

Roberto DePaz, Ph.D., Senior Scientist, Biopharmaceutical Development, MedImmune

Fusion proteins are a class of biopharmaceuticals engineered for longer half-life and multiple specificities. These multi-domain proteins may lack stabilizing interdomain interactions, complicating formulation development. The conformational and colloidal stability of a fusion protein and the individual domains each contribute to overall physical stability. Formulation considerations for fusion proteins will be discussed, including instances where the relative importance of conformational and colloidal stability varies depending on solution conditions.

3:05 Overcoming Formulation and Analytical Development Challenges for Novel Bispecific BEAT® Format

Julie Bonvin, Ph.D., Lead, Analytical Development Group, Glenmark Pharmaceuticals

Glenmark's novel bispecific format (scFv-Fab BEAT®) has opened the possibilities of providing a highly efficient treatment of cancer. The format is a fusion of a Fab and a scFv, where scFv arm binds to the target while Fab binds to T-cells, thereby redirecting T-cells to kill tumor cells. Little is known about our novel mAb formats and the presentation will address the issue by providing novel, relevant and contemporary data.

3:35 Protein Therapeutics Production: Personalities and Provisions

Sponsored by FUJIFILM Diosynth biotechnologies

Gayathri Vasudevan, Ph.D., Associate Principal Scientist, Analytical and Formulations Development, FUJIFILM Diosynth Biotechnologies

The expression of proteins with therapeutic potential and subsequent processing and purification challenges the goal to maintain a stable and active molecule. Use of advanced analytics and carefully designed studies to characterize these molecules enable the identification of risks in the manufacturing process. Case studies will be presented.

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

4:30 Impact of Uncontrolled Drug Substance Attributes on Downstream Biologic Product Quality

Shantanu Sule, Ph.D., Sr. Engineer, Protein Drug Product & Device Development, Biogen Inc.

This presentation will cover recent findings of how uncontrolled attributes during upstream drug substance process can influence the quality of downstream drug product. Formulation and control strategies will be presented to address such challenges along with opportunities to improve drug product stability. In addition, novel stability study design approaches will be examined specific to high titer and high concentration biopharmaceuticals where such situations can commonly arise.

5:00 Predictive Modeling to Support Early Stage Formulation Stability Analysis for Vaccines and Biologics

Manvi Hasija, Ph.D., Stability Scientist, BRD, Sanofi Pasteur

The talk will focus on advanced kinetic modeling approaches that can be applied for the selection of the most appropriate kinetic equation to describe the degradation rate of biopharmaceuticals subjected to accelerated conditions. Applications of the modeling technique to support expiry date estimation, temperature excursions, formulations ranking, batch to batch comparability and manufacturing process changes will be discussed.

5:45 BuzZ Session A

Join your peers and colleagues for interactive roundtable discussions.

Please see page 55 for additional information.

6:30-7:45 Welcome Reception in the Exhibit Hall with Poster Viewing

Sponsored by freeslate

7:45 Close of Day

TUESDAY, JANUARY 19

8:00 am Conference Registration and Morning Coffee

STRATEGIES FOR THE STAGES OF FORMULATION DEVELOPMENT

8:30 Chairperson's Remarks

Hardeep Samra, Ph.D., Senior Scientist, Formulation Sciences, MedImmune

Optimizing Biologics Formulation Development

Formulation Strategies for Different Stages of Development, New Product Formats, Device/Delivery Systems and Emerging Analytical Methods

8:35 Bioanalytical Tools for Developability Evaluation
Valentyn Antochshuk, Ph.D., Principal Scientist, Bioprocess Development, Merck
Successful product and process development is heavily dependent on the understanding of molecular properties and liabilities. Choice of analytical tools and stress conditions is critical for product attributes assessment, speed of development, data understanding, connection between preformulation/developability and formulation/process development. Implementation of high throughput and stage appropriate biophysical and biochemical toolbox accelerates feedback on candidate selection, program de-risking and successful pharmaceutical development.

9:05 Considerations and Approaches for Late Stage Formulation Characterization of Biologics
Hardeep Samra, Ph.D., Senior Scientist, Formulation Sciences, MedImmune
While most early formulation development focuses on screening solution conditions to obtain an optimal product stability profile, late stage formulation development typically involves minimal optimization and a greater focus characterization of the formulation and drug product presentation. Characterization usually entails evaluating robustness as well as identifying critical quality attributes of the product. This talk highlights various approaches and methodologies for demonstrating formulation and product robustness, as well as a discussion of various challenges and considerations involved.

9:35 Sponsored Presentation *(Opportunity Available)*

9:50 Coffee Break in the Exhibit Hall with Poster Viewing

DELIVERY AND DEVICES

11:00 Formulation Considerations for Developing a High Concentration Biologics Product in Multiple Presentations
Kapil Gupta, Ph.D., Principal Scientist and Group Leader, Protein Drug Product and Device Development, Biogen
Many biologics products are developed as combination products in multiple final market image for different patient population, dosing regimen and geography. This brings in tremendous complexity for formulation and drug product development as parallel development need to happen for many presentations using creative bracketing and risk mitigation strategy. This talk highlights some of the challenges of developing a high concentration biologic product in multiple presentations and potential strategies to overcome them.

11:30 Integrating Design Controls in Formulation Development for Combination Products
Ling Lu, Senior Principal Scientist, Design Controls, Pharmaceutical Research and Development, Biotherapeutic Pharmaceutical Sciences, Pfizer, Inc.
There are challenges for formulators when developing combination products per Final Rule. This case study will explain: 1) Streamlined process with value added design control activities per Final Rule and FDA draft guidance; and 2) Three kinds of combination products, and design controls based on complexities and risks of products, comparing early phases in clinical and market application, professional and home use.

12:00 pm ΔG UNchained: Developability Assessment and Formulations Optimization of Biologics Using ΔG
Sponsored by UNCHAINED LABS
Rick Brown, Ph.D., Unchained Labs
Stability optimization and aggregation minimization are important hurdles in the development of biologics. Chemical denaturation is the most accurate way to measure protein stability and determine the impact of formulation conditions. The HUNK fully automates chemical denaturation, enabling the direct determination of protein stability (ΔG) and a quantitative assessment of aggregation. The HUNK is ideally suited to optimize the formulation of mAbs, bispecific antibodies and antibody drug conjugates. We will discuss chemical denaturation and its use for the evaluation of protein stability and formulation condition optimization.

12:30 Session Break

12:45 pm Luncheon Presentation I: Novel High Concentration Formulations of Biotherapeutics Using Protein Crystal Suspensions
Sponsored by ALTHEA
Lynette Schroeter, Lead Associate Scientist, Crystalomics, Althea
Jonathan Alvarez, Research Associate II, Crystalomics, Althea
High-concentration, low-viscosity crystalline injectable therapeutics have enhanced purity, stability, and delivery options without changing the biochemical or in-vitro characteristics of the molecule. Althea's Crystalomics® technology is a portfolio of patents surrounding crystallization, cross-linking, and complexation of proteins for therapeutic use. We have successfully developed stable crystalline formulations and GMP manufacturing processes for crystalline bio-therapeutics.

1:45 Close of Conference

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Lyophilization and Emerging Drying Technologies

Formulation Development, QbD, Process Optimization and Delivery and Devices Challenges

The popular Lyophilization and Emerging Drying Technologies conference covers latest trends and challenges in lyophilization, spray drying, foam drying and emerging drying technologies. This conference features in-depth case studies, new and unpublished data and discussions on developing scientifically sound formulation, process optimization for biologics and vaccines. It also presents cutting-edge research and case studies on freeze/thaw and formulation challenges, drying in cartridges, storage stability, Quality by Design approaches and strategies for scale-up from Research & Development scale to full production level, and selection of container closure systems. We invite you to present a poster and join colleagues in this discussion of the key challenges and solutions in lyophilization and other drying technologies.

TUESDAY, JANUARY 19

1:00 pm Conference Registration

QUALITY BY DESIGN (QBD) AND PAT IN FREEZE DRYING

2:00 Chairperson's Opening Remarks

KEYNOTE PRESENTATION

2:05 Freeze Dryer Operational Qualification to Allow Science Based Scale-Up and Quality by Design
Michael Pikal, Ph.D., Distinguished Endowed Chair in Pharmaceutical Technology & Professor of Pharmaceutics, University of Connecticut
Traditionally, freeze dryer qualification has involved studies of shelf temperature variation under no load conditions and testing whether or not the condenser can "hold" the intended mass of ice. However, this testing does not allow meaningful science based scale-up and therefore is insufficient for supporting "Quality by Design". The use of science-based operational qualification protocols in facilitating scale-up and definition of "Design Space" will be discussed.

2:45 Quantifying Pressure Variation and Convection Effects in Lyophilization
Alina A. Alexeenko, Ph.D., Associate Professor, School of Aeronautics and Astronautics, Purdue University
Control of the chamber pressure is critical for maintaining a desired product temperature and sublimation rate during primary drying. Typically chamber pressure is measured at a fixed location, normally through a port at the top of the freeze dryer, and controlled by introducing non-condensable gas. We examine the pressure variation within chamber, the resulting flow patterns and effects on drying rate and uniformity.

3:15 Refreshment Break in the Exhibit Hall with Poster Awards

4:00 New Breakthroughs in Understanding Freeze Drying Heat Transfer for Better Protocol Transfer
Sponsored by MILLROCK TECHNOLOGY
T.N. Thompson, President, Millrock Technology, Inc.
One variable that affects freeze drying times is batch size.
As the number of vials is reduced the drying time decreases, therefore a critical mass of vials has been required for protocol development. In this presentation, we will discuss a new methodology using as few as 19 vials to simulate the heat transfer dynamics of much larger freeze dryers. The technique shows promising results which will allow development of transferrable protocols to laboratory and production freeze dryers.

4:15 Sponsored Presentation *(Opportunity Available)*

4:30 Variation in Heat Flow to Vials within a Batch is a Complex Function of Shelf Temperature and Chamber Pressure in a Laboratory Freeze-Dryer
Robin Bogner, Ph.D., Associate Professor, Pharmaceutical Sciences, School of Pharmacy, University of Connecticut
Heat flows from the temperature-controlled shelves and other non- controlled surfaces to the vial for sublimation of ice from the product during primary drying. While the batch average heat flow is relatively independent of shelf temperature, the position-dependent heat flow is highly dependent on shelf temperature. The variation in "soak time" added to the calculated primary drying time will be discussed relative to design space development.

5:00 Effect of Pressure upon Secondary Drying Rate
Jim Searles, Ph.D., Technical Fellow, Global Manufacturing Science and Technology, Hospira
The scientific literature suggests that pressure has little or no impact upon the final moisture content or the holding time needed to achieve it. However the past work was over a relatively narrow pressure range. This presentation will include new data, over a wider pressure range, that does indeed show an effect of chamber pressure.

5:30-5:45 Short Course Registration

5:45-8:45 Dinner Short Courses *See page 4 for details*

WEDNESDAY, JANUARY 20

8:00 am Conference Registration and Morning Coffee

ADVANCES IN LYOPHILIZATION AND ALTERNATE DRYING TECHNOLOGIES

8:30 Chairperson's Remarks
Robin Bogner, Ph.D., Associate Professor, Pharmaceutical Sciences, School of Pharmacy, University of Connecticut

▸ **FEATURED PRESENTATION**

8:35 Freezing and Drying of Protein: What We Know, What We Think We Know, and What We Don't Know
Evgenyi Shalaev, Ph.D., Research Investigator, Pharmaceutical Development, Allergan Inc.
Many therapeutic proteins are stored as either frozen solutions (common for protein drug substance) or freeze-dried powders, to achieve an acceptable shelf life. However, freeze/storage/thaw and freeze-drying/storage/reconstitution can (and does) result in protein destabilization. Such destabilization, as is currently believed, could be associated with ice formation. The presentation provides a critical overview of the existing data and formulates specific questions to be addressed in future studies.

Lyophilization and Emerging Drying Technologies

Formulation Development, QbD, Process Optimization and Delivery and Devices Challenges

9:05 Microheterogeneity in Frozen and Desiccated Formulations
Alptekin Aksan, Ph.D., Associate Professor, Mechanical Engineering, University of Minnesota
To minimize damage to biologicals during freezing, drying and storage protectants are added to the formulation or biospecimen. Physical separation of the biological from the cryo-/lyoprotectant usually occurs. Furthermore, these phenomena may cause spatial variations in distributions of the different phases and excipients. The spatial variations in local phase and composition in frozen or desiccated medium is called microheterogeneity. This talk focuses on the detection and minimization of microheterogeneity in frozen and desiccated systems.

9:35 Sponsored Presentation *(Opportunity Available)*

10:05 Coffee Break in the Exhibit Hall with Poster Viewing

10:50 Advances in Alternative Drying Technologies to Lyophilization for Biotherapeutics Applications
Satoshi Ohtake, Ph.D., Senior Director, Pharmaceutical R&D, BioTherapeutics Pharmaceutical Sciences, Pfizer, Inc
Lyophilization is the gold standard for processing of biologics to enhance stability. Spray drying and spray freeze-drying technologies have been evaluated in comparison to vial lyophilization for process efficiency and physical properties of the solid dosage form produced. Initial feasibility results suggest benefits and promise for their use and implementation in the biotechnology industry.

11:20 New Life of Spray Freeze-Drying- Application to Dehydration of Protein Solutions
Serguei Tchessalov, Ph.D., Associate Research Fellow, Biotherapeutics Pharmaceutical Research & Development, Pfizer, Inc.
Spray-freeze drying of biological materials is well documented in the literature. Until recently, however, no commercial application of this method has been demonstrated. Advances in high-throughput spray nozzle design in combination with rotary drying could potentially support implementation of this method to large scale manufacturing. Examples of spray-freeze drying of protein solutions, including low collapse materials, will be provided, focusing on improvement of product characteristics and process economics.

11:50 Integrated Heat Flux Measurements as a Non-Invasive Monitoring Technique for Freeze Drying
T.N. Thompson, President, Millrock Technology, Inc.
Ilona Konrad, Ph.D., Coriolis Pharma
We critically evaluated heat flux measurement (HFM) for its ability to non-invasively monitor freeze drying processes. It was shown that integrated HFM is a reliable new tool to record Tp during primary drying, to detect nucleation events and to determine the end of primary drying. Besides studying robustness and linearity of different types of sensors at different shelf positions we were also able to investigate effects of formulation parameters on Kv.

12:20 pm Sponsored Presentation *(Opportunity Available)*

12:50 Session Break

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

OPTIMIZATION OF FREEZE-DRIED FORMULATIONS: CONTROLLED NUCLEATION, NEW TOOLS AND ELEGANCE ISSUES

2:00 Chairperson's Remarks
Michael Pikal, Ph.D., Distinguished Endowed Chair in Pharmaceutical Technology and Professor, Pharmaceutics, University of Connecticut

2:05 Investigating Structure and Dynamics of Proteins in Amorphous Phases Using Neutron Scattering
Joseph E. Curtis, Ph.D., Research Chemist, Condensed Matter Science Group, NIST Center for Neutron Research, National Institute of Standards and Technology
Neutron scattering is an established technique to study structure and dynamics of materials in various phases. In this talk I will outline our work to study protein structure and dynamics at high concentration, frozen, and in lyophilized phases. Through the use of contrast methods, small-angle neutron scattering has proven useful to determine the packing and sequestration of proteins in solid phases. Our work is complemented using molecular simulation technology.

2:35 Atmospheric Spray-Freeze Drying (ASFD): A New Approach to Drying Pharmaceuticals
Thomas Robinson, M.D., Managing Director, Corporate, Aerosol Therapeutics, LLC
Atmospheric Spray Freeze Drying (ASFD) is an innovative, "next generation" process with broad potential. The process yields a fine, uniform powder from a solution. Specifically, the patented ASFD process promises an efficient, cost effective alternative to standard manufacturing. It should be ideal for heat sensitive products and, especially, the more expensive, easily degraded proteins. The more expensive and fragile the molecule, the greater should be the economic benefit.

3:05 Case Study: Optimize Protein Stability by Formulation and Lyophilization Process Design
Charlie (Xiaolin) Tang, Ph.D., Director, Formulation Development, Regeneron Pharmaceuticals, Inc.
Different formulations and lyophilization cycles are used for freeze drying a monoclonal antibody protein. Protein aggregation formation was observed after lyophilization. Experiments were performed to understand the stress to protein during different stages of lyophilization process including stages of freezing, annealing, primary drying and secondary drying. The specific lyophilization stages were identified to have the most stresses to cause protein aggregation formation. By optimization of the freeze drying cycle and protein formulation, the protein degradation was minimized.

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

4:30 Application of Controlled Nucleation during Lyophilization to Improve Cake Appearance and Protein Stability
Bingquan (Stuart) Wang, Ph.D., Senior Scientist, Technical Development, Biogen
It has been well understood that controlled nucleation could result in a lower cake resistance due to the formation of larger ice crystal and thus a shorter primary drying cycle. This case study examined the performance of controlled nucleation using several different proteins, and the quality attributes were compared side-by-side to those from the cycle without controlled nucleation. Improved product quality attributes including cake appearance, recon time and stability will be presented.

5:00 Lyophilized Drug Product Cake Appearance: What is Acceptable?
Sajal M. Patel, Ph.D., Senior Scientist, Formulation Sciences, Biopharmaceutical Development, MedImmune, Inc.

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Lyophilization and Emerging Drying Technologies

Formulation Development, QbD, Process Optimization and Delivery and Devices Challenges

5:45 BuzZ Session B
Join your peers and colleagues for interactive roundtable discussions.
Please see page 55 for additional information.

6:30-7:30 Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Conference

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Protein Aggregation and Emerging Analytical Tools

Mechanism, Prediction, Screening, Immunogenicity and Formulation Challenges

The popular Protein Aggregation and Emerging Analytical Tools conference covers latest trends, challenges and solutions in understanding, characterization and mitigation of protein aggregation. It features in-depth case studies, new and unpublished data and interactive discussions on mechanisms of aggregation, new tools for detection and quantitation of aggregates, and how the data is used in regulatory filings. It also discusses mechanistic understanding of protein aggregation and present case studies on prevention of particle formation by engineering and formulation approaches, impact of aggregation on production, aggregates as a factor for immunogenicity, and approaches for improvement of biophysical properties of protein solutions. We invite you to present a poster and join colleagues from around the world in this discussion of the key challenges and solutions in protein aggregation in biotherapeutics.

THURSDAY, JANUARY 21

7:45 am Conference Registration and Morning Coffee

PREDICTING AND UNDERSTANDING MECHANISMS OF PROTEIN AGGREGATION

8:15 Chairperson's Opening Remarks
Jan Jezek, Ph.D., CSO, Research & Development, Arecor Ltd.

KEYNOTE PRESENTATION

8:20 Aggregation of Antibodies
Dimiter S. Dimitrov, Ph.D., Senior Investigator, Protein Interaction Group, FNLCR, NCI, National Institute of Health
Aggregation of antibodies in several formats including full-size, domains and antibody-drug conjugates will be reviewed. Examples of computational analyses and experimental data will be discussed for several antibodies including some generated in our group. This results could help develop decrease or eliminate aggregation in newly identified antibodies and antibody-based fusion proteins.

9:00 The Mechanistic Understanding Protein Aggregation
Thomas Laue, Ph.D., Professor, Biochemistry and Molecular Biology; Director, Biomolecular Interaction Technologies Center (BITC), University of New Hampshire
The creation of antibody-drug conjugates, bispecific and multi-specific biotherapeutics raises concerns about whether there needs to be a fundamental shift in how these molecules are formulated. The simple answer is no - the underlying principles of macromolecular interaction remain unchanged. The energetics of the pathway leading to a protein-protein complex will be outlined, with special attention paid to the role of desolvation energies. Attention will be paid to how the properties of both the protein and the solvent impact the pathway energetics.

9:30 The Impact of Process Impurities on mAb Degradation
Zephania Kwong Glover, MSc, Senior Research Associate, Late Stage Pharmaceutical Development, Genentech, Inc.
Metal impurities, such as Cu2+, can bind to mAbs and undergo hydrolysis or oxidation, leading to fragmentation of the molecule. To better understand Cu2+-mediated mAb fragmentation, hinge cleavage products and their rates of formation were studied as a function of pH with and without Cu2+. Results suggest that a charge may contribute to stabilization of a specific molecular structure, leading to the possible formation of a Cu2+ binding pocket that causes increased susceptibility of the hinge to degradation.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

11:00 Modelling of the Aggregation Kinetics of a Monoclonal Antibody
Henrik Rajesh Kumar Parshad, Ph.D., Principal Scientist, Biopharm Formulation Development, Novo Nordisk A/S
Aggregation of a mAb was shown to depend on the mAb concentration in a way that could be described by first-order kinetics. The main population of the formed aggregates was observed to be reversible and formed monomers upon dilution. Based on the established model the aggregates formed during shelf life and in-use could be estimated.

11:30 Separation of Protein from Non-Proteinaceous Particles in Biopharmaceutical Formulations with MVAS by Microflow Imaging MFI
Sponsored by proteinsimple
Zahir Akhunzada, Ph.D., PPD Consultant, Analytical & Bioanalytical Development, Bristol-Myers Squibb
The presence of sub-visible particles (SVPs) is a major challenge in the development of therapeutic protein formulations. Distinction between proteinaceous and non-proteinaceous SVPs is vital in monitoring the formulation stability. The current compendial method based on light obscuration (LO) has limitations in analyzing translucent particles, requires large analysis volume and therefore demands urgent need for an unambiguous method to characterize SVPs. A number of attempts have been made to characterize SVPs, albeit with limited success. This presentation reveals a method that successfully characterizes and distinguishes, both potentially proteinaceous and non-proteinaceous SVPs in protein formulations by using Microflow Imaging (MFI) in conjunction with the MVAS (MFI View Analysis Suite) software.

12:00 pm Session Break

12:15 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Ice Cream Break in the Exhibit Hall with Poster Viewing

CHARACTERIZATION AND CONTROL OF AGGREGATES: NEW TOOLS, FORMULATION SCREENING AND STABILITY

2:00 Chairperson's Remarks
Marisa K. Joubert, Ph.D., Senior Scientist, Process Development, Amgen, Inc.

2:05 Novel Chromatography-Based Approaches to Investigate Protein-Protein Interactions and Its Application in Formulation Screening Workflows
Sanket Patke, Ph.D., Research Investigator, Drug Product Science and Technology, Pharmaceutical Development, Bristol-Myers Squibb
Protein-protein interactions influence colloidal stability parameters such as solubility and aggregation. Measurement of osmotic second-virial coefficients, B22, provides one method to quantify protein interactions at the molecular level. Self-interaction chromatography is a novel method of measuring B22 with modest material and time requirements. Here we discuss the application of this approach to investigate protein–protein interactions in mAbs. This approach can potentially be used as a tool during formulation screening.

Protein Aggregation and Emerging Analytical Tools

Mechanism, Prediction, Screening, Immunogenicity and Formulation Challenges

2:35 Innovative Approaches to Controlling Aggregation of Therapeutic Proteins

Jan Jezek, Ph.D., CSO, Research & Development, Arecor Ltd.

Aggregation of therapeutic proteins remains one of the key challenges during their manufacture and storage. Formulation is a powerful tool to minimise aggregation. The talk will outline innovative approaches to addressing protein aggregation to simplify production and enable products to be used outside the cold chain. This will be demonstrated on several data driven case studies using relevant therapeutic proteins, describing the specific formulation features employed to achieve superior stability.

3:05 Molar Mass, Size and Interactions: Light Scattering Tools for Essential Biophysical Characterization

Sponsored by WYATT TECHNOLOGY

Wafa Hassouneh, Ph.D., Application Scientist, Wyatt Technology Corp.

Biophysical techniques based on static and dynamic light scattering address many of the key analytical challenges in biotherapeutic R&D, from early candidate selection through scale-up, formulation, characterization and comparability studies. This seminar will review light scattering technology and instrumentation, then present select examples illustrating how Wyatt's light scattering solutions facilitate rapid and effective development of biologics including mAbs, ADCs, PEGylated and other proteins.

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

4:15 Characterization of High Concentration Monoclonal Antibodies by Combined DLS and Raman Spectroscopy

Geetha Thiagarajan, Ph.D., Associate Principal Scientist, Sterile Product and Analytical Development, Merck

The study highlights applications of Zetasizer Helix, which allows concurrent measurement of dynamic light scattering and Raman spectroscopy for high-concentration solutions (>50mg/ml), providing size and secondary/tertiary structural information. Distinct structural changes involving disulfides, aromatics, hydrogen bonding, and secondary structure were identified on thermally stressed mAbs, whereas DLS captured changes for photostressed mAb. Helix-measured unfolding temperatures correspond with DSC, while providing additional structural perturbations. Minimal sample volume and manipulations makes Zetasizer Helix a useful analytical tool for exploring stress/formulation induced-changes in therapeutic proteins.

4:45 Assessing Biotherapeutics Stability Using Raman Spectroscopy

Marinella Sandros, Ph.D., Assistant Professor, Department of Nanoscience, University of North Carolina at Greensboro

Self-administered protein-based therapeutics need to be developed at high concentrations. However, there is an increase in tendency for proteins to aggregate at these levels (>100 mg/m L). Our group has investigated the potential of Raman as a non-invasive and label-free tool to assess protein stability. Results from this study identified specific signature bands that can be used to highlight individual amino acid residues that are responsible for structural changes in proteins.

5:15 Site Directed Spin Labeling for Detection of Protein Aggregation: an Emerging Analytical Tool

Lawrence Berliner, Ph.D., Professor of Chemistry and Biochemistry, University of Denver; Emeritus, Ohio State University

The site-directed spin labeling technique utilizes cysteine substitutions in proteins, has been shown to be a boon to protein structure determination where other methods fail. It is highly suited for membrane proteins where crystallography is not feasible. The advantages are no requirement for optical transparency, molecular weight limits are not an issue and solid state matter is applicable. It can be applied to detection of protein aggregates and particulates.

5:45 Close of Day

6:00-7:00 Reception in the Tiki Pavilion

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FRIDAY, JANUARY 22

8:00 am Conference Registration and Morning Coffee

PROCESS AND PACKAGING FACTORS AFFECTING AGGREGATION, SAFETY AND EFFICACY OF BIOLOGICS

8:30 Chairperson's Remarks
Joël Richard, Ph.D., Vice President, Peptides, CMC & Engineering, Ipsen

8:35 Predicting the Risk of Extractables and Leachables (E&L) Interacting with Therapeutic Proteins
Kim Li, Ph.D., DABT, MPH, Senior Manager, Environment, Health, Safety and Sustainability, Amgen, Inc.
Therapeutic proteins can be subject to chemical modifications which may lead to product quality and safety concerns. Extractables and leachables (E&L) arising from process- and product-contact surfaces present the risk of interacting with the protein products. This presentation will describe the mechanisms of such interactions and the use of an *in silico* software that classifies E&L structures into reactive functional groups for risk prediction.

9:05 Extractables & Leachables in Liquid Formulations of Proteins: Impact on Stability, Aggregation, Potency and Immunogenicity of Drug Product
Joël Richard, Ph.D., Vice President, Peptides, CMC & Engineering, Ipsen
Extractables and leachables are impurities that can contaminate liquid formulations of biologics, leaching from the surface of glass walls or being extracted from the rubber stoppers and plungers. They can interact with and degrade proteins, modifying their higher order structure, forming mixed micelles, or composite protein aggregates. These impurities may have a strong impact on stability, quality attributes and immunogenicity profile of the protein drug products.

9:35 Oxidation of Methionine in Aggregated Antibodies does not Increase the Potential Risk of Immunogenicity
Marisa K. Joubert, Ph.D., Senior Scientist, Process Development, Amgen, Inc.
This talk will give an update on the aggregate attributes of monoclonal antibodies (mAbs) that may cause an immune response. The potential impact of Met oxidation of both aggregated and monomeric antibodies was investigated in a population of human peripheral blood mononuclear cells (PBMC) from healthy and disease state individuals (50+ donors tested) *in vitro*. Met oxidation was found not to increase the potential risk of immunogenicity of both aggregated and monomeric antibodies.

10:05 Coffee Break with a Poster Pavilion

11:00 Investigation of Reversible Self-Association during Early Stage Development of a Low Concentration Antibody-Drug Conjugate
Elizabeth Bartlett, Scientist II, Analytical & Pharmaceutical Sciences, ImmunoGen, Inc.
Reversible self-association is often present in high concentration antibody products, but may also occur in lower concentration preparations. In the case of antibody-drug conjugates (ADCs), a novel class of molecules for the treatment of cancers, this property can present substantial challenges to successful formulations. In this study, a multi-technique approach was used to identify and investigate the effects of various excipients on reversible self-association in a low concentration ADC.

11:30 Characterizing Changes in Protein Quality Attributes to Assess Leachable Risks from Single-Use Bioprocess Containers
Nina Xiao, Senior Research Associate, Late Stage Pharmaceutical Development, Genentech, Inc.
Application of single-use bioprocess containers for the manufacturing of biologics have increased significantly over the years. This study examines two monoclonal antibodies in a small-scale stressed model to detect and assess the presence of leachables by monitoring protein quality attributes. The results from this study demonstrate that the stress model can inform a risk assessment of leachables on protein quality attributes during routine manufacturing. Leachable characterization will also be discussed.

12:00 pm IT'S A WRAP: PEPTALK 2016 CLOSING PLENARY PANEL DISCUSSION ***See page 2 for details***

1:15 Close of Conference

Engineering Genes, Vectors, Constructs and Clones

Upstream Decisions Lead to Downstream Success

Engineering therapeutic protein expression platforms is not for the faint of heart. Many variables must be considered during the engineering process, including verification and sequence analysis of the gene or protein of interest, codon optimization, vector construction and clone / host selection. When challenges arise, protein expression engineers must design new cloning schemes by altering the DNA or amino acid sequence, moving a gene from one vector to another, transfecting the vector to an alternative host, re-selecting the clone, re-characterizing the expressed protein or any of the above – a laborious, time-consuming and expensive process.

Cambridge Healthtech Institute's 8th Annual Engineering Genes, Vectors, Constructs and Clones conference continues the tradition of applying effective engineering strategies for protein expression and production research leading to functional biotherapeutic products. Learn from seasoned, savvy researchers as they share their real-world experiences, applications and results.

SUNDAY, JANUARY 17

4:00-5:30 pm Registration

5:00-8:00 Dinner Short Courses *See page 4 for details*

MONDAY, JANUARY 18

7:30 am Conference Registration and Morning Coffee

GENOME ENGINEERING

9:00 Chairperson's Opening Remarks
Mark Welch, Ph.D., Vice President, Research and Development, DNA 2.0

KEYNOTE PRESENTATION

9:10 Use Integration-Defective Lentiviral Vectors to Measure the Off-Target Effect of Gene Editing
Jiing-Kuan Yee, Ph.D., Professor, Department of Diabetes and Metabolic Diseases Research, Beckman Research Institute, City of Hope National Medical Center
Integration-defective lentiviral vector (IDLV) can be selectively incorporated into double-strand DNA breaks. We use IDLV as an unbiased strategy to map off-target cleavage generated by gene editing. We find that IDLV is able to detect the off-target site efficiently. We also uncover off-target sites capable of forming bulge with the single guide RNA. This finding should improve the algorithms for designing the gene editing components.

9:50 Presentation to be Announced

10:20 Coffee Break

10:45 Expediting Protein Biomanufacturing through the UCOE Gene Expression Platform
Michael Antoniou, Ph.D., Reader, Molecular Genetics, Medical & Molecular Genetics, King's College London
Ubiquitous chromatin opening elements (UCOEs) derived from housekeeping gene loci are compact and easy to manipulate genetic regulatory elements, which provide highly reproducible and stable expression irrespective of transgene integration site within the host cell genome.

11:15 CRISPR-Cas Mediated Plasmid Integration into the Genome of Mammalian Cells via Non-Homologous End Joining
Ravichandra Bachu, Ph.D., Assistant Teaching Professor, Chemistry, Carnegie Mellon University
CRISPR-Cas9 system was used to insert ~5kb plasmids into a predetermined genomic site in mammalian cells via non-homologous end joining (NHEJ). We were able to achieve efficiencies up to 0.17% in HEK293 cells and 0.45% in CHO cells. This technique can be used for quick, efficient insertion of a plasmid harboring a gene of interest into the genome of mammalian cells, a key step in the production of therapeutic recombinant proteins.

11:45 SINEUPs: A New Class of Antisense Long Non-Coding RNAs that Specifically Activate Translation of Targeted Proteins
Silvia Zucchelli, Ph.D., Assistant Professor, University of Eastern Piedmont, UPO; CSO, TransSINE Technologies
SINEUPs represent a new functional class of natural and synthetic antisense long non-coding RNAs that UP-regulate translation of partially overlapping sense mRNAs through the activity of an inverted SINEB2 element. Given their modular structure, SINEUPs can be designed to increase protein synthesis of potentially any gene of interest. We propose SINEUPs as reagents for molecular biology experiments, in protein manufacturing as well as in therapy of haploinsufficiencies.

12:15 pm pm Manufacturing of Recombinant Biopharmaceuticals by FOLDTEC® - a Recent Case Study)
Sponsored by WACKER
Andreas Anton, Ph.D., Director, BioProcess Development, Wacker Biotech GmbH
Wacker Biotech is showcasing its novel refolding technology for bioengineered pharmaceutical proteins. With the new technology biopharmaceuticals that tend to aggregate can be efficiently produced in their soluble-active form in high yields. The proprietary process utilizes optimized bacterial strains and a patented, antibiotic-free expression system. WACKER can now cost-efficiently and reliably produce pharmaceutical proteins that are prone to aggregation, and thus difficult to manufacture, in high yields and utmost purity for its customers.

12:45 Session Break

1:00 Luncheon Presentation I: Engineering Biological Systems from Genes to Genomes
Sponsored by DNA 2.0
Mark Welch, Ph.D., Vice President, Research and Development, DNA 2.0
Recent developments in the synthetic biology toolbox allow comprehensive engineering of biological components and systems. We describe applications of the expanding toolbox where machine learning technologies are leveraged to engineer protein production and function for a range of target proteins and hosts.

1:30 Luncheon Presentation II *(Sponsorship Opportunity Available)*

Engineering Genes, Vectors, Constructs and Clones

Upstream Decisions Lead to Downstream Success

VECTOR DESIGN

2:00 Chairperson's Remarks
Andrea Throop, Ph.D., Production Manager, Center for Personalized Diagnostics, Biodesign Institute, Arizona State University

2:05 Expression Vector and Gene Engineering: Approaches to Improve Recombinant Protein Production in CHO Cells
*Janice Tan, Ph.D., Research Scientist, Bioprocessing Technology Institute, A*STAR*
The increasing demands for recombinant biologics produced in CHO cells highlights the need to improve efficiency and yield without compromising quality of these biologics. Two approaches were explored by our lab to achieve these objectives: (i) engineering selection stringency in the expression vector resulted in faster generation of stable cell pools with high titers and (ii) overexpression of CHO heat shock proteins improved performance of CHO cells in fed-batch bioreactors.

2:35 Selecting the Optimal Vector for High-Throughput Cloning and Protein Arrays
Andrea Throop, Ph.D., Production Manager, Center for Personalized Diagnostics, Biodesign Institute, Arizona State University
Large-scale experiments requiring protein expression from thousands of genes require an efficient method for cloning the genes into protein expression vectors. The choice of vector and cloning scheme is critical in obtaining reliable and consistent downstream experimental results. This talk discusses the selection and molecular characteristics of vectors utilized for high-throughput cloning and protein arrays.

3:05 Genome-Wide RNAi Screen for Improved Functional Expression of Neurotensin Receptor and Other Proteins
Joseph Shiloach, Ph.D., Head, Biotechnology Core Laboratory, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health
Genome-wide RNA interference screen is emerging as a powerful methodology for deducing gene functions in various diseases. We applied this technology to generate genome-wide profile of genes related to recombinant protein expression process from HEK293 cells. We utilized human microRNA library of 875 microRNA and siRNA library targeting 21,000 genes. By implementing high-throughput screening, we identified miRNAs/siRNAs that significantly increased expression of different recombinant proteins.

3:35 Sponsored Presentation *(Opportunity Available)*

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

4:30 Direct Expression of PCR-Amplified Genes in Mammalian Cells - Linear DNA Technology Using Terminator Primer and Lipofection Enhancer Reagents
Mikiko Nakamura, Ph.D., Research Fellow, Department of Applied Molecular Bioscience, Graduate School of Medicine, Yamaguchi University
We found two reagents that synergistically enhance mammalian cell transfection with lipofection reagents. The enhancers allowed PCR-amplified DNA as a source for gene transfection in 96-well cell cultures. In addition, transcriptional terminators were minimized to the length designable as oligonucleotide primers, which we called "terminator primer". The PCR-mediated gene manipulations in mammalian cells will transform gene expression by allowing for extremely simple and high-throughput experiments with small-scale cell cultures.

5:00 Modification of GENSAT BAC with Lambda-Red Recombineering System for Transgenic Animals or Cell Lines
JrGang Cheng, Ph.D., Associate Professor, The Neuroscience Center, University of North Carolina at Chapel Hill
Based on BAC transgenic mouse platform, GENSAT Brain Atlas provides an invaluable resource for studying gene expression and cellular migration *in vivo*. In order to use a specific GENSAT BAC with the desired expression profile and expand its implications, the modification of eGFP to a different transgene is greatly beneficial. Modified GENSAT BAC can not only be utilized in making transgenic animals but also in transfecting cell lines.

5:45 BuzZ Session A
Join your peers and colleagues for interactive roundtable discussions.
Please see page 55 for additional information.

BuzZ sessions

6:30-7:45 Welcome Reception in the Exhibit Hall with Poster Viewing

Sponsored by freeslate

7:45 Close of Day

TUESDAY, JANUARY 19

8:00 am Conference Registration and Morning Coffee

ENHANCING EXPRESSION SYSTEMS

8:30 Chairperson's Remarks
James D. Love, Ph.D., Director, Technology Development & Research Assistant Professor, Biochemistry, Albert Einstein College of Medicine

8:35 Computational Design Strategies for Synthesizing Genes and Fusion Proteins and Enhancing their Expression
*Dong-Yup Lee, Ph.D., Assistant Professor, Chemical and Biomolecular Engineering, National University of Singapore and Senior Scientist, Bioprocessing Technology Institute, A*STAR*
We develop a cost-effective computational platform for rationally designing synthetic genes and recombinant fusion proteins as well as enhancing their expression in commonly used microbial or mammalian hosts. This platform will facilitate synthetic (fusion) protein production for diverse biotechnological and biopharmaceutical applications. In this talk, several case studies of the applications will be presented.

9:05 A Systematic Approach to Engineering Antibody and Integral Membrane Protein Expression
James D. Love, Ph.D., Director, Technology Development & Research Assistant Professor, Biochemistry, Albert Einstein College of Medicine
A systematic engineering approach that combined machine learning methods with gene synthesis to explore vector element and codon optimization determinants of protein/antibody expression was investigated. Expression elements explored include secretion signals, transposases, viral amplifiers and RNA export signals in addition to novel combinations of enhancer, promoter, intron, polyadenylation signal elements. Systematic use of a panel of transient transfection vectors enabled rapid expression success of a series of high-value targets.

9:35 Sponsored Presentation *(Opportunity Available)*

9:50 Coffee Break in the Exhibit Hall with Poster Viewing

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Engineering Genes, Vectors, Constructs and Clones

Upstream Decisions Lead to Downstream Success

11:00 Development of Effective Expression Systems for the Production of Glycosyltransferases Used in the Glycoengineering of Biotherapeutics
James Meador, Senior Scientist, Protein Production, Research, Momenta Pharmaceuticals, Inc.
We have developed a highly efficient process to fully sialylate the Fc glycans of immunoglobulins that involves using two human glycosyltransferases. We needed to produce the two enzymes at sufficient quality and quantity to make such a process economical. We discuss the various expression systems screened and ultimately used to produce the highly purified enzymes at >100 mg/liter levels from HEK293 cells.

▸ **FEATURED PRESENTATION**
11:30 One for All
Anton Glieder, Ph.D., Professor, Molecular Biotechnology, Graz University of Technology
Since optimal genetic constructs for high-level gene expression remain target-dependent and unpredictable, feedback from fermentation scientists supports the design and construction of improved second-generation production strains. Alternatively, the design of new production strains employing differently regulated synthetic bidirectional promoters with additional copies of target genes allows construction of strains permitting use of different cultivation and production strategies to maximize yields for each target without additional steps back to strain development.

12:00 pm Sponsored Presentation *(Opportunity Available)*

12:30 Session Break

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

1:45 Close of Conference

Recombinant Protein Expression

Achieving Quality and Quantity

Biopharmaceuticals currently represent the fastest-growing sector of the pharmaceutical industry, driven by a rapid expansion in the manufacture of recombinant protein-based drugs. To meet the demand, it is crucial to increase the throughput of expression, production and purification processes and systems.

Cambridge Healthtech Institute's Recombinant Protein Expression conference explores the newest data and innovations relating to the best choices in hosts / systems, as well as ways to "rescue" existing systems and make them work more effectively to produce the quality and quantity of the desired biotherapeutic.

TUESDAY, JANUARY 19

1:00 pm Conference Registration

ALTERNATIVE EXPRESSION SYSTEMS

2:00 Chairperson's Opening Remarks
Lars Keld Nielsen, Ph.D., Chair & Professor, Biological Engineering, Australian Institute for Bioengineering and Nanotechnology (AIBN), The University of Queensland

KEYNOTE PRESENTATION

2:05 Expressing Human Intracellular and Integral Membrane Proteins for Structural and Functional Studies
Nicola Burgess-Brown, Ph.D., Principal Investigator, Biotechnology, Structural Genomics Consortium (SGC), University of Oxford
Production of human integral membrane proteins (IMPs) for structural studies, although still challenging, has advanced significantly over the past couple of years. Since 2004, the Structural Genomics Consortium (SGC) globally has solved more than 1700 soluble human protein structures in addition to five novel IMPs. These recombinant proteins have provided a rich resource for functional genomics, small molecule inhibitor screens and generation of antibodies. Our established expression systems will be presented as well as some new technologies to tackle challenging proteins.

2:45 Production of Human Lysosomal Enzymes in Microorganism: Achievements and Challenges
Carlos J. Alméciga-Díaz, Ph.D., BPharm, Associate Professor, Institute for the Study of Inborn Errors of Metabolism (IEIM), School of Sciences, Pontificia Universidad Javeriana
Lysosomal storage diseases are produced by the deficiency of an enzyme associated with the lysosomal catabolism of several substrates. Currently, the main treatment alternative is the use of recombinant enzymes produced in mammalian cells. As an alternative, microorganisms have been used as a host, showing the production of active and even therapeutic enzymes. Meanwhile, challenges involve the tailoring of N-glycosylation and the impact of O-glycosylations on protein production and efficacy.

3:15 Refreshment Break in the Exhibit Hall with Poster Awards

4:00 Selexis SUREcode™: De-Risking Research Cell Bank Generation with Comprehensive Genomic Analysis
Sponsored by SELEXIS
Pierre-Alain Girod, Ph.D., CSO, Selexis
RCBs are cell populations with neither identical genomes nor single integration sites even when selected from single isolated clones. The inherent genomic instability of CHO-K1 leads to the appearance of mixed populations that can result in decreased manufacturability. Selexis's proprietary SUREcode™ bioinformatics, based on Next Generation Sequencing of entire genomes, provides unique and detailed genomic maps of cell populations. It is used to fully characterize integration sites and transgene sequences as well as provide detailed genomic information that reduces and mitigates risk while manufacturing recombinant protein drugs.

4:30 High-Titer Production of Knob-into-Hole Bispecific Antibodies in *E. coli*
James Giulianotti, Senior Research Associate, Early Stage Cell Culture, Genentech, Inc.
Bispecific antibodies (bisAbs) are being developed by companies attempting to address complex disease states. Production of bisAbs in *E. coli* requires optimization of cellular processes within two distinct compartments (cytoplasm and periplasm) and across a single membrane (inner membrane). Over the past decade, technologies have been tested and implemented at Genentech that aid the production of bisAbs in *E. coli*. This talk discusses some recent work in this area.

5:00 Production of Complex Protein Therapeutics in the Chloroplast of the Green Algae *Chlamydomonas reinhardtii*
Miller Tran, Ph.D., Senior Scientist, Lead Discovery, Verdant Therapeutics, Inc.
Chlamydomonas reinhardtii chloroplasts have a unique biochemical environment that allows production of complex therapeutic proteins, including recombinant immunotoxins. Recent improvements in biomass and protein production in *C. reinhardtii* strains have been achieved through optimized fed-batch protocols and vector design. These improvements have made our system a potential platform for unique and complex protein products.

5:30-5:45 Short Course Registration

5:45-8:45 Dinner Short Courses *See page 4 for details*

WEDNESDAY, JANUARY 20

8:00 am Conference Registration and Morning Coffee

Recombinant Protein Expression

Achieving Quality and Quantity

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MEMBRANE PROTEINS

8:30 Chairperson's Remarks
Henry C. Chiou, Ph.D., Associate Director, Cell Biology, Life Science Solutions, Thermo Fisher Scientific

8:35 Light-Controlled Intracellular Delivery of Native Peptides and Proteins
Norbert O. Reich, Ph.D., Professor, Chemistry & Biochemistry, University of California, Santa Barbara
We have developed a nanoparticle-based platform to deliver proteins into specific cells with spatiotemporal control achieved through the use of highly penetrating near-infrared light. The delivery of therapeutic peptides as well as transcription factors provides a means to control the timing and amount of release for synthetic biology and translational applications.

9:05 Cell-Free Expression of High-Quality GPCRs in Eukaryotic and Prokaryotic Lysates
Ralf-Bernhardt Rues, Research Fellow, Institute of Biophysical Chemistry, Goethe University Frankfurt
GPCRs are crucial regulators of cellular physiology and play central roles in medical research. The development of efficient GPCR production pipelines based on synthetic biology is discussed. Key issues will be systems adaption to individual GPCRs, folding optimization with defined nanodisc and lysate combinations and directed engineering for sample stabilization. Presented examples are human endothelin as well as catecholamine binding receptors. GPCR sample properties obtained from either bacterial or insect cell lysates will be compared.

9:35 Automated Transient Transfection for High Throughput Protein Production
Sponsored by PhyNexus
Chris Suh, Ph.D., Business Development, PhyNexus, Inc.
Transient transfection of mammalian cell lines is being implemented by the pharmaceutical industry to produce the therapeutic protein candidates very rapidly compared to previous technology thus allowing large numbers of drug candidates to be screened and studied. However, high throughput automated transient transfection is required to cope with the dramatically increased sample load. Here we describe the integration, implementation and validation of different robotic platforms for automated transient transfection of mammalian cells.

10:05 Coffee Break in the Exhibit Hall with Poster Viewing

10:50 Nanodisc in Drug Discovery: Assembly, Characterization and Application
Han Xu, Ph.D., Principal Scientist, Amgen, Inc.
Integral membrane proteins (IMPs) are of therapeutic interest and are targeted by a majority of approved drugs. It's difficult to express, purify and maintain the functional conformation of IMPs. Nanodisc presents a reliable method to solubilize and stabilize IMPs in detergent-free condition. In this presentation, I detail assembly and characterization of KcsA-Kv1.3 Nanodisc and demonstrate applications of Nanodisc in drug discovery.

11:20 Presentation to be Announced

11:50 Expression of Membrane Recombinant Hemagglutinins, Components of Influenza Vaccine Flublok®, Using Baculovirus Expression System
Nikolai Khramtsov, Ph.D., Associate Director, Upstream Development, Process Development, Protein Sciences Corp.
We developed a universal process for the GMP production of influenza recombinant hemagglutinins (rHAs), components of seasonal influenza vaccine Flublok®. The GMP manufacture in BEVS (baculovirus expression vector system) begins in less than two months from the FDA announcement of vaccine composition for a new flu season (in February of each year). Our results suggest that BEVS is a highly efficient system for expression of membrane-bound biologically active HAs.

12:20 pm ExpiCHO Transient Expression System: Comparative Data, New Applications and Tips for Maximal Performance
Sponsored by ThermoFisher SCIENTIFIC
Nikolai Khramtsov, Ph.D., Associate Director, Upstream Development, Process Development, Protein Sciences Corp.
The ability to produce transient CHO-derived proteins early on during the drug development process is highly advantageous to minimize changes in critical quality attributes observed when progressing from discovery to bioproduction. Previous CHO-based transient systems have been hampered by low levels of protein production compared to HEK293 systems, in some instances 50-100 times less than the best 293-based systems. With the introduction of the ExpiCHO transient expression system, researchers have a flexible new tool to express proteins at significantly higher levels than in 293 cells, up to 3 grams per liter, while benefitting from the relevance of CHO cells. In this session we will present data comparing the ExpiCHO and Expi293 transient expression systems, newly-developed ExpiCHO applications notes as well as tips for ensuring easy set-up and maximal performance from the ExpiCHO transient expression system.

12:50 Session Break

1:00 Presentation to be Announced
Sponsored by ARAGEN

ENGINEERING MAMMALIAN-CELL EXPRESSION

2:00 Chairperson's Remarks
Dominic Esposito, Ph.D., Director, Protein Expression Laboratory, Frederick National Laboratory for Cancer Research, Leidos Biomedical Research, Inc.

▸ **FEATURED PRESENTATION**
2:05 Multi-Omics Approach for Comparative Studies of Monoclonal Antibody-Producing CHO Cells
Lars Keld Nielsen, Ph.D., Chair & Professor, Biological Engineering, Australian Institute for Bioengineering and Nanotechnology (AIBN), The University of Queensland
The availability of the CHO genome has renewed interest in using systems biology to guide rational strain design. Using optimized extraction, RNAseq and SWATH protocols for CHO, we here compared low- and high-producer clones from a single transfection pool. CVs of less than 5% were achieved for full biological triplicates and 55% of all identified proteins were differentially expressed. Targets for increased mAb production were identified and validated.

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Recombinant Protein Expression

Achieving Quality and Quantity

2:35 Designing CHO Cell Factories Using System Biology Models
Nathan E. Lewis, Ph.D., Assistant Professor, Department of Pediatrics, University of California, San Diego
Cell line selection and development is becoming increasingly important for controlling critical quality attributes of recombinant therapeutic proteins. To guide the rational engineering of CHO cell lines, we are developing computational models of cell processes that influence product quality and using these models for data interpretation and predictive modeling, thus enabling the development of enhanced protein production hosts.

3:05 High-Throughput Stable Cell Line Platform
Sarah Rue, Ph.D., Senior Research Investigator, Genomics Institute of the Novartis Research Foundation
We have developed methods to establish antibody-expressing stable cell lines in a fully automated and high-throughput platform. This platform is integrated with GNF's Protein Expression and Purification Platform (PEPP). This workstream is combined with different downstream expression workflows to enable fit-for-purpose use.

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

4:30 Speed-to-Clinic Cell Line Development without Compromising on Cell Line Stability
Gang Chen, Ph.D., Executive Director, Protein Expression Sciences, Regeneron Pharmaceuticals, Inc.
A key component of Regeneron's rapid response platform for emerging infectious diseases is our speed-to-clinic cell line technology. Manufacturing-ready cell lines producing antibody-drug candidates are constructed in as short as 18 days. These speed-to-clinic cell lines have several design features that ensure exceptional genetic stability in the absence of prior single-cell cloning and stability screen. The quality attributes of the speed-to-clinic cell lines will be presented.

5:00 Strategies for Optimal Scale-Up and Scale-Down of Cell Culture Bioprocess for Recombinant Protein Production
Kartik Subramanian, Ph.D., Group Leader, Cell Culture, Manufacturing Sciences, AbbVie Bioresearch Center, AbbVie
In this presentation, technical issues relevant to developing representative scale-down models and methodologies for scale-up will be discussed.

5:45 BuzZ Session B
Join your peers and colleagues for interactive roundtable discussions.
Please see page 55 for additional information.

6:30-7:30 Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Conference

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2nd Annual

Membrane Proteins

A Valuable Resource and Target

Membrane proteins are the gateways to the cell and are valuable drug targets. For researchers to design better-targeted drugs, they need to know their structure and functional characteristics. Cambridge Healthtech Institute's 2nd Annual Membrane Proteins conference addresses the strategies and solutions for their extraction, expression and purification, and features case studies showcasing their value as a drug target. Join the in-depth exploration of how to obtain functional membrane proteins, and learn more about this important protein class.

TUESDAY, JANUARY 19

1:00 pm Conference Registration

PURIFYING MEMBRANE PROTEINS

2:00 Chairperson's Opening Remarks
William Gillette, Ph.D., Senior Scientist, Protein Expression Laboratory, Cancer Research Technology Program, Leidos Biomedical Research, Inc., Frederick National Laboratory for Cancer Research (FNL)

KEYNOTE PRESENTATION

2:05 Making Water-Soluble Integral Membrane Proteins *in vivo* Using an Amphipathic Protein Fusion Strategy
Matthew P. DeLisa, Ph.D., William L. Lewis Professor, Chemical & Biomolecular Engineering, Cornell University
Here we devise a general strategy for *in vivo* solubilization of IMPs in structurally relevant conformations without the need for detergents or mutations to the IMP itself. This technique, called SIMPLEx (solubilization of IMPs with high levels of expression), allows the direct expression of soluble products in living cells by simply fusing an IMP target with truncated apolipoprotein A-I, which serves as an amphipathic proteic 'shield' that sequesters the IMP from water and promotes its solubilization.

▸ FEATURED PRESENTATION

2:45 Expression and Sample Preparation of Membrane Proteins for Structure Determination by NMR
Stanley Opella, Ph.D., Professor, Chemistry and Biochemistry, University of California, San Diego
The advantages of heterologous expression of proteins in bacteria include the ability to make relatively large amounts and the ready incorporation of stable isotopes. The use of a hydrophobic fusion protein enables the sequestration in inclusion bodies to avoid damaging the cell membrane.

3:15 Refreshment Break in the Exhibit Hall with Poster Awards

4:00 Selexis SUREcode™: De-Risking Research Cell Bank Generation with Comprehensive Genomic Analysis
Sponsored by SELEXIS
Pierre-Alain Girod, Ph.D., CSO, Selexis
RCBs are cell populations with neither identical genomes nor single integration sites even when selected from single isolated clones. The inherent genomic instability of CHO-K1 leads to the appearance of mixed populations that can result in decreased manufacturability. Selexis's proprietary SUREcode™ bioinformatics, based on Next Generation Sequencing of entire genomes, provides unique and detailed genomic maps of cell populations. It is used to fully characterize integration sites and transgene sequences as well as provide detailed genomic information that reduces and mitigates risk while manufacturing recombinant protein drugs.

4:30 It Takes Two to Tango—Structure/Function Studies Yield the Dance of the Permease
H. Ronald Kaback, M.D., Distinguished Professor, Physiology, University of California, Los Angeles
Lactose permease (LacY) catalyzes translocation of a galactoside and an H+ across the membrane. X-ray structures, and structure/function studies reveal that: (1) LacY utilizes an alternating access mechanism; (2) sugar binding involves induced fit; (3) Active transport does not involve a change in K_D for sugar on either side of the membrane, but the pK_a decreases markedly. (4) Transport is driven chemiosmotically, and $\Delta\tilde{\mu}H+$ acts kinetically to accelerate the process.

5:00 Strategies for High Yield Affinity Purification of Functional G Protein Coupled Receptor from Detergent Solutions
Alexei Yeliseev, Ph.D., Staff Scientist, LMBB, NIH/NIAAA
Human cannabinoid receptor CB2, a G protein-coupled receptor involved in regulation of immune response, is an important target for pharmaceutical drug development. We expressed the functional CB2 receptor in *E. coli*, and optimized its purification by tandem affinity chromatography using novel affinity resins StrepTactin XT Superflow and EF2 Ca-calbindin-based resin. Examples of successful purification and efficient recovery (over 80%) of CB2 from dilute detergent-containing solutions will be presented.

5:30-5:45 Short Course Registration

5:45-8:45 Dinner Short Courses *See page 4 for details*

WEDNESDAY, JANUARY 20

8:00 am Conference Registration and Morning Coffee

ENHANCING EXPRESSION

8:30 Chairperson's Remarks
Henry C. Chiou, Ph.D., Associate Director, Cell Biology, Life Science Solutions, Thermo Fisher Scientific

8:35 Light-Controlled Intracellular Delivery of Native Peptides and Proteins
Norbert O. Reich, Ph.D., Professor, Chemistry & Biochemistry, University of California, Santa Barbara
We have developed a nanoparticle-based platform to deliver proteins into specific cells with spatiotemporal control achieved through the use of highly penetrating near-infrared light. The delivery of therapeutic peptides as well as transcription factors provides a means to control the timing and amount of release for synthetic biology and translational applications.

9:05 Cell-Free Expression of High-Quality GPCRs in Eukaryotic and Prokaryotic Lysates
Ralf-Bernhardt Rues, Research Fellow, Institute of Biophysical Chemistry, Goethe University Frankfurt

GPCRs are crucial regulators of cellular physiology and play central roles in medical research. The development of efficient GPCR production pipelines based on synthetic biology is discussed. Key issues will be systems adaption to individual GPCRs, folding optimization with defined nanodisc and lysate combinations and directed engineering for sample stabilization. Presented examples are human endothelin as well as catecholamine binding receptors. GPCR sample properties obtained from either bacterial or insect cell lysates will be compared.

9:35 Automated Transient Transfection for High Throughput Protein Production

Sponsored by PhyNexus

Chris Suh, Ph.D., Business Development, PhyNexus, Inc.

Transient transfection of mammalian cell lines is being implemented by the pharmaceutical industry to produce the therapeutic protein candidates very rapidly compared to previous technology thus allowing large numbers of drug candidates to be screened and studied. However, high throughput automated transient transfection is required to cope with the dramatically increased sample load. Here we describe the integration, implementation and validation of different robotic platforms for automated transient transfection of mammalian cells.

10:05 Coffee Break in the Exhibit Hall with Poster Viewing

10:50 Nanodisc in Drug Discovery: Assembly, Characterization and Application

Han Xu, Ph.D., Principal Scientist, Amgen, Inc.

Integral membrane proteins (IMPs) are of therapeutic interest and are targeted by a majority of approved drugs. It's difficult to express, purify and maintain the functional conformation of IMPs. Nanodisc presents a reliable method to solubilize and stabilize IMPs in detergent-free condition. In this presentation, I detail assembly and characterization of KcsA-Kv1.3 Nanodisc and demonstrate applications of Nanodisc in drug discovery.

11:20 Presentation to be Announced

11:50 Expression of Membrane Recombinant Hemagglutinins, Components of Influenza Vaccine Flublok®, Using Baculovirus Expression System

Nikolai Khramtsov, Ph.D., Associate Director, Upstream Development, Process Development, Protein Sciences Corp.

We developed a universal process for the GMP production of influenza recombinant hemagglutinins (rHAs), components of seasonal influenza vaccine Flublok®. The GMP manufacture in BEVS (baculovirus expression vector system) begins in less than two months from the FDA announcement of vaccine composition for a new flu season (in February of each year). Our results suggest that BEVS is a highly efficient system for expression of membrane-bound biologically active HAs.

12:20 pm Presentation to be Announced

Sponsored by ThermoFisher SCIENTIFIC

12:50 Session Break

1:00 Presentation to be Announced

Sponsored by ARAGEN

DISCOVERY AND DEVELOPMENT OF ANTIBODIES FOR MEMBRANE PROTEIN TARGETS

2:00 Chairperson's Remarks

Caroline Colley, Ph.D., Senior Scientist, Antibody Discovery and Protein Engineering, MedImmune

2:05 Antibody Discovery Against GPCRs using Yeast Antibody Display Technology

Abhishek Datta, Ph.D., Scientist II, Drug Discovery, Biogen

G-protein coupled receptors (GPCRs) are membrane proteins that are important drug targets. The development of therapeutic antibodies against them has been challenging. We have employed multiple strategies to identify antibodies against a Class A GPCR. Here we present selection strategies that have enabled identification of antibodies using the Adimab yeast antibody discovery and optimization platform. Functional characterization of these antibodies and their potential use as a therapeutic in immunological disorders will be discussed.

2:35 Engineering Ion Channels for Structural Studies and Ligand Discovery

Susmith Mukund, Senior Research Associate, Genentech, Inc.

3:05 Antibody-Mediated Blockade of Human Orai1 Inhibits T Cell Activation *in vitro* and *in vivo*

Stefan Zahn, Ph.D., Principal Scientist, Antibody Technology, Novo Nordisk A/S

Ion channels are widely expressed on cells and tightly regulate the flow of ions between the extracellular and the intracellular environment. Dysregulation has been linked to pain, epilepsy and even autoimmune inflammatory diseases. We will present our recent work on targeting T cell specific ion channels like CRAC by antibodies inhibiting T cell activation *in vivo* and *in vitro*.

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

4:30 Targeting Tumor Selective Cell Surface Antigens Using Designer Antibodies

Madan Katragadda, Ph.D., Senior Principal Scientist, Pfizer, Inc.

Potent novel means of therapeutic intervention utilizing immune cell retargeting and antibody-drug conjugates necessitates tumor selective targets owing to their extremely high potent nature. Several strategies have evolved in the past decade to selectively target tumors by either exploiting antigens, antigen complexes and glycoepitopes that are selectively overexpressed on tumor cells relative to the normal cells or simultaneously targeting two or more antigens using antibody engineering techniques. Examples describing these strategies are presented.

5:00 Challenges in Generating Antibodies to Integral Membrane Proteins

Ramkrishna (Ramu) Sadhukhan, Senior Group Leader, AbbVie Bioresearch Center Center

Developing therapeutic antibodies against integral membrane proteins is difficult, as GPCRs and ion channels are often expressed at low levels on cell surface and are unstable when purified. Poor quality membrane protein immunogens has led to limited success in generating antibodies that bind native cell surface molecules and remains a bottleneck for membrane protein target validation and monoclonal antibody-based therapeutics. Here, we present antigen preparation and antibody generation against multispanner proteins.

5:45 BuzZ Session B

Join your peers and colleagues for interactive roundtable discussions.

Please see page 55 for additional information.

6:30-7:30 Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Conference

CHO Cell Culture

Enhancing Expression, Performance and Process

Advances in CHO cell culture technology continue to significantly improve biotherapeutic production. This achievement is due to progress in engineering stable and transient cell lines, enhancing cell culture conditions and performance, as well as optimizing process development. When all are accomplished, higher-production titers and better product quality result. The CHO Cell Culture conference gathers cell line engineers, cell culture specialists and bioprocess development managers to explore the latest data, tools and strategies for improving protein expression, production and product quality.

WEDNESDAY, JANUARY 20

1:00 pm Conference Registration

ENHANCING EXPRESSION THROUGH ENGINEERING

2:00 Chairperson's Remarks
Dominic Esposito, Ph.D., Director, Protein Expression Laboratory, Frederick National Laboratory for Cancer Research, Leidos Biomedical Research, Inc.

▸ **FEATURED PRESENTATION**
2:05 Multi-Omics Approach for Comparative Studies of Monoclonal Antibody-Producing CHO Cells
Lars Keld Nielsen, Ph.D., Chair & Professor, Biological Engineering, Australian Institute for Bioengineering and Nanotechnology (AIBN), The University of Queensland
The availability of the CHO genome has renewed interest in using systems biology to guide rational strain design. Using optimized extraction, RNAseq and SWATH protocols for CHO, we here compared low- and high-producer clones from a single transfection pool. CVs of less than 5% were achieved for full biological triplicates and 55% of all identified proteins were differentially expressed. Targets for increased mAb production were identified and validated.

2:35 Designing CHO Cell Factories Using System Biology Models
Nathan E. Lewis, Ph.D., Assistant Professor, Department of Pediatrics, University of California, San Diego
Cell line selection and development is becoming increasingly important for controlling critical quality attributes of recombinant therapeutic proteins. To guide the rational engineering of CHO cell lines, we are developing computational models of cell processes that influence product quality and using these models for data interpretation and predictive modeling, thus enabling the development of enhanced protein production hosts.

3:05 High-Throughput Stable Cell Line Platform
Sarah Rue, Ph.D., Senior Research Investigator, Genomics Institute of the Novartis Research Foundation
We have developed methods to establish antibody-expressing stable cell lines in a fully automated and high-throughput platform. This platform is integrated with GNF's Protein Expression and Purification Platform (PEPP). This workstream is combined with different downstream expression workflows to enable fit-for-purpose use.

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

4:30 Speed-to-Clinic Cell Line Development without Compromising on Cell Line Stability
Gang Chen, Ph.D., Executive Director, Protein Expression Sciences, Regeneron Pharmaceuticals, Inc.
A key component of Regeneron's rapid response platform for emerging infectious diseases is our speed-to-clinic cell line technology. Manufacturing-ready cell lines producing antibody-drug candidates are constructed in as short as 18 days. These speed-to-clinic cell lines have several design features that ensure exceptional genetic stability in the absence of prior single-cell cloning and stability screen. The quality attributes of the speed-to-clinic cell lines will be presented.

5:00 Strategies for Optimal Scale-Up and Scale-Down of Cell Culture Bioprocess for Recombinant Protein Production
Kartik Subramanian, Ph.D., Group Leader, Cell Culture, Manufacturing Sciences, AbbVie Bioresearch Center, AbbVie
In this presentation, technical issues relevant to developing representative scale-down models and methodologies for scale-up will be discussed.

5:45 BuzZ Session B
Join your peers and colleagues for interactive roundtable discussions.
Please see page 55 for additional information.

6:30-7:30 Reception in the Exhibit Hall with Poster Viewing

THURSDAY, JANUARY 21

7:45 am Morning Coffee

IMPROVING PERFORMANCE WITH ANALYTICS

8:15 Chairperson's Opening Remarks
Denise Krawitz, Ph.D., Senior Manager, Analytical Operations, Genentech, Inc.

KEYNOTE PRESENTATION

8:20 Product Quality Controls through Process- and Non-Process-Related Strategies
Zhimei Du, Ph.D., Principal Scientist, Cell Culture Development & Manufacturing, Teva Pharmaceuticals USA
N-linked glycosylation of monoclonal antibody is a critical quality attribute and the existence of the heterogeneous glyco-forms is a common scenario due to the incomplete glycosylation process inside the cell. This presentation reviews the molecular mechanisms and impacts of mAb glycosylation heterogeneity both *in vitro* and *in vivo*. Additionally, progress to date in controlling mAb glycosylation by optimizing manufacturing process and the novel non-process-related approaches will be discussed.

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9:00 Protein Expression Profiling of Different CHO Cell Lines: Striking Similarities
Denise Krawitz, Ph.D., Senior Manager, Analytical Operations, Genentech, Inc.
Host cell proteins (HCP) are a complex process-related impurity often monitored with multi-analyte immunoassays like ELISA. In order to use platform ELISAs to monitor HCPs in multiple products, we must demonstrate that the HCP population does not vary significantly with cell culture changes. Proteomics studies of different cell lines grown under different culture conditions suggest that the vast majority of proteins expressed are the same between cell lines.

9:30 Metabolomics for Optimizing CHO Cell Culture Conditions
Zhongqi Zhang, Ph.D., Scientific Director, Amgen, Inc.
A metabolomics platform was developed for metabolic profiling of complex raw materials, cell culture media and cell lysates. Data were used for the optimization of cell culture media for maximal product productivity and quality. For example, metabolic profiling of soy hydrolysate, a complex medium raw material, revealed several components as productivity markers, among which ornithine was found to promote cell growth and increase productivity.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

11:00 Exploiting the Proteomics Revolution in Biotechnology: From Disease and Antibody Targets to Optimizing Bioprocess Development
Deniz Baycin Hizal, Ph.D., Scientist II, Antibody Discovery & Protein Engineering, MedImmune
Recent advancements and applications of mass spectrophotometer-based proteomics are enriching biopharmaceutical research and development across multiple fields including target and biomarker discovery, understanding the mechanism of action of drugs, and bioprocess improvements. Quantitative proteomics approaches have been applied to enhance our understanding of recombinant protein production, increase cell growth, delay apoptosis and guide media formulation improvements.

11:30 A Novel Lipid Supplement Significantly Increases mAb Titer in Bioreactors, without Creating a Deleterious Metabolic Profile or Increasing Biomass
Sponsored by essential pharmaceuticals, LLC
Adam Elhofy, Ph.D., CSO, Essential Pharmaceuticals
A novel lipid supplement, Cell-Ess, creates a more robust animal free and chemically defined system (CD). Cell-Ess has been used to supplement to CD systems in bioreactors resulting in increased titers ranging from 20%-40% without significantly increasing the VCD. Increased productivity resulted in several improved characteristics for bio-production including no significant changes in metabolites or increased biomass including cell debris and host proteins. Protein quality was maintained in samples with increased titers.

12:00 pm Session Break

12:15 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Ice Cream Break in the Exhibit Hall with Poster Viewing

OPTIMIZING PRODUCTION THROUGH PROCESS

2:00 Chairperson's Remarks
Lynette Buck, Senior Associate Scientist, Amgen, Inc.

2:05 New Workflow Platform for High-Throughput Cell Line Development
Christian Bender, Ph.D., Computational Biologist, Antibody Lead Discovery, Bayer HealthCare
We present a new workflow system automating the Cell Line Development process for mammalian cells used to produce therapeutic antibodies and proteins. It tracks clones produced and screened in high-throughput mode, collects relevant characterization data and streamlines high-throughput workflows by interfacing with automation equipment and bioreactors. We show how Bayer's Global Biologics groups use it and present applications of the generation of GMP-ready cell lines and their transfer into process development.

2:35 Epigenetic Marks Enable Rejection of Unstable Chinese Hamster Ovary Cell Lines
Ulrich Goepfert, Ph.D., Principal Scientist, Cell Line & Molecular Development, Roche Innovation Center Penzberg
During expansion and maintenance, CHO cell lines are prone to production instability, which may be caused by promoter silencing, loss of transgene copies or posttranscriptional effects. Silencing of recombinant genes may be accompanied by DNA methylation and histone modification. We examined a variety of epigenetic modifications and identified molecular indicators which provide the opportunity to enrich stable producers.

3:05 Next Level of *E. coli* Expression - Higher Yields and Better Quality
Sponsored by XBRANE BIOSCIENCE
David Vikström, Ph.D., CTO, Xbrane Bioscience

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

4:15 Comparison of ExpiCHO and Expi293 Expression Systems: Considerations for Transient Protein Production
Nina Jain, Research Associate, Alexion Pharmaceuticals
We compare Thermo Fisher Scientific's high-density transient transfection systems, Expi293 and ExpiCHO. We discuss the expression and characterization of multiple proteins (mAbs, Fabs, bispecifics and fusion proteins) generated in both systems. We also compare the proteins expressed in these systems to reference standards generated in stable production cell lines and discuss the implications this data has for system selection.

4:45 A High-Yielding CHO Transient System: Coexpression of Genes Encoding EBNA-1 and GS Enhances Transient Protein Expression
Olalekan Daramola, Ph.D., Cell Sciences, Biopharmaceutical Development, MedImmune

5:00 A High Cell Density Transient Transfection System for Therapeutic Protein Expression Based on a CHO GS-Knockout Cell Line
Gavin Barnard, Ph.D., Group Leader, Eli Lilly and Company
We discuss the development of a PEI-mediated transient CHO expression system capable of generating high titers, scalable up to 6L. This was achieved through rigorous optimization of cell density, DNA and PEI concentrations followed by process development strategies. The system was further improved by the co-expression of a specific transcription factor (XBP1S). This platform enables rapid expression of therapeutic protein candidates, thus alleviating one bottleneck in the drug development process.

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5:15 Molecule Assessment and CLD for mAb Candidate Selection
Lynette Buck, Senior Associate Scientist, Amgen, Inc.
Molecule Assessment is the consideration of manufacturing, stability and product attributes when designing/selecting protein candidates for commercialization. This is done at the Cell Line Development stage not only to facilitate meeting First in Human needs but also to ensure productivity needs to meet future commercial demands.

6:00-7:00 Reception in the Tiki Pavilion

7:00 Close of Conference

Applying Expression Platforms

Transient, Stable or Both?

Speed, limiting risk and protein quality are often cited as advantages of transient protein production (TPP), while stable transfection – the longer and more complex process – has the advantage of producing long-term expression of the protein of interest. The rapidly increasing need for recombinant proteins necessitates further improvements in both technologies.

Cambridge Healthtech Institute's 3rd Annual Applying Expression Platforms conference convenes protein expression specialists who share their experiences with the differences, tradeoffs, advantages and improvements in producing recombinant proteins in transient and stable production systems, along with the systems' advantages and disadvantages and when to use both.

THURSDAY, JANUARY 21

7:45 am Conference Registration and Morning Coffee

TRANSIENT PROTEIN PRODUCTION

8:15 Chairperson's Opening Remarks
Christopher W. Kemp, Ph.D., President, Kempbio, Inc.

KEYNOTE PRESENTATION

8:20 Protein Sciences in Drug Discovery – Challenges and Future Trends
Ian Hunt, Ph.D., Head, Protein Sciences, Center for Proteomic Chemistry, Novartis Institutes for BioMedical Research
As drug discovery continues to evolve and develop, so too do the challenges and demands placed on protein sciences. This presentation describes some of the key strategies developed to meet these challenges. Topics covered include the discussion of multi-parallel expression and purification strategies, use of HT instrumentation and the potential utility of a number of new and enabling technologies for dealing with increasingly difficult-to-produce proteins.

9:00 A Comparison of Two Methods for the Gram-Scale Production of Recombinant IgG in Transiently Transfected Cultures of HEK-293 and CHO-S Cells
Christopher W. Kemp, Ph.D., President, Kempbio, Inc.
The use of transient transfection to produce significant quantities of recombinant immunoglobulins and other proteins is an important tool for development of new therapeutics and diagnostics. Transfections mediated by PEI and transductions mediated by BacMam viruses are diverse methods for the introduction of genes into cells at scale. This presentation compares the methodology and results for production of rIgG using these methods in expressions conducted using HEK-293 and CHO-S cells.

9:30 Respiratory Syncytial Virus-Like Particles (RSV VLPs) Made by Transient Transfection of HEK293 Cells Protects the Lower as Well as the Upper Respiratory Tract
Pramila Walpita, Ph.D., Assistant Professor, Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine, University of Hawaii at Manoa
In vitro studies demonstrated that these suspension-adapted transiently transfected RSV VLPs were functionally assembled and immuno-reactive. *In vivo* studies in cotton rats (CRs) showed that after two doses of these VLPs given three weeks apart induced potent neutralizing antibody response and protected both the lung and the nose when challenged with live RSV A2 virus.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

11:00 Transient Expression at Genmab: How to Keep the Engine Running
Tom Vink, Ph.D., Associate Director, Cell & Molecular Science, Genmab BV
The ever-increasing demands in volume and speed of our transient expressions has driven us to optimize both our process and our technologies. This presentation describes our recent improvements in this production process, using automation and linear expression elements to generate large panels of antibodies and optimizing each process step to decrease time lines.

11:30 HEK293 & CHO New Screening Tools, Tips and Tricks for Increasing Expression
Sponsored by THOMSON INSTRUMENT COMPANY
Sam Ellis, Vice President & Biochemist, Thomson Instrument Company
The conditions for HEK293, CHO need to be scalable at small scale 15mLs- up to medium production at 3L . Data will be presented on techniques and technology that allow for mimicking large scale fermentation with non-controlled devices . All of these techniques will be given with existing case studies for technologies involving protein or antibody production, structural biology, and can lead to successful transfer from different protein groups.

12:00 pm Session Break

12:15 Luncheon Presentation: rodA Stable Episomal Expression System in CHO for Mammalian Protein Puction
Sponsored by ICOSAGEN
Meelis Kadaja, Ph.D., MBA, Director, Business Development, Icosagen Technologies Inc
We have developed a novel technology to stably maintain expression vectors in dividing mammalian cells. This enables efficient and scalable production of recombinant proteins with low endotoxin levels in up to gram quantities. Our system is suitable for the generation of production cell banks in 10 days, and for the manufacturing of recombinant antibodies. In addition, we show that our expression system can be tailored to improve the quality of the recombinant protein.

1:15 Ice Cream Break in the Exhibit Hall with Poster Viewing

CHO CELLS: TRANSIENT, STABLE OR BOTH?

2:00 Chairperson's Remarks
Lynette Buck, Senior Associate Scientist, Amgen, Inc.

2:05 New Workflow Platform for High-Throughput Cell Line Development
Christian Bender, Ph.D., Computational Biologist, Antibody Lead Discovery, Bayer HealthCare
We present a new workflow system automating the Cell Line Development process for mammalian cells used to produce therapeutic antibodies and proteins. It tracks clones produced and screened in high-throughput mode, collects relevant characterization data and streamlines high-throughput workflows by interfacing with automation equipment and bioreactors. We show how Bayer's Global Biologics groups use it and present applications of the generation of GMP-ready cell lines and their transfer into process development.

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Lynette Buck, Senior Associate Scientist, Amgen, Inc.
Molecule Assessment is the consideration of manufacturing, stability and product attributes when designing/selecting protein candidates for commercialization. This is done at the Cell Line Development stage not only to facilitate meeting First in Human needs but also to ensure productivity needs to meet future commercial demands.

5:45 Close of Day

6:00-7:00 Reception in the Tiki Pavilion

FRIDAY, JANUARY 22

8:00 am Conference Registration and Morning Coffee

ESTABLISHING A FLEXIBLE PROTEIN PRODUCTION SYSTEM

8:30 Chairperson's Remarks
Richard Altman, MS, Research Scientist, Discovery Research, Alexion Pharmaceuticals

8:35 Challenges with Cell Line Development for Recombinant Coagulation Factors – Flexibility Is Key
Arna Andrews, Ph.D., Director, Cell Line Development, CSL Limited
The manufacture of recombinant antibody therapeutics has evolved dramatically over the last decade largely due to the fact that antibodies are generally well-behaved molecules compatible with a platform process approach. In contrast, these benefits are not generally applicable to non-antibody molecules, such as recombinant coagulation factors where higher degrees of molecule complexity lead to increased protein quality criteria and the need for more flexible approaches to cell line selection and process development.

9:05 Transient Production in *Nicotiana* and Its Role in the Development of an Anti-Ebola Virus Monoclonal Antibody Cocktail
Larry Zeitlin, Ph.D., President, Mapp Biopharmaceutical and LeafBio, Inc.
The pros and cons of transient production in *Nicotiana* will be presented with a focus on the unique development path of a monoclonal antibody cocktail experienced during the 2014-2015 Ebola outbreak in West Africa.

9:35 The Flexibility and Throughput of a Transient Protein Production Core Group Efficiently Supports the Protein Demands for Early Drug Discovery Studies
Richard Altman, MS, Research Scientist, Discovery Research, Alexion Pharmaceuticals
A robust, reproducible transient protein production facility provides critical support to drug discovery efforts. We review the genesis and evolution of our scalable transient protein production efforts. The impact to our overall drug discovery efforts will be discussed through case studies highlighting the variety of applications (functional studies, reagent production, etc.) and scale (microtiter plate to WAVE bioreactor) our system provides. We also discuss improvements to our throughput by automation.

10:05 Coffee Break with a Poster Pavilion

ENHANCED EFFICIENCY THROUGH AUTOMATION

▸ **FEATURED PRESENTATION**

11:00 Enhanced Protein Purification Efficiency through Automation and Laboratory Design
Kenneth Walker, Ph.D., Scientific Director, Biologics, Amgen, Inc.
In order to keep pace with the high-throughput cloning and expression needed to screen large panels of therapeutic candidates, we developed systems to substantially increase protein purification throughput through enhanced laboratory design and the use of novel chromatography instrument automation. With minimal user intervention, these systems can process a wide array of samples employing flexible, advanced chromatography methods that efficiently generate high-quality products.

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11:30 Automated High-Throughput Protein Purification Workflows for Discovery of Novel Therapeutics
Avinash Gill, Ph.D., Scientific Manager, Antibody Engineering, Genentech, Inc., a member of the Roche Group
In combination with automated HTP workflows for antibody expression and purification, an efficient process has been put in place for making large numbers of purified antibody variants available to be screened in biological/functional assays, epitope identification and manufacturability evaluation. Expression and purification are carried out at 2 scales of cell culture – 1mL (deepwell blocks) and 30 mL (tubespin columns), to generate antibodies, antibody fragments and other therapeutic protein formats.

12:00 pm IT'S A WRAP: PEPTALK 2016 CLOSING PLENARY PANEL DISCUSSION ***See page 2 for details***

1:15 Close of Conference

Characterization of Biotherapeutics

Improving Prediction, Screening and Characterization of New Biologics

New biotherapeutics formats are flooding the discovery and development pipelines and with this comes an increasing need for better and faster characterization tools and strategies, improved biomolecular and biophysical assays for the new biotherapeutics. The 2nd Annual Characterization of Biotherapeutics conference presents new tools, strategies and high-level case studies on analytical development and characterization of mAbs, ADCs, bispecifics and other novel protein formats. We are looking for cutting-edge tools, research findings and unpublished data to be featured at this forum.

We invite you to present a poster and join colleagues in this discussion of the key challenges and solutions improving prediction, screening and characterization of new biologics.

SUNDAY, JANUARY 17

4:00-5:30 pm Registration

5:00-8:00 Dinner Short Courses *See page 4 for details*

MONDAY, JANUARY 18

7:30 am Conference Registration and Morning Coffee

EMERGING TRENDS IN BIOANALYTICAL CHARACTERIZATION

9:00 Chairperson's Opening Remarks
Atul Saluja, Ph.D., Senior Research Investigator II, Drug Product Science & Technology, Bristol-Myers Squibb

KEYNOTE PRESENTATION

9:10 Emerging Bioanalytical Technologies to Characterize Biotherapeutics with Case Studies
Jihong Yang, Ph.D., Senior Scientist, Bioanalytical Sciences, Genentech, Inc.
Accurate and robust biochemical, biophysical and bioanalytical methods are critical to successful biotherapeutics development. These methods are used for mechanism of action elucidation, process and product quality control, and structure-function characterization. The talk will highlight emerging some of the analytical and bioanalytical technologies that can be used for characterization of biotherapeutics and provide case studies to demonstrate application of these methods in supporting therapeutics development.

9:50 New USP Chapter <212> Oligosaccharide Analysis for N-glycan Analysis
Edith Chang, Ph.D., Scientific Liaison, Biologics and Biotechnology, US Pharmacopeia
The United States Pharmacopeia publishes a new General Chapter to provide qualitative analysis of glycosylation through profiling of released N-linked oligosaccharides (or N-glycans). This chapter consists of validated analytical procedures and performance criteria. Furthermore, four reference standards (RSs) have been developed to assess the system suitability for the analytical procedures. Details of this chapter and the applications of RSs are presented.

10:20 Coffee Break

PROPERTY-BASED DEVELOPMENT, CHARACTERIZATION AND DEVELOPABILITY ASSESSMENT

10:45 Conjugation and Aggregation Aspects of an Antibody-Drug Conjugate: The Intimate Link between Drug Substance Process and Drug Product Quality
Atul Saluja, Ph.D., Senior Research Investigator II, Drug Product Science & Technology, Bristol-Myers Squibb
Given the chemical complexity of an antibody-drug conjugate (ADC), it is critical to understand drug related factors that can influence its physicochemical stability during manufacturing as well as storage. This presentation will explore the impact of conjugation and drug loading on physicochemical stability for a model ADC. Learnings should be applicable to current and future ADCs for aligning drug substance and drug product development activities.

11:15 Use of a Slope Measurement Method Employing Variable Pathlength UV-Vis Technology to Determine Antibody Concentration and Payload (Drug) To Antibody Ratio (DAR) in ADCs
Sonia Taktak, Ph.D., Analytical Scientist III, Analytical and Pharmaceutical Sciences, ImmunoGen, Inc.
The traditional approach to measuring antibody concentration and DAR in ADCs is based on fixed pathlength measurement by UV-Vis, which requires use of dilution factors that are time consuming and prone to error. In this presentation, we will review results of our evaluation of a new approach that uses Solo VPE variable pathlength technology, which does not require dilution of sample, and discuss its applicability for use in ADC manufacturing.

11:45 *In silico* Prediction of Tryptophan and Methionine Oxidation
Alexander Jarasch, Ph.D., Bioinformatics Scientist, Pharma Research and Early Development, Therapeutic Modalities, Roche Innovation Center Penzberg, Roche
Developability assessment of therapeutic antibodies during the selection process is a crucial step of today's drug development and helps to identify stable and manufacturable drug candidates. A frequent developability issue – besides Asp and Asn deamidation/isomerization-is the oxidation of Trp and Met. Here we present an *in silico* machine-learning algorithm which predicts oxidation by combining experimental mass spectrometry data with calculated structural features in antibodies.

12:15 pm Sponsored Presentation *(Opportunity Available)*

12:45 Session Break

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

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Characterization of Biotherapeutics

Improving Prediction, Screening and Characterization of New Biologics

TOOLS TO SUPPORT COMPARABILITY ASSESSMENT, CONTROL STRATEGY AND CRITICAL QUALITY ATTRIBUTES

2:00 Chairperson's Remarks
Shawn Russell, Ph.D., Associate Director, Process Development, Five Prime Therapeutics

2:05 Mass Spec Application in Analytical Comparability and Biosimilarity
Yan-Hui Liu, Ph.D., Principal Scientist, Sterile Product and Analytical Development, Biological Development, Merck

2:30 Characterization of Product Variants Observed During Pre-Comparability Assessment of a Monoclonal Antibody
Shawn Russell, Ph.D., Associate Director, Process Development, Five Prime Therapeutics
Product variants were noted in protein produced from two cell line candidates during a comparability assessment. Protein from the first candidate exhibited additional peaks by IEX and an extra band by SDS-PAGE. From the second candidate, we observed an additional peak by SEC. Characterization of the product variants showed the first candidate was not appropriate to move forward. The second candidate product variant was identified and deemed comparable after further purification.

2:55 High-Throughput Analytical Technologies for Accelerated Bioprocess Development and Continuous Processing
Jun Hyuk Heo, Analytical Scientist, Bioprocess Technology and Expression (BTE), Merck Co., Inc.
With implementation of high throughput process development and continuous processing tools, real-time and ht analytics are desired to support the development. PATROL UPLC was used for monitoring aggregates in perfusion bioreactor and near-IR based system was used to monitor and feedback glucose in real time. Microfluidic immunoassay system was used for quantification of protein analytes. The real-time monitoring by PATROL and near-IR system and fast turnaround time by microfluidic immunoassay system were proven to be highly effective for rapid bioprocess development.

3:20 Reducing the N-terminal Heterogeneity of a Monoclonal Antibody using a Combination of Enzymes
Liangyi Zhang, Ph.D., Senior Scientist II, Process Sciences, Abbvie
Recombinant monoclonal antibodies (mAb) often exhibit N-terminal heterogeneity resulting from incomplete signal peptide cleavage, enzymatic processing and/or chemical modification of N-terminal amino acids. Convoluted with the amino acid degradation, the N-terminal variants lead to complex charge variant profile, making analytical characterization and stability monitoring more difficult. We have used a combination of enzymes to reduce the N-terminal and C-terminal heterogeneity of a mAb that can greatly simplify the CEX charge variant profile. It thus enabled better characterization and monitoring of other charge variants that are related to amino acid degradation.

3:35 Sponsored Presentation *(Opportunity Available)*

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

4:30 Degradation of mAbs with Case Study
Ming Zeng, Ph.D., Group Leader, Mass Spec & Biophysics Center of Excellence, Biologics Development, Bristol-Meyer Squibb

CHARACTERIZATION OF BIODISTRIBUTION AND *IN VIVO* FATE OF BIOLOGICS

4:55 Probing the Stability of a Biotherapeutic in Ocular Matrices
Kelly Loyet, Ph.D., Scientist, Biochemical and Cellular Pharmacology, Research, Genentech, Inc.
Since the frequency of ocular biotherapeutic dosing is often monthly or longer, it is important that the biotherapeutic maintains ocular stability between dosing. This study examines both *in vitro* and *in vivo* ocular stability of a biotherapeutic. Immunoassay as well as mass spectrometry and SPR methods were used to probe attributes of the biotherapeutic over time. Long-term *in vitro* ocular stability was shown to translate to *in vivo* ocular stability.

5:20 Influence of the Antibody Variable Domain Charge Distribution on In-Vivo Fate and Pharmacokinetics
Hubert Kettenberger, Ph.D., Senior Principal Scientist, Roche Pharma Research and Early Development (pRED), Roche Innovation Center Penzberg
The interaction of monoclonal antibodies (mAbs) with the neonatal Fc receptor (FcRn) is essential for their long serum half-life. Comparing a series of mAbs with identical Fc domains, we identified a contribution of the variable region to FcRn binding and pharmacokinetics which correlates with the charge distribution in these variable domains. These findings can guide the design and selection of mAbs with long serum half-life.

5:45 BuzZ Session A
Join your peers and colleagues for interactive roundtable discussions.
Please see page 55 for additional information.

6:30-7:45 Welcome Reception in the Exhibit Hall with Poster Viewing

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7:45 Close of Day

TUESDAY, JANUARY 19

8:00 am Conference Registration and Morning Coffee

CHARACTERIZATION OF BISPECIFIC ANTIBODIES AND NEW BIOTHERAPEUTICS

8:30 Chairperson's Remarks
Mark Chiu, Ph.D., Associate Director, Multispecific Biologics Engineering, Janssen Biotechnology

8:35 Development and Characterization of Novel Antibody Formats
Melissa Geddie, Ph.D., Principal Scientist, Discovery, Merrimack Pharma
Multispecific antibodies and antibody-like molecules broaden the therapeutic application of IgGs, but can be challenging to engineer and manufacture. Using a network biology approach to identify key design parameters, we have engineered novel formats for specific biological targeting. We then use rapid design cycles followed by high-throughput characterization of these formats to select for potential therapeutic candidates with robust pharmaceutical properties.

Characterization of Biotherapeutics

Improving Prediction, Screening and Characterization of New Biologics

9:05 Purity Analysis of Bispecific Antibodies by Affinity Capillary Electrophoresis
Kathir Muthusamy, Ph.D., Staff Scientist, Regeneron Pharmaceuticals, Inc.
Despite wide therapeutic applications for bispecific antibodies (bsAbs), challenges associated with manufacture and purity analysis prevail. Co-expression of bsAbs with common light chain minimizes the number of homodimers (from 10 to 3) that are subsequently removed during purification. Conventional purity analysis methods are inadequate due to analogous physiochemical properties of bsAbs and homodimers. To address this challenge, a robust and powerful Capillary Zone Electrophoresis (CE) method combined with affinity CE has been developed.

9:35 Sponsored Presentation *(Opportunity Available)*

9:50 Coffee Break in the Exhibit Hall with Poster Viewing

11:00 Developability Risks that Are Particular to Bispecific Antibodies
Mark Chiu, Ph.D., Associate Director, Multispecific Biologics Engineering, Janssen Biotechnology
Multispecific antibodies deliver novel molecules that can access differentiated mechanisms of action. Preparations of bispecific antibodies can affect various criteria for manufacturability including protein integrity, structure-function, and serum compatibility. A review of the risks and mitigation will be provided.

11:30 Challenges and Chances for Bioanalysis of Bispecific Antibodies
Kay Stubenrauch, Ph.D., Senior Principal Scientist, Pharmaceutical Sciences, Roche/Genentech, pRED
While the emerging class of bispecific mAbs is characterized by the diversity of molecular constructs, it has in common two sets of different complementarity determining regions (CDRs). Bispecific antibodies also provide new challenges and chances in soluble target assays and immmunogenicity testing. A good understanding of the target biology and of the nature of the bispecific antibody combined with timely availability of specific assay reagents will facilitate more complex bioanalytical methods for analysis of bispecific antibodies.

12:00 pm Sponsored Presentation *(Opportunity Available)*

12:30 Session Break

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

1:45 Close of Conference

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Detection and Characterization of Particulates and Impurities

Rapid Tools and Strategies for Risk Assessment, Prediction and Characterization of Particles and Impurities from Products, Excipients and Processes

Particles and impurities can come from the products, any stage of bioprocessing or the packaging containers. The presence of particulates and impurities in the drug product can impact stability, safety, efficacy of the biomolecules and biologic products. Therefore, early understanding, detection and characterization of the impurities are critical to ensure safety and efficacy of the drug product for its intended duration of use. The 2nd Annual Detection and Characterization of Particulates and Impurities conference provides a platform to explore novel tools and strategies to detect, characterize and carry out risk assessment of particles and impurities.

We invite you to present a poster and join colleagues in this discussion of the key challenges and solutions for prediction, characterization, risk assessment of particles and impurities from products and processes.

TUESDAY, JANUARY 19

1:00 pm Conference Registration

SUBVISIBLE PARTICLES, IMPURITIES AND OTHER PARTICLES: REFERENCE STANDARDS, CHARACTERIZATION AND CONTROL

2:00 Chairperson's Opening Remarks
Shawn Cao, Ph.D., Principal Scientist, Process and Product Development, Amgen, Inc.

KEYNOTE PRESENTATIONS

2:05 Characterization of Biotherapeutics and Detection of Impurities
Fouad Atouf, Ph.D., Director, Biologics and Biotechnology, United States Pharmacopeia
This presentation will focus on the challenging and evolving topic of the characterization of biotherapeutics and, more specially, the detection of impurities. The talk will focus on the role of standards in measurement of related substances impurities and discuss recent learnings.

2:25 Measurement Biases & Calibration of Flow Imaging Instruments
Dean Ripple, Ph.D., Leader, Bioprocess Measurements Group, National Institute of Science and Technology
Flow imaging is a powerful tool for analysis of particles in the size range from 1 µm to 100 µm. This talk will discuss sources of measurement error that affect reported particle size or count, including fundamental limits on optical resolution and the effects of high protein monomer or excipient concentration. Calibration methods to correct for these errors are proposed, and the utility of these methods is assessed.

2:50 Process-Related Impurities that Critically Impact Drug Product Quality
Shantanu Sule, Ph.D., Sr. Engineer, Protein Drug Product & Device Development, Biogen Inc.
This presentation will review current knowledge and new findings of protein degradation pathways and impurities from drug substance process that impact drug product quality. Different aspects of product quality will be examined as a function of different level of uncontrolled process impurities. Control and formulation strategies will be presented to address such challenges. In addition, new approaches will be proposed that help analyze the impact of such impurities on product quality attributes.

3:15 Refreshment Break in the Exhibit Hall with Poster Awards

4:00 Sponsored Presentation *(Opportunity Available)*

4:30 Subvisible Particle Analysis: How to Get the Most Bang for Your Buck
Danny Chou, Ph.D., former Senior Research Scientist, Biologics Development, Gilead Sciences; President and Founder, Compassion BioSolution
Subvisible particles (SVP) analysis is a hot topic in the biopharmaceutical development and manufacturing due to their impact on quality and safety. With the imminent arrival of USP <1787> there will be significant expansion of recommended techniques. Given the reality of having limited resources to address the subvisible particle "challenge," the focus of this presentation is on how one can get the most value (lowest cost/benefit ratio) from the array of technologies available to advance drug development.

5:00 Visible and Subvisible Particles in BCG Immunotherapeutic Product
Marina Kirkitadze, Ph.D., MBA, Deputy Director, Analytical R&D Biochemistry, Sanofi Pasteur
Bacille Calmette-Guerin, BCG, is a live attenuated bovine tubercle bacillus used for treatment of non-muscle invasive bladder cancer. In this study, an Electrical Sensing Zone (ESZ) method was developed to measure the particle count and the size of BCG immunotherapeutic (BCG IT) vaccine using a Coulter Counter Multisizer 4® instrument. The developed method was used to assess manufacturing process consistency using 10 production scale lots of BCG IT product.

5:30-5:45 Short Course Registration

5:45-8:45 Dinner Short Courses *See page 4 for details*

WEDNESDAY, JANUARY 20

8:00 am Conference Registration and Morning Coffee

SUBVISIBLE PARTICLES, IMPURITIES AND OTHER PARTICLES (CONT'D)

8:30 Chairperson's Remarks
Sandeep Yadav, Ph.D., Scientist, Late Stage Pharmaceutical Development, Genentech, Inc.

8:35 Particle Identification by Multi-Technique Methods
Jonas Hoeg Thygesen, Ph.D., Research Scientist, R&D - Microanalysis Centre, Novo Nordisk Pharmatech
The USP <1787> gives guidance on how subvisible particles may be analyzed. This presentation will outline how several of the analytical techniques in USP <1787> (including SEM/EDS, FTIR and Raman spectroscopy) may be used during particle analysis and identification. The presentation will include discussions on the advantages of the different techniques, and illustrate how the combination of techniques may complement each other to ensure a robust and precise analytical answer.

9:05 Analysis of Subvisible Particles in Protein Therapeutics: Methods and Applications
Shawn Cao, Ph.D., Principal Scientist, Process and Product Development, Amgen, Inc.
The subvisible particles that might be present in protein therapeutics have been identified by the regulatory agencies as a potential safety issue. Analytical methods are needed for the monitoring and control of these subvisible particles, and to study the mechanism of particle formation. The methods available to subvisible particle analysis, their strengths and weaknesses, and some case studies showing how these techniques can be applied to address particle characterization during the product lifecycle will be discussed in this presentation.

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Detection and Characterization of Particulates and Impurities

Rapid Tools and Strategies for Risk Assessment, Prediction and Characterization of Particles and Impurities from Products, Excipients and Processes

9:35 Sponsored Presentation *(Opportunity Available)*

10:05 Coffee Break in the Exhibit Hall with Poster Viewing

EXCIPIENTS-RELATED IMPURITIES: PRODUCT STABILITY AND PARTICULATE ISSUES

10:50 Critical Considerations for Surfactant Stability in Biopharmaceutical Formulations
Sandeep Yadav, Ph.D., Scientist, Late Stage Pharmaceutical Development, Genentech, Inc.

11:20 Understanding Particle Formation: Solubility of Free Fatty Acids as Polysorbate 20 Degradation Byproducts in Therapeutic Monoclonal Antibody Formulations
Nidhi Doshi, Associate Scientist, Late Stage Pharmaceutical Development, Genentech, Inc.
The purpose of this work was to determine the aqueous solubilities at 2-8°C of the major free fatty acids (FFAs) formed by Polysorbate 20 (PS20) degradation and identify possible ways to predict, delay or mitigate subsequent particle formation in monoclonal antibody (mAb) formulations. For the first time, a 3D correlation between FFA solubility, PS20 concentration and pH has been reported providing a rationale approach for the formulator to balance these with regards to potential particle formation.

11:50 Recent Advances In Monitoring The Kinetics Of Protein Aggregation And The Onset And Evolution Of Particulates Using Simultaneous Multiple Sample Light Scattering (SMSLS)
Wayne F. Reed, Ph.D., Murchison Mallory Chair Professor of Physics and Founding Director, PolyRMC, Tulane University
Continuous monitoring of light scattering intensity from protein formulations allows stability to be assessed and, when aggregation occurs, a quantitative measure of the kinetics. Results presented will show kinetics under a variety of stressors, including temperature, controlled stirring and exposure to different air/liquid and solid/liquid interfaces. Furthermore, the method has been extended to monitoring the onset and evolution of particulate formation via large scattering spikes produced by particles that reach a certain size.

12:20 pm Sponsored Presentation *(Opportunity Available)*

12:50 Session Break

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

DETECTION AND CHARACTERIZATION PRODUCT AND PROCESS-RELATED IMPURITIES

2:00 Chairperson's Remarks
Vishal C. Nashine, Ph.D., Senior Research Investigator II, Drug Product Science & Technology, Bristol-Myers Squibb

2:05 Identification and Characterization of Impurities in Diagnostic Proteins
Jeffrey Fishpaugh, Ph.D., Senior Principal Research Scientist, Diagnostic Analytical Chemistry R&D, Abbott Laboratories
The analysis of pharmaceutical biologics has been well discussed; in contrast, biologics utilized in diagnostic assays have not been as well covered. Diagnostic biologics are reviewed by government regulatory bodies with similar requirements as pharmaceutical biologics, especially biologics used in commercial blood screening assays. We have recently completed an analysis of 40+ biologics to determine impurities present, variability of impurities and their potential impact on our assays.

2:35 Root Cause Analysis of Reversible Aggregates that Impact Opalescence of a Monoclonal Antibody Formulation
Radhakrishna K. Maroju, Ph.D., Scientist, CMC Management, Drug Product Development, Teva Biopharmaceuticals USA
High concentrated monoclonal antibody (mAb) formulations are generally associated with opalescence, which is known as a thermodynamic event rather than kinetic. However, reversible aggregates that usually cause opalescence can be formed by kinetic reactions. The present case study describes rare occurrence of increased opalescence over time of a mAb clinical inventory, focusing on possible root cause of the reversible aggregates to essentially correlate the observed opalescence with identified chemical degradation products.

3:05 Assessment of Protein Sensitivity to Residual Hydrogen Peroxide when Filled in Isolator
Y. John Wang, Ph.D., Principal Scientist, Late Stage Pharmaceutical Development, Genentech, Inc.
Protein product filled in isolator is vulnerable to the residual hydrogen peroxide. Reaction mechanism and kinetics between hydrogen peroxide and the Fc methionine in mAb products will be presented. Also formulation excipients that may influence the reaction rates will be discussed. With this understanding, one can estimate the duration of the study needed in order to qualify filling operation in isolator, or if such study is needed.

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

4:30 Probing Protein-Surface Interactions and Their Role in Particulate Formation: A Case Study
Vishal C. Nashine, Ph.D., Senior Research Investigator II, Drug Product Science & Technology, Bristol-Myers Squibb

5:00 Separation of Protein from Non-Proteinaceous Particles in Biopharmaceutical Formulations with MVAS by Microflow Imaging MFI
Zahir Akhunzada, Ph.D., Research Scientist, ABD, Bristol-Myers Squibb
Subvisible Particles (SVPs) are major challenge in development of therapeutic protein formulations. Distinction between proteinaceous and non-proteinaceous SVPs is vital in monitoring the formulation stability. The current compendial method based on light obscuration (LO) has limitations. This presentation reveals a method that successfully characterizes and distinguishes, both potentially proteinaceous and non-proteinaceous SVPs in protein formulations by using Microflow Imaging (MFI) in conjunction with the MVAS (MFI View Analysis Suite) software.

5:45 BuzZ Session B
Join your peers and colleagues for interactive roundtable discussions.
Please see page 55 for additional information.

6:30-7:30 Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Conference

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Extractables and Leachables

Protecting Quality of Biologics by Ensuring Safety and Compatibility

In biopharmaceutical development and manufacturing, containers, drug combination products, and even disposable equipment may leach chemicals into the product that can pose significant risks to product quality and potentially compromise the stability, safety and efficacy of the biotherapeutics. The 4th Annual Extractables and Leachables (E&L) conference brings together industry experts and thought leaders to share their insights on latest updates and guidelines, how to design analytical testing strategies for E&L, case studies on identification and risk assessment E&L in single-use system, container closure system and delivery devices, and impact of leachables on biologics safety.

We invite you to present a poster and join colleagues from around the world in this discussion of the key challenges and solutions for E&L testing in biologics.

THURSDAY, JANUARY 21

7:45 am Conference Registration and Morning Coffee

REGULATORY EXPECTATIONS AND UPDATES FROM WORKING GROUPS

8:15 Chairperson's Opening Remarks
Ken Wong, Deputy Director, MTech/AP&T - Extractables & Leachables, Sanofi Pasteur

8:20 The PQRI Parenteral and Ophthalmic (PODP) Leachable and Extractable Working Group: Outcomes and Practical Applications
Diane Paskiet, MS, Director of Scientific Affairs, West Pharmaceutical
The PODP recommendations for safety thresholds and best practices will be reviewed. Data from material characterization and simulation studies will be put into perspective based on biologics.

▸ **FEATURED PRESENTATION**
9:00 Part 1 - BPOG's Risk Assessment Tool/Proces
Dhaval Tapiawala, Technical Project Leader, Fujifilm Diosynth Biotechnologies

▸ **FEATURED PRESENTATION**
9:30 Part 2 - BPOG's Best Practice Guide for SUS Leachables Testing: Leachables Study Design for Single Use Components
Kathryn A. McGohan, MS, Associate Scientist II, Manufacturing Sciences and Technology: Materials Science, Bristol-Myers Squibb
These presentations will discuss the BPOG's standard extractable protocol along with regard to flexibilities, myths and misconceptions. Followed by the presentation of data from the completed proof of concept case studies data using bags and O-rings to demonstrate viability of the study design. Introduction of the new BPOG's Best Practice Guide for SUS leachables testing, covering: risk assessment; leachable study design for SUS components; leachable test method(s). Closing with end user perspective on how a member company BPOG's recommendations.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

E&L TESTING FOR SINGLE-USE MANUFACTURING SYSTEMS

11:00 CMO Tech Transfer Material Control Strategies: A Case Study
Michael DiFiore, Scientist I, Materials Science, Bristol-Myers Squibb
Chemical compatibility of a process stream with a disposable is a critical element of determining the suitability of the single use system. A case study is presented on the investigation and impact assessment of an incompatible filtration of a polyethersulfone (PES) membrane with 100% benzyl alcohol, resulting from a tech transfer to a CMO. The presentation will also discuss material control strategies related to CMO tech transfers.

11:30 Presentation to be Announced

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11:45 Sponsored Presentation *(Opportunity Available)*

12:00 pm Session Break

12:15 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Ice Cream Break in the Exhibit Hall with Poster Viewing

MATERIAL CHARACTERIZATION AND ANALYTICAL STRATEGY

2:00 Chairperson's Remarks
Diane Paskiet, MS, Director of Scientific Affairs, West Pharmaceutical

2:05 Experimental Design Considerations for Extractables Simulation Studies
Dennis Jenke, Ph.D., Baxter Distinguished Scientist, Technology Resources, Baxter Healthcare Corp.
A simulation study produces an extractables profile that appropriately mirrors a test article's leachables profile. This is accomplished via a controlled extraction study which uses an extraction solvent to mimic the "leaching power" of the contact solution (such as drug product) and accelerates the clinical conditions of contact (shorter duration at higher temperature). This presentation addresses those factors to consider in terms of simulating solvent selection and proper acceleration.

2:35 Qualitative Characterization and Visualization of Complex Mixtures of Extractables/Leachables and Other Pharmaceutically Relevant Compounds Using High Resolution LC-MS with 2-D and 3-D Mass Mapping
Douglas E. Kiehl, Principal Research Scientist, Spectroscopy & Raw Materials, Bioproduct Research & Development, Eli Lilly & Company
Extractables and leachables (E&L) associated with packaging and container systems, delivery devices and process equipment can pose risk to the safety and quality of drug products. E&L samples may represent complex mixtures of diverse organic molecules, presenting significant analytical challenges. This presentation discusses the application of 2-D/3-D mass mapping, mass difference correlation and visualization of high resolution exact mass LC-MS datasets to simplify interpretation of such complex mixtures.

3:05 Sponsored Presentation *(Opportunity Available)*

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

4:15 Extractables and Leachables Strategy for Parenteral Drug Products
Meera Agarkhed, Manager, Formulation Development, Eli Lilly and Company
This presentation will discuss extractables and leachables risk assessment strategy for manufacturing and fill finish operations and their impact on biotherapeutics safety, efficacy and stability.

Extractables and Leachables

Protecting Quality of Biologics by Ensuring Safety and Compatibility

4:45 The Value of the "Simulated Study" as a Tool to Predict Actual Leachables in Parenteral Drug Products
Carsten Worsøe, Principal Scientist, CMC Analytical Support, Novo Nordisk
This presentation will describe the simulated study as the optimal study to predict actual leachables in different parenteral drug products including cartridges, vials and prefilled syringes and how it can be used to reduce the risk for having critical leachables and reactions between leachables and formulation components or the active ingredient at a late drug development phase. The presentation will also describe a number of different opportunities on how to perform simulated studies and finally a number of cases will be presented showing the value.

5:15 A Vision of Understanding Extractables and Leachables; Impact on Drug and Device Manufacturing Processes
Yasser Nashed-Samuel, Ph.D., Principal Scientist, Process and Product Development, Amgen, Inc.
Extractables and leachables are critical product contact assessments throughout the product life cycle due to their possible impact on product quality and patient safety. A thorough evaluation of the extractables from product contact surfaces during product development will ensure successful long term leachables testing, process robustness, product quality, device functionality and patient safety. Selected case studies presented will reflect the importance of extractables evaluation to product development.

5:45 Close of Day

6:00-7:00 Reception in the Tiki Pavilion

FRIDAY, JANUARY 22

8:00 am Conference Registration and Morning Coffee

PROCESS AND PACKAGING FACTORS AFFECTING AGGREGATION, SAFETY AND EFFICACY OF BIOLOGICS

8:30 Chairperson's Remarks
Joël Richard, Ph.D., Vice President, Peptides, CMC & Engineering, Ipsen

8:35 Predicting the Risk of Extractables and Leachables (E&L) Interacting with Therapeutic Proteins
Kim Li, Ph.D., DABT, MPH, Senior Manager, Environment, Health, Safety and Sustainability, Amgen, Inc.
Therapeutic proteins can be subject to chemical modifications which may lead to product quality and safety concerns. Extractables and leachables (E&L) arising from process- and product-contact surfaces present the risk of interacting with the protein products. This presentation will describe the mechanisms of such interactions and the use of an *in silico* software that classifies E&L structures into reactive functional groups for risk prediction.

9:05 Extractables & Leachables in Liquid Formulations of Proteins: Impact on Stability, Aggregation, Potency and Immunogenicity of Drug Product
Joël Richard, Ph.D., Vice President, Peptides, CMC & Engineering, Ipsen
Extractables and leachables are impurities that can contaminate liquid formulations of biologics, leaching from the surface of glass walls or being extracted from the rubber stoppers and plungers. They can interact with and degrade proteins, modifying their higher order structure, forming mixed micelles, or composite protein aggregates. These impurities may have a strong impact on stability, quality attributes and immunogenicity profile of the protein drug products.

9:35 Oxidation of Methionine in Aggregated Antibodies does not Increase the Potential Risk of Immunogenicity
Marisa K. Joubert, Ph.D., Senior Scientist, Process Development, Amgen, Inc.
This talk will give an update on the aggregate attributes of monoclonal antibodies (mAbs) that may cause an immune response. The potential impact of Met oxidation of both aggregated and monomeric antibodies was investigated in a population of human peripheral blood mononuclear cells (PBMC) from healthy and disease state individuals (50+ donors tested) *in vitro*. Met oxidation was found not to increase the potential risk of immunogenicity of both aggregated and monomeric antibodies.

10:05 Coffee Break with a Poster Pavilion

11:00 Investigation of Reversible Self-Association during Early Stage Development of a Low Concentration Antibody-Drug Conjugate
Elizabeth Bartlett, Scientist II, Analytical & Pharmaceutical Sciences, ImmunoGen, Inc.
Reversible self-association is often present in high concentration antibody products, but may also occur in lower concentration preparations. In the case of antibody-drug conjugates (ADCs), a novel class of molecules for the treatment of cancers, this property can present substantial challenges to successful formulations. In this study, a multi-technique approach was used to identify and investigate the effects of various excipients on reversible self-association in a low concentration ADC.

11:30 Characterizing Changes in Protein Quality Attributes to Assess Leachable Risks from Single-Use Bioprocess Containers
Nina Xiao, Senior Research Associate, Late Stage Pharmaceutical Development, Genentech, Inc.
Application of single-use bioprocess containers for the manufacturing of biologics have increased significantly over the years. This study examines two monoclonal antibodies in a small-scale stressed model to detect and assess the presence of leachables by monitoring protein quality attributes. The results from this study demonstrate that the stress model can inform a risk assessment of leachables on protein quality attributes during routine manufacturing. Leachable characterization will also be discussed.

12:00 pm IT'S A WRAP: PEPTALK 2016 CLOSING PLENARY PANEL DISCUSSION ***See page 2 for details***

1:15 Close of Conference

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3rd Annual

Single-Use Technologies and Continuous Processing

Advancing Bioprocessing through Technological Innovation

Cambridge Healthtech Institute's 3rd Annual Single-Use Technologies and Continuous Processing conference once again gathers technology and equipment providers along with end users to discuss innovative approaches to current challenges, update companies on the trends in technology, share case studies on successful implementation and ultimately identify how to derive as much value as possible from these technological advances.

SUNDAY, JANUARY 17

4:00-5:30 pm Registration

5:00-8:00 Dinner Short Courses *See page 4 for details*

MONDAY, JANUARY 18

7:30 am Conference Registration and Morning Coffee

THE FUTURE OF BIOPRECESSING: DISPOSABLE AND CONTINUOUS PROCESSING

9:00 Chairperson's Opening Remarks
Jerold Martin, MSc, Chairman, BPSA BoD and Technology (E+L) Committee

KEYNOTE PRESENTATIONS

9:10 Challenges and Limitations of Continuous Processing and Use of Disposables
Berthold Boedeker, Ph.D., Chief Scientist, Global Biologics Development, Bayer Pharma AG
Continuous processing in combination with use of disposables has made significant advances in the past years. However, despite many advantages to standard processing, there are still many hurdles ahead of us, before these technologies will be suitable for routine production. This talk will summarize several aspects of necessary improvements as well as some risks associated with these technologies, which are often underestimated in their impact, such as process validation, process characterization and scale down models.

9:50 Combining Single-Use Technologies with Flexible Workforce to Maximize Utilization of Manufacturing
Wolfgang Noe, Ph.D., Vice President, Technical Operations, Agensys, Inc.
Use of disposables for manufacturing is becoming a 'standard' in the biotech industry. There is a perception that the use of disposables will make biotech processes more economical, however, very often the effective interaction between involved departments during early clinical manufacturing is underestimated. This presentation will give a detailed insight into effective manufacturing by using a flexible work model where many departments will contribute to the on-time availability of clinical material as well as the start of clinical trials.

10:20 Coffee Break

STANDARDS AND RECOMMENDATIONS FOR SINGLE-USE EQUIPMENT AND PROCESS

10:45 Wide-Scale Adoption of Single-Use Systems – What Are the Challenges Ahead from the Regulators', Suppliers' and End Users' Perspectives?
Jerold Martin, MSc, Chairman, BPSA BoD and Technology (E+L) Committee
This presentation will focus on continuing developments in implementation and standardization of single use technologies and practices, especially the ongoing efforts to standardize extractables testing, but also other activites like change control and notification, GMP practices for particulate control, integrity testing, etc. I will also focus on BPSA activities along with the those of USP, ISO, ASME and ASTM.

11:15 BPOG and BPSA User Requirements for Single-Use Systems
Zhaoli Zhou, Ph.D., Manager and Senior Engineer, Process Technology Group, Manufacturing Technology, Sanofi Pasteur
BPOG and BPSA single-use system user requirement joint team consists of three major sections including pre-evaluation of single-use systems, quality system requirements and product specification requirements. The joint team is currently working to establish common understanding between suppliers and end users on quality audit guide, internal/external quality release procedure and also regulatory expectations. This presentation summarizes the progress of the user requirement work stream including the whitepaper guidance from each section.

11:45 Vendor Change Notifications for Single-Use Systems
Jeff Carter, Ph.D., Manager, Product Strategy, ReadyToProcess Product Line, GE Healthcare
As single-use system end users, biopharmaceutical manufacturers need to have rigorous change management pro-cedures to ensure these products have consistent quality and performance for their intended applications. This talk presents major activities of the BPOG and BPSA joint team for single-use system change notifications. The goal is to align the requirements, share responsibilities and develop best practices to address key issues related to vendor change notifications.

12:15 pm Streamlined Bioprocess Definition Using a Novel Laboratory Focused on Automated Hardware, PAT and Data Harmonization

Sponsored by BEND RESEARCH ACHIEVE VALUE THROUGH SCIENCE A DIVISION OF CAPSUGEL DOSAGE FORM SOLUTIONS

Jeffery Breit, Ph.D., Director, Biologic Technologies, Bend Research, a division of Capsugel
Bend Research has built a new laboratory that enables rapid data production and knowledge generation in order to better understand processes that impact productivity and protein quality. The lab incorporates fed batch and perfusion bioreactors with a modular automated sampling technology (MAST™) that shuttles samples to in-line and on-line analytical tools, as well as sample retention hardware. These capabilities enable the generation of robust and high-density datasets that can be used to develop statistical modeling tools to understand and control bioreactor processes better than traditional "once-a-day" sampling experiments.

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Single-Use Technologies and Continuous Processing

Advancing Bioprocessing through Technological Innovation

12:45 Session Break

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

RISK MITIGATION STRATEGIES FOR SINGLE-USE TECHNOLOGIES

2:00 Chairperson's Remarks
Adam Goldstein, MSc, Principal Scientist, Global Technology, Roche/Genentech, Inc.

2:05 Extractables from Single-Use Bioreactors and Impact on Cell Culture Performance
Yasser Nashed-Samuel, Ph.D., Principal Scientist, Attribute Sciences, Process Development, Amgen, Inc.
Biopharmaceuticals are drugs manufactured by growing genetically engineered cells in bioreactors to produce a therapeutic protein. Plastic single use bioreactors are of interest to biopharmaceutical drug manufacturers due its significant environmental and cost benefits and flexibility over stainless steel bioreactors. Effect of plastics on the bio-manufacturing process is not yet completely understood. A case study on extractables from single use bioreactors and impact on cell culture performance will be presented.

2:35 Extractable Study Design and Data Evaluation of Polymeric Product Materials
Ping Wang, Ph.D., Principal Scientist and Senior Manager, Janssen R&D, a Pharmaceutical Company of Johnson & Johnson
Though the application of polymeric disposable materials in the biomanufacturing process has become more popular, the extractables and leachables (E&L) are the major concerns from safety and quality perspective. The lack of relevant E&L data from suppliers presents end-users a great challenge. Strategies of developing relevant extractable data and applying that in the evaluation of safety concern threshold level will be discussed.

3:05 Homogenizing Biopharmaceutical Drug Substance Bulk Using Single-Use Mixing Systems
Benson Gikanga, Senior Research Associate, Pharmaceutical Processing and Technology Development, Genentech, Inc.
Depending on mixer design, shearing of biopharmaceutical formulations may be observed. The shearing may generate elevated amount of subvisible particles in the DS solution which in turn may lead to filter fouling during filtration through a 0.22-µm pore size filter. Newer and advanced technologies incorporated in single-use mixing systems may help overcome this challenge. Impact on product quality and process performance following homogenization with various bottom-mounted single-use mixers will be presented.

3:35 Sponsored Presentation *(Opportunity Available)*

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

4:30 A Single-Use Strategy to Enable Manufacturing of Affordable Biologics
Renaud Jacquemart, Ph.D., Principal Scientist, Process Sciences, Natrix Separations
Single-use technologies and continuous upstream processes have proven to be cost-efficient options to increase biomass production but as of today the adoption has been only minimal for the purification operations, partly in reason of scale-up and costs concerns. This case study summarizes how a single-use strategy including a holistic process approach, continuous operation, full utilization of media life and high throughput chromatography can overcome scale limitations and enable cost-efficient manufacturing.

5:00 Implementation Strategies and Challenges for Single-Use at Clinical to Commercial Scale: Integrity Testing, Material Qualification, Handling Risks
Adam Goldstein, MSc, Principal Scientist, Global Technology, Roche/Genentech, Inc.
This talk will focus on those challenges single-use applications currently have and may have in the future of biotech manufacturing processes. Areas of focus will be regulatory challenges for filings, leak testing and large-scale process limitations for SUTs. Strategies for on-boarding new technologies will be discussed as well.

5:45 BuzZ Session A
Join your peers and colleagues for interactive roundtable discussions.
Please see page 55 for additional information.

6:30-7:45 Welcome Reception in the Exhibit Hall with Poster Viewing
Sponsored by freeslate

7:45 Close of Day

TUESDAY, JANUARY 19

7:45 am Conference Registration and Morning Coffee

CONTINUOUS PROCESSING: ADVANCES, IMPLEMENTATION AND ENABLING TECHNOLOGIES

8:30 Chairperson's Remarks
Jay Stout, Ph.D., Executive Director, Center for Biopharmaceutical Manufacturing Sciences, Merck

8:35 Continuous Processing – Rewrite of the Rules?
Jay Stout, Ph.D., Executive Director, Center for Biopharmaceutical Manufacturing Sciences, Merck

9:05 End-to-End Integrated Fully Continuous Production of Recombinant Monoclonal Antibodies
Michael Coolbaugh, Ph.D., Staff Scientist, Late Stage Purification Process Development, Genzyme
This work represents the first demonstration of feasibility for end-to-end continuous bioprocess for biologics. The study shows significant process train simplification, uninterrupted and fully automated purification to the DS over an extended period of time, steady state operation with respect to process flows and product quality. No change with time in the quantities held up in the unit operations. This work serves as a starting point towards achieving highly efficient, universal, end-to-end, fully continuous bio-manufacturing platform.

9:35 Presentation to be Announced
Sponsored by BIOVEST INTERNATIONAL

9:50 Coffee Break in the Exhibit Hall with Poster Viewing

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Single-Use Technologies and Continuous Processing

Advancing Bioprocessing through Technological Innovation

11:00 Flexible Facility Designs Complimenting Continuous Processing - Examples and Cases

Maik Jornitz, Founder and Principal Consultant, BioProcess Resources LLC; Vice Chair, Marketing Advisory Board, PDA

Continuous processing and single-use technologies create a processing environment and volume range, which allow such processes to be more compact and flexible. The flexibility of these processes is though hindered by inflexible cleanroom environments and facilities. That trend is changing and innovative facility designs start supporting the processing flexibilities.

11:30 Development of a Perfusion System in a Microbioreactor Using Sedimentation as a Scale Down Tool for ATF Perfusion Bioreactors

Steffen Kreye, Scientist, Upstream Process Development, Glycotope GmbH

With the biotech industry moving to continuous bioprocessing and focusing increasingly on product quality, perfusion bioreactors are becoming more and more important. Here, we demonstrate the development of a sedimentation based perfusion system in the single-use ambr system with good comparability to 1 L ATF perfusion bioreactors when comparing cell growth, viability and product quality, especially glycosylation, for GlycoExpress (GEX) and CHO cells. The system is better suited for clone screening, media optimization and the prediction of qualitly.

12:00 pm Sponsored Presentation *(Opportunity Available)*

12:30 Session Break

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

1:45 Close of Conference

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Protein Purification and Recovery

Streamlining Processes with Innovative Technologies

Protein purification is the most costly and time-consuming process in the manufacturing of proteins. Challenges are multiplied when purifying complex molecules, such as membrane proteins, bispecifics and antibody-drug conjugates. The Protein Purification and Recovery conference explores how experts are optimizing processes to achieve pure protein while curtailing cost and time. Along with innovating "traditional" technologies such as Protein A and chromatography, leaders also address alternatives and breakthroughs, such as continuous processing. This leading purification meeting includes a highlighted session focused on purifying membrane proteins.

TUESDAY, JANUARY 19

1:00 pm Conference Registration

PURIFYING MEMBRANE PROTEINS

2:00 Chairperson's Opening Remarks
William Gillette, Ph.D., Senior Scientist, Protein Expression Laboratory, Cancer Research Technology Program, Leidos Biomedical Research, Inc., Frederick National Laboratory for Cancer Research (FNL)

KEYNOTE PRESENTATION

2:05 Making Water-Soluble Integral Membrane Proteins *in vivo* Using an Amphipathic Protein Fusion Strategy
Matthew P. DeLisa, Ph.D., William L. Lewis Professor, Chemical & Biomolecular Engineering, Cornell University
Here we devise a general strategy for *in vivo* solubilization of IMPs in structurally relevant conformations without the need for detergents or mutations to the IMP itself. This technique, called SIMPLEx (solubilization of IMPs with high levels of expression), allows the direct expression of soluble products in living cells by simply fusing an IMP target with truncated apolipoprotein A-I, which serves as an amphipathic proteic 'shield' that sequesters the IMP from water and promotes its solubilization.

▸ **FEATURED PRESENTATION**

2:45 Expression and Sample Preparation of Membrane Proteins for Structure Determination by NMR
Stanley Opella, Ph.D., Professor, Chemistry and Biochemistry, University of California, San Diego
The advantages of heterologous expression of proteins in bacteria include the ability to make relatively large amounts and the ready incorporation of stable isotopes. The use of a hydrophobic fusion protein enables the sequestration in inclusion bodies to avoid damaging the cell membrane.

3:15 Refreshment Break in the Exhibit Hall with Poster Awards

4:00 Overcoming the Purification Challenges with Bone Morphogenetic Proteins
Sponsored by FUJIFILM Diosynth Biotechnologies
Patrick Robertson, Ph.D., Senior Scientist, Purification Development, FUJIFILM Diosynth Biotechnologies
The distinctive nature of bone morphogenetic proteins creates unique challenges in purification, such as low solubility near physiological pH and a tendency to aggregate and/or precipitate in the presence of salts limiting the design space for developing an effective and scalable purification strategy. We will present an approach that leverages their unique structural characteristics in purification development.

4:15 Sponsored Presentation *(Opportunity Available)*

4:30 It Takes Two to Tango—Structure/Function Studies Yield the Dance of the Permease
H. Ronald Kaback, M.D., Distinguished Professor, Physiology, University of California, Los Angeles
Lactose permease (LacY) catalyzes translocation of a galactoside and an H+ across the membrane. X-ray structures, and structure/function studies reveal that: (1) LacY utilizes an alternating access mechanism; (2) sugar binding involves induced fit; (3) Active transport does not involve a change in K_D for sugar on either side of the membrane, but the pK_a decreases markedly. (4) Transport is driven chemiosmotically, and $\Delta\tilde{\mu}H+$ acts kinetically to accelerate the process.

5:00 Strategies for High Yield Affinity Purification of Functional G Protein Coupled Receptor from Detergent Solutions
Alexei Yeliseev, Ph.D., Staff Scientist, LMBB, NIH/NIAAA
Human cannabinoid receptor CB2, a G protein-coupled receptor involved in regulation of immune response, is an important target for pharmaceutical drug development. We expressed the functional CB2 receptor in *E. coli*, and optimized its purification by tandem affinity chromatography using novel affinity resins StrepTactin XT Superflow and EF2 Ca-calbindin-based resin. Examples of successful purification and efficient recovery (over 80%) of CB2 from dilute detergent-containing solutions will be presented.

5:30-5:45 Short Course Registration

5:45-8:45 Dinner Short Courses *See page 4 for details*

WEDNESDAY, JANUARY 20

8:00 am Conference Registration and Morning Coffee

PURIFYING ANTIBODIES

8:30 Chairperson's Remarks
Patrick Robertson, Ph.D., Senior Scientist, Purification Development, FUJIFILM Diosynth Biotechnologies

8:35 Purification of Common-Light-Chain Bispecific Antibodies
Juergen Nett, Ph.D., Associate Director, High Throughput Expression, Adimab, LLC
A variety of bispecific constructs benefit from the use of a single variable light region pairing with multiple distinct variable heavy regions. This talk will demonstrate new techniques to purify these common-light-chain bispecific IgG molecules to homogeneity. A panel of bispecific constructs are then generated that bind to each target with high affinity and exhibit favorable biophysical properties similar to traditional therapeutic antibodies.

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Protein Purification and Recovery

Streamlining Processes with Innovative Technologies

9:05 A Simple, Robust Two-Column Purification Platform for Antibody Fragment Manufacturing
Green Guihang Zhang, Ph.D., Director, Protein Sciences, ImaginAb, Inc.
Minibody and cys-diabody are unique types of antibody fragments developed for clinical imaging. Purification of minibodies and cys-diabodies has proved to be challenging due to their high aggregation and low-pH sensitivity. We have recently developed a simple and robust two-column purification platform for manufacturing minibody and cys-diabody for clinical applications with high purity and stability. The same platform may be used for other types of antibody fragment purification.

9:35 Presentation to be Announced *(Opportunity Available)*

10:05 Coffee Break in the Exhibit Hall with Poster Viewing

10:50 Developing a Purification Platform for FAB
Jiansheng Wu, Ph.D., Senior Scientist, Protein Chemistry, Genentech, Inc.
FAB has gained more attention in recent years due to its broad applications in therapeutics and diagnostics. Generating grams level of FAB from *E.coli* cell pellets is important for many preclinical studies. We evaluated several resins for FAB purification and developed a robust purification platform to obtain up to 20 grams of FAB from *E. coli* cells.

11:20 The Challenges of Developing a Purification Process for Bispecific Protein Product for Early Phase Clinical Trial
Yun Bai, Ph.D., Director, Process Development, Ambrx, Inc.

11:50 Aggregation Challenges during the Purification Development of a Low pI Monoclonal Antibody
Sandra Rios, Ph.D., Principal Scientist, Process Development & Engineering, Merck
Monoclonal antibodies typically have a high degree of homology and similar physicochemical properties leading to utilization of platform processes for production and purification. However, there are instances where significant modifications to these processes are needed due to uncommon characteristics, such as low pI and aggregation propensity. In this study, process buffers, intermediate stability, and optimization of multiple polishing chromatography steps were required to mediate the protein behavior to develop a suitable purification process.

12:20 pm Sponsored Presentation *(Opportunity Available)*

12:50 Session Break

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

PURIFICATION STRATEGIES

2:00 Chairperson's Remarks
Jiansheng Wu, Ph.D., Senior Scientist, Protein Chemistry, Genentech, Inc.

2:05 Purification of Secretory IgA from *Lemna minor* (Duckweed)
Daniëlle van Wijk, Ph.D., Lead Scientist / Project Leader, Down Stream Processing, Synthon Biopharmaceuticals B.V.
Here we present the duckweed *Lemna minor* as a promising platform for production of SIgA antibodies. The production process comprises (1) expression of SIgA in stably-transformed duckweed; (2) extraction of SIgA by disruption of the plant material; (3) removal of naturally abundant impurities by acidic precipitation; (4) clarification by depth filtration and TFF; (5) purification by affinity chromatography followed by polishing steps; and (6) formulation in a stable buffer.

2:35 Protein Purification for the RAS Initiative at the Frederick National Lab
William Gillette, Ph.D., Senior Scientist, Protein Expression Laboratory, Cancer Research Technology Program, Leidos Biomedical Research, Inc., Frederick National Laboratory for Cancer Research (FNL)
One of the major goals of the RAS Initiative at the Frederick National Lab is to deepen the knowledge of the RAS proteins. In support of that effort, the Protein Expression Laboratory has focused its effort on the purification of KRAS4b, its oncogenic mutants, and interacting protein partners in a multidisciplinary effort. Biophysical characterization and functional assays of the proteins will be discussed.

3:05 The Use of Affinity Tags to Overcome Obstacles in Recombinant Protein Expression and Purification
Jian-Ping Jin, M.D., Ph.D., Professor and William D. Traitel Endowed Chair, Physiology, Wayne State University School of Medicine
To overcome obstacles in the expression and purification of recombinant proteins are of importance in research and industrial applications. A strategy is the use of affinity tags or carrier peptide. Strategies have also been developed to remove the tag after purification and obtain native protein and peptide products. There are unsolved problems and imperfect applications. The pros and cons of current approaches will be discussed for improvement and future development.

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

STREAMLINING PURIFICATION PROCESSES

4:30 Crystallization as a Tool for Scalable, Efficient Purification Techniques in Early Process Step for Purifying Recombinant Proteins
Partha Hazra, Ph.D., Chief Scientific Manager, Research, Biocon
Crystallization/precipitation can be a simplified, efficient and cost effective tool for separation of both process and product related impurities in processing of recombinant therapeutic proteins. I will present a Case Study comparing traditional Capture chromatography and Crystallization/precipitation steps, and will cover the advantages of one over the other when manufacturing at large scale. Comparative quality observed in the scale up experiences also will be covered in the case study.

5:00 pH-Dependent Sharkbodies for Affinity Purification of Biologics
Harald Kolmar, Ph.D., Professor and Head, Applied Biochemistry, Chemistry, Technical University of Darmstadt
We have established a platform for generation of shark-based antibody domains that display pH-dependent target protein binding. To this end, a master library of sharkbodies with random histidine-enriched binding loops was generated that are displayed on yeast cells and screened by high-throughput FACS. Due to their high inherent stability and pH-dependent binding characteristics they are excellently suited for affinity chromatography purification of biologics, particularly for non-antibody protein therapeutics.

5:45 BuzZ Session B
Join your peers and colleagues for interactive roundtable discussions.
Please see page 55 for additional information.

6:30-7:30 Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Conference

Higher-Throughput Protein Purification

Innovating Processes

High-throughput processes have transformed the traditional protein-by-protein trial-and-error approach for testing criteria and scaling up. In this leading meeting on Higher-Throughput Protein Purification, HTP will be explored in the quest to develop methods that ensure quality and translate to large scale. Automation, robotics and liquid handlers will be discussed, along with developing small-scale models that shed light on bioproduction. Case studies will be presented that illustrate how leaders in the field are integrating HTP approaches in order to reduce the time and effort needed to successfully establish parameters and achieve pure protein.

THURSDAY, JANUARY 21

7:45 am Conference Registration and Morning Coffee

ENHANCING PROCESSES

8:15 Chairperson's Opening Remarks
David Wood, Ph.D., Associate Professor, Chemical & Biomolecular Engineering, The Ohio State University

KEYNOTE PRESENTATION

8:20 Enhancing Biotherapeutic Discovery and Optimization Using High-Throughput Protein Platforms
Scott Lesley, Ph.D., Director, Protein Sciences and Biotherapeutics, The Genomics Institute of the Novartis Research Foundation & Scripps Research Institute
HT protein expression and purification permits experimental iteration to find optimal activities and biophysical characteristics. While each protein is inherently unique, generalized approaches for expression, screening and purification have largely overcome this challenge to standardization. Automation adds both throughput and consistency to the process while integrated analytical methods allow for rapid characterization and sample triage. These robust platforms have found great utility for biologics discovery, expression and optimization.

9:00 Membrane Ultrafiltration – Opportunities for Higher Throughput Processes
Junfen Ma, Ph.D., Principal Scientist, Amgen, Inc.

9:30 The Use of High-Throughput Robotic Purification Platforms and Online, Real-Time Systems to Streamline Process Development
Susan Callahan, Scientist, Amgen, Inc.
Biopharmaceutical companies are moving towards high-throughput assays to meet analytical needs with accuracy, precision and speed. Many technological improvements/breakthroughs in robotics and instrumentation have been made recently which have allowed for enhancements in the analysis of various critical attributes. This presentation will focus on the evolution of traditional methods to the most recent breakthroughs in high-throughput purification, advanced analytical technologies and online real-time systems used to streamline process development.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

11:00 Characterization of the Poly(ADP-ribose) Proteome during DNA Damage
Guy G. Poirier, Ph.D., Professor, Biochemistry, and Canada Chair, tier1 in Proteomics and PROTEO, CHU de Québec Research Center, Laval University
We have developed a high throughput protein purification of poly(ADP-ribose) interacting proteome by using mass spectrometry hybrid instruments. More recently, we have established a new technology to analyze, on a proteome basis, sites of poly(ADP-ribosyl)ation on aspartic and glutamic acids on chromatin and on nuclear proteins. The identification of these sites modified by PARP-1 was achieved both by chemical and biochemical methods generating hydroxamic and ribose-P adducts.

11:30 Sponsored Presentation *(Opportunity Available)*

12:00 pm Session Break

12:15 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Ice Cream Break in the Exhibit Hall with Poster Viewing

SYNTHETIC BIOLOGY

2:00 Chairperson's Remarks
Dietmar Reusch, Ph.D., Director, Development Characterization, Pharma Biotech Production and Development, Roche Diagnostics GmbH

2:05 The Application of Synthetic Biochemistry: HTP Approaches to Enhance the Sustainability, Cost Effectiveness and Safety Efficiency of Manufacture for Small Molecule APIs
Andrew Fosberry, Ph.D., Manager, Expression and Fermentation Sciences, GlaxoSmithKline
Traditionally, the enzymes and microbes available for screening against chemical transformations were limited in number, single sourced from a commercial supplier, and came with restricted freedom to operate. Due to these constraints, it was necessary to fit a chemical process to a specific enzyme. Combined with the recent improvements in molecular biology and enzyme evolution technologies, it is now possible and practical to find and modify an enzyme hit to suit a specified process.

2:35 High-Throughput Purification of Synthetic Peptides by Reversed Phase Chromatography
Mathias Schaffrath, Ph.D., LGCR Chemistry, Library and Peptide Purification, Sanofi-Aventis Deutschland GmbH
The purification of large synthetic peptides (25-55 amino acids) is still a challenge. The unwanted by-products of these peptides are often peptides with only one wrong amino acid in the sequence. Therefore, the peptide and the by-products elute at the same time during the chromatographic separation. Chromatographic experience, thorough method development and scaling up is needed for successful separations. Partial automation of the process leads to a "really" high throughput purification.

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Higher-Throughput Protein Purification

Innovating Processes

3:05 Sponsored Presentation *(Opportunity Available)*

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

HIGH-THROUGHPUT INNOVATIONS

4:15 A Practical Self-Cleaving Tag System for Complex Glycoproteins
David Wood, Ph.D., Associate Professor, Chemical & Biomolecular Engineering, The Ohio State University
Premature cleaving and thiol requirements have made self-cleaving intein affinity tag methods ineffective for complex mammalian glycoproteins. We have recently developed a re-engineered intein and resin combination for these targets, and have successfully used it to purify fully glycosylated and active human tPA and secreted alkaline phosphatase expressed in HEK293 cells. This approach provides all the power of Protein A affinity methods, but with applications to non-mAb targets.

4:45 High-Throughput Purification of Toxins in *E. coli* for the Development of Novel Therapeutics
Renaud Vincentelli, Ph.D., Head, Protein Production, Structural Biology Facility, AFMB, CNRS University Aix Marseille
For the development of novel drugs, animal venoms constitute a library of millions of toxins which is unexplored due to the difficulty of getting these proteins correctly folded in *E. coli*. After modifying our custom HTP *E. coli* protein production pipeline (Saez NJ and Vincentelli R, Methods Mol Biol 2014), we could purify in a few months the majority of the 4000 recombinant toxins of the European FP7 VENOMICS project.

5:15 High-Throughput Production of Human Proteins for Structural Genomics and Generation of Affinity Reagents
Susanne Gräslund, Ph.D., Principal Investigator, Structural Genomics Consortium, Medical Biochemistry and Biophysics, Karolinska Institute
The Structural Genomics Consortium has deposited more than 1700 structures in PDB. The focus on high-throughput protein production combined with a multi-construct approach has laid the foundation for this success. The methods used for cloning, expression screening in various expression hosts and parallel protein purification will be presented as well as some recent advances to increase throughput. Development areas like producing protein complexes and biotinylated antigens will also be included.

5:45 Close of Day

6:00-7:00 Reception in the Tiki Pavilion

FRIDAY, JANUARY 22

8:00 am Conference Registration and Morning Coffee

HIGH-THROUGHPUT ANALYSIS

8:30 Chairperson's Remarks
Jonas Schaefer, Ph.D., Head, High-Throughput Binder Selection Facility, Biochemistry, University of Zurich

8:35 High-Throughput Protein Expression, Purification and Analysis for Next-Generation Binder Selection
Jonas Schaefer, Ph.D., Head, High-Throughput Binder Selection Facility, Biochemistry, University of Zurich
Expressing, screening and analyzing thousands of affinity reagent candidates for their properties remains one of the major bottleneck in binder generation. In my presentation, I will highlight our recent developments using a mixture of adapted and novel technologies to improve these steps, and thus to increase the speed and efficiency of our binder generation pipeline. In addition, innovative applications of our selected binders will be presented.

9:05 High-Throughput Techniques for Glycosylation Analysis of Therapeutic Antibodies
Dietmar Reusch, Ph.D., Director, Development Characterization, Pharma Biotech Production and Development, Roche Diagnostics GmbH
Several methods for glycoanalysis of antibodies are presented, including chromatographic, electrophoretic and mass spectrometry-based methods, with a focus on high-throughput techniques. We developed a method that is based on a DNA Sequencer. After APTS labelling, the glycans are detected with a fluorescence detector. The other method is based on glycopeptides. We compared the results for a therapeutic antibody obtained with the two high-throughput techniques with other methods for glycosylation analysis.

9:35 High-Throughput Mutagenesis and Molecular Dynamics Studies of Large Recombinant Protein Complexes
Robert O.J. Weinzierl, Ph.D., Reader, Molecular Biology, Life Sciences, Imperial College London
We have carried out a concerted experimental program focused on nanomechanically active portions of a multi-subunit RNA polymerase that are known to play a critical role in coordinating the translocation of nucleic acid substrates through the active site. Using a fully automated robotic *in vitro* reconstitution method, we tested the functional consequences of more than 600 site-directed mutants. We complement these approaches with atomistic molecular dynamics simulations.

10:05 Coffee Break with a Poster Pavilion

ENHANCED EFFICIENCY THROUGH AUTOMATION

▸ **FEATURED PRESENTATION**

11:00 Enhanced Protein Purification Efficiency through Automation and Laboratory Design
Kenneth Walker, Ph.D., Scientific Director, Biologics, Amgen, Inc.
In order to keep pace with the high-throughput cloning and expression needed to screen large panels of therapeutic candidates, we developed systems to substantially increase protein purification throughput through enhanced laboratory design and the use of novel chromatography instrument automation. With minimal user intervention, these systems can process a wide array of samples employing flexible, advanced chromatography methods that efficiently generate high-quality products.

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11:30 Automated High-Throughput Protein Purification Workflows for Discovery of Novel Therapeutics

Avinash Gill, Ph.D., Scientific Manager, Antibody Engineering, Genentech, Inc., a member of the Roche Group

In combination with automated HTP workflows for antibody expression and purification, an efficient process has been put in place for making large numbers of purified antibody variants available to be screened in biological/functional assays, epitope identification and manufacturability evaluation. Expression and purification are carried out at 2 scales of cell culture – 1mL (deepwell blocks) and 30 mL (tubespin columns), to generate antibodies, antibody fragments and other therapeutic protein formats.

12:00 pm IT'S A WRAP: PEPTALK 2016 CLOSING PLENARY PANEL DISCUSSION ***See page 2 for details***

1:15 Close of Conference

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Monday, January 18, 5:45-6:30 pm
Wednesday, January 20, 5:45-6:30 pm

BuzZ Sessions are facilitated, small-group discussions. Interactive participation leads to problem-solving solutions and future collaborations around focused topics.

If you have a topic idea or would like to moderate a table, please contact: Ann Nguyen at anguyen@healthtech.com

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SC1: How to Set Up Collaborations between Academia and Industrial Biotech Companies
SC2: Next-Generation Sequencing of Antibody Libraries
SC3: A Rational Approach to Formulation Development of Biologic Therapeutics
SC4: Insect Cell Expression Systems: Cutting-Edge Advances for Enhancing Protein Production
SC5: Accelerated Stability Testing of Biologics
SC6: DNA Matters: Applications for High-Throughput Rational Design

Tuesday, January 19 | 5:45-8:45 PM
SC7: Targeting of GPCRs with Monoclonal Antibodies
SC8: Designing Antibodies for Function and Low Risk of Immunogenicity
SC9: Lyophilization Formulation Development and Process Optimization
SC10: Transient Protein Production in Mammalian Cells
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