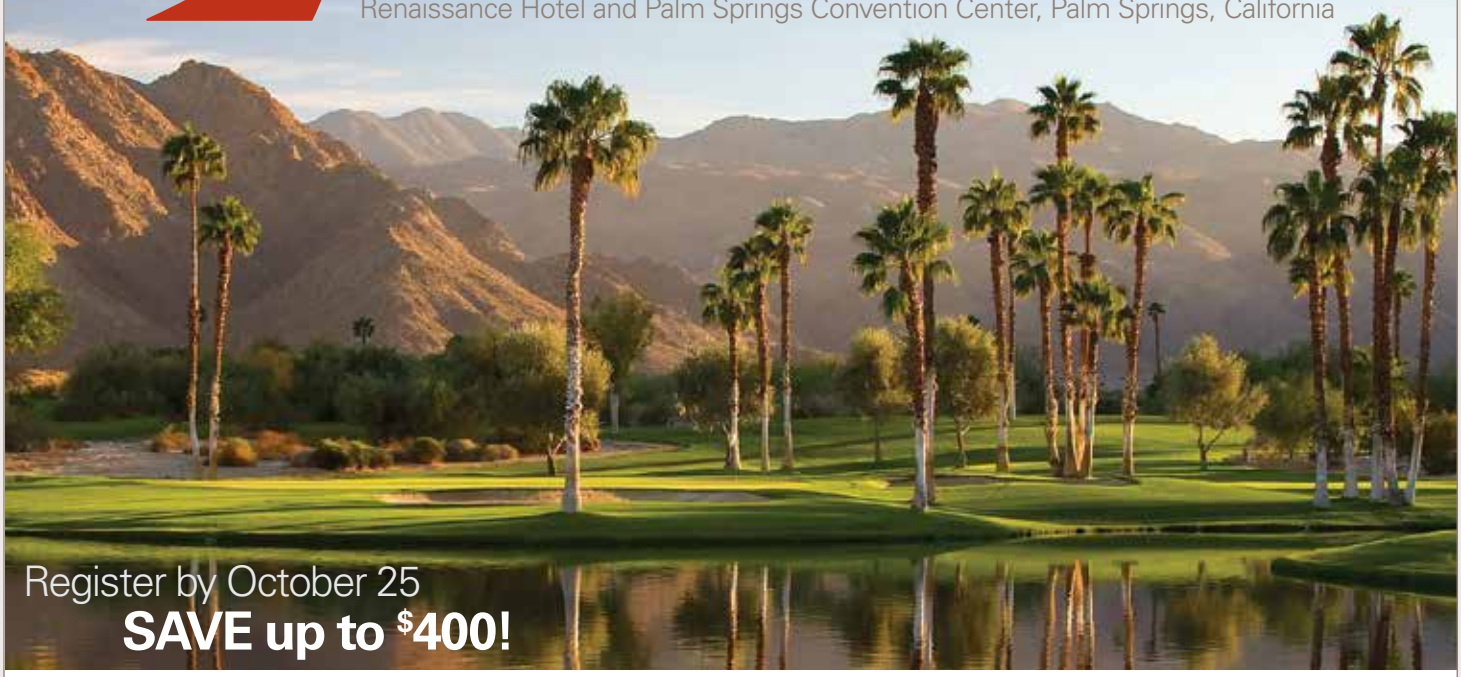
Cambridge Healthtech Institute's 13th Annual

**January 13-17, 2014**

# PepTalk

## The Protein Science Week

Renaissance Hotel and Palm Springs Convention Center, Palm Springs, California



Register by October 25

**SAVE up to $400!**

ENGINEERING

### Pipeline 1: Antibody Optimization and Development

Enhancing Antibody Binding and Specificity

Improving the Clinical Efficacy of Antibody Therapeutics

Turning Antibodies into Drug Products

### Pipeline 2: Protein and Antibody Therapeutics

Recombinant Protein Therapeutics

Antibody-Drug Conjugates

Bispecific Antibody Therapeutics

DEVELOPMENT

### Pipeline 3: Formulation and Stability

Optimizing Biologics Formulation Development

Lyophilization and Emerging Drying Technologies

Protein Aggregation and Emerging Analytical Tools

### Pipeline 4: Delivery and Packaging

Optimizing Biologics Formulation Development

Protein-Device Combinations

Extractables and Leachables

PRODUCTION

### Pipeline 5: Expression and Production

Engineering Genes, Vectors, Constructs and Clones

Recombinant Protein Expression and Production

Transient Protein Production

### Pipeline 6: Purification and Aggregation

Protein Purification and Recovery

Higher-Throughput Protein Purification

Protein Aggregation and Emerging Analytical Tools

### Pipeline 7: Manufacturing and Facilities

Single-Use Technologies and Continuous Processing

Flexible Manufacturing of Biopharmaceuticals

Extractables and Leachables

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Organized by CHI Cambridge Healthtech Institute

CHI-PepTalk.com

# CONFERENCE AT-A-GLANCE

| | | Sunday (Jan. 12), 5:00-8:00 pm **Dinner Short Courses*** | Monday-Tuesday (Jan. 13-14) | Tuesday (Jan. 14), 5:00-8:00 pm **Dinner Short Courses*** | Wednesday-Thursday (Jan. 15-16) | Thursday-Friday (Jan. 16-17) |
|---|---|---|---|---|---|---|
| ENGINEERING | Pipeline 1 **Antibody Optimization and Development** | Targeting of GPCRs with Monoclonal Antibodies | **Enhancing Antibody Binding and Specificity** | | **Improving the Clinical Efficacy of Antibody Therapeutics** | **Turning Antibodies into Drug Products** |
| ENGINEERING | Pipeline 2 **Protein and Antibody Therapeutics** | | **Recombinant Protein Therapeutics** | *In silico* Immunogenicity Predictions (Hands-On) Workshop | **Antibody-Drug Conjugates** | **Bispecific Antibody Therapeutics** |
| DEVELOPMENT | Pipeline 3 **Formulation and Stability** | Vaccine Formulation and Characterization, Status Quo and New Opportunities | **Optimizing Biologics Formulation Development** | Protein Aggregation: Mechanism and Characterization | **Lyophilization and Emerging Drying Technologies** | **Protein Aggregation and Emerging Analytical Tools** |
| DEVELOPMENT | Pipeline 4 **Delivery and Packaging** | QbD Strategies for Formulation Development of Protein Therapeutics | **Optimizing Biologics Formulation Development** | Extractables and Leachables: Applications to Final Packaging and Single-Use Systems | **Protein-Device Combinations** | **Extractables and Leachables** |
| PRODUCTION | Pipeline 5 **Expression and Production** | Advances in Cell Line Engineering | **Engineering Genes, Vectors, Constructs and Clones** | Transient Protein Production in Mammalian Cells | **Recombinant Protein Expression and Production** | **Transient Protein Production** |
| PRODUCTION | Pipeline 6 **Purification and Aggregation** | Strategies for Purifying Proteins: Optimizing Buffers and Overcoming Aggregation | **Protein Purification and Recovery** | | **Higher-Throughput Protein Purification** | **Protein Aggregation and Emerging Analytical Tools** |
| PRODUCTION | Pipeline 7 **Manufacturing and Facilities** | | **Single-Use Technologies and Continuous Processing** | Challenges of Multi-Column Continuous Chromatography | **Flexible Manufacturing of Biopharmaceuticals** | **Extractables and Leachables** |
| **1.5 DAY TRAINING SEMINAR*** | | | Biologics Formulation and Delivery | | | ~~Cancelled~~ |

*Separate registration is required

Cambridge Healthtech Institute (CHI) is excited to announce its **13th Annual PepTalk: The Protein Science Week** event taking place January 13-17, 2014 in Palm Springs, California. PepTalk is a key meeting place for leaders in biotherapeutics and a frequently used platform for major announcements.

PepTalk has experienced record attendance over the past three years, and will deliver an international delegation of over 1,200 participants in 2014. Its continued growth and success is due to its high-quality scientific programming, expanded exhibit hall, and ample networking opportunities.

In addition to new programs focused on "Antibody Optimization and Development" as well as "Manufacturing and Facilities" — expanding coverage from upstream engineering and discovery research to downstream production — **PepTalk now offers introductory-level training seminars to help you learn more about the fundamentals of a specific topic**.

PepTalk is designed to let you create your own agenda by track hopping and choosing the sessions that best fit your research and networking needs. Additional networking opportunities will be available through BuzZ Session discussion groups, panel discussions, short courses, and dedicated exhibit hall and poster viewing hours.

PepTalk is a community dedicated to the evolving field and future of biotherapeutics. Whether this is your first time attending PepTalk or you're a returning participant, you'll enjoy a week of innovative presentations given by researchers on the forefront of biologics. Collaborate with leading scientists and academics, and experience the history and wealth of activities in Palm Springs, California, the ultimate destination for outdoor adventure, arts and culture, gaming and entertainment.

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# Sponsorship & Exhibit Opportunities

CHI offers comprehensive sponsorship packages which include presentation opportunities, exhibit space and branding, as well as the use of the pre- and post-show delegate lists. Customizable sponsorship packages allow you to achieve your objectives before, during, and long after the event. Signing on early will allow you to maximize exposure to qualified decision-makers!

## AGENDA, BREAKFAST, AND LUNCHEON PRESENTATIONS

Showcase your solutions to a guaranteed, highly-targeted audience. Package includes a 15 or 30-minute podium presentation within the scientific agenda, exhibit space, on-site branding, and access to cooperative marketing efforts by CHI. For the luncheon option, boxed lunches are delivered into the main session room. Presentations will sell out quickly. Sign on early to secure your talk!

## INVITATION-ONLY VIP DINNER/HOSPITALITY SUITE

Sponsors will select their top prospects from the conference pre-registration list for an evening of networking at the hotel or at a choice local venue. CHI will extend invitations and deliver prospects.

***Inquire about additional branding opportunities!***

## LEAD GENERATION

Obtain more targeted, qualified leads within life sciences with CHI's Lead Generation programs. We will mine our database of 800,000+ life science professionals to your specific needs. We guarantee a minimum of 100 leads per program! Opportunities include:

- Whitepapers
- Web Symposia
- Custom Market Research Survey
- Podcasts

*Advertising opportunities such as marketing and promotional emails are also available.*

**To customize your participation at this event, please contact:**

*Companies A - K:*

Jason Gerardi
Manager, Business Development
781-972-5452
jgerardi@healthtech.com

*Companies L - Z:*

Carol Dinerstein
Director, Business Development
781-972-5471
dinerstein@healthtech.com

## CURRENT EXHIBITORS AND SPONSORS AS OF 8/9/13

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## TOP REASONS TO STAY AT RENAISSANCE PALM SPRING HOTEL

- No Commute! All conference events are taking place at the Convention Center – attached to the Hotel
- Only 10 Minutes from the Palm Springs Airport
- Complimentary wireless internet in your guest room
- Downtown Palm Springs restaurant and shops are just minutes from the hotel
- Nearby attractions such as The Palm Spring Aerial Tramway to experience the breathtaking journey up the Chino Canyon is just minutes away

# Hotel & Travel Information

**Conference Venue:**

Palm Springs Convention Center
277 N. Avenida Caballeros
Palm Springs, CA 92262

**Host Hotel:**

Renaissance Palm Springs Hotel
888 E. Tahquitz Canyon Way
Palm Springs, CA 92262
Phone: 760-322-6000

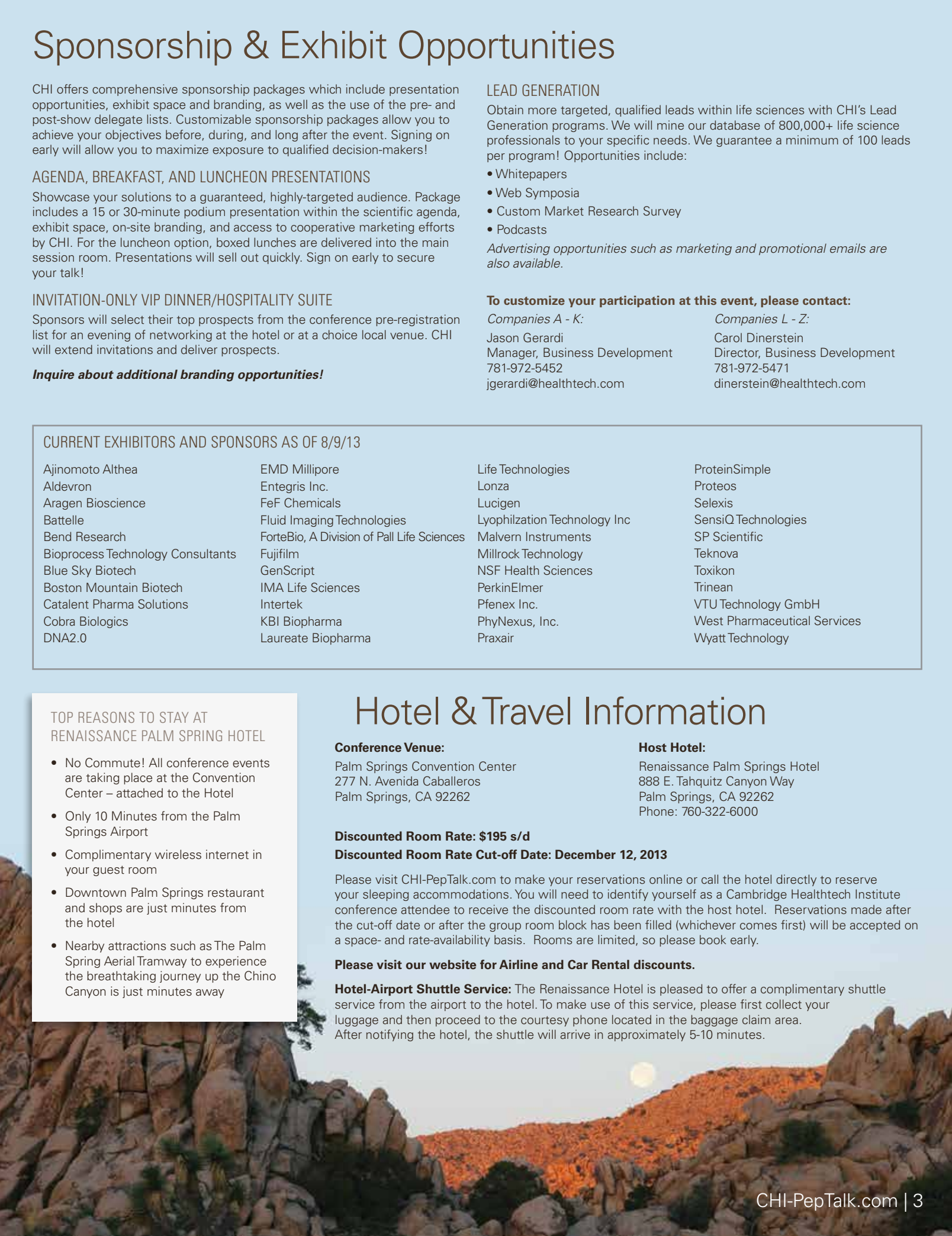
**Discounted Room Rate: $195 s/d**

**Discounted Room Rate Cut-off Date: December 12, 2013**

Please visit CHI-PepTalk.com to make your reservations online or call the hotel directly to reserve your sleeping accommodations. You will need to identify yourself as a Cambridge Healthtech Institute conference attendee to receive the discounted room rate with the host hotel. Reservations made after the cut-off date or after the group room block has been filled (whichever comes first) will be accepted on a space- and rate-availability basis. Rooms are limited, so please book early.

**Please visit our website for Airline and Car Rental discounts.**

**Hotel-Airport Shuttle Service:** The Renaissance Hotel is pleased to offer a complimentary shuttle service from the airport to the hotel. To make use of this service, please first collect your luggage and then proceed to the courtesy phone located in the baggage claim area. After notifying the hotel, the shuttle will arrive in approximately 5-10 minutes.



# Dinner Short Courses*

## Sunday, January 12 | 5:00-8:00 pm

**SC1: Targeting of GPCRs with Monoclonal Antibodies**

While GPCRs (G protein-coupled receptors) are important therapeutic targets, it has been challenging to discover therapeutically relevant antibodies against them. This course will examine different steps along the anti-GPCR antibody discovery pathway and highlight various approaches to accomplishing each step.

*Instructor: Barbara Swanson, Ph.D., Director, Research, Sorrento Therapeutics, Inc.*

**SC3: Vaccine Formulation and Characterization, Status Quo and New Opportunities**

After water sanitization, vaccines may be the most successful method to prevent deadly or devastating infectious diseases. To overcome the hurdles that reduce vaccine efficacy, novel techniques to identify and improve vaccines are necessary. These new approaches help increase potency but also challenges related to formulation characterization and the stability of each component. The course will describe the current status of vaccine formulation characterization with a focus on alum-based formulations and describe steps that can improve it.

*Instructor: Michele Pallaoro, Ph.D., Unit Head, Formulation Analytics, Novartis Vaccines & Diagnostics*

**SC4: QbD Strategies for Formulation Development of Protein Therapeutics**

The course will discuss how to perform protein formulation development to meet QbD expectations from the health authorities. Case studies will be presented on how to conduct Force degradation and stability-indicating analytical methods, design DOE and multivariate experiments and how to analyze data.

*Instructors: Kevin Zen, Ph.D., Manager, Biologics Development, Allergan*

*Vishal C. Nashine, Ph.D., Senior Research Investigator, Drug Product Science & Technology, Bristol-Myers Squibb Co.*

**SC5: Advances in Cell Line Engineering**

Discovering and designing novel therapeutic monoclonal antibodies (mAb) is just the beginning. The expanding demand for high-quality antibodies with better specificities has resulted in significant improvements in traditional hybridoma and genetically modified cell line engineering and production methods. However, these newly formed hybridomas and cells often grow poorly or die, and their selection and cloning are laborious and time-consuming. This course is designed to explain recent advances in cell line engineering technologies and provide practical examples through case studies.

*Instructors: Camille Delebecque, Ph.D., Founder and CEO, SynBio Consulting*

*Robert Horlick, Ph.D., Senior Director, Molecular Biology, AnaptysBio, Inc.*

*Takeshi Omasa, Ph.D., Professor, Institute of Technology and Science, University of Tokushima*

**SC6: Strategies for Purifying Proteins: Optimizing Buffers and Overcoming Aggregation**

This course will provide strategies for purifying proteins, such as identifying and overcoming aggregation and stabilizing proteins through buffer optimization, including analyzing quality, pH, salt, stabilizing elements, buffering systems and identifying solubility-promoting buffers.

*Instructors:*

*Sarah E. Bondos, Ph.D., Assistant Professor, Molecular and Cellular Medicine, Texas A&M Health Science Center*

*Mark Arbing, Ph.D., Director, Protein Expression Technology Center, UCLA-DOE Institute for Genomics & Proteomics*

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

## Tuesday, January 14 | 5:00-8:00 pm

**SC9: *In silico* Immunogenicity Predictions (Hands-On) Workshop**

Computational immunogenicity predictions for antibodies as well as pathogens help in the rational design and re-engineering. This facilitates the minimization of anti-drug antibodies (ADA) as well as better vaccine design. The latest *in silico* tools can shorten the process from design to preclinical validations.

*Instructor: Vinodh Kurella, Ph.D., Visiting Research Fellow, C3 Bioinformatics, Harvard Medical School*

**SC10: Protein Aggregation: Mechanism and Characterization**

We will discuss the phenomena described by protein aggregation, how aggregates form, what factors influence their formation and consequences of aggregate formation. We will also discuss how to predict aggregation and key analytical challenges and tools for characterization of aggregates.

*Instructors: Elizabeth M. Topp, Ph.D., Dane O. Kildsig Chair and Head, Industrial and Physical Pharmacy, Purdue University*

*Daniel Some, Ph.D., Principal Scientist, Wyatt Technology*

**SC11: Extractables and Leachables: Applications to Final Packaging and Single-Use Systems**

The course will outline fundamentals to material chemistry and leachable sources, while also highlighting properties that govern migration of compounds. Case studies will be presented on how to develop evaluation strategies and design appropriate analytical studies for Controlled Extractables Testing, Leachables Studies and Tox Assessment.

*Instructors: Michael A. Ruberto, Ph.D., President, Material Needs Consulting, LLC*

*John Iannone, Program Manager and Technical Specialist, Toxikon Corporation*

**SC12: Transient Protein Production in Mammalian Cells**

We will introduce the fundamental concepts needed to establish transient protein production (TPP) in mammalian cells. TPP allows for the rapid generation of milligram to gram quantities of recombinant proteins for therapeutic, functional and structural studies. This course will provide an introduction to TPP through instruction and case studies in an interactive environment.

*Instructors: Richard Altman, MS, Research Scientist, Alexion Pharmaceuticals*

*Henry C. Chiou, Ph.D., Senior Product Manager, Life Technologies*

*Krista Johnson, MSc, Research Scientist, Alexion Pharmaceuticals*

**SC14: Challenges of Multi-Column Continuous Chromatography**

MCC chromatography in sequential and countercurrent mode has become an attractive tool to overcome the "bottleneck." Although the SMB technology has a proven record in the manufacture of synthetic pharmaceuticals, barriers still remain to implement the technology into the biopharmaceutical industry.

*Instructor: Dr.-Ing. Kathleen Mihlbachler, Independent Consultant*

** Please visit our website for more details. Separate registration is required.*

Cambridge Healthtech
# Training SEMINARS
Comprehensive and Practical Training

MONDAY, JANUARY 13, 8:30 AM-5:30 PM – TUESDAY, JANUARY 14, 8:30 AM-12:30 PM

**Introduction to Biologics Formulation and Delivery**

The course will focus 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 both liquid and lyophilized products.

- 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

*Instructors: Pooja Arora, Ph.D., Senior Manufacturing Technical Specialist, Genentech-A member of the Roche Group*

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

***Course Information:*** *Course is 1.5 days, and lunch is provided on the first full day. Course attendees will each receive a handbook with instructor presentation materials.*

** Please visit our website for more details. Separate registration is required.*

INAUGURAL | JANUARY 13-14

# Enhancing Antibody Binding and Specificity

Emerging Science and New Technologies to Fine-Tune Antibody-Antigen Binding

## SUNDAY, JANUARY 12

**4:00-5:00 pm Short Course Registration**
**5:00-8:00 Dinner Short Courses (SC1-SC7)** *See page 4 for details*

**4:00-8:00 Main Conference Registration**

## MONDAY, JANUARY 13

**7:30 am Conference Registration and Morning Coffee**

### Library Design and Screening for Novel Specificities

**9:00 Chairperson's Opening Remarks**
*Germaine Fuh, Ph.D., Senior Scientist, Antibody Engineering, Genentech, Inc.*

**» KEYNOTE PRESENTATION**
**9:10 Selections for Challenging Targets**
*Jim Wells, Ph.D., Professor, Pharmaceutical Chemistry and Cellular & Molecular Pharmacology, University of California, San Francisco*

**9:50 Identifying Antibodies with Novel Specificity**
*Caroline Colley, Ph.D., Senior Scientist, Antibody Discovery and Protein Engineering, MedImmune*

**10:20 Coffee Break**

**10:45 Polyspecific Antibodies: Prediction of Structure and Design of Function**
*David Nannemann, Ph.D., Postdoctoral Scholar, Chemistry and Pharmacology, Vanderbilt University*

**11:15 Enhanced Selection of Cross-Reactive Neutralizing Antibodies**
*Dimiter S. Dimitrov, Ph.D., Senior Investigator, Protein Interactions Group, National Cancer Institute, NIH*

**11:45 Cell-Based Selections against Complex Targets**
*Eric V. Shusta, Ph.D., Professor, Chemical and Biological Engineering, University of Wisconsin-Madison*

**12:15 pm Antibody Library Display on a Mammalian Virus: Combining the Advantages of Panning and Cell Sorting in One Technology**
*Sponsored by* VACCINEX
*Ernest S. Smith, Ph.D., Senior Vice President, Research & Chief Scientific Officer, Vaccinex, Inc.*

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

### Specificity Engineering

**2:00 Chairperson's Remarks**
*Randall Brezski, Ph.D., Senior Scientist, Janssen R&D*

**2:05 Engineering Ph-Selective Antibodies**
*Nathan Scott, Ph.D., Principal Scientist, Biotherapeutic Discovery & Engineering, Pfizer*

**2:35 Engineering Antibodies against the Müllerian Inhibiting Substance Type II Receptor – Overcoming Obstacles Associated with a Highly Conserved Target**
*Greg Adams, Ph.D., Co-Leader, Developmental Therapeutics Program, Fox Chase Cancer Center*

**3:05 Molecular Mechanism and Utility of Converting a Monospecific Antibody to a Dual-Specific Two-in-One Antibody**
*Germaine Fuh, Ph.D., Senior Scientist, Antibody Engineering, Genentech, Inc.*

**3:35 Selected Oral Poster Presentation: Target Identificationand Characterization of Antibodiesby Pathogen-Specific Genome-WideProtein Microarrays**
*Emmanuel Yaw Dotsey, Ph.D., Postdoctoral Fellow, Department of MedicineDivision of Infectious Disease, University of California, Irvine*

**3:50 Refreshment Break**

**4:15 Optimizing Antigen Affinity, Selectivity, and Clearance for Improved Antibody Therapeutics**
*John Desjarlais, Ph.D., Vice President, Research, Xencor*

**4:45 Engineering the Binding Site of an Antibody Against N-glycolyl GM3: From Functional Mapping to Novel Anti-Ganglioside Specificities**
*Gertrudis Rojas, Ph.D., Group Leader (Protein Engineering), Systems Biology, Center of Molecular Immunology*

**5:15 SMART-Ig: Novel Recycling and Sweeping Antibody Technology**
*Shinya Ishii, Ph.D., Research Scientist, Research Division, Chugai Pharmaceutical Co Ltd., Japan*

**5:45-7:00 Welcome Reception in the Exhibit Hall with Poster Viewing**
*Sponsored by* proteinsimple

## TUESDAY, JANUARY 14

**7:15 am Conference Registration**

**7:30 Breakfast Presentation** *(Sponsorship Opportunity Available)* **or Morning Coffee**

### Binding to Difficult Protein Targets

**8:30 Chairperson's Remarks**
*Caroline Colley, Ph.D., Senior Scientist, Antibody Discovery and Protein Engineering, MedImmune*

**8:35 Recombinant Expression and Surface Plasmon Resonance Studies of Cannabinoid Receptor CB2**
*Alexei Yeliseev, Ph.D., Staff Scientist, Protein Biochemistry, LMBB, NIH*

**9:05 Meet Me at the Membrane: Antibody Discovery Efforts for Challenging Protein Targets**
*Jian Payandeh, Ph.D., Scientist, Structural Biology, Genentech, Inc.*

**9:35 Selected Oral Poster Presentation:**

**Facile Chemical Functionalization of Antibodies Through Intein-Linked Yeast Display**
*Carrie Marshall, Research Assistant/Ph.D. Candidate, Department of Chemical and Biological Engineering, University of Wisconsin-Madison*

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

### Deep Sequencing of Antibody Libraries

**10:50 IonPython: An Open Source Tool for the Rapid Analysis of Antibody Repertoires**
*Csaba Kiss, Ph.D., Team Leader, Bioscience Division, Los Alamos National Laboratory*

**11:20 Predicting Efficacy and Safety of Antibody Therapeutics from Genomic Sequences**
*Hsih-Te Yang, Ph.D., Visiting Assistant Professor, Department of Systems Medicine, Keio University School of Medicine*

**11:50 A Unified Framework for Computer-Aided Biologics Design**
*Sponsored by* CHEMICAL COMPUTING GROUP
*Christopher R. Corbeil, Ph.D., Chemical Computing Group*

**12:20 pm 12:20 pm Improved Antibody Design Using Structure-Based Analysis and Computation** *Sponsored by* SCHRÖDINGER.

*David A. Pearlman, Ph.D., Senior Principal Scientist, Schrödinger*

**2:00 BuzZ Session A (Please visit our website for topics)**

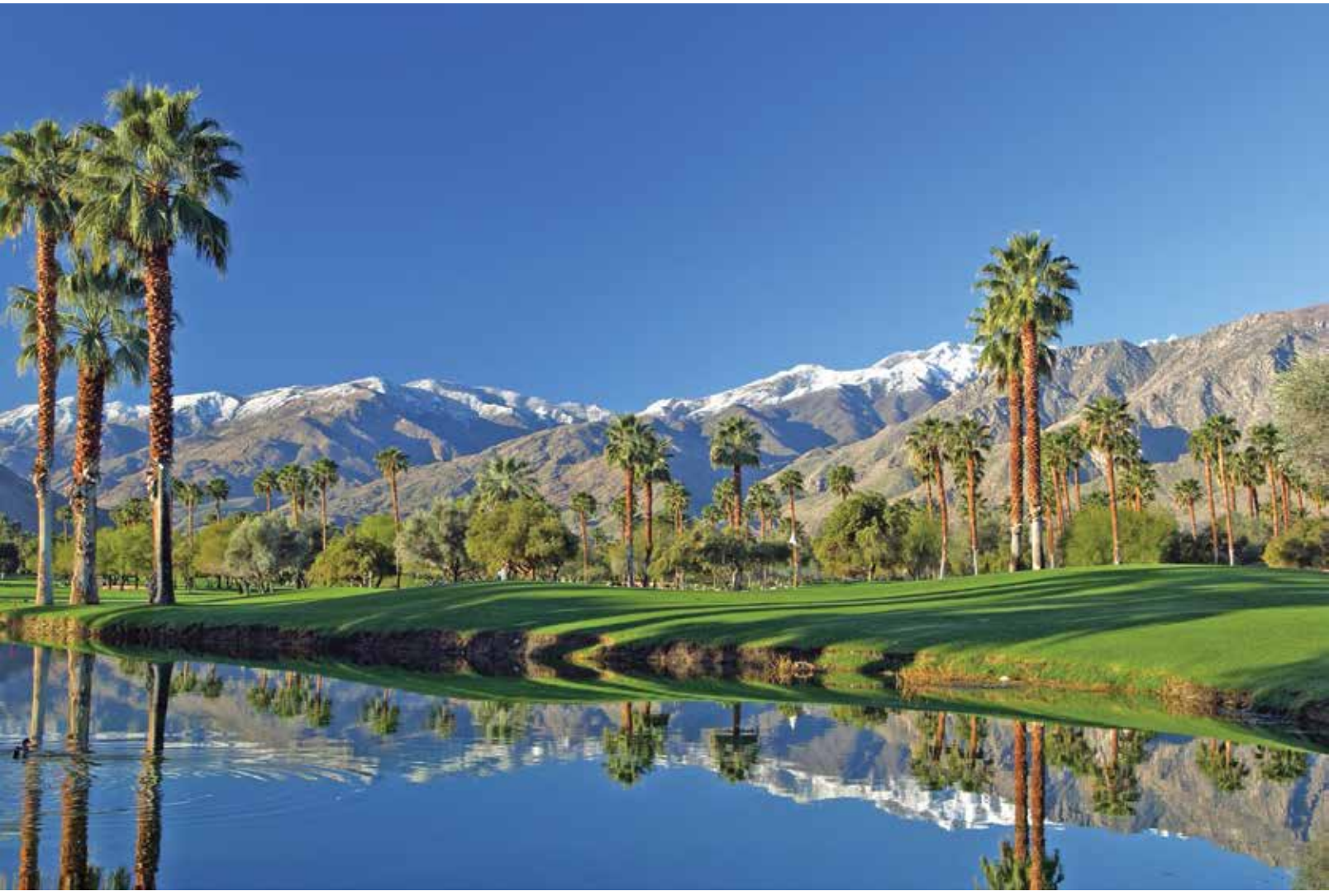
**3:00 Refreshment Break in the Exhibit Hall with Poster Awards**

**3:45 BuzZ Session B (Please visit our website for topics)**

**4:45 Close of Conference**

**4:30-5:00 Short Course Registration**

**5:00-8:00 Dinner Short Courses (SC8-SC14)** *See page 4 for details*



INAUGURAL | JANUARY 15-16

# Improving the Clinical Efficacy of Antibody Therapeutics

Cutting-Edge Protein Engineering for the Next Generation of Safe and Effective Biotherapeutics

## TUESDAY, JANUARY 14

**1:30-2:00 pm Conference Registration**

**2:00 BuzZ Session A (Please visit our website for topics)**

**3:00 Refreshment Break in the Exhibit Hall with Poster Awards**

**3:45 BuzZ Session B (Please visit our website for topics)**

**4:30-5:00 Short Course Registration**

**5:00-8:00 Dinner Short Courses (SC8-SC14)** *See page 4 for details*

## WEDNESDAY, JANUARY 15

**7:30 am Conference Registration**

**8:00 Morning Coffee**

### Immune System Modulation with Antibody Therapeutics

**8:15 Chairperson's Opening Remarks**
*Dimiter S. Dimitrov, Ph.D., Senior Investigator, Protein Interactions Group, National Cancer Institute, NIH*

**» KEYNOTE PRESENTATION**

**8:20 Coordinated Tumor Growth Suppression via Synergistic Innate and Adaptive Immunotherapy**
*K. Dane Wittrup, Ph.D., C.P. Dubbs Professor of Chemical Engineering and Biological Engineering, Massachusetts Institute of Technology*

**9:00 Antibody-Based Approaches Targeting ERBB2**
*Mark D. Pegram, M.D., Professor of Medicine, Stanford University Medical Center*

**9:30 Selection of Isotypes for Immune Modulatory Antibodies**
*Ann White, Ph.D., Senior Research Fellow, University of Southampton*

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

### Biomarkers for Targeted Antibody Therapeutics

**10:45 Assessing Factors for Predictive Response to ADC Targets in Clinical Tissue for Companion Diagnostic Development**
*Steven Potts, Ph.D., CEO, Histopathology Services, Flagship Biosciences*

**11:15 Co-Development of Antibody Therapeutic and Companion Diagnostic for Atherosclerosis Related Cardiovascular Events**
*Knut Pettersson, Ph.D., Vice President, Preclinical Development, Athera Biotechnologies AB*

**11:45 Molecular Imaging of Monoclonal Antibodies for Biomarkers and Companion Diagnostics**
*Anna M. Wu, Ph.D., Professor, Molecular and Medical Pharmacology, David Geffen School of Medicine; Founder and Chief Scientist, ImaginAb*

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

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

### Antibody Cocktails and Combinations

**2:00 Chairperson's Remarks**
*Greg Adams, Ph.D., Co-Leader - Developmental Therapeutics Program, Fox Chase Cancer Center*

**2:05 Antibody Mixtures – A Novel Strategy to Treat Cancer**
*Ivan Horak, M.D., CSO & CMO, Symphogen*

**2:35 Synthetic Lethality Approach to Anti-EGFR Targeting in Cancer**
*Igor Astsaturov, M.D., Ph.D., Assistant Professor, Fox Chase Cancer Center*

**3:05 HER2 Antibodies Induce Anticancer Activity with Trastuzumab or Overcome Resistance of Trastuzumab in HER2+ Breast Cancer Cells**
*Kyu-Tae Kim, Ph.D., Director, Therapeutic Antibodies, AbClon, Inc.*

**3:35 Selected Oral Poster Presentation:**

**Computationally Driven Deimmunization of an ADEPT Enzyme**
*Karl E. Griswold, Ph.D., Associate Professor, Thayer School of Engineering, Dartmouth College*

**3:50 Refreshment Break**

**4:15 Targeting the HER Family Receptors with a Tri-Specific Antibody**
*Viktor Roschke, Ph.D., Vice President, Biopharmaceutical Research, Zyngenia, Inc.*

### Special Presentation

**4:45 Recent Changes in Intellectual Property Law – Will Your Therapeutic Antibody Patents Survive?**
*John L. Marquardt, Jr., J.D., MBA, Ph.D., Attorney at Law, Marquardt Law*

**5:15-6:30 Reception in the Exhibit Hall with Poster Viewing**

## THURSDAY, JANUARY 16

**7:15 am Conference Registration**

**7:30 Breakfast Presentation** *(Sponsorship Opportunity Available)* **or Morning Coffee**

### The Next Generation of Antibody Therapeutics

**8:30 Chairperson's Remarks**
*John Desjarlais, Ph.D., Vice President, Research, Xencor*

**8:35 Novel Mechanisms of Action for Antibody Therapeutics**
*Randall Brezski, Ph.D., Senior Scientist, Biotechnology Center of Excellence, Janssen R&D*

**9:05 Advancing Next-Generation Fully Human Therapeutic Antibodies Using the VelocImmuneTM Platform**
*David Buckler, Ph.D., Director, Therapeutic Proteins, Regeneron Pharmaceuticals*

**9:35 Selected Oral Poster Presentation: Origins of Specificity and Affinity in Antibody-Protein Interactions**
*An-Suei Yang, Ph.D., Research Fellow, Genomics Research Center, Academia Sinica, Taiwan*

**9:50 Coffee Break in the Exhibit Hall with Poster Awards**

**10:50 Antibody Targets for Cardiometabolic Disorders**
*Jim Larrick, Ph.D., CEO, Panorama Research*

**11:20 Selection of Antibody Product Format Based on Target and Therapeutic Area**
*Mark Flory, Ph.D., Principal Scientist, Target Discovery and Validation, Igenica*

**11:50 Broadening the Scope of Antibody Therapeutics: Antibody Therapies for Your Pet**
*Lisa M Bergeron, Ph.D., Principal Scientist, Biotherapeutics Discovery & Engineering, Zoetis Inc*

*Sponsored by* zoetis

**12:20 pm Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

**1:45 Close of Conference**

INAUGURAL | JANUARY 16-17

# Turning Antibodies into Drug Products

Protein Science Impacts on the Progression from Discovery to Biotherapeutic Product

## THURSDAY, JANUARY 16

**1:00-1:45 pm Conference Registration**

### Antibody Developability

**2:00 Chairperson's Opening Remarks**
*Mark Flory, Ph.D., Principal Scientist, Target Discovery and Validation, Igenica*

**» KEYNOTE PRESENTATION**

**2:05 Developability Assessment of Therapeutic Antibodies – A Concept for Early Lead Selection**
*Thorsten Lorenz, Ph.D., Principal Scientist, Integrated Biologics Profiling, Novartis Pharma AG*

**2:45 Microscale Assays for Screening Drug-Like Properties**
*Allan Capili, Ph.D., Scientist, Protein Biochemistry, Biogen Idec*

**3:15 An Antibody Engineering Platform for High-Throughput Candidate Screening, Engineering & Optimization**
*Lorenzo Benatuil, Ph.D., Senior Scientist, Biologics, Abbvie Bioresearch Center*

**3:45 Selected Oral Poster Presentation:**
**Targeted Delivery into Sensory Neurons of a SNARE Protease Using a Single Chain Antibody (scFv) Against the Extracellular Domain of P2X3 Inhibits the Release of a Pain Mediator**
*Hui Ma, Ph.D., Post-Doctoral Researcher, Biomedical Diagnostics Institute, Dublin City University, Ireland*

**4:00 Refreshment Break in the Exhibit Hall with Poster Viewing**

**4:45 New Algorithm for Screening Aggregation-Prone Regions in Antibodies and Other Proteins**
*Marco Blanco, Ph.D., Postdoctoral Researcher, Chemical and Biomolecular Engineering, University of Delaware*

**5:15 MAb-mAb Interactions Controlled by Buffer Species and Arginine Salts**
*Christopher van der Walle, Ph.D., Principal Scientist, Development, MedImmune*

**5:45 Close of Day**

## FRIDAY, JANUARY 17

**7:15 am Conference Registration**

**7:30 Breakfast Presentation** *(Sponsorship Opportunity Available)*
**or Morning Coffee**

### Controlling Glycosylation

**8:30 Chairperson's Remarks**
*David Buckler, Ph.D., Director, Therapeutic Proteins, Regeneron Pharmaceuticals*

**8:35 Engineering a Monomeric Fc Modality by N-Glycosylation for the Half-Life Extension of Biotherapeutics**
*Tetsuya Ishino, Ph.D., Senior Principal Scientist, Pfizer*

**9:05 Understanding the Role of Glycosylation in Antibody Effector Function**
*Margaret Ackerman, Ph.D., Assistant Professor, Engineering, Dartmouth University*

**9:35 IgG Glycosylation Engineering in *Pichia Pastoris***
*Bing Gong, Ph.D., Senior Research Biologist, Glycofi/Merck*

**10:05 Selected Oral Poster Presentation: Towards Improved Antibody Therapeutics: Studying the Effect of Glycosylation on IgG2**
*Khalid Al-Kinani, Graduate Student, Department of Pharmaceutical Chemistry, The University of Kansas*

**10:20 Coffee Break in the Exhibit Hall with Poster Awards**

### Species Cross-Reactivity

**11:15 pm Engineering Species Cross-Reactivity in a Therapeutic Antibody**
*Francois Rousseau, Ph.D., Head, Antibody Engineering Unit, Novimmune SA*

**11:45 Selection Campaigns Based on Species Cross-Reactivity**
*Maria Groves, Ph.D., Senior Scientist, Lead Generation, MedImmune*

**12:15 Holy Cow - Reshaping Bovine Antibody Diversity with Disulfide-Bonded Ultralong CDR H3s**
*Vaughn Smider, M.D., Ph.D., Assistant Professor, Molecular Biology, The Scripps Research Institute*

**12:45 Sponsored Presentation** *(Opportunity Available)*

**1:15 Luncheon Presentation** *(Sponsorship Opportunity Available)*
**or Lunch on Your Own**

### Optimization of Antibody Therapeutic Development

**2:00 Chairperson's Remarks**
*Eugene Zhukovsky, Ph.D., CSO, Research, Affimed Therapeutics AG*

**2:05 Antibody Engineering to Improve Manufacturability**
*Arnie Horwitz, Ph.D., Senior Director, Expression Technologies, XOMA*

**2:35 Rapid Prototyping and Optimization for Therapeutic Antibody-Like Molecules**
*Lihui Xu, Group Leader, Antibody Technology Team, Merrimack Pharmaceuticals*

**3:05 Bispecific Tetravalent TandAbs Recruit NK and T Cells to Treat Cancer**
*Eugene Zhukovsky, Ph.D., CSO, Research, Affimed Therapeutics AG*

**3:35 Meditopes and meMabs; Non-Covalent Functionalization of mAbs**
*John Williams, Ph.D., Associate Professor, Molecular Medicine, Beckman Research Institute*

**4:05 Close of Conference**

## Present a Poster

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TENTH ANNUAL | JANUARY 13-14

# Recombinant Protein Therapeutics

Fusion Proteins and Beyond

## SUNDAY, JANUARY 12

**4:00-5:00 pm Short Course Registration**

**5:00-8:00 Dinner Short Courses (SC1-SC7)** *See page 4 for details*

**4:00-8:00 Main Conference Registration**

## MONDAY, JANUARY 13

**7:30 am Conference Registration and Morning Coffee**

### Fighting Cancer

**9:00 Chairperson's Opening Remarks**
*Stefan Schmidt, Ph.D., Vice President, DSP, Rentschler Biotechnology*

**» KEYNOTE PRESENTATION**

**9:10 Recombinant Immunotoxins as New Approaches to Cancer Treatment**
*Ira H. Pastan, M.D., Head, Molecular Biology, NCI, NIH*

**9:50 Antibody-Interferon Fusion Protein for the Treatment of Malignancy**
*Sherie Morrison, Ph.D., Professor, Microbiology Immunology & Molecular Genetics, University of California, Los Angeles*

**10:20 Coffee Break**

### Conquering Disease

**» 10:45 FEATURED PRESENTATION:**

**Cytokine Traps: From Engineering Concept to Clinical Development**
*Aris N. Economides, Ph.D., Senior Director, Genome Engineering Technologies Group & Skeletal Diseases TFA Group, Regeneron Pharmaceuticals, Inc.*

**11:15 Ultra-High Affinity Engineered Protein Therapeutics for Treating Metastatic Disease**
*Jennifer Cochran, Ph.D., Associate Professor, Bioengineering & Chemical Engineering, Stanford University*

**11:45 Re-Engineering Recombinant Protein Therapeutics for Penetration of the Blood-Brain Barrier Via Transport on the Human Insulin Receptor**
*Ruben Boado, Ph.D., President, ArmaGen Technologies, Inc.*

**12:15 pm Extending Serum Half-Life of Albumin by Engineering FcRn Binding**
*Jason Cameron, Science Manager, Pharma R&D, Novozymes Biopharma Ltd.*

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

### Overcoming Engineering Challenges

**2:00 Chairperson's Remarks**
*Xiaotian Zhong, Ph.D., Principal Scientist & Lab Head, GBT, Pfizer Global BioTherapeutic R&D*

**2:05 ImmTACs – Novel Bi-Functional Monoclonal T Cell Receptor Fusions**
*Annelise Vuidepot, Ph.D., Head, Protein Engineering & Biochemistry, Immunocore, Ltd.*

**2:35 Targeting Intracellular Protein-Protein Interactions with Engineered Cyclotides**
*Julio A. Camarero, Ph.D., Associate Professor, Pharmacology and Pharmaceutical Sciences, University of Southern California*

**3:05 i-Bodies: Single Domain Human Scaffolds as Novel Therapeutics**
*Mick Foley, Ph.D., CSO, Biochemistry, AdAlta*

**3:35 Extended Q&A**

**3:50 Refreshment Break**

### Enhancing Properties

**4:15 Albumin Fusion Technology: A Highly Efficient Method to Extend the Half-Life of Complex Proteins**
*Thomas Weimer, Ph.D., Director, Recombinant Technology, CSL Behring GmbH*

**4:45 XTEN: A Protein-Based Polymer for Targeted Drug Delivery**
*Volker Schellenberger, Ph.D., CEO and President, Amunix*

**5:15 Engineered Affibody Molecules in Multiple Formats for Targeted Therapy and Diagnosis**
*Joachim Feldwisch, Ph.D., Director, Preclinical Development, Affibody AB*

**5:45-7:00 Welcome Reception in the Exhibit Hall with Poster Viewing**

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## TUESDAY, JANUARY 14

**7:15 am Conference Registration**

**7:30 Breakfast Presentation** *(Sponsorship Opportunity Available)* **or Morning Coffee**

### Overcoming Production Challenges

**8:30 Chairperson's Remarks**
*Jennifer Cochran, Ph.D., Associate Professor, Bioengineering & Chemical Engineering, Stanford University*

**8:35 Structural Variation among Antibody Fc Fusion Proteins for Human Therapy**
*Steven Chamow, Ph.D., Principal Consultant, Chamow & Associates, Inc.*

**9:05 Microalgae as a Production Platform for Recombinant Oral Vaccines**
*Elizabeth A. Specht, Ph.D., Scientist, Biological Sciences, University of California, San Diego*

**9:35 Sponsored Presentation** *(Opportunity Available)*

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

**10:50 Functional Production of a Peptide-Antibody Bispecific Genetic Fusion and Biological Influences of Therapeutic Protein Modifications throughout Trafficking**
*Xiaotian Zhong, Ph.D., Principal Scientist & Lab Head, GBT, Pfizer Global BioTherapeutic R&D*

**11:20 Solving Purification and Production Issues of Therapeutic usion Proteins**
*Stefan Schmidt, Ph.D., Vice President, DSP, Rentschler Biotechnology*

**11:50 Developability: Reducing the Risk of Failure of Biotherapeutics**
*Georg Blaser, Ph.D. Group Leader, Applied Protein Services, Lonza Biologics*

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**12:20 pm Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

**2:00 BuzZ Session A (Please visit our website for topics)**

**3:00 Refreshment Break in the Exhibit Hall with Poster Awards**

**3:45 BuzZ Session B (Please visit our website for topics)**

**4:45 Close of Conference**

**4:30-5:00 Short Course Registration**

**5:00-8:00 Dinner Short Courses (SC8-SC14)** *See page 4 for details*

INAUGURAL | JANUARY 15-16

# Antibody-Drug Conjugates

Engineering Targeted Therapeutics

## TUESDAY, JANUARY 14

**1:30-2:00 pm Conference Registration**

**2:00 BuzZ Session A (Please visit our website for topics)**

**3:00 Refreshment Break in the Exhibit Hall with Poster Awards**

**3:45 BuzZ Session B (Please visit our website for topics)**

**4:30-5:00 Short Course Registration**

**5:00-8:00 Dinner Short Courses (SC8-SC14)** *See page 4 for details*

## WEDNESDAY, JANUARY 15

**7:30 am Conference Registration**

**8:00 Morning Coffee**

### Safety and Design

**8:15 Chairperson's Opening Remarks**
*Jean E. Lachowicz, Ph.D., CSO, Angiochem*

**» KEYNOTE PRESENTATION**

**8:20 Antibody-Drug Conjugates: Another View of the Therapeutic Window**
*Robert S. Kahn, M.D., CPI, Safety Science Leader, Early Clinical Development, Global Safety Risk Management, Genentech, Inc.*

**» FEATURED PRESENTATION**

**9:00 Antibody-Drug Conjugate Design and Optimization**
*Lioudmila Tchistiakova, Ph.D., Senior Director, Global Biotherapeutic Technologies, Pfizer BioTx*

**9:30 The Role of Analytics in the Safety and Design of Antibody Drug Conjugates**
*Samadhi Vitharana, Ph.D., Senior Scientist, Core Sciences & Technology, Takeda*

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

### Conjugation

**10:45 Location Matters: Site of Conjugation Modulates Stability and Pharmacokinetics of Antibody Drug Conjugates**
*Arvind Rajpal, Ph.D., Vice President, Protein Engineering, Rinat Pfizer*

**11:15 Site-Specific Antibody Conjugates Created with an Expanded Genetic Code**
*Olivier Laurent, Ph.D., Vice President, CMC, Ambrx, Inc.*

**11:45 A Universal Chemically Driven Approach for Constructing Homogeneous ADCs**
*David Y. Jackson, Ph.D., Principal Scientist, ADC Discovery, Igenica, Inc.*

**12:15 pm Optimized Solutions for Better ADC Design Through SMARTag™ Technology**
*Greg Bleck, Ph.D., R&D Platform Director, Biologics, Catalent Pharma Solutions*

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

### Creating Next-Generation ADCs

**2:00 Chairperson's Remarks**
*Robert S. Kahn, M.D., CPI, Safety Science Leader, Early Clinical Development, Global Safety Risk Management, Genentech, Inc.*

**2:05 Creating Next-Generation ADCs: Enabling Higher Capacity for Payloads and Stabilization of Interchain Cysteines by Fleximer-Based Antibody Drug Conjugates**
*Peter Park, Ph.D., Vice President, Biology, Mersana Therapeutics*

**2:35 Producing Homogeneous ADCs with Combination Warheads**
*Aaron K. Sato, Ph.D, Vice President, Research, Sutro Biopharma*

**3:05 Interactive Panel Discussion: Promise and Challenges for Creating Next-Generation ADCs**
*Moderator: Robert S. Kahn, M.D., CPI, Safety Science Leader, Early Clinical Development, Global Safety Risk Management, Genentech, Inc.*
*Panelists: Lioudmila Tchistiakova, Ph.D., Senior Director, Global Biotherapeutic Technologies, Pfizer BioTx*
*Peter Park, Ph.D., Vice President, Biology, Mersana Therapeutics*
*Aaron K. Sato, Ph.D, Vice President, Research, Sutro Biopharma*

**3:50 Refreshment Break**

**4:15 The Probody Platform Enables Tumor-Specific Targeting of Widely Expressed Antigens by Probody Drug Conjugates (PDC)**
*James W. West, Ph.D., Director, Research, CytomX Therapeutics, Inc.*

**4:45 A Peptide-Antibody-Drug Conjugate for Brain-Penetrant Targeted Cytotoxicity**
*Jean E. Lachowicz, Ph.D., CSO, Angiochem*

**5:15-6:30 Reception in the Exhibit Hall with Poster Viewing**

## THURSDAY, JANUARY 16

**7:15 am Conference Registration**

**7:30 Breakfast Presentation** *(Sponsorship Opportunity Available)* **or Morning Coffee**

### ADCs to Fight Cancer

**8:30 Chairperson's Remarks**
*Alan C. Rigby, Ph.D., Vice President Research, Computational Discovery and Chemistry, ImClone Systems, A wholly-owned subsidiary of Eli Lilly and Company*

**8:35 Expanding the Reach of ADC Therapeutics: Advances in Conjugate Design**
*John M. Lambert, CSO & Executive Vice President, ImmunoGen, Inc.*

**9:05 Lessons for and from the Clinic in Prostate Cancer**
*Hagop Youssoufian, M.S.c., M.D., Executive Vice President, Research & Development, Progenics Pharmaceuticals, Inc.*

**9:35 Sponsored Presentation** *(Opportunity Available)*

**9:50 Coffee Break in the Exhibit Hall with Poster Awards**

**10:50 Antibody Formulated Drug Conjugates (AfDC) as Alternatives for Targeted Drug Delivery**
*Gunnar Kaufmann, Ph.D., Senior Director, R&D, Sorrento Therapeutics, Inc.*

**11:20 Development of AGS15E an ADC for the Treatment of Bladder Cancer: Preclinical Modeling and Method Development to Address Challenging mAbs**
*Kendall Morrison, Ph.D., Director, Protein Technologies, Agensys, Inc.*

**11:50 Producing Better Antibody-Drug Conjugates (ADCs) Using ThioBridge™ Conjugation**
*Antony Godwin, Ph.D., Vice President, Chemistry, PolyTherics Ltd*

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**12:20 pm Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

**1:45 Close of Conference**

THIRD ANNUAL | JANUARY 16-17

# Bispecific Antibody Therapeutics

Engineering Multispecificity

## THURSDAY, JANUARY 16

**1:00-1:45 pm Conference Registration**

### New Approaches for Creating Efficacious Bispecifics

**2:00 Chairperson's Opening Remarks**
*Michael J. Feldhaus, Ph.D., Co-Founder and CEO, Arus Biologics*

**» KEYNOTE PRESENTATION**

**2:05 Teaching Antibodies New Tricks: From Simulation to Clinical Benefits of Bispecific Antibodies**
*Ulrik Nielsen, Ph.D., CSO, Merrimack Pharmaceuticals*

**2:45 Safety and Efficacy Considerations in Designing Bispecific Therapeutics**
*Jijie Gu, Ph.D., Senior Principal Research Scientist, Global Biologics, AbbVie Pharmaceuticals*

**3:15 Bispecific Antibodies as a New Weapon in the Fight Against Antibiotic-Resistant Bacterial Pathogens**
*G. Jonah Rainey, Ph.D., Scientist II, ADPE/Research, MedImmune, LLC*

**3:45 Sponsored Presentation** *(Opportunity Available)*

**4:00 Refreshment Break in the Exhibit Hall with Poster Viewing**

**4:45 A Novel Modular Antibody Technology for Generating Bispecific Antibodies**
*Mihriban Tuna, Ph.D., Vice President, Discovery, F-star*

**5:15 Targeting Cancer Stem Cells with a Multispecific Antibody**
*Christopher L. Reyes, Vice President, Research and Development Biologics, Bionomics*

**5:45 Close of Day**

## FRIDAY, JANUARY 17

**7:15 am Conference Registration**

**7:30 Breakfast Presentation** *(Sponsorship Opportunity Available)* **or Morning Coffee**

### Fighting Cancer with Bispecifics

**8:30 Chairperson's Remarks**
*G. Jonah Rainey, Ph.D., Senior Scientist, ADPE/Research, MedImmune, LLC*

**8:35 Novel Agonistic Bispecific Tetravalent DR5 Antibodies for Tumor Targeted Induction of Apoptosis with Superior *in vivo* Efficacy**
*Peter Brünker, Ph.D., Head, Large Molecule Research, Pharma Research and Early Development (pRED), Roche Glycart AG*

**9:05 Targeting Notch/Delta-Like Ligand 4 (DLL4) and Vascular Endothelial Growth Factor (VEGF) Pathways by an Anti-DLL4/Anti-VEGF Bispecific Monoclonal Antibody Inhibits Tumor Growth and Reduces Cancer Stem Cell Frequency in Solid Tumors**
*Wan-Ching Yen, Ph.D., Senior Scientist II, Cancer Biology, OncoMed Pharmaceuticals, Inc.*

**9:35 Targeting of HER2 Receptor with Bispecific DARPin Agents**
*Martin Schwill, Ph.D., Scientist, Biochemistry, University of Zurich*

**10:05 Selected Poster Presentation: Selective Inhibition of CD47 in Cancer Cells by Fully Human Bispecific Antibodies**
*François Rousseau, Ph.D., Head, Antibody Engineering & Research, NovImmune SA*

**10:20 Coffee Break in the Exhibit Hall with Poster Awards**

### Next-Generation Engineering

**11:15 An Efficient Route to Generate Bispecific Antibodies with Natural Architecture from Distinct Half-Antibodies**
*Christoph Spiess, Ph.D., Scientist, Antibody Engineering, Genentech, Inc.*

**11:45 The Duobody Platform: Efficient Generation of Stable Bispecific Antibodies by Controlled Fab-Arm Exchange**
*Paul Parren, Ph.D., Senior Vice President and Scientific Director, Genmab*

**12:15 pm CrossMAb Ang2-VEGF: From Idea to Technical Development**
*Jörg T. Regula, Ph.D., Head, Protein Analytics, Pharma Research and Early Development (pRED), Roche Diagnostics*

**12:45 Binning Strategies for Characterization of a Large Panel of Fully Human Therapeutic Monoclonal Antibodies**
*Vishal Kamat, Ph.D., Scientist, Biomolecular HTS Center, Therapeutic Proteins, Regeneron Pharmaceuticals*

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**1:15 Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

### Enhancing Properties

**2:00 Chairperson's Remarks**
*Christopher L. Reyes, Vice President, Research and Development Biologics, Bionomics*

**2:05 Human Bispecific IgG Antibodies with a Common Light Chain: Combining Superior Functionality and Developmental Reliability**
*John de Kruif, Ph.D., CSO, Merus Biopharmaceuticals*

**2:35 Stable Variable Domains as Building Blocks for the Engineering of Bispecific Antibody Fragments with Unique Characteristics**
*David Urech, Ph.D., CSO and Co-CEO, Numab AG*

**3:05 Unlocking New Biology through Flexible Architecture**
*Wibke Lembke, Ph.D., Scientist, Covagen AG*

**3:35 Close of Conference**

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BuzZ sessions

PepTalk BuzZ Sessions

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SIXTH ANNUAL | JANUARY 13-14

# Optimizing Biologics Formulation Development

Automation, Emerging Analytical Methods and New Product Formats

## SUNDAY, JANUARY 12

**4:00-5:00 pm Short Course Registration**

**5:00-8:00 Dinner Short Courses (SC1-SC7)** *See page 4 for details*

**4:00-8:00 Main Conference Registration**

## MONDAY, JANUARY 13

**7:30 am Conference Registration and Morning Coffee**

### Predictive Analytical Studies

**9:00 Chairperson's Opening Remarks**
*Steven LaBrenz, Ph.D., Scientific Director, Drug Product Development, Janssen R&D*

**» KEYNOTE PRESENTATION**

**9:10 Major Trends and Challenges in Biotherapeutic Product Development**
*Hanns-Christian Mahler, Ph.D., Head Pharmaceutical Development & Supplies, Biologics EU, F. Hoffmann-La Roche*

**9:50 High-Throughput Biophysical Analysis of IgG1 mAb Stability and Preliminary Correlations with Local Flexibility as Measured by H/D Exchange Mass Spectrometry**
*David Volkin, Ph.D., Takeru and Aya Higuchi Distinguished Professor, The University of Kansas*

**10:20 Coffee Break**

**10:45 Correlation of Predictive Analytical Studies with Actual Results**
*Vladimir Razinkov, Ph.D., Principal Scientist, Amgen*

**11:15 Predictive Analytical Studies to Support the Development of High Concentration Protein Therapeutics**
*Mark Brader, Ph.D., Principal Scientist, Biogen Idec*

**11:45 Formation and Characterization of Glycation on Recombinant Monoclonal Antibodies (MAbs)**
*Hong Liu, Ph.D., Senior Research Associate, Early Stage Pharmaceutical Development, Genentech*

**12:15 pm Panel Discussion with Session Speakers**

**12:45 Highly-Automated Procedures for the Assessment of Protein Formulations**
*Russell G. Burge, Ph.D., Application Scientist, Freeslate, Inc.*

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### Automation and Data Management

**2:00 Chairperson's Remarks**
*Murali Bilikallahalli, Ph.D., Associate Director, Formulation Sciences, Proteins, Vaccines & Oligos, MedImmune*

**2:05 Use of Automation and High-Throughput Analysis in Formulation Development**
*Steven LaBrenz, Ph.D., Scientific Director, Drug Product Development, Janssen R&D*

**2:35 Evaluation of Prote*in Silico*ne Oil Compatibility in Pre-Filled Glass Syringes**
*Shujun Bai, Ph.D., Scientist, Protein Pharmaceutical Sciences, Biogen Idec*

**3:05 Automation and Data Management in Early Vaccine Formulation Development**
*Nicolas Moniotte, Ph.D., Technology Development Leader, R&D Formulation Development, GlaxoSmithKline Vaccines*

**3:35 Selected Oral Poster Presentation: Development of a Lyophilized Nanoemulsion Adjuvanted Vaccine against Tuberculosis**
*Ryan Kramer, Ph.D., Manager, Characterization and Production Development, Infectious Disease Research Institute*

**3:50 Refreshment Break**

### Measuring and Controlling in-Use Stability

**4:15 Designing In-Use Stability Studies with Customer Focus**
*Jason K. Cheung, Ph.D., Principal Scientist, Sterile Product Development, Merck*

**4:45 In-Use Stability Challenges for Protein Therapeutics**
*Meera Agarkhed, Principal Associate, Formulation Development, ImClone Systems, a Wholly-Owned Subsidiary of Eli Lilly & Co.*

**5:15 Challenges in Formulation of High Concentration Monoclonal Antibody Formulations: Effect and Mitigation of iso-Asp Formation**
*Henrik Rajesh Kumar Parshad, Principal Scientist, Novo Nordisk A/S*

**5:45-7:00 Welcome Reception in the Exhibit Hall with Poster Viewing**

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## TUESDAY, JANUARY 14

**7:15 am Conference Registration**

**7:30 Breakfast Presentation** *(Sponsorship Opportunity Available)* **or Morning Coffee**

### Antibody-Drug Conjugates and Novel Product Formats

**8:30 Chairperson's Remarks**
*Mark Brader, Ph.D., Principal Scientist, Biogen Idec*

**8:35 Modulating Molecular Properties of IgG1 through Fc Engineering**
*Murali Bilikallahalli, Ph.D., Associate Director, Formulation Sciences, Proteins, Vaccines & Oligos, MedImmune*

**9:05 Challenges with Formulation Development of ADCs**
*Andrea Ji, Ph.D., Senior Scientist, Late Stage Pharmaceutical Development, Genentech, Inc.*

**9:35 Selected Oral Poster Presentation: Formulation Development and Stability Challenges of Venezuelan, Eastern and Western Equine Encephalitus VirusVirus-Like Particles**
*Lisa A. Kueltzo, Ph.D., Formulation Group Lead, Vaccine Production Program, National Institutes for Allergy and Infectious Disease, NIH*

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

**10:50 Challenges in the Formulation Development for an Antibody-Drug Conjugate**
*Jianxin Guo, Ph.D., Principal Scientist, Pharmaceutical Sciences, Pfizer*

**11:20 Formulation Implications for Antibody-Drug Conjugates**
*Juan Davagnino, Ph.D., Senior Director, KBI Biopharma*

**11:50 In Sub-Visible Particle Characterization – Image Is Everything**
*Angelica Olcott, Ph.D., MFI Product Manager, ProteinSimple*

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**12:20 pm Preventing Aggregation of Therapeutic Peptides**
*Jens Thostrup Bukrinski, Ph.D., Senior Scientist, Pharma R&D, Novozymes A/S*

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**2:00 BuzZ Session A (Please visit our website for topics)**

**3:00 Refreshment Break in the Exhibit Hall with Poster Awards**

**3:45 BuzZ Session B (Please visit our website for topics)**

**4:45 Close of Conference**

**4:30-5:00 Short Course Registration**

**5:00-8:00 Dinner Short Courses (SC8-SC14)** *See page 4 for details*

SEVENTH ANNUAL | JANUARY 15-16

# Lyophilization and Emerging Drying Technologies

Formulation Development, Process Optimization, Validation and Regulatory Compliance

## TUESDAY, JANUARY 14

**1:30-2:00 pm Conference Registration**

**2:00 BuzZ Session A (Please visit our website for topics)**
**3:00 Refreshment Break in the Exhibit Hall with Poster Awards**
**3:45 BuzZ Session B (Please visit our website for topics)**

**4:30-5:00 Short Course Registration**
**5:00-8:00 Dinner Short Courses (SC8-SC14)** *See page 4 for details*

## WEDNESDAY, JANUARY 15

**7:30 am Conference Registration**

**8:00 Morning Coffee**

### Regulatory Guidance and Commercial Considerations

**8:15 Chairperson's Opening Remarks**
*David Cipolla, Ph.D., Senior Director, Pharmaceutical Sciences, Aradigm Corp.*
*Co-Chair: Robin Bogner, Ph.D., Associate Professor, School of Pharmacy, University of Connecticut*

**» KEYNOTE PRESENTATION**

**8:20 Stabilization of Proteins by Freeze Drying: New Guidelines, or "Formulation and Process Heresy"**
*Michael Pikal, Ph.D., Pfizer Distinguished Endowed Chair in Pharmaceutical Technology & Professor of Pharmaceutics, University of Connecticut*

**9:00 FDA Regulatory Requirements and Guidance for the Development and Marketing of Prefilled Syringes and Advanced Drug Delivery Devices**
*Michael Gross, Ph.D., Owner and Principal Consultant, Chimera Consulting North America*

**» FEATURED PRESENTATION**

**9:30 Commercial Considerations that Drive Protein Device Combinations Strategies**
*Sesha Neervannan, Ph.D., Vice President, Pharmaceutical Development, Allergan, Inc.*

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

### Lyophilized Formulation Development and Protein Stability

**10:45 Role of Water in Stability of Freeze-Dried Proteins: Practical Aspects and Mechanisms**
*Evgenyi Shalaev, Ph.D., FAAPS, Research Investigator, Allergan, Inc.*

**11:15 The Impact of Excipient State on the Structure and Stability of Lyophilized Biopharmaceuticals**
*Sean Cullen, Development Scientist, Technical Development, Genzyme Ireland Ltd in collaboration with University College Cork*

**11:45 Variation of Protein Stability with Ice Nucleation Temperature**
*Vamsi Mudhivarthi, Ph.D., Postdoctoral Fellow, Pharmaceutical Sciences, University of Connecticut*

**12:15 pm Effect of Nucleation Temperature on Protein Folding and Presence of Sub-Visible Particles**
*Sponsored by* SP SCIENTIFIC
*Mark Shon, MBA, Vice President, Technology Development, Technology Marketing, SP Scientific*
*Jeff Schwegman, Ph.D., Founder and CEO, AB Biotechnologies, Inc.*

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

### Innovation in Emerging Drying Technologies

**2:00 Chairperson's Remarks**
*Satoshi Ohtake, Ph.D., Senior Principal Scientist, Pharmaceutical R&D, BioTherapeutics Pharmaceutical Sciences, Pfizer, Inc.*

**2:05 Current Status of Emerging Drying Technologies**
*Satoshi Ohtake, Ph.D., Senior Principal Scientist, Pharmaceutical R&D, BioTherapeutics Pharmaceutical Sciences, Pfizer, Inc.*

**2:35 Development of a Room Temperature Stable Flu Vaccine Formulation Using Spray Drying**
*Sponsored by* BEND RESEARCH
*Jeffrey Breit, Ph.D., Director, Pharmaceutical, Bend Research*

### Modeling in Lyophilization Process Development

**3:05 Toward System-Level Modeling and Control of Freeze-Drying Process Dynamics**
*Arnab Ganguly, Ph.D. Candidate, School of Aeronautics & Astronautics, Purdue University*

**3:35 LyoPAT - True PAT for Freezing and Primary Drying**
*Sponsored by* MILLROCK TECHNOLOGY
*T.N. Thompson, President, Millrock Technology, Inc.*

**3:50 Refreshment Break**

**4:15 A Simplified Experimental and FEM Approach for Lyophilization Scale-Up**
*Vikram Sadineni, Ph.D., Senior Research Investigator, Drug Product Science and Technology, Bristol-Myers Squibb Co.*

**4:45 Mathematical Modeling of Lyophilization Process – How Can It Help Robust Process Development while Reducing Development Timelines?**
*Venkat R. Koganti, Ph.D., MBA, Associate Director, Formulation & Process Development, Celsion Corp.*

**5:15-6:30 Reception in the Exhibit Hall with Poster Viewing**

## THURSDAY, JANUARY 16

**7:15 am Conference Registration**

**7:30 Breakfast Presentation** *(Sponsorship Opportunity Available)* **or Morning Coffee**

### QbD in Lyophilization Process Development and Scale-Up

**8:30 Chairperson's Remarks**
*Jeffrey Breit, Ph.D., Director, Pharmaceutical, Bend Research*

**» 8:35 FEATURED PRESENTATION**

**QbD in Freeze Drying Process Development: Construction of the Primary Drying Design Space**
*Steven L. Nail, Ph.D., Senior Baxter Research Scientist, Pharmaceutical Research & Development, Baxter Healthcare Corp.*

**9:05 The Effect of Natural Variation on Freeze-Drying Design Space: Determining the Variation in Heat Transfer and Ice Nucleation Temperature on the Distribution of Product Temperatures and Drying Times within a Batch**
*Robin Bogner, Ph.D., Associate Professor, School of Pharmacy, University of Connecticut*

**9:35 Selected Oral Poster Presentation: Evaluation of Drying Stabilization on Attenuated Enveloped Viral Vaccine Candidate**
*Lillian Li, Ph.D., Scientist, Formulation and Stability Platform, Bio-Process R&D, Sanofi Pasteur Canada*

**9:50 Coffee Break in the Exhibit Hall with Poster Awards**

### Reconstitution of Lyophilized Proteins: Case Studies

**10:50 Insights into the Reconstitution Behavior of Highly Concentrated Lyophilized Proteins**
*Bakul Bhatnagar, Ph.D., Principal Scientist, Formulation & Process Development, Pfizer, Inc.*

**11:20 Mitigating the Challenge of Slow Reconstitution of High Concentration Protein Formulations**
*Wenjin Cao, Ph.D., Senior Scientist, Amgen, Inc.*

**11:50 Sponsored Presentation** *(Opportunity Available)*

**12:20 pm Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

**1:45 Close of Conference**

FIFTH ANNUAL | JANUARY 16-17

# Protein Aggregation and Emerging Analytical Tools

Mechanistic, Predictive, Screening and Formulation Challenges

## THURSDAY, JANUARY 16

**1:00-1:45 pm Conference Registration**

### Mechanism of Protein Aggregation

**2:00 Chairperson's Opening Remarks**
*Norman Garceau, Ph.D, CSO, Blue Sky BioServices, Inc*

**» KEYNOTE PRESENTATION**

**2:05 Mechanisms of Protein Aggregation**
*Thomas Laue, Ph.D., Professor, Biochemistry and Molecular Biology; Director, Biomolecular Interaction Technologies Center (BITC), University of New Hampshire*

**2:45 The Effect of Formulation Factors on Opalescence in Protein Solutions**
*Ashlesha S. Raut, Ph.D. Candidate, Department of Pharmaceutical Sciences, University of Connecticut*

**3:15 Selected Oral Poster Presentation**

**3:30 The Light Scattering Toolbox for Predicting and Characterizing Aggregation**
*Sponsored by* WYATT TECHNOLOGY
*Daniel Some, Ph.D., Principal Scientist, Wyatt Technology Corp.*

**4:00 Refreshment Break in the Exhibit Hall with Poster Viewing**

### Aggregate Characterization and Protein Stability

**4:45 Hydrogen-Deuterium Exchange Mass Spectrometry for Measurements of Protein-Protein Interactions**
*Jeffrey W. Hudgens, Ph.D., Research Chemist, Institute for Bioscience and Biotechnology Research, BioProcess Measurements Group, Biomolecular Measurement Division, NIST*

**5:15 Analytical Challenges in Detecting Protein Aggregates**
*Elizabeth M. Topp, Ph.D., Dane O. Kildsig Chair and Head, Department of Industrial and Physical Pharmacy, Purdue University*

**5:45 Close of Day**

## FRIDAY, JANUARY 17

**7:15 am Conference Registration**

**7:30 Breakfast Presentation** *(Sponsorship Opportunity Available)* **or Morning Coffee**

### Predictive Tools and High-Throughput Screening

**8:30 Chairperson's Remarks**
*Murali Bilikallahalli, Ph.D., Associate Director, Formulation Sciences, Proteins, Vaccines & Oligos, MedImmune*

**» FEATURED PRESENTATION**

**8:35 Aggregation of Isolated Antibody Domains and Drug Conjugates**
*Dimiter S. Dimitrov, Ph.D., Senior Investigator, Protein Interaction Group, FNLCR, NCI, NIH*

**9:05 Predictability and Implementation of HTS Technologies during Early Formulation Development**
*Hardeep Samra, Ph.D., Scientist II, Formulation Sciences Department, MedImmune, Inc.*

**9:35 High-Throughput Detection of Antibody Self-Interaction by Biolayer Interferometry**
*Yingda Xu, Ph.D., Group Leader, Protein Analytics, Adimab*

**10:05 Selected Oral Poster Presentation: Peptide Aggregation Measurement and Prevention**
*Jeffrey Lampert, Research Scientist, Technical Service/Manufacturing Science, Eli Lilly and Company*

**10:20 Coffee Break in the Exhibit Hall with Poster Awards**

### Analytical Methods for Assessment of Protein Aggregation

**11:15 Applications of Spin Labeling to Aggregated Proteins: A Sensitive Diagnostic Technique for Protein Structure, Folding and Misfolding**
*Lawrence Berliner, Professor of Chemistry and Biochemistry, Chemistry and Biochemistry, University of Denver; Emeritus, Ohio State University*

**11:45 Detecting the Aggregation Propensity of Proteins by Bis-ANS: Binding Kinetics and Thermodynamics**
*Murali Bilikallahalli, Ph.D., Associate Director, Formulation Sciences, Proteins, Vaccines & Oligos, MedImmune*

**» FEATURED PRESENTATION**

**12:15 pm Fluorogenic Tagging to Rapidly Screen for Oxidized and Covalently Aggregated Proteins**
*Christian Schöneich, Ph.D., Professor and Chair, Pharmaceutical Chemistry, University of Kansas*

**12:45 Mid-Infrared Method for Protein Quantitation, Antibodies Aggregation Monitoring and Lipid Content Analysis of Biological Samples**
*Sponsored by* EMD MILLIPORE
*Ivona Strug, Ph.D., Senior Biochemical Scientist, EMD Millipore*

**1:15 Luncheon Presentation: Counting and Sizing Protein Aggregates Down to 0.15 um in sub-mL Samples Using New Focused Beam SPOS Technology**
*Sponsored by* PSS
*David F. Nicoli, Ph.D., Vice President, R&D, Particle Sizing Systems, LLC*

### Ensuring Safety and Efficacy of Biologics

**2:00 Chairperson's Remarks**
*Christian Schöneich, Ph.D., Professor and Chair, Pharmaceutical Chemistry, University of Kansas*

**2:05 Structure-based Predictive Modeling of Methionine Oxidation Stability in Proteins**
*Vishal C. Nashine, Ph.D., Senior Research Investigator, Drug Product Science & Technology, Bristol-Myers Squibb Co*

**2:35 Correlating Monoclonal Antibody Stability with Local Dynamics Using H/D Exchange Mass Spectrometry**
*Prakash Manikwar, Ph.D., Scientist I, Formulation Sciences, MedImmune, Inc.*

**3:05 Overview of Current Glass Delamination Issues and Implications**
*Edward J. Smith, Ph.D., Principal, Packaging Science Resources, LLC*

**3:15 Selected Oral Poster Presentation: Investigating Bioprocessing Variables that Influence Antibody Stability During Therapeutic IgG Production**
*Stephanie A. Davies, Postgraduate Research Student, Centre for Molecular Processing and School of Biosciences, University of Kent*

**3:35 Adapting to Biology: Maintaining Container Closure System Compatibility with the Biopharmaceutical Revolution**
*Dominick DeGrazio, Associate Scientist, Analytical Laboratory, West Pharmaceutical Services*

**4:05 Close of Conference**

FOURTH ANNUAL | JANUARY 15-16

# Protein-Device Combinations

Integrating Protein Formulations with Parenteral and Alternative Administration Devices

## TUESDAY, JANUARY 14

**1:30-2:00 pm Conference Registration**

**2:00 BuzZ Session A (Please visit our website for topics)**

**3:00 Refreshment Break in the Exhibit Hall with Poster Awards**

**3:45 BuzZ Session B (Please visit our website for topics)**

**4:30-5:00 Short Course Registration**

**5:00-8:00 Dinner Short Courses (SC8-SC14)** *See page 4 for details*

## WEDNESDAY, JANUARY 15

**7:30 am Conference Registration**

**8:00 Morning Coffee**

### Regulatory Guidance and Commercial Considerations

**8:15 Chairperson's Opening Remarks**
*David Cipolla, Ph.D., Senior Director, Pharmaceutical Sciences, Aradigm Corp.*

*Co-Chair: Robin Bogner, Ph.D., Associate Professor, School of Pharmacy, University of Connecticut*

**» KEYNOTE PRESENTATION**

**8:20 Stabilization of Proteins by Freeze Drying: New Guidelines, or "Formulation and Process Heresy"**
*Michael Pikal, Ph.D., Pfizer Distinguished Endowed Chair in Pharmaceutical Technology & Professor of Pharmaceutics, University of Connecticut*

**9:00 FDA Regulatory Requirements and Guidance for the Development and Marketing of Prefilled Syringes and Advanced Drug Delivery Devices**
*Michael Gross, Ph.D., Owner and Principal Consultant, Chimera Consulting North America*

**» FEATURED PRESENTATION**

**9:30 Commercial Considerations that Drive Protein Device Combinations Strategies**
*Sesha Neervannan, Ph.D., Vice President, Pharmaceutical Development, Allergan, Inc.*

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

**10:45 Rethinking Systemic Delivery Approaches for the CNS**
*Pankaj Karande, Ph.D., Assistant Professor, Department of Chemical & Biological Engineering, Center for Biotechnology and Interdisciplinary Studies, Rensselaer Polytechnic Institute*

### Needle-Free Injections

**11:15 Needle-Free Injection of Viscous Biologic Formulations**
*Brooks Boyd, Ph.D., Senior Director, Pharmaceutical Development, Zogenix, Inc.*
*Co-Presenter: Amy M. Heintz, Ph.D., Senior Research Scientist, Battelle*

**11:45 A New Technology for High Volume/High Viscosity Biologics**
*Michael D. Hooven, President and CEO, Enable Injections, LLC*

**12:15 pm The Importance of Considering All Aspects of an Integrated Delivery System to Help Optimize Patient Outcomes**
*Graham Reynolds, Vice President, Marketing and Innovation, West Pharmaceutical Services*

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

### Next-Gen and Alternative Delivery Technologies for Biologics

**2:00 Chairperson's Remarks**
*Pankaj Karande, Ph.D., Assistant Professor, Department of Chemical & Biological Engineering, Center for Biotechnology and Interdisciplinary Studies, Rensselaer Polytechnic Institute*

**2:05 Improving Patient Compliance through Alternative Formulation and Pulmonary Delivery Technologies**
*David Cipolla, Ph.D., Senior Director, Pharmaceutical Sciences, Aradigm Corp.*

**2:35 Oral Inhalation as a Delivery Option for Protein and Peptide Drugs**
*Kieran Curley, Ph.D., Senior Principal Scientist, Formulations Development, Mannkind Corp*

**3:05 Implantable Miniaturized Biosensors for Metabolic Monitoring**
*Diane J. Burgess, Ph.D., Board of Trustees Distinguished Professor of Pharmaceutics, Department of Pharmaceutical Sciences, University of Connecticut*

**3:35 Selected Oral Poster Presentation: Lyophilization in Plastic versus Glass Syringes and Cartridges**
*Timothy Dutill, Associate Scientist, Lyophilization Technology, Inc.*

**3:50 Refreshment Break**

**4:15 Achieving Long-Term Antibody Release from Polymer-Based Drug Delivery Systems**
*Karthik Rajagopal, Ph.D., Scientist, Drug Delivery, Genentech, Inc.*

**4:45 Extended Q&A Session**

**5:15-6:30 Reception in the Exhibit Hall with Poster Viewing**

## THURSDAY, JANUARY 16

**7:15 am Conference Registration**

**7:30 Breakfast Presentation** *(Sponsorship Opportunity Available)* **or Morning Coffee**

### Integrating Formulation and Device: Injections, Syringes and High Volume Delivery Devices

**8:30 Chairperson's Remarks**
*William J. Lambert, Ph.D., Fellow, Drug Delivery and Device Development, MedImmune, Inc.*

**» FEATURED PRESENTATION**

**8:35 High Volume Delivery: How to Keep it Circulating and Make it Bioavailable**
*Pankaj Karande, Ph.D.,Assistant Professor, Department of Chemical and Biological Engineering, Centre of Biotechnology and Interdisciplinary Studies, Rensselaer Polytechnic Institute*

**9:05 Large Volume Bolus Injectors for Subcutaneous Delivery**
*William J. Lambert, Ph.D., Fellow, Drug Delivery and Device Development, MedImmune, Inc.*

**9:35 Selected Oral Poster Presentation: Impact of Water Resorption on Manometric Product Temperature Measurement of Amorphous Solids**
*Lokesh Kumar, Post Doctoral Fellow, Department of Pharmaceutical Sciences, University of Connecticut*

**9:50 Coffee Break in the Exhibit Hall with Poster Awards**

### Reconstitution of Lyophilized Proteins: Case Studies

**10:50 Insights into the Reconstitution Behavior of Highly Concentrated Lyophilized Proteins**
*Bakul Bhatnagar, Ph.D., Principal Scientist, Formulation & Process Development, Pfizer, Inc.*

**11:20 Mitigating the Challenge of Slow Reconstitution of High Concentration Protein Formulations**
*Wenjin Cao, Ph.D., Senior Scientist, Amgen, Inc.*

**11:50 Sponsored Presentation** *(Opportunity Available)*

**12:20 pm Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

**1:45 Close of Conference**

SECOND ANNUAL | JANUARY 16-17

# Extractables and Leachables

Addressing Toxicological and Biochemical Challenges for Drug Product Integrity

## THURSDAY, JANUARY 16

**1:00-1:45 pm Conference Registration**

### Regulatory Guidance, Toxicological Considerations and Updates

**2:00 Chairperson's Opening Remarks**
*William P. Beierschmitt, Ph.D., DABT, FATS, Regulatory Strategy Lead, Worldwide Research and Development Drug Safety Research & Development, Pfizer, Inc.*

**» KEYNOTE PRESENTATIONS**

**2:05 Determining Suitability of Plastic Packaging Systems for Therapeutic Products: USP Standards**
*Desmond G. Hunt, Ph.D., Senior Scientific Liaison, Department of Standards Development, United States Pharmacopoeia*

**2:45 A Detailed Discussion of the USP Chapters Related to Extractables and Leachables, specifically <661> Plastic Packaging Systems and Their Materials of Construction and <1663> Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems**
*Dennis Jenke, Ph.D., Baxter Distinguished Scientist, Technology Resources, Baxter Healthcare Corp.*

**3:15 Assessing Material Compatibility for Use in Manufacture, Storage and Delivery of Biologics**
*Diane Paskiet, Ph.D., Director, Scientific Affairs, West Pharmaceutical Services*

**3:45 Key Considerations in Designing an Extractable and/or Leachable Study**
*Sponsored by* TOXIKON ADVANCING YOUR INNOVATION
*John Iannone, Program Manager and Technical Specialist, Toxikon Corporation*

**4:00 Refreshment Break in the Exhibit Hall with Poster Viewing**

**4:45 The Toxicological Risk Assessment of Extractables and Leachables: Practices and Procedures to Ensure Patient Safety**
*William P. Beierschmitt, Ph.D., DABT, FATS, Regulatory Strategy Lead, Worldwide Research and Development Drug Safety Research & Development, Pfizer, Inc.*

**5:15 ADME Considerations for Risk Assessment of Extractables and Leachables**
*Christopher Brynczka, Ph.D., Senior Toxicologist, Toxicology, Gradient Corp.*

**5:45 Close of Day**

## FRIDAY, JANUARY 17

**7:15 am Conference Registration**

**7:30 Breakfast Presentation** *(Sponsorship Opportunity Available)* **or Morning Coffee**

### Material Characterization and Analytical Strategy

**8:30 Chairperson's Remarks**
*Pranhitha Reddy, Director, Cell Sciences, BioProcess and Analytical Sciences, Seattle Genetics*

**8:35 Leachable and Extractable Study Design for Components Used Across Multiple Programs**
*Seamus O'Connor, Ph.D., Senior Analytical Scientist, Analytical Sciences, Industrial Operations and Product Supply, Regeneron Pharmaceuticals, Inc.*

**9:05 Risk-Based Assessment of Extractable Data and Its Application to the Evaluation of Materials Used in the Biomanufacturing**
*Ping Wang, Ph.D., MBA, Senior Manager, Pharmaceutical & Material Sciences, DPD, PDMS, Janssen Research & Development*

**9:35 Leachables from Unexpected Sources**
*Michael A. Ruberto, Ph.D., President, Material Needs Consulting, LLC*

**10:05 Selected Oral Poster Presentation: Feasibility of Using Disposable Mixing Systems for Homogenizing Biologic Drug Substance Bulk**
*Benson Gikanga, Sr. Research Associate, Pharmaceutical Processing and Technology Development, Genentech, Inc.*

**10:20 Coffee Break in the Exhibit Hall with Poster Awards**

**11:15 Analytical Testing or Low Level Leachables in Large Volume Parenteral Products: Analytical Method Development and Validation Issues for Trace Level Testing**
*Gyorgy Vas, Ph.D., Research Fellow, Intertek Pharmaceutical Services*

### Case Studies: Impact of E&L from Single-Use Technologies

**» FEATURED PRESENTATION**

**11:45 Extractables from Single-Use Bioreactors and Impact on Cell Culture Performance**
*Yasser Nashed-Samuel, Ph.D., Principal Scientist, Process and Product Development, Amgen, Inc.*

**12:15 pm Case Studies on the Impact of Disposables on Cell Culture Processes**
*Pranhitha Reddy, Director, Cell Sciences, BioProcess and Analytical Sciences, Seattle Genetics*

**12:45 Sponsored Presentation** *(Opportunity Available)*

**1:15 Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

### Ensuring Safety and Efficacy of Biologics

**2:00 Chairperson's Remarks**

**2:05 Structure-based Predictive Modeling of Methionine Oxidation Stability in Proteins**
*Vishal C. Nashine, Ph.D., Senior Research Investigator, Drug Product Science & Technology, Bristol-Myers Squibb Co*

**2:35 Correlating Monoclonal Antibody Stability with Local Dynamics Using H/D Exchange Mass Spectrometry**
*Prakash Manikwar, Ph.D., Scientist I, Formulation Sciences, MedImmune, Inc.*

**3:05 Overview of Current Glass Delamination Issues and Implications**
*Edward J. Smith, Ph.D., Principal, Packaging Science Resources, LLC*

**3:35 Adapting to Biology: Maintaining Container Closure System Compatibility with the Biopharmaceutical Revolution**
*Dominick DeGrazio, Associate Scientist, Analytical Laboratory, West Pharmaceutical Services*

**4:05 Close of Conference**

SIXTH ANNUAL | JANUARY 13-14

# Engineering Genes, Vectors, Constructs and Clones

Upstream Decisions Lead to Downstream Success

## SUNDAY, JANUARY 12

**4:00-5:00 pm Short Course Registration**

**5:00-8:00 Dinner Short Courses (SC1-SC7)** *See page 4 for details*

**4:00-8:00 Main Conference Registration**

## MONDAY, JANUARY 13

**7:30 am Conference Registration and Morning Coffee**

### Gene Engineering

**9:00 Chairperson's Opening Remarks**

*James L. Hartley, Ph.D., Senior Scientist, Protein Expression Laboratory, Advanced Technology Program, Frederick National Laboratory for Cancer Research*

**» KEYNOTE PRESENTATION**

**9:10 Next-Generation DNA Synthesis to Optimize Gene Expression**

*Sriram Kosuri, Ph.D., Assistant Professor, Chemistry and Biochemistry, University of California, Los Angeles*

**9:50 Tools and Processes to Design, Write and Assemble DNA Sequences**

*Sponsored by* life technologies

*James Kaysen, Ph.D., Staff Scientist, Life Technologies*

**10:20 Coffee Break**

**10:45 High-Throughput Recombinant Antibody Discovery Platform: From Antigen Production to Binder Validation**

*Marcin Paduch, Ph.D., Technical Director, Recombinant Antibody Network, Biochemistry and Molecular Biology, The University of Chicago*

**11:15 Complete Knockout of the Lactate Dehydrogenase-A Gene Is Lethal in Pyruvate Dehydrogenase Kinase 1, 2, 3 Down-Regulated CHO Cells**

*Yongping Crawford, Ph.D., Scientist, Early Stage Cell Culture, Genentech, Inc.*

**11:45 "Reverse Engineering" of Clone Cell Line Developments for Effective and Efficient Biomanufacturing**

*Wei Chen, Ph.D., Managing Director, BioPharmaneer, Inc.*

**12:15 pm Uniform GlcNAc2Man5-Decorated Proteins by *Pichia pastoris*: Achievements in High-Level Production and Characterization**

*Sponsored by* VTU technology

*Roland Weis, Ph.D., Head, Operations, VTU Technology GmbH*

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

### Libraries

**2:00 Chairperson's Remarks**

*Wei Chen, Ph.D., Managing Director, BioPhmaneer, Inc.*

**2:05 Ventures into Synonymous Codon Space**

*James L. Hartley, Ph.D., Senior Scientist, Protein Expression Laboratory, Advanced Technology Program, Frederick National Laboratory for Cancer Research*

**2:35 Bacterial Chromosomal Engineering for Optimization of Protein Expression and Function**

*Joseph Kittle, Jr., Ph.D., Assistant Professor, Chemistry and Biochemistry, Ohio University and CSO, Molecular Technologies Laboratories, LLC*

**3:05 Molecular Evolution of Human Butyrylcholinesterase**

*John Cashman, Ph.D., President and Founder, Human BioMolecular Research Institute*

**3:35 New Endotoxin-Free *E. coli* Cell Strains for Plasmid and Protein Production without Endotoxin Removal**

*Sponsored by* Lucigen Simplifying Genomics

*Curtis Knox, Vice President, Marketing & Sales, Lucigen Corp.*

**3:50 Refreshment Break**

**4:15 Screening Antibody Phage Libraries in Product Format**

*Partha Chowdhury, Ph.D., Principal Scientist, Antibody Discovery and Protein Engineering, MedImmune, Inc.*

**» FEATURED PRESENTATION**

**4:45 Genetic Engineering and Preclinical Testing of *Salmonella* Live Vaccines**

*James E. Galen, Ph.D., Professor, Medicine, Chief, Salmonella Live Vector Vaccine Section, University of Maryland School of Medicine*

**5:30 Close of Session**

**5:45-7:00 Welcome Reception in the Exhibit Hall with Poster Viewing**

*Sponsored by* proteinsimple

## TUESDAY, JANUARY 14

**7:15 am Conference Registration**

**7:30 Breakfast Presentation: Leveraging Gene Synthesis for the Systematic Optimization of Protein Production**

*Sponsored by* DNA 2.0

*Mark Welch, Ph.D., Director, Gene Design, DNA2.0, Inc.*

### Engineering Expression Systems

**8:30 Chairperson's Remarks**

*James E. Galen, Ph.D., Professor, Medicine, Chief, Salmonella Live Vector Vaccine Section, University of Maryland School of Medicine*

**8:35 Molecular Cloning, Overexpression and an Efficient One-Step Purification of αVβ5 and α5β1 Integrin**

*Lawrence J. Tartaglia, Ph.D., Research Scientist, Biochemistry and Molecular Biology, Center for Structural Biology, University of Florida*

**9:05 *Brevibacillus*, a New Tool for High-Level Intracellular Expression of Bacterial Antigens**

*Domenico Maione, Ph.D., Unit Head, Cloning and Expression, Novartis Vaccines and Diagnostics*

**9:35 Selected Oral Poster Presentation: The Photosynthetic Bacterium Rhodobacter capsulatus as an Alternative Platform Organism for the Expression of Human Membrane Proteins**

*Armagan Özgür, Research Scientist, Institute of Molecular Enzyme Technology, Forschungszentrum Jülich, Heinrich-Heine University*

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

**10:50 A New and Versatile Concept for Systematic Multi-Gene Constructs Generation**

*Wassim Abdulrahman, Ph.D., Research Scientist, Mechanisms of Cancer, Friedrich Miescher Institute for Biomedical Research and CPC Novartis*

**11:20 Data Management and Automation of Protein Production Workflows in Biologics R&D**

*Christoph Freiberg, Ph.D., Senior Scientist, Biologics Research, Bayer HealthCare*

**11:50 Sponsored Presentation** *(Opportunity Available)*

**12:20 pm Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

**2:00 BuzZ Session A (Please visit our website for topics)**

**3:00 Refreshment Break in the Exhibit Hall with Poster Awards**

**3:45 BuzZ Session B (Please visit our website for topics)**

**4:45 Close of Conference**

**4:30-5:00 Short Course Registration**

**5:00-8:00 Dinner Short Courses (SC8-SC14)** *See page 4 for details*

SIXTEENTH ANNUAL | JANUARY 15-16

# Recombinant Protein Expression and Production

Achieving Quality and Quantity

## TUESDAY, JANUARY 14 (SEE PAGE 21 FOR DETAILS)

**1:30-2:00 pm Conference Registration**

## WEDNESDAY, JANUARY 15

**7:30 am Conference Registration**

**8:00 Morning Coffee**

### Expression: Improving Yields

**8:15 Chairperson's Opening Remarks**
*Karl E. Griswold, Ph.D., Associate Professor, Thayer School of Engineering, Dartmouth College*

**» KEYNOTE PRESENTATION**

**8:20 Protein Expression Technologies: Evolution or Revolution?**
*Lorenz M. Mayr, Ph.D., Vice President, Reagents & Assay Development, AstraZeneca, Inc.*

**9:00 Novel Strategy for Production of Difficult-to-Express Proteins in *E. coli* Based on an Anchored Periplasmic Expression System**
*Ki Jun Jeong, Ph.D., Assistant Professor, Chemical and Biomolecular Engineering, KAIST*

**9:30 Production of Disulfide-Rich Peptides via Expression in the Periplasm of *Escherichia coli***
*Glenn F. King, Ph.D., Research Scientist, Institute for Molecular Bioscience, University of Queensland*

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

**10:45 A Simple PiggyBac Transposon-Based Mammalian Cell Expression System for Inducible Protein Production**
*James M. Rini, Ph.D., Professor, Molecular Genetics and Biochemistry, University of Toronto*

**11:15 High-Throughput Imaging to Increase the Assurance of Clonality during Cell Line Development**
*David Shaw, Ph.D., Scientist, Early Stage Cell Culture, Genentech, Inc.*

**11:45 Cell Line Development: Can Modifications at the Early Stages Improve Therapeutic Cell Line Selection?**
*Bernie Sweeney, Ph.D., Senior Group Leader, Mammalian Expression, UCB*

**12:15 pm Selexis SURE CHO-Mplus™ Libraries: Custom Solutions for Protein Expression Bottlenecks**
*Igor Fisch, Ph.D., CEO, Selexis SA*
Sponsored by SELEXIS

**12:45 Luncheon Presentation: Why Are You Still Doing Westerns?**
*John Proctor, Ph.D., Director, Corporate Development, ProteinSimple*
Sponsored by proteinsimple

### Purification: Improving Product Quality

**1:50 Chairperson's Remarks**
*James M. Rini, Ph.D., Professor, Molecular Genetics and Biochemistry, University of Toronto*

**1:55 Microbial Production of Folded and Fully Functional Antibacterial Enzymes**
*Karl E. Griswold, Ph.D., Associate Professor, Thayer School of Engineering, Dartmouth College*

**2:20 A Yeast-Based Platform for High-Yield, High-Quality Production and Purification of Eukaryotic Membrane Proteins**
*Per Amstrup Pedersen, Ph.D., Professor, Biology, University of Copenhagen*

**2:45 Optimizing Expression Tags and Fermentation for Production of Functional Human Integral Membrane Protein Receptor**
*Alexei Yeliseev, Ph.D., Staff Scientist, Protein Biochemistry, LMBB, National Institutes of Health*

**3:10 Reversible Labeling of Native and Fusion-Proteins**
*Michael D. Burkart, Ph.D., Professor, Chemistry and Biochemistry, University of California, San Diego*

**3:35 Discovery Protein Expression Enabled by Pƒēnex Expression Technology™**
*Russell Coleman, Senior Scientist, Pƒēnex Inc.*
Sponsored by Pfēnex Strain Engineering

**3:50 Refreshment Break**

**4:15 Unfolded Protein Response (UPR) During CHO Cell Production Product Quality**
*Zhimei Du, Ph.D., Senior Scientist, Cell Sciences & Technology, Amgen, Inc.*

**4:45 Engineering a Mammalian Cell Line Toolkit that Exhibits Multiple Productivity and Product Quality Profiles**
*Mark Tié, Associate Scientist, Cell Culture Development, Biogen Idec*

**5:15-6:30 Reception in the Exhibit Hall with Poster Viewing**

## THURSDAY, JANUARY 16

**7:15 am Conference Registration**

**7:30 Breakfast Presentation** *(Sponsorship Opportunity Available)* **or Morning Coffee**

### Production: Meeting the Demands

**9:00 Chairperson's Remarks**
*Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute*

**9:05 Process Fitting and Improvements of a Virus-Like Particle (VLP)-Based Therapeutic Vaccine Production Platform**
*Inci Ozdemir, Ph.D., Senior Scientist, Culture Process Development, Pfizer, Inc.*

**9:35 Streamlining Recombinant Protein Manufacturing with Secretion of Biologically Active Proteins from Bacteria**
*Kristin DeFife, Ph.D., Director, Biologics, Ajinomoto Althea*
Sponsored by AJINOMOTO ALTHEA

**9:50 Coffee Break in the Exhibit Hall with Poster Awards**

**10:50 Antibodies to Plant-Produced *P. falciparum* Sexual Stage Proteins Exhibit Transmission Blocking Activity**
*R. Mark Jones, Ph.D., Senior Scientist, Fraunhofer USA Center for Molecular Biotechnology*

**11:20 Production of Antibody Toxin Genetic Conjugates in Algal Chloroplasts**
*Miller Tran, Ph.D., Senior Scientist, Triton Algae Innovations*

**11:50 Sponsored Presentations** *(Opportunities Available)*

**12:20 pm Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

**1:45 Close of Conference**

INAUGURAL | JANUARY 16-17

# Transient Protein Production

From Small-Scale to Large-Scale

## THURSDAY, JANUARY 16

**1:00-1:45 pm Conference Registration**

### Cell Lines: New Developments

**2:00 Chairperson's Opening Remarks**
*Athena Wong, Ph.D., Scientist, Early Stage Cell Culture, Genentech, Inc.*

**» KEYNOTE PRESENTATION**

**2:05 Recombinant Protein Production in Transient Fashion: A Mature Technology?**
*Sabine Geisse, Ph.D., Director/NLS, Novartis Institutes for BioMedical Research*

**2:45 Application of a New Human Cell Line, F2N78, as a Host Cell for Transient Production of Biopharmaceuticals**
*Jong-Mook Kim, Ph.D., Director, Cell Science Team, R&D Division, Celltrion. Inc.*

**3:15 Use of an Anti-Apoptotic Cell Line for High-Throughput Transient Gene Expression**
*Athena Wong, Ph.D., Scientist, Early Stage Cell Culture, Genentech, Inc.*

**3:45 The Impact of Scalable Transient Gene Expression: Maximizing CHO Antibody Production to Accelerate Project Timelines** *Sponsored by* MaxCyte
*James Brady, Ph.D., Director, Technical Applications, MaxCyte, Inc.*

**4:00 Refreshment Break in the Exhibit Hall with Poster Viewing**

**4:45 Rapid Screening of Membrane Protein Expression in Transiently Transfected Insect Cells**
*Hao Chen, Ph.D., Senior Scientist, Protein Technologies, Amgen, Inc.*

**5:15 Optimized Signal Peptides for the Development of High-Expressing CHO Cell Lines**
*Lars Kober, Ph.D., Scientist, Cellca GmbH*

**5:45 Close of Day**

## FRIDAY, JANUARY 17

**7:15 am Conference Registration**

**7:30 Breakfast Presentation** *(Sponsorship Opportunity Available)* **or Morning Coffee**

### Cell Lines: Plants

**8:30 Chairperson's Remarks**
*Peter Gray, Ph.D., Director, Australian Institute for Bioengineering and Nanotechnology, University of Queensland*

**8:35 Transient Plant Production of Therapeutic Molecules to Prevent Viral Transmission and Neurotoxicity in Macaques**
*Yvonne J. Rosenberg, Ph.D., CEO, PlantVax, Inc.*

**9:05 Plant-Produced Human Recombinant Erythropoietic Growth Factors Support Erythroid Differentiation *in vitro***
*R. Mark Jones, Ph.D., Senior Scientist, Fraunhofer USA Center for Molecular Biotechnology*

**9:35 Protein Body-Inducing Fusions for High-Level Accumulation and Purification of Recombinant Proteins in Plants**
*Rima Menassa, Ph.D., Research Scientist and Adjunct Professor, Biology, Agriculture and Agri-Food Canada, Western University*

**10:05 Selected Oral Poster Presentation: Large-Scale Automation of Plasmid DNA Purification for Transient Mammalian Expression**
*Mark Nagel, Senior Research Associate, Protein Chemistry, Genentech, Inc.*

**10:20 Coffee Break in the Exhibit Hall with Poster Awards**

### Cell Lines: Stable or Transient or Both?

**11:15 Transient and Stable Expression of the Neurotensin Receptor NTS1: A Comparison of the Baculovirus-Insect Cell and the T-REx-293 Expression Systems**
*Joseph Shiloach, Ph.D., Head, Biotechnology Core Laboratory, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH*

**11:45 Productivity and Quality of Recombinant Proteins Produced by Stable CHO Cell Clones can be Predicted by Transient Expression in HEK Cells**
*Rüdiger Neef, Ph.D., Principal Scientist, USP Development, Amgen, Inc.*

**12:15 pm Expression of Monoclonal Antibody Variants in Transient and Stable Cultures, the Effects of Sequence on Stability and Expression Level**
*Susan Sharfstein, Ph.D., Associate Professor, Nanobioscience, Nanoscale Science and Engineering, University at Albany, State University of New York*

**12:45 Combine Expression-Optimized Genes with High-Density 293 Cultures to Maximize Protein Yields** *Sponsored by* life technologies
*Henry C. Chiou, Ph.D., Senior Product Manager, Life Technologies*

**1:15 Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

### Production: Milligrams to Grams of Therapeutic Proteins

**2:00 Chairperson's Remarks**
*Richard Altman, MS, Research Scientist, Alexion Pharmaceuticals*

**2:05 Production of Human Full-Length PPARγ2 in HEK293 Cells by Transient Expression**
*Jianming Liu, Ph.D., Senior Scientist, Discovery Sciences, AstraZeneca, Inc.*

**2:35 High-Throughput Mammalian Expression of Antibodies Enabling Functional Screening in Product Format**
*Robin Butler, Senior R&D Manager, Protein Sciences, Antibody Discovery and Protein Engineering, MedImmune*

**3:05 Optimising Transient Gene Expression**
*Katharine Cain, Ph.D., Principal Scientist, Protein Expression and Purification Group, UCB*

**» FEATURED PRESENTATION**

**3:35 Epi-CHO, a Novel CHO Cell Line Capable of High-Level Transient Protein Productivity**
*Peter Gray, Ph.D., Director, Australian Institute for Bioengineering and Nanotechnology, University of Queensland*

**4:05 Close of Conference**

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SIXTH ANNUAL | JANUARY 13-14

# Protein Purification and Recovery

Streamlining Processes

## SUNDAY, JANUARY 12

**4:00-5:00 pm Short Course Registration**

**5:00-8:00 Dinner Short Courses (SC1-SC7)** *See page 4 for details*

**4:00-8:00 Main Conference Registration**

## MONDAY, JANUARY 13

**7:30 am Conference Registration and Morning Coffee**

### Process Development Towards Improvement

**9:00 Chairperson's Opening Remarks**
*Jennifer Nemeth, Ph.D., Associate Scientific Director and Head, Biologics Mass Spectrometry & Allied Technologies, Janssen R&D LLC*

**» KEYNOTE PRESENTATION**

**9:10 From Protein Purification to Vaccine Development – A Challenging but Rewarding Journey**
*Yan-ping Yang, Ph.D., Director, Downstream Purification, Bioprocess Research & Development, Sanofi Pasteur*

**9:50 Insight in the Formation of DNA-Protein Precipitates During Downstream Processing and Implications for Process Development**
*André Dumetz, Ph.D., Investigator, GlaxoSmithKline*

**10:20 Coffee Break**

**10:45 Purification Strategies and Considerations in Overproduction, Isolation and Reconstitution of Labile Metalloproteins**
*Gareth Butland, Ph.D., Staff Scientist, Lawrence Berkeley National Laboratory*

**11:15 Bacterial Strains Based on the Separatome of *Escherichia coli***
*Ellen Brune, Ph.D., CSO, Boston Mountain Biotech*

**11:45 Endotoxin Removal from Proteins Expressed in *E. coli***
*Barry Holwerda, Ph.D., President, Molecular Throughput, Inc.*

**12:15 pm Addressing Purification Challenges for Recombinant Proteins Expressed in Non-Mammalian Systems** *(Subject to change)*
*Shannon Ryan, Ph.D., Process Development Scientist, EMD Millipore Corporation*

*Sponsored by* EMD MILLIPORE

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

### Continuous Processing and Technologies that Support Protein Purification

**2:00 Chairperson's Remarks**
*Ellen Brune, Ph.D., CSO, Boston Mountain Biotech*

**2:05 Downstream Processing of Biologics Using Twin-Countercurrent Chromatography**
*Thomas Müller-Späth, Ph.D., CSO, ChromaCon AG*

**2:35 IQGAP1 Protein Purification and X-Ray Crystallography**
*Vinodh Kurella, Ph.D., Research Fellow, Bioinformatics, Harvard Medical School*

**3:05 Mass Spectrometric Applications for Assessing and Characterizing Biologics for Driving Development Success**
*Jennifer Nemeth, Ph.D., Associate Scientific Director and Head, Biologics Mass Spectrometry & Allied Technologies, Janssen R&D LLC*

**3:35 Versatile Use of Mixed-Mode Sorbents for Removal of Aggregates from Monoclonal Antibodies**
*Yamuna Dasarathy, Ph.D., Director, Marketing, Pall Life Sciences*

*Sponsored by* fortéBIO A Division of Pall Life Sciences

**3:50 Refreshment Break**

### Purifying Antibodies

**4:15 Development of a Non-Protein A MAb Capture Step Based on Selective Precipitation Combined with CEX**
*Guy de Roo, Ph.D., Project Leader, Downstream Processing, Biopharmaceuticals, Synthon*

**4:45 Development of a Goat Polyclonal Antibody Purification Process for Improved Yield and Stability**
*Steven P. Allen, Ph.D., Manager, Biologics Process Design R&D, Diagnostics R&D, Abbott*

**5:15 A Novel Cell Culture Flocculation Process to Streamline Antibody Purification and Downstream Processing**
*Kenneth (Yun) Kang, Ph.D., Principal Scientist, BioProcess Sciences, ImClone Systems, a wholly owned subsidiary of Eli Lilly & Co.*

**5:45-7:00 Welcome Reception in the Exhibit Hall with Poster Viewing**

*Sponsored by* proteinsimple

## TUESDAY, JANUARY 14

**7:15 am Conference Registration**

**7:30 Breakfast Presentation** *(Sponsorship Opportunity Available)* **or Morning Coffee**

### Purifying Kinases

**8:30 Chairperson's Remarks**

**8:35 The Purification of JAK Kinases**
*Jiansheng Wu, Ph.D., Scientist, Protein Chemistry, Genentech, Inc.*

**9:05 Expression, Purification and Characterization of Recombinant Necroptotic RIP Kinases**
*Alexei Degterev, Ph.D., Associate Professor, Biochemistry, Tufts University*

**9:35 Extended Q&A**

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

### Purifying Membrane Proteins

**10:50 Exploring Affinity Tags for Expression, Purification and Recovery of G Protein-Coupled Cannabinoid Receptor Type II (CB2)**
*Silvia Locatelli-Hoops, Ph.D., Scientist, Membrane Biochemistry and Biophysics, National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institutes of Health (NIH)*

**11:20 New Chemical Tools for Stabilizing Membrane Proteins**
*Qinghai Zhang, Ph.D., Associate Professor, Integral Structural and Computational Biology, The Scripps Research Institute*

**11:50 Sponsored Presentation** *(Opportunity Available)*

**12:20 pm Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

**2:00 BuzZ Session A (Please visit our website for topics)**

**3:00 Refreshment Break in the Exhibit Hall with Poster Awards**

**3:45 BuzZ Session B (Please visit our website for topics)**

**4:45 Close of Conference**

**4:30-5:00 Short Course Registration**

**5:00-8:00 Dinner Short Courses (SC8-SC14)** *See page 4 for details*

THIRD ANNUAL | JANUARY 15-16

# Higher-Throughput Protein Purification

Supporting Technologies

## TUESDAY, JANUARY 14

**1:30-2:00 pm Conference Registration**

**2:00 BuzZ Session A (Please visit our website for topics)**

**3:00 Refreshment Break in the Exhibit Hall with Poster Awards**

**3:45 BuzZ Session B (Please visit our website for topics)**

**4:30-5:00 Short Course Registration**

**5:00-8:00 Dinner Short Courses (SC8-SC14)** *See page 4 for details*

## WEDNESDAY, JANUARY 15

**7:30 am Conference Registration**

**8:00 Morning Coffee**

### Industrial Scale High-Throughput Processing

**8:15 Chairperson's Opening Remarks**
*Ray Owens, Ph.D., NDM Senior Research Fellow, Division of Structural Biology, Oxford Protein Production Facility, University of Oxford*

**» KEYNOTE PRESENTATION**

**8:20 High-Throughput Protein Expression & Drug Discovery – A Review**
*Ian Hunt, Ph.D., Group Leader, Protein Sciences, Novartis*

**9:00 Directed Evolution of Enzymes on an Industrial Scale**
*Andrew Fosberry, Ph.D., Manager, Expression & Fermentation Sciences, Biological Reagents and Assay Development, PTS, GlaxoSmithKline Research & Development Limited*

**9:30 Case Study: Tools for High-Throughput DSP Development**
*Guy de Roo, Ph.D., Project Leader, Downstream Processing, Biopharmaceuticals, Synthon*

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

### HTP Process Development

**10:45 From Start to Finish, Applications of HTS to Accelerate Process Development**
*Ronald Gillespie, Ph.D., Scientist, Purification Process Development, Amgen, Inc.*

**11:15 Implementing a Buffer Optimization Screen into a High-Throughput Protein Production Core Service**
*William Gillette, Ph.D., Senior Scientist, SAIC-Frederick, Inc.*

**11:45 A Multi-Platform Approach for High-Throughput Production of Secreted Proteins**
*Brandan Hillerich, Ph.D., Managing Director, High Throughput Protein Production, Albert Einstein College of Medicine*

**12:15 pm Application of Automated Purification Methods and Analysis for Process Development** *Sponsored by*
*Brian Gerwe, Ph.D., Product Manager, PerkinElmer*

PerkinElmer For the Better

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

### Improving Processes

**2:00 Chairperson's Remarks**
*Brian Gerwe, Ph.D., Product Manager, PerkinElmer*

**2:05 Membrane Ultrafiltration – Opportunities for Higher Throughput Processes**
*Junfen Ma, Ph.D., Principal Scientist, Amgen*

**2:35 High-Throughput Measurements of Protein Transport in Ion-Exchange**
*Abraham M. Lenhoff, Ph.D., Chair & AP Colburn Professor, Chemical & Biomolecular Engineering, Delaware Biotechnology Institute, University of Delaware*

**3:05 High-Throughout Protein Characterization: Parallel Assessment of Thermal Stability and Aggregation**
*Andrew Stephen, Ph.D., Acting Director, Protein Chemistry Laboratory, Frederick National Laboratory for Cancer Research, SAIC-Frederick, Inc.*

**3:35 Sponsored Presentation** *(Opportunity Available)*

**3:50 Refreshment Break**

### Automation

**4:15 Automation and Streamlining of Biopharmaceutical Purification Processes with High-Throughput Screening and Analytical Tools**
*Julia Spitz, Ph.D., Associate Director, Protein Science, Boehringer Ingelheim Pharma GmbH & Co. KG*

**4:45 Development of a High-Throughput Pipeline for the Expression and Purification of Membrane Proteins**
*Ray Owens, Ph.D., NDM Senior Research Fellow, Division of Structural Biology, Oxford Protein Production Facility, University of Oxford*

**5:15-6:30 Reception in the Exhibit Hall with Poster Viewing**

## THURSDAY, JANUARY 16

**7:15 am Conference Registration**

**7:30 Breakfast Presentation** *(Sponsorship Opportunity Available)*
**or Morning Coffee**

### Analytical Technologies

**8:30 Chairperson's Remarks**
*Brandan Hillerich, Ph.D., Managing Director, High Throughput Protein Production, Albert Einstein College of Medicine*

**8:35 Making and Using Protein Microarrays: High-Throughput Tools for Proteomics**
*Michael Taussig, Ph.D., Head, Technology Research Group, Babraham Bioscience Technologies*

**9:05 High-Throughput and Advanced Analytical Technologies Used for Streamlining Process Development**
*Susan Callahan, Ph.D., Senior Associate Scientist, Amgen*

**9:35 Sponsored Presentation** *(Opportunity Available)*

**9:50 Coffee Break in the Exhibit Hall with Poster Awards**

**10:50 VirD – A Virion Display Array for Profiling Functional Membrane Proteins**
*Heng Zhu, Ph.D., Associate Professor, Pharmacology and Molecular Sciences, High Throughput Biology Center (HIT Center), Johns Hopkins University School of Medicine*

**11:20 Optimizing Protein Production *in vitro* for Incorporation into High-Throughput Analytical Platforms**
*David W. Galbraith, Ph.D., Professor, Plant Sciences & Bio5 Institute, University of Arizona*

**11:50 Sponsored Presentation** *(Opportunity Available)*

**12:20 pm Luncheon Presentation** *(Sponsorship Opportunity Available)*
**or Lunch on Your Own**

**1:45 Close of Conference**

INAUGURAL | JANUARY 13-14

# Single-Use Technologies and Continuous Processing in Biopharm Manufacturing

Toward Wide-Scale Implementation of Disposables

## SUNDAY, JANUARY 12

**4:00-5:00 pm Short Course Registration**

**5:00-8:00 Dinner Short Courses (SC1-SC7)** *See page 4 for details*

**4:00-8:00 Main Conference Registration**

## MONDAY, JANUARY 13

**7:30 am Conference Registration and Morning Coffee**

### E&L, Particulates and Supply Chain Risk Assessment

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

**» KEYNOTE PRESENTATION**

**9:10 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*

**9:50 BPOG's Extractable Protocol Standardization Journey – Review 2013 Progress and Planning for 2014**
*Ken Wong, Deputy Director, Mtech/AP&T, Sanofi Pasteur*

**10:20 Coffee Break**

**10:45 Particle Contamination of Single-Use Systems**
*Mike Johnson, Life Science Applications Engineer, Entegris*

*Sponsored by* Entegris

**11:15 Single-Use Supply Chain Risk**
*Leslie Cianella, EMBA, CPIM, CQA, Senior Sourcing and Procurement Manager, MedImmune, Inc.*

### Analytics of Single-Use Systems

**11:45 PAT Solutions for In-Line and At-Line Analytics from Single-Use Bioreactors**
*Jens Traenkle, Ph.D., Head, PAT Biotechnology, Bayer Technology Services*

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

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

### Overcoming Scalability and Downstream Processing Challenges

**2:00 Chairperson's Remarks**
*Adam Goldstein, Principal Engineer, Genentech, Inc.*

**2:05 How to Integrate Single-Use Bioreactors into Vaccine Process Development and Scaling Up?**
*Sandrine Dessoy, Senior Manager, New Product Development, GlaxoSmithKline*

**2:35 Scaleable and Continuous Cultivation of Anchorage Dependent Cells in Single-Use Bioreactors: Challenges and Solutions**
*Brian Lee, Ph.D., President, PBS Biotech*

**3:05 Challenges in Developing a Completely Disposable Downstream Process**
*Ronald Bates, Ph.D., Director, MS&T, Bristol-Myers Squibb*

**3:35 Selected Oral Poster Presentation**
**Qualification and Management of Single-Use Consumable Materials in Biopharmaceutical Industry**
*Zhaoli Zhou, Ph.D., Materials Specialist, Manufacturing Sciences and Technology, Bristol-Myers Squibb Co.*

**3:50 Refreshment Break**

**4:15 Challenges of Multi-Column Continuous Chromatography in Downstream Processing**
*Dr.-Ing. Kathleen Mihlbachler, Independent Consultant*

### Continuous Processing for Downstream Optimization

**4:45 Continuous Antibody Capture Using Countercurrent Tangential Chromatography**
*Andrew Zydney, Ph.D., Professor and Department Head, Chemical Engineering, The Pennsylvania State University*

**5:15 Simulation and Optimization of Continuous Downstream Process in Biopharmaceutical Manufacturing**
*SeongKyu Yoon, Ph.D., Assistant Professor & Director, Department of Chemical Engineering, Massachusetts Bio Manufacturing Center, University of Massachusetts*

**5:45-7:00 Welcome Reception in the Exhibit Hall with Poster Viewing**

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## TUESDAY, JANUARY 14

**7:15 am Conference Registration**

**7:30 Breakfast Presentation** *(Sponsorship Opportunity Available)* **or Morning Coffee**

### Case Studies and New Data on Single-Use Applications and Processes

**8:30 Chairperson's Remarks**
*Brian Lee, Ph.D., President, PBS Biotech*

**8:35 The Opportunities for Full Scale GMP Single-Use Applications – From Upstream to Large Scale Freeze System**
*Adam Goldstein, Principal Engineer, Genentech, Inc.*

**9:05 Joint Presentation: Transfer and Implementation of A New Process - A Successful Case Study**
*Lars Dreesmann, Ph.D., Executive Director, Upstream Manufacturing & Tech Transfer, Biopharmaceuticals Operations Germany, Boehinger Ingelheim Pharma GmbH & Co.*
*Abdul Wajid, Ph.D., Senior Director, Process and Manufacturing Sciences, XOMA*

**9:35 Sponsored Presentation** *(Opportunity Available)*

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

**10:50 Application of Single-Use Technology in VLP and Nanoparticle Vaccine Production**
*Jason Li, Ph.D., Sr. Manager, Downstream Process Development, Novavax, Inc.*

**11:20 Case Study - Rapid Development & Manufacturing of Monoclonal Antibodies Using Single Use Bioreactors**
*Abdul Wajid, Ph.D., Senior Director, Process and Manufacturing Sciences, XOMA*

**11:50 Sponsored Presentation** *(Opportunity Available)*

**12:20 pm Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

**2:00 BuzZ Session A (Please visit our website for topics)**

**3:00 Refreshment Break in the Exhibit Hall with Poster Awards**

**3:45 BuzZ Session B (Please visit our website for topics)**

**4:45 Close of Conference**

**4:30-5:00 Short Course Registration**

**5:00-8:00 Dinner Short Courses (SC8-SC14)** *See page 4 for details*

INAUGURAL | JANUARY 15-16

# Flexible Manufacturing of Biopharmaceuticals

Scalable, Compact, Cost-Effective, Modular and Plastic

## TUESDAY, JANUARY 14

**1:30-2:00 pm Conference Registration**

**2:00 BuzZ Session A (Please visit our website for topics)**
**3:00 Refreshment Break in the Exhibit Hall with Poster Awards**
**3:45 BuzZ Session B (Please visit our website for topics)**

**4:30-5:00 Short Course Registration**
**5:00-8:00 Dinner Short Courses (SC8-SC14)** *See page 4 for details*

## WEDNESDAY, JANUARY 15

**7:30 am Conference Registration**

**8:00 Morning Coffee**

### Trends, Requirements, Economics and Design Considerations for Modular, Flexible Facilities

**8:15 Chairperson's Opening Remarks**
*Jens H. Vogel, Ph.D., Executive Director & Head, Process Science USA, Boehringer Ingelheim*

**» KEYNOTE PRESENTATION**
**8:20 The Future of Biomanufacturing: Flexible, Compact, Cost-Effective and Modular Facilities**
*Sadettin S. Ozturk, Ph.D., Head, Process and Analytical Development, MassBiologics*

**9:00 Regulatory Considerations for Flexible Multiproduct Facilities**
*John Godshalk, Senior Consultant, GMP, CMC, Biologics Consulting Group, Inc.; former Review/Inspector, Division of Manufacturing and Product Quality, CBER, U.S. FDA*

**9:30 Personalized Therapeutics, Biosimilars and Pandemic Risks Demand New Approaches to BioManufacturing**
*Sid Backstrom, Director, Business Management, G-Con Manufacturing*

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

**10:45 Economics of Modular Facility Design and Construction**
*Howard L. Levine, Ph.D., President, BioProcess Technology Consultants*

**11:15 Design Considerations for Platform Development: A New Approach to Advance Manufacturing Facility Design**
*Rich Smith, Director, Business Development - Life Sciences, M+W U.S., Inc. - A Company of the M+W Group, and Peter Cramer, AIA, Vice President, M+W U.S., Inc., - A Company of the M+W Group*

**11:45 Process and Product Considerations for Flexible Manufacturing**
*Kenneth D. Green, Ph.D., Director, Continuous Improvement, Global Technical Services, Pfizer, Inc.*

**12:15 pm Flexible and Rapidly Deployed Manufacturing Facilities – Combining Modularization, Standardization and Single Use Strategies**
*Par Almhem, Co-Founder and President, ModWave LLC.*

**12:45 Leveraging Development and Process Platforms to Streamline Delivery of Reliable and Flexible Biomanufacturing Processes**
*Sponsored by* FUJIFILM Diosynth biotechnologies
*Stewart McNaull, Ph.D., Director, Development and Technical Services, Fujifilm Diosynth Biotechnologies*

### Technology and Process Innovations Driving Flexible Biomanufacturing

**2:00 Chairperson's Remarks**
*Peter Cramer, AIA, Vice President, M+W U.S. Inc. – a Company of the M+W Group*

**2:05 Innovation Driving Fast & Flexible Development and Manufacturing of Biologics**
*Jens H. Vogel, Ph.D., Executive Director & Head, Process Science USA, Boehringer-Ingelheim*

**2:35 Panel Discussion and Q&A : Technology and Process Innovations Driving Flexible Biomanufacturing**
*Moderator: Peter Cramer, AIA, Vice President, M+W U.S. Inc. - a Company of the M+W Group*
*Panelists: Speakers of the Day*

**3:05 Combining Single-Use Technologies with Flexible Workforce to Maximize Utilization of Manufacturing**
*Wolfgang Noe, Ph.D., Vice President, Technical Operations, Agensys, Inc.*

**3:35 Selected Oral Poster Presentation**

**Modular Production Systems at the National Center for Therapeutics Manufacturing**
*Michael Pishko, Ph.D., Director, National Center for Therapeutics Manufacturing, Texas A&M University*

**3:50 Refreshment Break**

**4:15 Design, Qualification and Scale-Up to a Disposable Cell Culture Suite to Improve Operational Flexibility**
*Patrick Sheehy, Ph.D., Associate Director, Pharmaceutical Development, Janssen Biologics Ireland*

**4:45 Flexible Manufacturing Solutions for the Animal Health Market**
*Philip Elrod, Scientist, Zoetis*

**5:15-6:30 Reception in the Exhibit Hall with Poster Viewing**

## THURSDAY, JANUARY 16

**7:15 am Conference Registration**

**7:30 Breakfast Presentation** *(Sponsorship Opportunity Available)* **or Morning Coffee**

### Increasing Flexibility With Single-Use Systems and Processes

**8:30 Chairperson's Remarks**
*Yan-ping Yang, Ph.D., Director, Downstream Purification, Bioprocess Research & Development, Sanofi Pasteur*

**8:35 Increasing Flexibility in Vaccine Manufacturing Processes and Facilities with Single-Use Disposable Technologies and Process Modeling**
*Yan-ping Yang, Ph.D., Director, Downstream Purification, Bioprocess Research & Development, Sanofi Pasteur*

**9:05 Advantages and Challenges of Single-Use Systems in Biopharmaceutical Development and Manufacturing**
*John Knighton, MBA, Senior Director, API Large Molecule Technologies & Alliances, Janssen R&D*

**9:35 Selected Oral Poster Presentation**
**Incorporation of Single-Use Mixing Systems into a Large-Scale Live-Viral Vaccine Upstream Manufacturing Process**
*Daniel Vellom, Ph.D., Sr. Director, Global Technology Innovation, Sanofi Pasteur Biologics LLC.*

**9:50 Coffee Break in the Exhibit Hall with Poster Awards**

**10:50 Evaluating Where Single-Use Technology Provides the Most Value for a Company with a Well Established Manufacturing Infrastructure**
*Terry Hudson, Ph.D., Associate Director, Process Development Engineering, Genentech, Inc.*

**11:20 Setting Up a Successful Multi-Product Clinical Fill & Finish Operation**
*Claudia Roth, Ph.D., President, Vetter Development Services USA, Inc.*

**11:50 Sponsored Presentation** *(Opportunity Available)*

**12:20 pm Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

**1:45 Close of Conference**

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| Standard Registration after October 25 | $1495 | $995 |

### CONFERENCE PRICING

**PREMIUM PACKAGE BEST VALUE! (Includes access to all conferences Monday-Friday, excludes Short Courses and Seminars)**

| | | |
|---|---|---|
| Early Registration Rate until October 25 | $2899 | $1399 |
| Advance Registration Rate until November 22 | $3099 | $1629 |
| Standard Rate after November 22 and Onsite | $3249 | $1729 |

**STANDARD PACKAGE (Includes access to 2 conferences, excludes Short Courses and Seminars)**

| | | |
|---|---|---|
| Early Registration Rate until October 25 | $2499 | $1199 |
| Advance Registration Rate until November 22 | $2699 | $1299 |
| Standard Rate after November 22 and Onsite | $2899 | $1349 |

**BASIC PACKAGE (Includes access to 1 conference, excludes Short Courses and Seminars)**

| | | |
|---|---|---|
| Early Registration Rate until October 25 | $1399 | $749 |
| Advance Registration Rate until November 22 | $1599 | $829 |
| Standard Rate after November 22 and Onsite | $1799 | $899 |

### CONFERENCE DISCOUNTS

**Poster Submission - Discount: ($50 off)** Poster abstracts are due by November 22. Once your registration has been fully processed, we will send an email containing a unique link allowing you to submit your poster abstract. *CHI reserves the right to publish your poster title and abstract in various marketing materials and products.

**Protein Society Members: (20% off)** CHI is pleased to offer all Protein Society Members a 20% discount to attend. Records must indicate you are a member at time of registration.

**Antibody Society Members: (20% off)** CHI is pleased to offer all Antibody Society Members a 20% discount to attend. Records must indicate you are a member at time of registration.

**REGISTER 3 - 4th IS FREE:** Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply.

**Alumni Discount: (20% off)** CHI appreciates your past participation at PepTalk. Through loyalty like yours, CHI has been able to build this event into a must-attend for senior-level decision makers. As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate. Just check off the box marked Alumni Discount on the registration form to receive the discount!

**Group Discounts:** Discounts are available for multiple attendees from the same organization. For more information on group rates contact David Cunningham at +1-781-972-5472.

**Alumni, Antibody Society, Protein Society, Twitter, LinkedIn, Facebook or any other promotional discounts cannot be combined. Discounts not applicable on Event Short Courses or Training Seminars.*

If you are unable to attend but would like to purchase the PepTalk CD for $750 (plus shipping), please visit CHI-PepTalk.com. Massachusetts delivery will include sales tax.



### ADDITIONAL REGISTRATION DETAILS

Each registration includes all conference sessions, posters and exhibits, food functions, and access to the conference proceedings link.

Handicapped Equal Access: In accordance with the ADA, Cambridge Healthtech Institute is pleased to arrange special accommodations for attendees with special needs. All requests for such assistance must be submitted in writing to CHI at least 30 days prior to the start of the meeting.

**To view our Substitutions/Cancellations Policy, go to http://www.healthtech.com/regdetails**

Video and or audio recording of any kind is prohibited onsite at all CHI events.

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