BIOLOGICS PARTNERING FORUM

ENGINEERING STREAM

- Phage and Yeast Display
- Engineering Antibodies
- Engineering Bispecific Antibodies

ONCOLOGY STREAM

- Antibodies for Cancer Therapy
- Bispecific Antibodies for Oncology
- Antibody-Drug Conjugates

EXPRESSION STREAM

- Difficult to Express Proteins
- Optimizing Protein Expression
- High-Throughput Protein Expression

ANALYTICAL STREAM

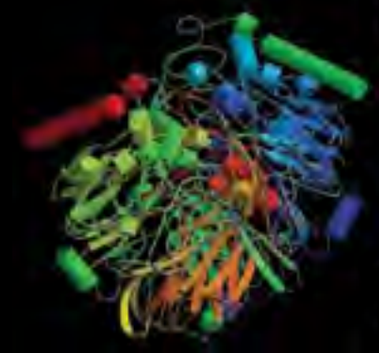
- Characterization of Biotherapeutics
- Biophysical Analysis of Biotherapeutics
- Protein Aggregation and Stability

SAFETY STREAM

- Immunogenicity for Regulatory Success
- Immunogenicity Prediction & Mitigation
- PK/PD of Antibody-Derived Molecules

PURIFICATION STREAM

- Purifying Antibodies and Recombinant Proteins
- Protein Aggregation and Stability



Ninth Annual

PEGS

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April 29 - May 3, 2013

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EVENT-AT-A-GLANCE

	ENGINEERING STREAM	ONCOLOGY STREAM	EXPRESSION STREAM	ANALYTICAL STREAM	SAFETY STREAM	PURIFICATION STREAM	BIOLOGICS PARTNERING FORUM
Sunday April 28	Pre-Conference Short Courses*						
Monday April 29	Phage and Yeast Display	Antibodies for Cancer Therapy	Difficult to Express Proteins	Characterization of Biotherapeutics	Immunogenicity for Regulatory Success		Biologics Partnering
Tuesday April 30	Phage and Yeast Display	Antibodies for Cancer Therapy	Difficult to Express Proteins	Characterization of Biotherapeutics	Immunogenicity for Regulatory Success		Biologics Partnering
	Plenary Panel Discussion						
	Dinner Short Courses*						
Wednesday May 1	Engineering Antibodies	Advancing Bispecific Antibodies to the Clinic for Oncology	Optimizing Protein Expression	Biophysical Analysis of Biotherapeutics	Immunogenicity Prediction and Mitigation	Purifying Antibodies & Recombinant Proteins	
Thursday May 2 (am)	Engineering Antibodies	Advancing Bispecific Antibodies to the Clinic for Oncology	Optimizing Protein Expression	Biophysical Analysis of Biotherapeutics	Immunogenicity Prediction and Mitigation	Purifying Antibodies & Recombinant Proteins	
Thursday May 2 (pm)	Engineering Bispecific Antibodies	Antibody-Drug Conjugates	High-Throughput Protein Expression	Protein Aggregation and Stability in Biopharmaceuticals	PK/PD of Antibody-Derived Molecules	Protein Aggregation and Stability in Biopharmaceuticals	
	Dinner Short Courses*						
Friday May 3	Engineering Bispecific Antibodies	Antibody-Drug Conjugates	High-Throughput Protein Expression	Protein Aggregation and Stability in Biopharmaceuticals	PK/PD of Antibody-Derived Molecules	Protein Aggregation and Stability in Biopharmaceuticals	

*Separate Registration Required.

PLENARY KEYNOTE PANEL

TUESDAY, APRIL 30, 2013

4:15 – 5:30 pm

Conventional vs. Non-Conventional Formats

Moderator: Janice Reichert, Ph.D., Editor-in-Chief, mAbs; Managing Director, Reichert Biotechnology Consulting LLC

With the explosion in the number of formats available, what are the potential benefits and risks to patients? This panel will discuss the realistic outlook and uncertainties with developing a diverse array of non-canonical antibodies in terms of immunogenicity, safety, competitive marketplace, commercial development, business strategies, regulatory approval, target validation and clinical development.

Panelists:

David Meininger, Ph.D., MBA, Executive Director, Molecular Discovery, Merck

Tillman Gerngross, Ph.D., CEO and Co-Founder, Adimab LLC; Professor, Bioengineering, Thayer School of Engineering, Dartmouth College

Trudi Veldman, Ph.D., Senior Director, Biologics Generation, AbbVie

SHORT COURSES*

SUNDAY, APRIL 28, 2013

Morning Courses | 10:00 am – 1:00 pm

(SC1) Antibody Humanization via One Hot Homology Model – Hands-On Workshop

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

- Create an antibody homology model from the mouse/rat/rabbit primary sequence
- Humanization strategies based on the antibody homology model
- Steric clashes within the humanized antibody and rational methods to fix it
- Affinity maturation of the humanized antibody

All materials, including tutorials/exercises and scripts, will be available for users during and after the workshop. No prior programming experience necessary. Please bring your laptop for the workshop.

(SC2) Basics of Immunogenicity

Instructors: Jim McNally, Ph.D., Senior Principal Scientist,
Pfizer, Inc.
Darshani Jani, Ph.D., Senior Associate Scientist, R&D, Biogen Idec, Inc.

- Basic issues regarding screening, confirmatory and titer assays
- Assay methodologies and various technologies
- Current approaches to data analysis and cutpoints
- Preclinical and clinical considerations
- Common problems

(SC3) Phage and Yeast Display Libraries

Instructors: Andrew M. Bradbury, M.B., B.S., Ph.D., Staff Scientist, Biosciences, Los Alamos National Laboratory
James D. Marks, M.D., Ph.D., Professor, Anesthesia & Pharmaceutical Chemistry, UC, San Francisco; Chief, Anesthesia and Vice Chairman, Anesthesia & Perioperative Care, San Francisco General Hospital

- Phage display and construction of phage-displayed scFv and Fab libraries
- Yeast display and construction of yeast-displayed scFv and Fab libraries
- Selection and screening technologies that are compatible with phage and yeast-display libraries
- Combining phage and yeast display for antibody selection and epitope identification

(SC4) Translational Considerations for Development of Monoclonal Antibodies Part I: Focus on Early Discovery

Chair: Mohammad Tabrizi, Ph.D., Head, PK/PD & Senior Fellow, Merck
Instructors: Gadi Bornstein, Ph.D., Associate Research Fellow, Centers for Therapeutic Innovation, Pfizer Inc.
Scott L. Klakamp, Ph.D., Principal Consultant, SKD Consulting LLC
Randall Brezski, Ph.D., Senior Research Scientist, Biotechnology Center of Excellence, Janssen R&D, Inc.

- Considerations for target selection, antibody screening and mAb preclinical development
- Antibody affinity and biophysical characterization: Biacore, Kinexa, and FACS
- Application of antibody engineering in the development of next generation antibody-based therapeutics

Afternoon Courses | 2:00 – 5:00 pm

(SC5) Biosimilars & Biobetters: Development, Regulation and Prospects

Chair: Zahra Shahrokh, Consultant, CMC, ZDev Consulting
Instructors: Steven A. Grossman, J.D., Public Policy and FDA Regulatory Consultant, HPS Group, LLC
Carolyn C. Huntenburg, Ph.D., Vice President, Regulatory Affairs, Momenta Pharmaceuticals
Magdalena Leszczyniecka, Ph.D., MBA, President and CEO, STC Biologics, Inc.

- Regulatory guidelines & issues
- Case studies
- Developing biosimilars/biobetters
- Unique requirements

(SC6) Overcoming the Challenges of Immunogenicity Assessment

Instructors: Jim McNally, Ph.D., Senior Principal Scientist,Pfizer, Inc.
Darshani Jani, Ph.D., Senior Associate Scientist, R&D, Biogen Idec, Inc.

- Challenges and approaches to resolve commonly encountered issues
- Emerging trends in the development of neutralizing antibody assays
- Cross reactivity to endogenous proteins
- Clinical implications of ADAs

*Separate Registration Required.

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SHORT COURSES* *(CONTINUED)*

(SC7) Alternate Display Technologies

Instructors: John Löfblom, Ph.D., Assistant Professor, Molecular Biotechnology, AlbaNova University Center, Royal Institute of Technology (KTH)

Birgit Dreier, Ph.D., Senior Scientist, Laboratory of Prof. Dr. A. Plückthun, Department of Biochemistry, University of Zurich

- Development of new display systems to address shortcomings of phage and yeast display
- Constructing libraries and assessing library quality
- Screening and selection methods for generation of new affinity proteins as well as for epitope mapping purposes
- Coverage of bacterial display, *E. coli* display, and ribosome display

(SC8) Cancelled

(SC9) Translational Considerations for Development of Monoclonal Antibodies Part II: Focus on Nonclinical Development to Clinic

Chair: Mohammad Tabrizi, Ph.D., Head, PK/PD & Senior Fellow, Merck

Instructors: Cherryl Funelas, Bioanalytical Manager, Genentech

Isabel Figueroa, Associate Principal Scientist, PK/PD, Merck

- Considerations for immunoassay development in support of pharmacokinetic, immunogenicity & biomarker evaluation
- Considerations for Development of Novel Antibody- Based Therapeutics
- Preclinical considerations, a science-based approach: Design goal, MOA, choice of species, and preclinical plans
- Translation of exposure-response data from discovery into the clinic in support of FIH dosing

TUESDAY, APRIL 30, 2013

Dinner Short Courses | 6:00 – 8:00 pm

(SC10) Immunogenicity Risk Assessment and Regulatory Strategy

Instructor: Bridget Heelan, Ph.D., Clinical Assessor, Medicines and Healthcare Products Regulatory Agency (MHRA) UK

- Priorities for the regulator: Hierarchy of concerns; Data requirements; Common gaps
- Integrated approach: Risk identification; Aligning identified risks with CMC; Bioanalytical, non-clinical and clinical strategy; Ongoing risk management
- Interactive case study: Illustration of preparation of an effective response to a regulatory scenario pertaining to immunogenicity-related risks for an investigational therapeutic protein

(SC11) Boosting Anti-Tumor Immunity with Monoclonal Antibodies

Instructors: Wayne A. Marasco, M.D., Ph.D., Professor, Cancer Immunology and AIDS, Dana-Farber Cancer Institute; Professor of Medicine, Department of Medicine, Harvard Medical School

Michael A. Postow, M.D., Medical Oncology Fellow, Memorial Sloan-Kettering Cancer Center

Lawrence J. Thomas, Ph.D., DABT, CMAR, Senior Director, Preclinical Research and Development, Celldex Therapeutics, Inc.

Lauren Harshman, M.D., Assistant Professor, Dana-Farber Cancer Institute

- CTLA-4 blockade: Past, present, and future
- Development of a human monoclonal antibody for potential therapy of CD27-expressing lymphoma and leukemia
- A Human anti-CCR4 monoclonal antibody with potent tumor cell killing and immunomodulatory activities
- Targeting the Programmed Death-1 (PD-1) Pathway in Renal Cell Carcinoma

(SC12) How to Obtain Reliable Information from Light Scattering: Theory, Practical Advice and Data Interpretation

Instructors: David Dolak, MBA, Product Manager, Light Scattering Technologies, Malvern Instruments

Kevin Mattison, Ph.D., Principal Scientist, Bioanalytics, Malvern Instruments

Ulf Nobbmann, Ph.D., Product Manager, GPC/SEC Technologies, Malvern Instruments

Mark Pothecary, Ph.D., Product Manager, Light Scattering Products, Malvern Instruments

- Which key indicators assure reliable DLS & SEC-LS data quality?
- What are hydrodynamic size & polydispersity?
- How is the mass distribution determined in DLS and how valid is it?
- Is light scattering suitable for quality control applications?

THURSDAY, MAY 2, 2013

Dinner Short Courses | 5:30 – 7:30 pm

(SC13) Cancelled

(SC14) Antibody-Drug Conjugate Therapeutics: Potential and Challenges

Instructors: Pam Trail, Ph.D., Vice President, Oncology, Regeneron Pharmaceuticals

Jan Pinkas, Ph.D., Director, Pharmacology, ImmunoGen, Inc.

Christopher D. Thanos, Ph.D., Director, Protein Engineering, Sutro Biopharma, Inc.

Ho Sung-Cho, Ph.D., CTO, Ambrx, Inc

- Target Selection for ADCs
- Selection of the Antibody for a Target
- Cleavable Linkers
- Linker Modification & Resistance
- Overcoming Drug Resistance
- Novel Drugs and Payloads
- Regulatory Issues

*Separate Registration Required.

PHARMA-BIO PARTNERING FORUMS

Biologics Partnering Forum: Antibody & Protein Engineering

Program Advisors *(as of November 30, 2012)*

Brian Atwood, MBA, *Managing Director, Versant Ventures*

Daniel Blom, Director, Cardiovascular Diseases, Merck & Co.

Ray Camphausen, Ph.D., Associate Vice President, Protein Design, Adnexus, Bristol-Myers Squibb

Jon Ellis, Ph.D., *Vice President, Business Development, Biopharmaceutical R&D and Platform Technology & Science, GlaxoSmithKline*

Richard Harkins, Ph.D., Principal Scientist, Global Drug Discovery, Bayer Healthcare Pharmaceuticals

Robert Hayes, Ph.D., Vice President & Venture Leader, Janssen R & D

Margaret Karow, Ph.D., *Executive Director, Protein Sciences, Amgen, Inc.*

Nilesh Kumar, Ph.D., Merck Serono

Luke Li, M.D., Executive Director, Head, Global BioTherapeutic Technologies, Pfizer, Inc.

Thomas Li, Ph.D., *Senior Director, Technology, Roche Diagnostics*

Kia Motesharei, Ph.D., *Vice President, Business Development & Alliance Management, Dyax Corp.*

Hilde Revets, Ph.D., *Senior Research Fellow, Technology, Ablynx NV*

Janine Schuurman, *Director, Strategic Research, GenMab BV*

Barry Springer, Ph.D., *Head, External Research and Innovation, Biologics Research, Johnson & Johnson*

PARTIAL LIST OF CONFIRMED PRESENTATIONS

Antibody Discovery and Optimization: GMP-ready Human Antibodies for Therapeutic Applications
Volker Lang, Ph.D., Managing Director, AbCheck s.r.o.

Single Domain Shark Antibodies and their Human Equivalent, i-bodies, as Novel Therapeutics
Michael Foley, Ph.D., Department of Biochemistry, Latrobe University; CSO, AdAlta Pty. Ltd.

Functional Diversity as the key to choice in Human Antibody Drug Discovery
Debbie Allen, Ph.D., Senior Director, Business Development, arGEN-X

Affimers: Engineered Alternatives to Antibodies that Provide a Toolkit for Discovery and Dissection of Biological and Pathological Processes
Paul Ko Ferrigno, Ph.D., Group Head, Discovery Technology, Avacta Group plc

Tribodies for Two-in-One Bispecific Antibody Fragments
Nico Mertens, Ph.D., Director, Antibody Research, Biotecnol, Inc.

Fynomab Platform for the Generation of Unique Bispecific Biotherapeutics
Fabian Buller, Ph.D., Director, Business Development, Covagen AG

Fully Human VH Antibody Fragments from the Crescendo Mouse Platform
Mike Romanos, Ph.D., CEO, Crescendo Biologics Ltd.

PENTRA®: A Tissue-Penetrating Class of Antibodies for Dermatology and Other Diseases
Titus Kretzschmar, CSO, Delenex Therapeutics AG

DutaMabs: A Novel Bi-specific Monoclonal Antibody Platform
Kristian Jensen, Ph.D., Vice President Research, Dutalys GmbH

NanoMabs: A New Leap in Antibody-Drug Conjugates
Oshrat Frenkel, Ph.D., Director of Research, Immune Pharmaceuticals

ImmTACS: a Novel Class of Bi-specifics for Cancer
Stephen Megit, Ph.D., Senior Business Development Manager, Immunocore Ltd.

A Novel Strategy to Engineer Agonists and Antagonists to Complex Membrane Targets Utilizing V(D)J Recombination in a Mammalian Cell
Michael Gallo, President, Innovative Targeting Solutions

The MPS™ Platform for Discovery of Antibodies against Difficult Membrane Protein Targets
Benjamin Doranz, Ph.D., President and CSO, Integral Molecular, Inc.

The Kymab Discovery Platform: Harnessing Human Antibody Diversity *in vivo*
Allan Bradley, Ph.D., CSO, Kymab Ltd.

MeMo® + Spleen to Screen™ - The Platform for Human Therapeutic Bispecific Antibody and Antibody Combination Discovery
Jason Avery, Chief Business Officer, Merus BV

Simple, Stable, Smart – The Kappa/Lambda-Body Next-Generation Bispecific Drug Discovery Platform
David Slack, Head, Corporate & Business Development, NovImmune SA

Tanibirumab Phase I Study and GBM/HCC Phase II Preparation and its Rationale
Jin-San Yoo, Ph.D., President and CEO, PharmAbcine, Inc.

Development of Angiogenesis Inhibitors Targeting Pathways other than VEGF
Charles Theuer, Ph.D., CEO, TRACON Pharmaceuticals, Inc.

Deep Screening of the OMT OmniRat™ Repertoire Using CellSpot™ Single Cell Multiplexing
Larry Kauvar, Ph.D., SVP & CSO, Trellis Bioscience

Antibody Library Display on a Mammalian Virus Vector: Combining the Advantages of both Phage and Yeast Display into One Technology
Ernest Smith, Ph.D., CSO, Vaccinex, Inc.

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STAY CONNECTED

Phage and Yeast Display of Antibodies and Recombinant Proteins

MONDAY, APRIL 29

7:00 am Conference Registration and Morning Coffee

8:30 Chairperson's Opening Remarks
Gregory A. Weiss, Ph.D., Professor, Chemistry, Molecular Biology & Biochemistry, UC Irvine

» KEYNOTE SESSION

8:40 Challenging Targets for Phage Display
James A. Wells, Ph.D., Professor and Chair, Pharmaceutical Chemistry, UCSF

9:25 Ubiquitin Variants as Potent Inhibitors and Activators of Enzymes in the Ubiquitin Pathway
Sachdev Sidhu, Ph.D., Associate Professor, Banting and Best Department of Medical Research, University of Toronto

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

Improving Developability of Proteins

11:10 Towards High-Affinity, Aggregation-Resistant Domain Antibodies by Design
Peter Tessier, Ph.D., Assistant Professor, Chemical & Biological Engineering, Ctr for Biotechnology & Interdisciplinary Studies, Rensselaer Polytechnic Institute

11:40 Engineering Drug-Like Properties of Therapeutic Proteins
Andrew Buchanan, Ph.D., Sr Scientist, Protein Engineering, MedImmune Ltd.

12:10 pm Automated High-Throughput Antibody Discovery and Optimization
Christopher Smith, Ph.D., Scientific Consultant, Biologics, Genedata Inc.

12:40 Luncheon Presentation I
Sponsored by morphosys
When Worlds Collide: Antibody Technologies and GPCRs
Stefanie Urlinger, Ph.D., Director, Discovery Alliances & Technologies, MorphoSys AG

1:10 Luncheon Presentation II *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

Improving Developability of Proteins

2:00 Chairperson's Remarks

2:05 Developability by Design
K. Dane Wittrup, Ph.D., J.R. Mares Professor, Chemical Engineering & Bioengineering, Massachusetts Institute of Technology; Co-Founder, Adimab

2:35 Stability Engineering of the Human Antibody Repertoire Using Phage Display and X-Ray Crystallography
Daniel Christ, Ph.D., Group Leader, Immunology Department; Director, Therapeutic Antibody Development, Garvan Institute of Medical Research

3:05 Discovery, Characterization, and Manufacturing of Next Generation ADC's and Bispecific Antibodies by Cell Free Protein Synthesis
Christopher Thanos, Ph.D., Director, Protein Engineering, Sutro Biopharma, Inc.

3:35 Best Poster Presentation: Rapid, Multiplexed Microfluidic Phage Display
Kellye Cung, Princeton University

3:50 Best Poster Presentation: Dissecting Cell Signaling Network Rewiring with Phage Display Generated Synthetic Antibodies
Frederic A. Fellouse, Ph.D., Postdoctoral Fellow, Samuel Lunenfeld Research Institute, University of Toronto

4:05 Refreshment Break in the Exhibit Hall with Poster Viewing

4:45 Problem Solving Breakout Discussions

5:45 - 6:45 Welcoming Reception in Exhibit Hall with Poster Viewing

TUESDAY, APRIL 30

8:00 am Registration and Morning Coffee

Novel Applications of Phage Display

8:25 Chairperson's Opening Remarks

8:30 Employing Phage Display as a Means to Interrogate Dynamic Structural States of Force-Bearing Proteins in the Extracellular Matrix
Thomas Barker, Ph.D., Associate Professor, Wallace H. Coulter Department of Biomedical Engineering, Georgia Institute of Technology

9:00 Targeting Glycans and Viral Glycoproteins with Synthetic Antibodies
Jonathan R. Lai, Ph.D., Assistant Professor, Biochemistry, Albert Einstein College of Medicine

9:30 Directed Evolution of DNA Polymerases for Next- Generation Sequencing
Floyd E. Romesberg, Ph.D., Associate Professor, Chemistry, The Scripps Research Institute

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

Deep Sequencing of Antibody Libraries

10:45 Molecular Deconvolution of the Circulating Antibody Repertoire in Human Health and Disease
George Georgiou, Ph.D., Professor, Molecular Genetics & Microbiology, University of Texas, Austin

11:15 Deep Panning: Steps towards Probing the IgOme
Jonathan M. Gershoni, Ph.D., Cell Research and Immunology, Tel Aviv University

11:45 Deep Sequencing Analysis of Phage Libraries
Ratmir Derda, Ph.D., Principal Investigator, Alberta Glycomics Centre; Assistant Professor, Department of Chemistry, University of Alberta, Edmonton

12:15 pm Discovery & Development of DX-2930: A Phage Display Case Study
Sponsored by Dyax
Andrew Nixon, Ph.D., Vice President, Discovery Research, Dyax Corp.

12:45 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

1:15 Ice Cream Break in the Exhibit Hall

Phage Improvements

2:00 Chairperson's Remarks
David C. Lowe, Ph.D., Fellow, R&D, MedImmune Ltd

2:05 3CARD: Ultra-Fast Single Round Phage and Yeast Display Antibody Library Screening Using Coupled Enzyme Reactions
Harald Kolmar, Ph.D., Professor of Applied Biochemistry, TU Darmstadt

2:35 Rapid, Multiplexed Microfluidic Phage Display
Michael C. McAlpine, Ph.D., Assistant Professor, Chemical and Biological Engineering, Princeton University

3:05 Antibody Selections Performed on Live Cells that Express Challenging Membrane Protein Targets by dsDNA Display with Deep Sequencing Analysis
Yan Chen, Ph.D., Sr VP, Research & Development, X-BODY BioSciences

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

4:15 - 5:30 PLENARY KEYNOTE PANEL **- for details see page 2**

5:30 Close of Conference

Engineering Antibodies

Challenging Targets, Next-Generation Research Methods and Antibody Therapeutics for Autoimmune Diseases

WEDNESDAY, MAY 1

7:00 am Conference Registration

Sponsored by OMT

7:45 Breakfast Presentation
OmniRat and OmniMouse – Naturally Optimized Human Antibodies
Roland Buelow, Ph.D., CEO, Open Monoclonal Technology, Inc.

Structural and Sequencing Methods for Antibody Screening and Design

8:30 Chairperson's Opening Remarks
Susanne Gräslund, Ph.D., Principal Investigator, Biotechnology, Structural Genomics Consortium, Canada

8:40 A Family-Based Approach to Study Proteins Involved in Epigenetic Signaling
Susanne Gräslund, Ph.D., Principal Investigator, Biotechnology, Structural Genomics Consortium, Canada

9:10 Functional Single-Cell Hybridoma Screening Using Droplet-Based Microfluidics
Christoph Merten, Ph.D., Group Leader, Principal Investigator, Genome Biology Unit, European Molecular Biology Laboratory, Germany

9:40 Molecular Computational Tools for Designing and Screening of Stable Antibodies
Neeraj J. Agrawal, Ph.D., Postdoctoral Associate, Chemical Engineering, Massachusetts Institute of Technology

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

Antibody Mixtures and Combinations

11:10 Simultaneous Inhibition of EGFR, HER2 and HER3 by an Antibody Mixture (Pan-HER) Provides Broad and Potent Tumor Inhibition
Johan Lantto, Ph.D., Principal Scientist, Project Leader, Symphogen A/S, Denmark

11:40 Mechanisms of Action of MM-151, a Triobody™ Targeting EGFR: Has EGFR Met Its Match?
Jeffrey. D. Kearns, Ph.D., Senior Scientist, MM-151, Merrimack Pharmaceuticals, Inc.

New Technologies for Antibody Engineering

Sponsored by Chemical Computing Group

12:10 pm A Uniform Framework for Computer-Aided Biologics Design
Christopher R. Corbeil, Ph.D., Research Scientist, Chemical Computing Group

Sponsored by isogenica

12:40 Luncheon Presentation I: Addressing Challenges in Synthetic Antibody Design Using Combinatorial Libraries
Chris Ullman, Ph.D., CSO, Isogenica Ltd.

Sponsored by sdix

1:10 Luncheon Presentation II: Multipass Membrane Protein Monoclonal Antibodies by DNA Immunization and High Throughput Flow Cytometry Screening
James W. Stave, Ph.D., CSO, SDIX

1:40 Session Break

Antibodies Against Intracellular and Membrane Targets

2:00 Chairperson's Remarks
Luis Pardo, Ph.D., Max-Planck Research Group Leader, AG Oncophysiology, Max-Planck Institute of Experimental Medicine, Germany

2:05 Bifunctional TRAIL Antibodies Targeting Kv10.1 Potassium Channels Induce Selective Apoptosis of Tumor Cells
Luis Pardo, Ph.D., Max-Planck Research Group Leader, AG Oncophysiology, Max-Planck Institute of Experimental Medicine, Germany

2:35 Rapid and Reliable Characterization of Fabs for Structural Analysis of an ABC Transporter
JungMin Kim, Ph.D., Postdoctoral Scholar, Pharmaceutical Chemistry, University of California, San Francisco

Sponsored by SELEXIS

3:05 The Selexis SURE CHO-Mplus™ Library: Next Generation Innovation for Addressing Difficult-to-Express Proteins
Andrew Sanford, Vice President, Business Development, Selexis, Inc.

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

4:20 Problem Solving Breakout Discussions

Sponsored by Blue Sky BioServices

5:20 - 6:30 Networking Reception in the Exhibit Hall with Poster Viewing

THURSDAY, MAY 2

Sponsored by SCHRÖDINGER

7:45 am Breakfast Presentation
Advanced Structural Modeling with Schrödinger's Biologics Suite
David A. Pearlman, Ph.D., Senior Principal Scientist, Schrodinger

Clinical and Preclinical Results for Antibody Therapeutics for Autoimmune Diseases

8:30 Chairperson's Opening Remarks
Sam Wu, Ph.D., Senior Scientist, Biologics Research, Janssen R&D

8:35 From Structural Insights to Functional Mechanisms: Antibody Interaction Mapping in Toll-like Receptor 3 Therapeutic Discovery
Sam Wu, Ph.D., Senior Scientist, Biologics Research, Janssen R&D

9:05 Targeting the BLyS/BAFF Pathway: Will Important Differences Emerge among Different Inhibitors?
William Stohl, M.D., Ph.D., Professor of Medicine, Division of Rheumatology, Keck School of Medicine, University of Southern California

9:35 Epratuzumab, a Humanized Monoclonal Antibody Targeting the B Cell Receptor CD22 for the Treatment of Systemic Lupus Erythematosus (SLE)
Tony Shock, Ph.D., Director, Immunology Portfolio, UCB, United Kingdom

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

11:05 Mechanism of Action (MOA) of Daclizumab in Multiple Sclerosis (MS)
Bibiana Bielekova, M.D., Chief, Neuroimmunological Diseases Unit, Neuroimmunology Branch, NINDS, National Institutes of Health

11:35 Simultaneous Engineering and Epitope Mapping in Order to Introduce Species Crossreactivity in a Therapeutic Antibody
Francois Rousseau, Ph.D., Head, Antibody Engineering, Research, Novimmune SA, Switzerland

12:05 pm Close of Conference

Engineering Bispecific Antibodies

The Future of Antibody Development

THURSDAY, MAY 2

12:30 pm Conference Registration

Opening Session

1:30 Chairperson's Remarks

» 1:40 KEYNOTE PRESENTATION
Ideas for Novel Targets and Target Pairs for Bispecific Antibody Approaches
William R. Strohl, Ph.D., Vice President, Biologics Research, Janssen Pharmaceuticals, Inc.

2:10 Symmetry Breaking: Bispecific Antibodies, the Beginnings, and 50 Years On
Gert Riethmüller, M.D., Institute for Immunology Ludwig-Maximilians-Universität

2:40 Designing and Engineering Azymetric™ Antibodies Towards Solving the "Light Chain Problem"
David Poon, Ph.D., Director, External R&D and Alliances, Zymeworks

Sponsored by zymeworks

3:10 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 Problem Solving Breakout Discussions

5:00 End of Day

FRIDAY, MAY 3

7:45 am Continental Breakfast in the Exhibit Hall with Poster Viewing

Novel Targets

8:30 Chairperson's Opening Remarks

8:35 Novel Tumor-Targeted, Engineered IL-2 Variant (IL-2v)-Based Immunocytokines for Immunotherapy of Cancer
Christian Klein, Ph.D., Discovery Oncology oDTA, Pharma Research and Early Development (pRED), Roche Glycart AG

9:05 Inducing Memory Immune Responses with Bispecific Antibody Infusions
Lawrence Lum, M.D., D.Sc., Professor of Immunology & Microbiology & Scientific Director, Immunotherapy & BMT, Karmanos Cancer Institute

9:35 Improving Chronic Wound Healing with Self-Signaling Bispecific Antibodies for Bacterial Detection
D. Jason Riley, Ph.D., Department of Materials, Imperial College London

10:05 Coffee Break in the Exhibit Hall with Poster Viewing; Poster Award & Raffle Drawing

Optimizing Drug-Like Properties

10:50 Efficient Generation of Stable Bispecific IgG1 by Controlled Fab-arm Exchange
Janine Schuurman, Ph.D., Director, Strategic Research, Genmab BV

11:20 The Adimab Platform and its Utility for Discovering Bispecific Antibodies: Do Yeast Based Discovery Platforms Yield More Developable Molecular Entities?
Robert Mabry, Ph.D., Associate Director, Antibody Discovery and Bispecific Engineering, Adimab, LLC

11:50 Chemically Programmed Bispecific Antibodies that Recruit and Activate T Cells
Christoph Rader, Ph.D., Associate Professor, Department of Cancer Biology and Department of Molecular Therapeutics, The Scripps Research Institute, Scripps Florida

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

12:50 Session Break

Innovative Designs

1:35 Chairperson's Opening Remarks

1:40 Novel Formats for Fc-Containing Bispecifics
Gregory L. Moore, Ph.D., Senior Scientist, Protein Engineering, Xencor, Inc.

2:10 An Innovative and Generic Route to Generate Bispecific Antibodies Monovalent for each Antigen in Conventional IgG Format
Nazzareno Dimasi, Ph.D., Senior Scientist, Antibody Discovery & Protein Engineering, MedImmune

2:40 Generating Bispecific Human IgG1 and IgG2 Antibodies from Any Antibody Pair
Jaume Pons, Ph.D., Senior Vice President, CTO, Biotech Unit R&D Group; CSO, Rinat-Pfizer, Inc.

Indications Outside Oncology

3:10 A Bispecific Multi-Mechanistic mAb Approach for a Serious Bacterial Pathogen
Charles (Ken) Stover, Ph.D., Senior Director, Discovery Infectious Disease, MedImmune

3:40 Antibody Fragment Phamacokinetics in the Eye and Implications for Bispecific Therapeutics
Justin Scheer, Ph.D., Scientist, Protein Chemistry, Genentech, Inc.

4:10 Close of Conference

Antibodies for Cancer Therapy

Challenging the Current Treatment Paradigm

MONDAY, APRIL 29

7:00 am Conference Registration and Morning Coffee

Novel Constructs

8:30 Chairperson's Opening Remarks

8:40 Design Considerations for Development of an Optimal Antibody-Drug Conjugate
Kenneth Geles, Ph.D., Senior Principal Scientist, Oncology Research Unit, Pfizer, Inc.

9:10 Multivalent Antibody-TRAIL Fusion Proteins for Cancer Therapy
Roland Kontermann, Ph.D., Professor, Biomedical Engineering, Institute of Cell Biology and Immunology, University of Stuttgart

9:40 Bispecific Antibodies for Selective Inhibition of CD47 in Cancer Cells
Krzysztof Masternak, Ph.D., Head, Biology, Research, Novimmune

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

Intracellular and Membrane Targeting

11:10 Is Pancreatic Cancer Still Untouchable in this Golden Age of Antibody Therapeutics?
Lei Zheng, M.D., Ph.D., Assistant Professor, Oncology and Surgery, Gastrointestinal Oncology Program, Johns Hopkins University School of Medicine

11:40 Targeting Intracellular Oncoproteins with Antibody Therapy or Vaccination
*Qi Zeng, Ph.D., Principal Investigator, Institute of Molecular and Cell Biology, A*STAR Singapore*

12:10 pm High-Throughput Discovery of Rare Native Human Therapeutic Monoclonal Antibodies from Human Donors
Sponsored by Vivalis
Majid Mehtali, Ph.D., Managing Director & CSO, VIVALIS

12:40 Luncheon Presentations *(Sponsorship Opportunities Available)*
or Lunch on Your Own

Antibodies in the Clinic

2:00 Chairperson's Remarks

2:05 Antibody Therapies: From Concept to Clinical Trial
Andrew Scott, M.D., FRACP, Lab Head, Tumor Targeting Lab, Ludwig Institute for Cancer Research, Australia

2:35 Antibody Based Immunotherapy Targeting GD2
Nai-Kong V. Cheung, M.D., Ph.D., Head, Neuroblastoma Program; Enid A. Haupt Chair in Pediatric Oncology, Memorial Sloan-Kettering Cancer Center

3:05 CTLA-4 Blockade: Past, Present, and Future
Michael Postow, M.D., Medical Oncology Fellow, Medicine, Memorial Sloan-Kettering Cancer Center

3:35 PD-1 Blockade in Cancer Therapy
Antoni Ribas, M.D., Ph.D., Professor, Medicine, Division of Hematology & Oncology, David Geffen School of Medicine, University of California Los Angeles

4:05 Refreshment Break in the Exhibit Hall with Poster Viewing

4:45 Problem Solving Breakout Discussions

5:45 - 6:45 Welcoming Reception in Exhibit Hall with Poster Viewing

TUESDAY, APRIL 30

8:00 am Registration and Morning Coffee

Promising New Targets

8:25 Chairperson's Opening Remarks

8:30 Discovery of Human Antibodies Targeting Glypican-3 for the Treatment of Liver Cancer
Mitchell Ho, Ph.D., Head, Antibody Therapy Section, Molecular Biology, NCI, NIH

9:00 WNT Pathway Inhibition via the Targeting of Frizzled Receptors Results in Decreased Growth and Tumorigenicity of Human Tumors
Jennifer Cain, Ph.D., Scientist, OncoMed Pharmaceuticals, Inc.

930 Tumor Vascular Targeting: Designing Therapeutic Antibodies that Distinguish Physiological and Pathological Angiogenesis
Bradley St. Croix, Ph.D., Tumor Angiogenesis Section, Mouse Cancer Genetics Program, Frederick National Laboratory for Cancer Research

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

10:45 Targeting Cancer Stem Cells: Development of a Novel Therapeutic Antibody Against LGR5 that Inhibits Tumor Growth and Reduces Frequency of Cancer-Initiating Cells
Christopher L. Reyes, Vice President, Research and Development Biologics, Bionomics

11:15 Clinical Implications and Challenges of Next Generation Therapeutics
Aymen Elfiky, M.D., MPH, Instructor, Department of Medicine, Harvard Medical School; Instructor, Medical Oncology, Dana-Farber Cancer Institute

11:45 ARGX-110, a Novel Human Anti-CD70 Antibody Functioning as an Immune Checkpoint Inhibitor and Proliferation Blocker
Sponsored by arGEN-X
Karen Silence, Ph.D., Research Fellow, arGEN-X BV

12:15pm Discovery of Functionally Superior Clinically Relevant Targets and Therapeutic Antibodies
Sponsored by BioInvent
Mikael Mattsson, Ph.D., Principal Scientist, Preclinical Research – Antibody Discovery, BioInvent International

12:45 Luncheon Presentation
Opportunities in Research - Platform Innovations and the Realization of Innovative Products
Sponsored by Genentech
Justin Scheer, Ph.D., Senior Scientist, Protein Chemistry, Genentech, Inc. A Member of the Roche Group

1:15 Ice Cream Break in the Exhibit Hall

Immunotherapy Approaches

2:00 Chairperson's Remarks

» 2:05 KEYNOTE PRESENTATION
Cancer Stem Cells and Malignant Progression
Robert A. Weinberg, Ph.D., Member, Whitehead Institute for Biomedical Research, and Professor, Biology, Massachusetts Institute of Technology

2:35 Treatment of Cancer with Recombinant Immunotoxins
Ira Pastan, M.D., Co-Chief, Molecular Biology, NCI, NIH

3:05 Immunotherapy Program
Helen Sabzevari, Ph.D., Global Head, Oncology & Immunotherapy, EMD Serono Research Institute

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

4:15 - 5:30 PLENARY KEYNOTE PANEL - for details see page 2

5:30 Close of Conference

Advancing Bispecific Antibodies to the Clinic for Oncology

Review of Recent Results

WEDNESDAY, MAY 1

7:00 am Conference Registration and Morning Coffee

8:30 Chairperson's Opening Remarks

» KEYNOTE SESSION

8:40 Bispecific Oncology Biologics: Challenges and Opportunities in Reducing R&D Cost and Enhancing Benefits to Patients
Rakesh Dixit, Ph.D., DABT, Vice President, R&D, Global Head Biologics Safety Assessment, MedImmune

9:10 Clinical Applications of Bispecific T Cell Engaging Antibodies in Oncology
Stanley R. Frankel, M.D., Medical Sciences Executive Medical Director, Amgen Rockville, Inc.

9:40 DARTS
Syd Johnson, Ph.D., Vice President, Antibody Engineering, Macrogenics

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

Intracellular Targets

11:10 Concomitant Targeting of Her-Family Receptors through Antibody-Based Multi-Specific Therapies
David M. Hilbert, Ph.D., CSO and Head, R&D, Zyngenia, Inc.

11:40 SAR156597: An Innovative Bispecific IL-4/IL-13 Antibody as a Potential Treatment for Idiopathic Pulmonary Fibrosis
Ercole Rao, Ph.D., Group Leader, R&D Biologics Center Frankfurt, SANOFI Deutschland GmbH

12:10 pm Luncheon Presentations *(Sponsorship Opportunities Available)*
or Lunch on Your Own

1:40 Session Break

Preclinical and Clinical Data: Understanding Safety Implications and Lessons Learned

2:00 Chairperson's Remarks

2:05 Selective Elimination of Cancer Cells Mediated by Dual-Targeting Triplebodies
Georg H. Fey, Ph.D., Professor emeritus, Genetics, Department of Biology, University of Erlangen-Nuremberg

2:35 Network Biology-Driven Discovery and Development of Bispecific Antibodies in Oncology
Ulrik B. Nielsen, Ph.D., Senior Vice President & Chief Scientific Officer, Merrimack Pharmaceuticals

3:05 Sponsored Presentation *(Opportunity Available)*

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

4:20 Problem Solving Breakout Discussions

5:20 - 6:30 Networking Reception in the Exhibit Hall with Poster Viewing

Sponsored by Blue Sky BioServices Pathways to Productivity

THURSDAY, MAY 2

8:00 am Registration and Morning Coffee

Preclinical and Clinical Data: Understanding Safety Implications and Lessons Learned

8:30 Chairperson's Opening Remarks

8:35 Clinical Aspects of Bispecific TCR Melanoma Program
Annelise Vuidepot, Ph.D., Head, Protein Science, Immunocore

9:05 Talk Title to be Announced
Tariq Ghayur, Ph.D., Senior Principal Scientist & Research Fellow, Abbott Bioresearch Center

9:35 Panel Discussion: Compare and Contrast Preclinical Work Required for IND Approval for a Standard Antibody vs a Bispecific
Moderator: Michael J. Feldhaus, Ph.D., Founder and CEO, Arus Biologics

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

T Cell Engaging Bispecifics and the Elicitation of Vaccination Effects

11:05 Recruitment of Cytotoxic Immune Cells by Bispecific TandAb Antibodies to Treat Cancer
Eugene Zhukovsky, Ph.D., Chief Scientific Officer, Research, Affimed Therapeutics AG

11:35 Bispecific Engagement by Antibodies Based on the T Cell Receptor: BEAT™ Platform
Stanislas Blein, Ph.D., Head, Antibody Engineering, Biologics, Glenmark Pharmaceuticals S.A.

12:05 Close of Conference

> "It's my third time at PEGS and I think people keep coming back because of the content. PEGS has really become the premier meetings for antibody and protein engineers."

THURSDAY, MAY 2

12:30 pm Conference Registration

Updates from the Clinic

1:30 Chairperson's Remarks
Peter Park, Ph.D., Vice President, Biology, Mersana Therapeutics, Inc.

1:40 Early Clinical Development of ADCs at Seattle Genetics
Nancy Whiting, Pharm.D., Senior Medical Director, Seattle Genetics

2:10 Development of AGS15E, a Novel Antibody Drug Conjugate Targeting SLITRK6 for the Treatment of Bladder Cancer
Kendall Morrison, Ph.D., Director, Protein Technologies, Agensys, Inc. (An affiliate of Astellas Pharma)

2:40 Application of Gyrolab for Efficient Bioanalysis in Anti-Drug Conjugate (ADC) Programs
Tracey Clark, Ph.D., Senior Scientist, Drug Metabolism, PDM Biotherapeutics, PGRD Pfizer

3:10 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 Innovations in the Antibody-Drug Conjugate Program at Pfizer Oncology Research
Puja Sapra, Ph.D., Director, Bioconjugates Group, Oncology Research Unit, Pfizer, Inc.

4:30 PSMA ADC: An Antibody-Drug Conjugate in Phase 2 Clinical Trial in Prostate Cancer
William C. Olson, Ph.D., Senior Vice President, Research & Development, Progenics Pharmaceuticals, Inc.

5:00 End of Day

FRIDAY, MAY 3

7:45 am Continental Breakfast in the Exhibit Hall with Poster Viewing

Updates from the Clinic (continued)

8:30 Chairperson's Opening Remarks
Pam Trail, Ph.D., Vice President, Oncology, Regeneron Pharmaceuticals

8:35 Antibody-Maytansinoid Conjugates: From Bench to Bedside...and Back
Robert J. Lutz, Ph.D., Vice President, Translational Research and Development, ImmunoGen, Inc.

Cutting Edge Engineering

9:05 Case Study
Kevin Hamblett, Ph.D., Senior Scientist, Oncology, Amgen

9:35 Antibody Vehicle Optimization in Application to ADC
Lioudmila Tchistiakova, Ph.D., Senior Director, Global Biotherapeutic Technologies, Pfizer

10:05 Coffee Break in the Exhibit Hall with Poster Viewing; Poster Award & Raffle Drawing

10:50 Empowering Antibodies for Cancer Therapy
Dennis Benjamin, Ph.D., Executive Director, Experimental Therapeutics, Seattle Genetics

11:20 Optimizing the Performance of ADCs Using an Expanded Genetic Code
Ho Sung-Cho, Ph.D., CTO, Ambrx, Inc

11:50 NanomAbs: Next Generation Antibody-Drug Conjugates
Oshrat Frenkel, Ph.D., Director, Research, Immune Pharmaceuticals

12:05 Probody™ Therapeutics Enable an Expanded Universe of ADC Targets
Henry B. Lowman, CSO, CytomX Therapeutics, Inc.

Sponsored by QUANTA BIODESIGN

12:20 pm Luncheon Presentation: What Can dPEG®'s Potentially Do for Your ADC Development Process? *in vivo* Studies with Branched dPEG® Constructs
Paul D. Davis, Ph.D., President & CEO, Quanta BioDesign, Ltd.

12:50 Session Break

Novel Payload, Linker and Chemical Conjugation

1:35 Chairperson's Opening Remarks
Scott Forrest, Vice President, Business Development, The Scripps Research Institute

1:40 Creating Next-Generation ADCs – Enabling New Payload Mechanisms & Alternative Targeting Moieties
Timothy B. Lowinger, Ph.D., CSO, Mersana

2:10 Positional Optimization of Non-Natural Amino Acids to Enable Discovery and Production of Single Species ADCs
Aaron K. Sato, Ph.D., Vice President, Research, Sutro Biopharma

2:40 An Approach for Assessing and Optimizing ADC Linker Stability
L. Nathan Tumey, Ph.D., Principal Research Scientist, Pfizer Global R&D

3:10 Speaker to be Announced, Synthon

Emerging Company Presentations

3:40 Tumor-Targeted Drug Conjugates with Precisely Controlled Chemical Composition Based on XTEN, a Protein Polymer
Volker Schellenberger, Ph.D., CSO, Discovery, Amunix, Inc.

3:55 A Novel Hydrophilic Linker for ADC
Ron (Rong Hwa) Lin, Ph.D., CEO, AbGenomics International, Inc.

4:10 Close of Conference

MONDAY, APRIL 29

7:00am Conference Registration and Morning Coffee

Kinases and GPCRs

8:30 Chairperson's Opening Remarks
Stephen Bottomley, Ph.D., Research Fellow, Biochemistry & Molecular Biology, Monash University

» 8:40 KEYNOTE PRESENTATION:
Strategies for the Generation of Difficult to Express Recombinant Proteins
Ian Hunt, Ph.D., Head, Protein Sciences, Center for Proteomic Chemistry, NIBR

9:10 *De novo* Synthesis and Characterization of Functional Kinases and GPCRs for Structural Biology
Matthew Coleman, Ph.D., Professor, Radiation Oncology, UC Davis

9:40 A Robust and Rapid Method of Producing Soluble, Stable, and Functional G-Protein Coupled Receptors
Karolina Corin, Ph.D., Researcher, Center for Biomedical Engineering, MIT

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

Refolding and Disulfide Bonds

11:10 REFOLD: Providing an Insightful Way to Refold Your Protein
Stephen Bottomley, Ph.D., Research Fellow, Biochemistry and Molecular Biology, Monash University

11:40 Bioengineering of Coagulation Factor VIII for Efficient Expression through Elimination of a Dispensable Disulfide Loop
Randal J. Kaufman, Ph.D., Director, Degenerative Disease, Neuroscience, Aging, and Stem Cell Research Center, Burnam Medical Research Institute

12:10 pm Maximizing Recombinant Protein Expression through Systematic Gene Design
Mark Welch, Ph.D., Director, Research & Development, DNA2.0, Inc.

12:40 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

Rescuing Proteins and Peptides and Improving Stability

2:00 Chairperson's Remarks
Alan Dombkowski, Ph.D., Assistant Professor, Division of Clinical Pharmacology and Toxicology, Pediatrics, Wayne State University School of Medicine

2:05 Improving Protein Stability and Function through Disulfide Engineering: A Computational Approach
Alan Dombkowski, Ph.D., Wayne State University School of Medicine

2:35 Best Poster Presentation

3:05 A Novel Method for the Large-Scale Production of PG-CNP37, a C-Type Natriuretic Peptide Analogue
Shinong Long, Ph.D., Senior Scientist, BioMarin Pharmaceutical, Inc.

3:35 Structural Biology Perspectives and Strategies for Rescuing Insoluble Protein Expression
Stephen Nakazawa Hewitt, Ph.D., Head, Bioreactor Core Facility, Univ ersity of Washington

4:05 Refreshment Break in the Exhibit Hall with Poster Viewing

4:45 Problem Solving Breakout Discussions

5:45-6:45 Welcoming Reception in the Exhibit Hall with Poster Viewing

TUESDAY, APRIL 30

8:00 am Registration and Morning Coffee

Strategies to Enhance Finicky Protein Expression

8:25 Chairperson's Opening Remarks
David Merkler, Associate Professor, Chemistry, Univ of South Florida

8:30 The Successful Expression of Two Enzymes in *E. coli*: Human Peptidylglycine α-hydroxylating Monooxygenase (hPHMcc) and Plasmodium vivax 1-deoxy-D-xylulose-5-phosphate Synthase (DXS)
David J. Merkler, Ph.D., Professor of Chemistry, University of South Florida

9:00 A PagP Fusion Protein System for Expressing Long Unstructured Polypeptides in *E. coli*
Peter Hwang, M.D., PhD, FRCP(C), Assistant Clinical Professor, Biochemistry, University of Alberta

9:30 Expression of Novel Molecules in Pfenex Expression Technology™
Ron Schoner, Ph.D., Fellow, MedImmune
Sponsored by Pfenex Inc.

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

Engineering for Results

10:45 Development of a Drosophila S2 Insect-Cell Based Placental Malaria Vaccine Production Process
Wian De Jongh, Ph.D.,University of Copenhagen, Center for Medical Parasitology, Department of International Health, Immunology and Microbiology, University of Copenhagen; ExpreS2ion Biotechnologies

11:15Expression and stabilization of pathologic GPCR Mutations and Arrestin Complexes for Structural Studies
Joerg Standfuss, Ph.D., Senior Scientist and Group Leader, Biomolecular Research, Paul Scherrer Institute

11:45 Direct and Specific Chemical Control of Eukaryotic Translation with a Synthetic RNA–Protein Interaction
Jacquin C. Niles, Ph.D., Assistant Professor, Pfizer-Laubach Career Development; Chair, Department of Biological Engineering, MIT

12:15 pm Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

1:15 Ice Cream Break in the Exhibit Hall

Science for Success

2:00 Chairperson's Remarks

2:05 Translation Levels Control Multi-Spanning Membrane Protein Expression
Hok Seon Kim, Ph.D., Researcher, Protein Chemistry, Genentech Inc.

2:35 Synthesis, Purification, and Characterization of Single Helix Membrane Peptides and Proteins for NMR Spectroscopy
Steven O. Smith, Ph.D., Professor, Department of Biochemistry and Cell Biology, Stony Brook University

3:05 New Tools for Difficult Expression Problems: Endotoxin-Free Proteins, Biotinlyated Proteins, and More
Curtis Knox, Director, Marketing, Lucigen Corp.
Sponsored by Lucigen Simplifying Genomics

3:20 From Lab to Pilot Scale – The Story of Transfer, Optimization and Up-Scaling of a Fermentation Process for Recombinant rPTH 1-34
Andreas Anton, Ph.D., Director, Contract Development, Scil Proteins GmbH
Sponsored by scil proteins

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

4:15 - 5:30 PLENARY KEYNOTE PANEL - for details see page 2

5:30 Close of Conference

WEDNESDAY, MAY 1

7:00 am Conference Registration and Morning Coffee

Protein Expression Challenges and Regulation

8:30 Chairperson's Opening Remarks

» 8:40 OPENING KEYNOTE PRESENTATION:
Protein Expression: Past Achievements and Future Prospects
John Birch, Ph.D., Consultant, Henley-on-Thames (former CSO of Lonza Biopharmaceuticals)

9:10 Featured Presentation
Regulatory Expectations for Expression Systems for Manufacturing Therapeutic Proteins
Baolin Zhang, Ph.D., Senior Investigator & Drug Quality Reviewer, Division of Therapeutic Proteins, Office of Biotechnology Products, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA)

9:40 Featured Presentation
Developing and Regulating Bioengineered Therapeutic Proteins: Synonymous Mutations Might Matter
Chava Kimchi-Sarfaty, Ph.D., Principal Investigator, Senior Staff Fellow, Hematology, Center for Biologics, Evaluation and Research (CBER) Food and Drug Administration (FDA)

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

Compare/Contrast Expression Systems

11:10 Comparing Host Systems for Heterologous Protein Expression: Predicting a Likely Best Choice or Testing in Parallel
Dominic Esposito, Ph.D., Director, Protein Expression Lab, Advanced Technology Program Directorate, SAIC Frederick

11:40 Expression Optimization Strategy Guided by Russell Body-Inducing Propensity of Individual IgG Clones
Haruki Hasegawa, Ph.D., Senior Scientist, Protein Science, Amgen, Inc.

12:10 pm Secretory *E. Coli* Technology: An Innovative System for the Production of Novel Biopharmaceuticals
Silvana Di Cesare, Ph.D., Manager, Business Development, Wacker Biotech GmbH
Sponsored by WACKER

12:40 Luncheon Presentation I: Cell Line Engineering Case Studies Using Multiple Human and CHO Cell Lines in Combination with GPEx®
Gregory Bleck, Ph.D., Research & Development Platform Lead, Biologics, Catalent Pharma Solutions
Sponsored by Catalent

1:10 Luncheon Presentation II: Novel UNic™ Vectors Boosting Recombinant Protein Production
Maurice van der Heijden, Ph.D., Research Manager, ProteoNic
Sponsored by ProteoNic

Expression in Chinese Hamster Ovary Cells (CHO)

2:00 Chairperson's Remarks

2:05 Early Prediction of Instability of CHO Cell Lines
Subinay Ganguly, Ph.D., Scientific Director, CMC Team Lead, Centyrex, Janssen R&D, Johnson & Johnson

2:35 Can Modification of Untranslated and Signal Sequences Improve Recombinant Protein Expression from CHO Cells?
John E. Hesketh, Ph.D., Professor, Mammalian Molecular Biology, Institute for Cell and Molecular Biosciences, University of Newcastle Medical School

3:05 Streamlining Antibody Development Using Large Scale, CHO Transient Gene Expression (TGE) followed by Rapid Production of CHO Stable Pools
James Brady, Ph.D., Director, Technical Applications, MaxCyte Inc.
Sponsored by MaxCyte

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

Baculovirus & Recombinant Vaccine Expression Challenges

4:20 Expression of Human Major Vault Protein in Whole Insects Using Baculovirus: Formulation of a Vault-CCL21 Nanocapsule as a Lung Cancer Treatment
George W. Buchman, Ph.D., Vice President and CSO, Chesapeake PERL, Inc.

4:50 Tackling Recombinant Vaccine Expression Challenges: Screening and Optimization of Platforms
Shyamsundar Subramanian, Ph.D., Principal Scientist and Head, Expression Systems Group, Vaccine R&D, Merck & Co.

5:20 - 6:30 Networking Reception in the Exhibit Hall with Poster Viewing
Sponsored by Blue Sky BioServices

THURSDAY, MAY 2

8:00 am Registration and Morning Coffee

Expression in *E.Coli*

8:30 Chairperson's Opening Remarks

8:35 *E. coli*-Based Recombinant Protein Production – A Phasing-Out Technology or Still on the Pulse of Time?
Gerald Striedner, Ph.D., Assistant Professor, Biotechnology, University of Life Sciences and Natural Resources, Vienna

9:05 *Escherichia coli* Expression System for Recombinant Protein Production
Francis Rajamohan, Ph.D., Senior Principal Scientist, Molecular and Structural Biology, Pfizer Global Research & Development

9:35 Optimizing Heterologous Protein Production in the Periplasm of *E. coli*
Jan-Willem de Gier, Ph.D., Associate Professor, Center for Biomembrane Research, Stockholm University; CSO, Xbrane Bioscience AB

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

Protein Production

11:05 Enhancing Protein Secretion
Tsafi Danieli, Ph.D., Head, Protein Expression Facility, Structural Biology, Hebrew University

11:35 Increasing Control and Flexibility for Development and Manufacturing Processes
Sebastien Ribault, Ph.D., Director, Development and BioProduction, Merck Biodevelopment

12:05 pm Luncheon Presentation
Improving Protein Production in CHO and HEK-293 Cells Using a PEI Optimized for Large Scale TGE: PEIpro™
Romuald Menth, Bioproduction Technical Support Specialist, Polyplus-transfection
Sponsored by Polyplus transfection

12:35 Close of Conference

Inaugural

High-Throughput Protein Expression

Strategies for Successful Outcomes

THURSDAY, MAY 2

12:30 pm Conference Registration

High-Throughput Clone Selection

1:30 Chairperson's Remarks
Andrew Bradbury, Ph.D., Research Scientist and Team Leader, Biosciences, Los Alamos National Laboratory

» 1:40 KEYNOTE:
Novel Technologies to Enable High-Throughput Expression
Govind Rao, Ph.D., Professor and Director, Center for Advanced Sensor Technology, University of Maryland

2:10 Filtering "Genic" Open Reading Frames from Genomic DNA by Antibiotic Selection
Sarah D'Angelo, Ph.D., Researcher, Los Alamos National Laboratory

2:40 High-Throughput Protein Production Within the Swedish Human Protein Atlas Project
Hanna Tegel, Group Leader, Proteomics, KTH Royal Institute of Technology

3:10 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 Problem Solving Breakout Discussions

5:00 End of Day

FRIDAY, MAY 3

7:45 am Continental Breakfast in the Exhibit Hall with Poster Viewing

Screens, Assays, and Miniaturization

8:30 Chairperson's Opening Remarks
Peter Neubauer, Ph.D., Laboratory of Bioprocessing, Biotechnology, Technische Universität Berlin

8:35 Real-Time Assay for Testing Components of Protein Synthesis
Barry S. Cooperman, Ph.D., Professor, The Department of Chemistry, University of Pennsylvania

9:05 Use of Transposons and MAR Elements for High-Throughput Protein Expression and Screening
Valerie LeFourn, Ph.D., Post Doctoral Researcher, Institute of Biotechnology, University of Lausanne-EPFL

9:35 HTP Protein Folding, Solubility and Expression Screening Using Fluorescent Reporters
Geoffrey S. Waldo, Ph.D., Team Leader, Biosciences, Los Alamos National Laboratory

10:05 Coffee Break in the Exhibit Hall with Poster Viewing; Poster Award & Raffle Drawing

10:50 Reconstituted Nonribosomal Production of the Peptide Antibiotic Valinomycin in the Heterologous Host Escherichia coli: High-Throughput Screening
Peter Neubauer, Ph.D., Laboratory of Bioprocessing, Department of Biotechnology, Technische Universität Berlin

11:20 Miniaturization and Parallelization of Biological and Chemical Assays in Microfluidic Devices
Saurabh Vyawahare, Ph.D., Director, Microfluidics Laboratory, Physical Sciences-Oncology Center, Princeton University

11:50 Tracking Expression and Subcellular Localization of RNA and Protein Species Using High-Throughput Single Cell Imaging Flow Cytometry
Lisa Nichols, Ph.D., Western Regional Director, Cytek Development, Inc.

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

12:50 Session Break

Improving Yield and Stability

1:35 Chairperson's Opening Remarks
Jonas Schaefer, Ph.D., Head, High-Throughput Laboratory, Department of Biochemistry, University of Zurich

1:40 Transferring Engineered Properties between Antibody Formats and Expression Systems - Effects of Framework Mutations on Stability and Structural Homogeneity
Jonas Schaefer, Ph.D., Head, High-Throughput Laboratory, Department of Biochemistry, University of Zurich

2:10 Improving Recombinant Protein Purification Yield
Heping Cao, Ph.D., Principal Research Scientist, Southern Regional Research Center, U.S. Department of Agriculture

2:40 Obtaining Hundreds of Antibodies Against Targets of Interest
Andrew M. Bradbury, Ph.D., Research Scientist and Team Leader, Los Alamos National Laboratory

HT Characterization Methods

3:10 Expression, Purification, and Surface Plasmon Resonance Characterization of Functional Human Cannabinoid Receptor CB2
Alexei Yeliseev, Ph.D., Staff Scientist, NIAAA, NIH

3:40 High-Throughput Single-Cell and Multiple-Cell Micro-Encapsulation
Todd Lagus, MS, Researcher, Edd Research Group, Department of Mechanical Engineering, Vanderbilt University

4:10 Close of Conference

Characterization of Biotherapeutics

Effective Analytical Strategies for the Development of Complex Biotherapeutics

MONDAY, APRIL 29

7:00 am Conference Registration and Morning Coffee

Characterization for Early Biotherapeutic Development

8:30 Chairperson's Opening Remarks
Lawrence Gan, Ph.D., Senior Director, Drug Metabolism & Pharmacokinetics, Biogen Idec

8:40 Pharmacokinetic and Disposition Profiling of Biotherapeutics in Drug Discovery
Lawrence Gan, Ph.D., Senior Director, Drug Metabolism & Pharmacokinetics, Biogen Idec

9:10 Discovering Protein-Ligand Interactions on a Proteomic Scale
Chiwook Park, Ph.D., Associate Professor, Medicinal Chemistry and Molecular Pharmacology, Purdue University

9:40 Early Stage Biophysical Screening Strategies to Identify Quality Biotherapeutic Candidates
Simon Low, Ph.D., Senior Scientist, Protein Analytics, Adnexus, A BMS Company

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

11:10 Effect of Post-Translational Modifications on Antibody Functions
T. Shantha Raju, Ph.D., Scientific Director, Discovery Technology Research, Janssen Research & Development, LLC

11:40 Characterization of Monoclonal Antibodies Binding Interactions
Maria Leonor Alvarenga, Ph.D., Scientific Co-Worker, Merck Serono, Germany

12:10 pm Selection of Recombinant Antibodies for Diagnostics Using Kinetic Screening by SPR
Alexander Kele, Ph.D., Global Marketing Manager, GE Healthcare Life Sciences

Sponsored by GE Healthcare

12:40 Luncheon Presentation
Discovery of High Quality Antibody Targets Using a Function-Led Approach: Solving the Target Deconvolution Bottleneck
Jim Freeth, Ph.D., Managing Director, Retrogenix, Ltd

Sponsored by RETROGENIX

Late Stage Development and Manufacturing

2:00 Chairperson's Remarks
T. Shantha Raju, Janssen Research & Development, LLC

2:05 An Image is Worth a Thousand Words
Ivan Correia, Ph.D., Principal Research Scientist, Protein Analytics, Global Pharmaceutical Organization, Abbott Bioresearch Center

2:35 Quantitative Evaluation of Fucose Reducing Effects in a Humanized Antibody on Fcγ Receptor Binding and Antibody-Dependent Cell-Mediated Cytotoxicity Activities
Shan Chung, Ph.D., Senior Scientist, Bioanalytical Technologies & Strategies, Genentech

3:05 Identification and Quantification of Host Cell Protein Impurities in Biotherapeutics Using Mass Spectrometry
Andrew M. Goetze, Ph.D., Scientific Director, Product Attribute Science, Amgen

3:35 Characterizing Higher Order Structure of Biologics by Hydrogen/Deuterium Exchange Mass Spectrometry: From Comparability Studies to Epitope Mapping Analysis
Hui Wei, Ph.D., Senior Research Investigator, PCO BDAS Mass Spectrometry, Bristol-Myers Squibb Co.

4:05 Refreshment Break in the Exhibit Hall with Poster Viewing

4:45 Problem Solving Breakout Discussions

5:45 - 6:45 Welcoming Reception in the Exhibit Hallwith Poster Viewing

TUESDAY, APRIL 30

8:00 am Registration and Morning Coffee

Next-Gen Characterization Methods for Biotherapeutics

8:25 Chairperson's Opening Remarks

8:30 Advanced Biophysical Tools for Assessing the Consistency and Comparability of the Higher Order Structure of Protein Biopharmaceuticals
Steven A. Berkowitz, Ph.D., Principal Scientist, Analytical Development, Biogen Idec, Inc.

9:00 Characterization of DVD-Ig molecules for Optimal Drug-like Properties
Jijie Gu, Ph.D., Senior Principal Research Scientist Global Biologics, AbbVie

9:30 What Color is Your Drug Product Protein Solution? Using a Quantitative Color Assessment Method
Trevor Swartz, Ph.D., Scientist, Early Stage Pharmaceutical Development, Genentech, Inc.

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

10:45 State-of-the-Art Methods for Glycoanalysis of Antibodies including High-Throughput Techniques
Dietmar Reusch, Director, Analytics Characterization, Pharma Biotech Development, Roche, Germany

11:15 Streamlining Antibody Discovery and Development by Leveraging Technology
Robin Barbour, Head of Antibody Generation, Prothena Biosciences

11:45 Applications of Förster Resonance Energy Transfer to the Study of Antibody Structure
Cathrine A. Southern, Ph.D., Assistant Professor, Chemistry, DePaul University

12:15 pm Fast and Reliable Identification of Differences in Large Peptide Mapping Data Sets of Stressed Recombinant Proteins
Matthias Berg, Ph.D., Technical Lead, Mass Spectrometry, TRD, Biologics Process R&D, Novartis AG

12:45 Luncheon Presentation
Accelerating Cell Line Optimization and Process Development Using Automated Solutions for Protein Purification and Characterization
Jeremy Lambert, Strategic Marketing, PerkinElmer

Sponsored by PerkinElmer

1:15 Ice Cream Break in the Exhibit Hall

Biological Assays In Antibody Drug Discovery

2:00 Chairperson's Remarks
Francesca Civoli, Ph.D., Principal Scientist, Clinical Immunology, Amgen, Inc.

2:05 Implementation of DOE in the Development and Validation of a Cell-Based Bioassay for the Detection of Anti-Drug Neutralizing Antibodies
Francesca Civoli, Ph.D., Principal Scientist, Clinical Immunology, Amgen, Inc.

2:35 Assays in Human Serum to Characterize Lead Antibodies Binding to their Native Targets
Yasmina Abdiche, Ph.D., Research Fellow, Rinat-Pfizer

Sponsored by forte

3:05 Tag-Free Quantitative Analysis of Interactions Between Two Ig-Fc-Containing Proteins
Yen-Ming Hsu, Ph.D., AB Biosciences, Inc.

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

4:15 - 5:30 PLENARY KEYNOTE PANEL - for details see page 2

5:30 Close of Conference

Inaugural

Biophysical Analysis of Biotherapeutics

Characterizing the Physical Properties of Proteins in Biotherapeutic Research and Development

ANALYTICAL STREAM
May 1-2, 2013

WEDNESDAY, MAY 1

7:00 am Conference Registration and Morning Coffee

Biophysical Characterization in Early Development

8:30 Chairperson's Opening Remarks
Peter M. Tessier, Ph.D., Assistant Professor of Chemical and Biological Engineering, Center for Biotechnology & Interdisciplinary Studies, Rensselaer Polytechnic Institute

8:40 High-Throughput Analysis of Monoclonal Antibody Self-Association in Complex Mixtures for Improved Antibody Selection and Formulation
Peter M. Tessier, Ph.D., Assistant Professor of Chemical and Biological Engineering, Center for Biotechnology & Interdisciplinary Studies, Rensselaer Polytechnic Institute

9:10 Application of a High-Throughput Solubility Assay for Selecting De-Risked Protein Therapeutic Candidates in Discovery
Aaron Yamniuk, Ph.D., Research Investigator, Research and Development, Bristol-Myers Squibb

9:40 Analytical Characterization of Biotherapeutics in Early Phase Clinical Development: Application of Biophysical Methods
Gopalan Soman, Ph.D., Development Manager III, Biopharmaceutical Development Program, SAIC-Frederick, Inc., National Laboratory for Cancer Research

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

Biophysical Evaluation of Proteins at High Concentration

11:10 Mind the Gap: Light Scattering Analysis of Biotherapeutics in High and Low Concentration
Michael Marlow, Ph.D., Staff Scientist, Protein Biochemistry, Regeneron Pharmaceuticals, Inc.

11:40 Application of Higher Order Structural Characterization Techniques to Understand the Functional Relationship of a Monoclonal Antibody and its Target Ligand
Kelly K. Arthur, Senior Associate Scientist, Analytical Sciences, Amgen, Inc.

12:10 pm Screening and Characterizing Biomolecular Interactions by Static and Dynamic Light Scattering
Sponsored by WYATT TECHNOLOGY
John Champagne, Ph.D., Senior Applications Scientist, Wyatt Technology Corp.
Daniel Some, Ph.D., Principal Scientist, Wyatt Technology Corp.

12:40 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

1:40 Session Break

Biophysical Tools to Identify and Solve Stability Problems in Biopharmaceutical Development

2:00 Chairperson's Remarks
JJ Phillips, Ph.D., Postdoctoral Fellow, Antibody Characterization, Antibody Discovery and Lead Optimization, MedImmune, United Kingdom

2:05 Qualification of Differential Scanning Calorimetry for Thermal Stability Analysis of Proteins
Jie Wen, Ph.D., Senior Scientist, Product Attribute Sciences, Amgen, Inc.

2:35 Engineering Stability into Therapeutic Antibodies - Structure and Dynamics Studies of Chemical and Physical Degradation
JJ Phillips, Ph.D., Postdoctoral Fellow, Antibody Characterization, Antibody Discovery and Lead Optimization, MedImmune, United Kingdom

3:05 Antibody Characterization Using Multiplexed SPR
Sponsored by BIO-RAD
Hassan Issafras, Ph.D., XOMA Corp.

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

4:20 Problem Solving Breakout Discussions

5:20 - 6:30 Networking Reception in the Exhibit Hall with Poster Viewing
Sponsored by Blue Sky BioServices Pathways to Productivity

THURSDAY, MAY 2

8:00 am Registration and Morning Coffee

Biophysical Characterization of Protein Aggregation

8:30 Chairperson's Opening Remarks
Elizabeth M. Topp, Ph.D., Dane O. Kildsig Chair and Head, Department of Industrial and Physical Pharmacy, Purdue University

8:35 Characterization and Release Testing of Protein Aggregates in Biotherapeutics: New Methods and New Analytical Strategies
Ewa Marszal, Ph.D., Chemist, Division of Hematology, Office of Blood Research and Review, Center for Biologics Evaluation and Research, Food and Drug Administration

9:05 Population Balance Modeling of Antibody Aggregation Kinetics
Paolo Arosio, Ph.D., Postdoctoral Researcher, Chemistry, University of Cambridge, United Kingdom

9:35 New Methods for Characterizing Aggregates and Pre-Aggregates in Lyophilized Solids
Elizabeth M. Topp, Ph.D., Dane O. Kildsig Chair and Head, Department of Industrial and Physical Pharmacy, Purdue University

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

Biophysical Methods to Characterize Antibody-Antigen Binding

11:05 Leveraging the Strengths of Biosensor and KinExA Platforms in Characterizing Antibody-Antigen Interactions
Giuseppe A. Papalia, Ph.D., Senior Research Scientist, Department of Biology, Gilead Sciences Inc.

11:35 Single Domain Binding Proteins for the Intervention of Neurodegenerative Diseases and Cancer: Structural Studies on Soluble VL Domains and on Anticalins
André Schiefner, Ph.D., Senior PostDoc, Biological Chemistry, Technical University of Munich, Germany

12:05 pm Close of Conference

THURSDAY, MAY 2

12:30 pm Conference Registration

Protein Self-Association: Mechanistic Understanding Critical for Successful Formulation

1:30 Chairperson's Remarks
Henryk Mach, Ph.D., Principal Scientist, Vaccine Drug Product Development, Merck

» KEYNOTE PRESENTATIONS:

1:40 Aggregation versus Association: Theory and Practical Examples
Hans-Joachim Schönfeld, Ph.D., Senior Principal Scientist, Cardiovascular and Metabolism, F. Hoffmann-La Roche, Inc.

2:10 Defining the Attributes and Threshold of Aggregated Biotherapeutics that Drive Activation of an *in vitro* Human Immune Response
Marisa Joubert, Ph.D., Senior Scientist, Product Attribute Sciences, Product and Process Development R&D, Amgen, Inc.

2:40 Avoiding Aggregation & Viscosity Challenges – Early Development Formulation Screening
Kevin Mattison, Ph.D., Principal Scientist, Bioanalytics, Malvern Instruments
Sponsored by Malvern

3:10 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 Problem Solving Breakout Discussions

5:00 End of Day

FRIDAY, MAY 3

7:45 am Continental Breakfast in the Exhibit Hall with Poster Viewing

Protein Self-Association: Mechanistic Understanding Critical for Successful Formulation

8:30 Chairperson's Opening Remarks
Marisa Joubert, Ph.D., Scientist, Product Attribute Sciences, Product and Process Development R&D, Amgen, Inc.

8:35 Mechanism of Aggregation of Abatacept, a Fusion Protein for the Treatment of Rheumatoid Arthritis
Satish Mallya, Ph.D., Senior Research Investigator, Biologics Manufacturing and Process Development, Bristol-Myers Squibb

9:05 Revisiting the Effect of Surfactants in Biopharmaceutical Formulation
Sumit Goswami, Ph.D., Senior Scientist, Pharmaceutical R&D, Biotherapeutics Pharmaceutical Sciences, Pfizer

Chemical Degradation: Rational Approaches for Damage Control

9:35 Effects of Solution Conditions on Methionine Oxidation in Albinterferon Alfa-2b and the Role of Oxidation in its Conformation and Aggregation
Danny Chou, Ph.D., Senior Research Scientist, Biologics Development, Gilead Sciences, Inc.

10:05 Coffee Break in the Exhibit Hall with Poster Viewing; Poster Award & Raffle Drawing

10:50 Featured Presentation
Linker Stability and Aggregation of ADCs
Andrea Ji, Ph.D., Senior Scientist, Late Stage Pharmaceutical Development, Genentech, Inc.

11:20 Spectroscopic Studies of Oxidized Antibody-Maytansinoid Conjugates
Elizabeth Bartlett, Ph.D., Scientist, Analytical and Pharmaceutical Sciences, ImmunoGen, Inc.

11:50 Novel *in silico* Prediction Algorithms for the Design of Stable Biologics
Francisco G. Hernandez-Guzman, Ph.D., Senior Product Manager, Accelrys, Inc.
Sponsored by accelrys

12:20 pm Luncheon Presentation
Counting and Sizing Protein Aggregates Down to 150nm Using New Focused Beam Light Scattering Technology
David F. Nicoli, Ph.D., Vice President, Research & Development, Particle Sizing Systems LLC
Sponsored by

1:05 Session Break

Biophysical Methodologies: Uncovering Critical Aspects of Protein Stability

1:35 Chairperson's Opening Remarks
Danny Chou, Ph.D., Senior Research Scientist, Biologics Development, Gilead Sciences, Inc.

1:40 Electrostatic Modeling and Native State Aggregation
Paul Dubin, Ph.D., Professor, Chemistry, University of Massachusetts, Amherst

2:10 Dual Variable Domain Igs: Considerations during Early Molecule Selection and Formulation Development
Sonal Saluja, Ph.D., Senior Scientist, Preformulations, AbbVie

2:40 The Effect of Protein Charge Landscape on Conformational and Colloidal Stability
Henryk Mach, Ph.D., Principal Scientist, Vaccine Drug Product Development, Merck

3:10 Thioflavin-S Staining Coupled to Flow Cytometry: A Screening Tool to Detect *in vivo* Protein Aggregation
Salvador Ventura, Ph.D., Full Professor, Institute of Biotechnology and Biomedicine, Universitat Autònoma de Barcelona

3:40 Elucidating the Effect of Protein Desorption on Biotherapeutics Aggregation
Tatiana Perevozchikova, Ph.D., Researcher, nSoft Consortium, National Institute of Standards and Technology

4:10 Close of Conference

Immunogenicity for Regulatory Success

Regulatory Guidance, Risk Assessment , Preclinical and Clinical Assays, and Strategy

MONDAY, APRIL 29

7:00 am Conference Registration and Morning Coffee

Experiences with Risk Assessment and Working the Regulatory Authorities

8:30 Chairperson's Opening Remarks
George R. Gunn, III, Ph.D., Associate Scientific Director, Biologics Clinical Pharmacology, Janssen Research & Development, LLC

8:40 Immunogenicity Risk Assessment and the Impact on Biological Drug Development
Holly W. Smith, B.A., Principal Research Scientist, Toxicology, Eli Lilly & Co.

9:10 Performing Timely Risk Assessment and Deploying Phase-Appropriate Risk Management Strategies for Immunogenicity
Renuka C. Pillutla, Ph.D., Director, Immunochemistry & Biomarker Development, Bristol-Myers Squibb

9:40 Evaluating the Relationship between Immunogenicity Assay Results and PK in Clinical Studies on Human Monoclonal Antibodies
Albert Torri, Ph.D., Senior Director, Bioanalytical Sciences, Regeneron Pharmaceuticals, Inc.

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

Regulatory Guidance and Expectations

» KEYNOTE SESSION:

11:10 Immunogenicity Considerations for Novel Antibody Products
Laurie Graham, Product Quality Reviewer, Division of Monoclonal Antibodies FDA/CDER

11:40 Strategies for Managing Drug Interference in Neutralizing Antibody Assays
Marie T. Rock, Ph.D., Vice President, Protein Bioanalysis, Midwest BioResearch LLC, a Wil Research Company

12:10 pm Tools and Technologies for Comprehensive Immunogenicity Risk Management *Sponsored by*
Nikolai Schwabe, Ph.D., CEO, ProImmune Inc

12:40 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

Development, Validation and Interpretation of Assays

2:00 Chairperson's Remarks
Renuka C. Pillutla, Ph.D., Director, Immunochemistry & Biomarker Development, Bristol-Myers Squibb

2:05 Rationalized Design and Validation of a Cell-Based Luciferase Assay for Detection of Neutralizing Antibodies to rhGM-CSF and Demonstration of Advantages over the Cell Proliferation-Based Method
Yuanxin Xu, Ph.D., Senior Scientific Director, Clinical Assay Development, Clinical Laboratory Sciences, Genzyme, a Sanofi Company

2:35 Neutralizing Antibody Assay Challenges: Cell-Based vs. Ligand Binding Assay Format Feasibility vs. Utility in a Clinical Program
Lakshmi Amaravadi, Ph.D., Director, Translational Medicine, Biogen Idec, Inc. and Chair, Ligand Binding Assay Focus Group-AAPS

3:05 Humanized Mouse Models, Part One: Model Development and Challenges in Assessing Immunogenicity
Kristina E. Howard, DVM, Ph.D., Staff Fellow, Division of Drug Safety Research, FDA, CDER

3:35 Increasing ADA Method Drug Tolerance: Does it Really Tell Us More?
George R. Gunn, III, Ph.D., Associate Scientific Director, Biologics Clinical Pharmacology, Janssen Research & Development, LLC

4:05 Refreshment Break in the Exhibit Hall with Poster Viewing

4:45 Problem Solving Breakout Discussions

5:45 - 6:45 Welcoming Reception in the Exhibit Hall with Poster Viewing

TUESDAY, APRIL 30

8:00 am Registration and Morning Coffee

Immunogenicity of Enzymes, Novel Products and Gene Therapy Products / Pre-Existing ADAs

8:25 Chairperson's Opening Remarks
Eric Wakshull, Ph.D., Senior Scientist & Group Leader, Bioanalytical Sciences, Genentech, Inc.

8:30 Assessment of the Immunogenicity of Next-Generation Therapeutic Proteins
Michael Tovey, Ph.D., Laboratory of Biotechnology & Applied Pharmacology, Ecole Normale Supérieure de Cachan

9:00 Novel Antibody Therapeutics with Engineered Features and Impact on Immunogenicity: Case Study of the Effect of an FcRn Mutation
Sally Fischer, Ph.D., Sr Scientist, Group Leader, Bioanalytical R&D, Genentech, Inc.

9:30 Clinical Relevance of Anti-Drug Antibodies in Enzyme Replacement Therapy
Becky Schweighardt, Ph.D., Principal Scientist, Director of Immunogenicity Assessment, Pharmacological Sciences, BioMarin Pharmaceuticals, Inc.

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

10:45 Overcoming Immune Hurdles in AAV-Mediated Gene Transfer to Liver: Lessons from Clinical Trials
Katherine A. High, M.D., Director, Ctr for Cellular and Molecular Therapeutics, and Investigator, Children's Hospital of Philadelphia and Howard Hughes Medical Institute.

11:15 Pre-Existing Anti-Drug Antibody, Related Reactivity and Risk Mitigation
Boris Gorovits, Ph.D., Director, PDM, Pfizer, Inc.

11:45 Pre-Existing Antibodies to F(Ab')2: Impact on Immunogenicity Assay Development And Data Interpretation
Eric Wakshull, Ph.D., Senior Scientist & Group Leader, Bioanalytical Sciences, Genentech, Inc

12:15 pm Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

1:15 Ice Cream Break in the Exhibit Hall

Characterization of Immune Complexes and their Impact on Risk Assessment

2:00 Chairperson's Remarks
Michael Tovey, Ph.D., Laboratory of Biotechnology & Applied Pharmacology, Ecole Normale Supérieure de Cachan

2:05 Understanding Hypersensitivity Reactions in the NHP: Immune Complexes, IgE and Other Biomarkers
Dan Mytych, Ph.D., Principal Scientist, Clinical Immunology, Amgen, Inc.

2:35 Formation of Immune Complexes in Nonclinical Studies
Deborah Finco, Ph.D., Immunotoxicology COE, Pfizer, Inc.

3:05 Update on EU Regulatory Guidance for Unwanted Immunogenicity Assessment
Bridget Heelan, Ph.D., Clinical Assessor, Medicines and Healthcare Products Regulatory Agency (MHRA) UK

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

4:15 - 5:30 PLENARY KEYNOTE PANEL - for details see page 2

5:30 Close of Conference

Inaugural

Immunogenicity Prediction & Mitigation

Predictive Tools & Risk Assessment - How Far Have we Come?

WEDNESDAY, MAY 1

7:00 am Conference Registration and Morning Coffee

Predictive Tools & Risk Assessment

8:30 Chairperson's Opening Remarks
Bonnie Rup, Ph.D., Research Fellow, Immunogenicity Sciences Lead, Pfizer

8:40 Immunogenicity Risk Prediction: An Overview of Current Tools and Approaches
Theresa J. Goletz, Ph.D., Director, Clinical Immunology, Amgen

9:10 Aiming for Improved Biotherapeutic Immunogenicity Risk Profiles through Implementation of New Risk Assessment Tools
Bonnie Rup, Ph.D., Research Fellow, Immunogenicity Sciences Lead, Pfizer

9:40 An Overview of the ABIRISK Initiative
Dan Sikkema, Ph.D., Head, BioPharma Clinical Immunology, GlaxoSmithKline

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

11:10 Prediction of Clinical Immunogenicity of Adnectins: Guiding Lead Optimization
Jochem Gokemeijer, Associate Director, Preclinical Discovery & Development, Adnexus, a Bristol-Myers Squibb R&D Company

11:40 XTEN: A Protein-Based, Biodegradable PEG Alternative with Low Immunogenicity
Beth Pei-Yun Chang, Ph.D., Associate Director, Cell Biology, Amunix, Inc.

12:10 pm Developability: Predicting, Avoiding and Reducing Immunogenicity and the Risk of Failure of Biotherapeutics
Yvette Stallwood, Ph.D., Head, Applied Protein Services, Lonza Biologics

Sponsored by Lonza

12:40 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

1:40 Session Break

Protein Aggregates and Associated Immune Activation

2:00 Chairperson's Remarks
Theresa J. Goletz, Ph.D., Director, Clinical Immunology, Amgen

2:05 Preclinical Assessment of the Immunogenicity Potential of Protein Aggregates
Anja Langenkamp, Ph.D., Laboratory Head, Immunosafety, F. Hoffmann-La Roche Ltd.

2:35 Impact of Light and Chemical Degradation on Protein Therapeutics, and Cascade of Events that can Result in Immunogenicity
Christian Schoneich, Ph.D., Takeru Higuchi Distinguished Professor and Chair, Pharmaceutical Chemistry, University of Kansas

3:05 Panel Discussion - Predictive Tools and Risk Assessment: How Far Have We Come?
Theresa J. Goletz, Ph.D., Director, Clinical Immunology, Amgen
Bernard Maillere, Ph.D., Research Director, Head of Laboratory, Immunochemistry, CEA-Saclay
Nicholas Marsh, Ph.D., Senior Director, Preclinical Discovery & Development, Adnexus
Bonnie Rup, Ph.D., Research Fellow, Immunogenicity Sciences Lead, Pfizer
Dan Sikkema, Ph.D., Head, BioPharma Clinical Immunology, GlaxoSmithKline

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

4:20 Problem Solving Breakout Discussions

5:20 - 6:30 Networking Reception in the Exhibit Hall with Poster Viewing

Sponsored by Blue Sky BioServices Pathways to Productivity

THURSDAY, MAY 2

8:00 am Registration and Morning Coffee

Humanized Models

8:30 Chairperson's Opening Remarks
Dan Sikkema, Ph.D., Head, BioPharma Clinical Immunology, GlaxoSmithKline

8:35 Humanized Mouse Models, Part Two: Progress Testing Biologics in Humanized Mice
Kristina E. Howard, DVM, Ph.D., Staff Fellow, Division of Drug Safety Research, FDA, CDER

9:05 Implementation of Predictive Strategies During Early Development of Human Biotherapeutics to Reduce Immunogenicity Risk in the Clinic
Vivian Bi, M.S., Research Scientist, Protein Technologies, Amgen, Inc.

9:35 Immunogenicity Studies using Immune Tolerant Mice
Vera Brinks, Ph.D., Utrecht Institute for Pharmaceutical Sciences, Department of Pharmacy, Utrecht University

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

Reducing Immunogenicity

11:05 Quantification of Pre-Existing T Cells to Predict Immunogenicity Potential of Therapeutic Proteins
Bernard Maillere, Ph.D., Research Director, Head of Laboratory, Immunochemistry, CEA-Saclay

11:35 Immunotoxins with Low Immunogenicity by Identifying and Removing T Cell Epitopes
Ronit Mazor, Ph.D., Laboratory of Molecular Biology, National Cancer Institute, National Institutes of Health

12:05 Close of Conference

Inaugural

PK/PD of Antibody-Derived Molecules

Improving Pre Clinical Results for Clinical Success

THURSDAY, MAY 2

12:30 pm Conference Registration

Linking PK/PD with Immunogenicity

1:30 Chairperson's Remarks

1:40 An Integrated Analytical Strategy for Biologics
Peter Lloyd, Head, PK/PD, Biologics, Novartis

2:10 Immunogenicity of Therapeutic Proteins: Strategies for Assessing Antidrug Antibodies and Their Impact
Theresa J. Goletz, Ph.D., Director, Clinical Immunology, Amgen, Inc.

2:40 Talk Title to be Announced
Yulia Vugmeyster, Ph.D., Principal Research Scientist, Pharmacokinetics, Dynamics, and Metabolism, Pfizer Research Labs

3:10 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 Problem Solving Breakout Discussions

5:00 End of Day

FRIDAY, MAY 3

7:45 am Continental Breakfast in the Exhibit Hall with Poster Viewing

The Business of Pharmacometrics

8:30 Chairperson's Opening Remarks

8:35 Return on Investment of Pharmacometrics
Joga Gobburu, Ph.D., FCP, MBA, Professor, School of Pharmacy; Executive Director, School of Medicine, Center for Translational Medicine, University of Maryland

Optimizing Outcomes through Modeling

9:05 Optimization of Dosing Regimens for Combination Therapies Using Mathematical Modeling and Quantitative Biology
Daniel C. Kirouac, Ph.D., P.Eng., Senior Scientist, Computational Biology, Merrimack Pharmaceuticals

9:35 PK/PD Method Development in Support of Preclinical and Clinical Studies from a PK/PD Modeling Perspective
Meina Liang, Ph.D., Director, Clinical Pharmacology & DMPK, Translational Sciences, MedImmune

10:05 Coffee Break in the Exhibit Hall with Poster Viewing; Poster Award & Raffle Drawing

Beyond Mathematical Models

10:50 Systems Pharmacology and Biologics: Facilitating Translation of Target Biology and Preclinical PK/PD to Make Accurate Human Clinical Predictions
John Burke, Ph.D., Senior Principal Scientists, Head, Systems Biology, Boehringer Ingelheim Pharmaceuticals, Inc.

11:20 Humanized Mouse Models for Modeling Antibody Pharmacokinetics
Gabriele Proetzel, Ph.D., Associate Director Technology Transfer, The Jackson Laboratory

11:50 Supermin™: Discovering a Variant of Serum Albumin with Extended Half-Life Based on Preclinical Models
Mike Schmidt, Ph.D., Scientist II,Molecular and Cellular Biology, Eleven Biotherapeutics

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

12:50 Session Break

PK/PD of ADCs

1:35 Chairperson's Opening Remarks

1:40 Featured Presentation
A Population Pharmacokinetic/Pharmacodynamic Model of Thrombocytopenia Characterizing the Effect of Trastuzumab Emtansine (T-DM1) on Platelet Counts in Patients with HER2-Positive Metastatic Breast Cancer
Brendan C. Bender, Senior Research Associate, Clinical Pharmacology Department, Genentech, Inc.

2:10 Development and Validation of a Mechanism Based PK/PD Model for Preclinical to Clinical Translation of ADC Efficacy
Dhavalkumar K. Shah, Ph.D., Senior Scientist, Modeling & Simulation, Pfizer

2:40 ADME of Antibody-Maytansinoid Conjugates
Xiuxia Sun, Ph.D., Scientist, ADC Biochemistry, ImmunoGen, Inc.

Improving Performance

3:10 Design Concepts for Antibody Drug Conjugates
Isabel Figueroa, Associate Principal Scientist, PK/PD, Merck

3:40 Optimizing Pharmacokinetic Stability of Protein Therapeutics
Josh Pearson, Ph.D., Senior Scientist, Biochemistry & Biophysics Group, Department of Pharmacokinetics & Drug Metabolism, Amgen, Inc.

4:10 Close of Conference

> "PEGS is a must-attend annual conference for those who want an unparalleled view of the latest developments and future of biologics."

WEDNESDAY, MAY 1

7:00 am Conference Registration and Morning Coffee

Process Development & Antibody Purification

8:30 Chairperson's Opening Remarks

» 8:40 OPENING KEYNOTE PRESENTATION:

How Purification Process Development is Meeting Today's Science and Business Challenges
Kristopher A. Barnthouse, Ph.D., Director, API Large Molecule Development, Pharmaceutical Development and Manufacturing Science, Janssen Pharmaceutical Companies of Johnson & Johnson

9:10 A Comparison of Protein A and Mixed-Mode Chromatography for the Purification of Monoclonal Antibodies
Stephen F. Anderson, Ph.D., Director, Protein Chemistry, Sanofi Pasteur Vaccines

9:40 Targeting the Not-So-Well-Known Nucleotide Binding Site for Antibody Purification
Başar Bilgiçer, Ph.D., Assistant Professor, Chemical & Biomolecular Engineering, University of Notre Dame

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

Improving Productivity

11:10 Featured Presentation
Continuous Chromatography (MCSGP) for the Purification of Therapeutic Proteins
Massimo Morbidelli, Ph.D., Professor, Institute for Chemical and Bioengineering, Department of Chemistry and Applied Biosciences, ETH Zürich

11:40 Capillary-Channeled Polymer (C-CP) Fibers: Structures and Chemistries for High-Throughput Protein Processing
R. Kenneth Marcus, Ph.D., Professor, Chemistry, Clemson University

12:10 pm Sponsored Presentation *(Opportunity Available)*

12:40 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

Improving Productivity

2:00 Chairperson's Remarks

2:05 Microgels for Efficient Protein Purification
Boaz Mizrahi, Ph.D., Research Fellow, Children's Hospital Boston, and Postdoc, Massachusetts Institute of Techology

2:35 Scaling-Up of a Downstream Purification Process for a New Recombinant Product (Human-cl rhFVIII)
Martin Linhult, Ph.D., Team Manager, Biopharmaceutical Development, Octapharma AB

3:05 Speeding Bioprocess Decision-Making with Label-Free Protein Quantitation
Craig Tin, Senior Product Manager, ForteBio – A Division of Pall Life Sciences
Sponsored by ForteBio

3:20 Sponsored Presentation *(Opportunity Available)*

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

4:20 Problem Solving Breakout Discussions

5:20 - 6:30 Networking Reception in the Exhibit Hall with Poster Viewing
Sponsored by Blue Sky BioServices

THURSDAY, MAY 2

8:00 am Registration and Morning Coffee

Purification Technologies

8:30 Chairperson's Opening Remarks

8:35 Enhancing Protein A Selectivity via PEGylation
Todd M. Przybycien, Ph.D., Professor, Biomedical Engineering and Chemical Engineering, Carnegie Mellon University

9:05 Chemoenzymatic Reversible Immobilization and Labeling of Proteins without Prior Purification
Mark Distefano, Ph.D., Professor, Chemistry, University of Minnesota

9:35 Generation and Characterization of Ligand Binding Assay Critical Reagents to Support Non-Regulated and Regulated Pharmacokinetic and Immunogenicity Studies
Teresa Caiazzo, Senior Scientist, Pharmacokinetics, Dynamics and Metabolism, Pfizer, Inc.

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

To Tag or Not to Tag

11:05 A Novel Approach to Automated Large Scale Purification of Antibodies and Fc-Tagged Proteins
Maciej Paluch, Research Associate, Protein Chemistry, Genentech

11:35 A New Approach to the Generation of Tag-Free Proteins in CHO Cells
Philip E. Hass, Senior Scientific Manager, Genentech

12:05 pm Close of Conference

Protein Aggregation and Stability in Biopharmaceuticals

Mechanisms, Measurement, Prediction and Control

THURSDAY, MAY 2

12:30 pm Conference Registration

Protein Self-Association: Mechanistic Understanding Critical for Successful Formulation

1:30 Chairperson's Remarks
Henryk Mach, Ph.D., Principal Scientist, Vaccine Drug Product Development, Merck

» KEYNOTE PRESENTATIONS:

1:40 Aggregation versus Association: Theory and Practical Examples
Hans-Joachim Schönfeld, Ph.D., Senior Principal Scientist, Cardiovascular and Metabolism, F. Hoffmann-La Roche, Inc.

2:10 Defining the Attributes and Threshold of Aggregated Biotherapeutics that Drive Activation of an *in vitro* Human Immune Response
Marisa Joubert, Ph.D., Senior Scientist, Product Attribute Sciences, Product and Process Development R&D, Amgen, Inc.

2:40 Avoiding Aggregation & Viscosity Challenges – Early Development Formulation Screening
Kevin Mattison, Ph.D., Principal Scientist, Bioanalytics, Malvern Instruments

Sponsored by Malvern

3:10 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 Problem Solving Breakout Discussions

5:00 End of Day

FRIDAY, MAY 3

7:45 am Continental Breakfast in the Exhibit Hall with Poster Viewing

Protein Self-Association: Mechanistic Understanding Critical for Successful Formulation

8:30 Chairperson's Opening Remarks
Marisa Joubert, Ph.D., Scientist, Product Attribute Sciences, Product and Process Development R&D, Amgen, Inc.

8:35 Mechanism of Aggregation of Abatacept, a Fusion Protein for the Treatment of Rheumatoid Arthritis
Satish Mallya, Ph.D., Senior Research Investigator, Biologics Manufacturing and Process Development, Bristol-Myers Squibb

9:05 Revisiting the Effect of Surfactants in Biopharmaceutical Formulation
Sumit Goswami, Ph.D., Senior Scientist, Pharmaceutical R&D, Biotherapeutics Pharmaceutical Sciences, Pfizer

Chemical Degradation: Rational Approaches for Damage Control

9:35 Effects of Solution Conditions on Methionine Oxidation in Albinterferon Alfa-2b and the Role of Oxidation in its Conformation and Aggregation
Danny Chou, Ph.D., Senior Research Scientist, Biologics Development, Gilead Sciences, Inc.

10:05 Coffee Break in the Exhibit Hall with Poster Viewing; Poster Award & Raffle Drawing

10:50 Featured Presentation
Linker Stability and Aggregation of ADCs
Andrea Ji, Ph.D., Senior Scientist, Late Stage Pharmaceutical Development, Genentech, Inc.

11:20 Spectroscopic Studies of Oxidized Antibody-Maytansinoid Conjugates
Elizabeth Bartlett, Ph.D., Scientist, Analytical and Pharmaceutical Sciences, ImmunoGen, Inc.

11:50 Novel *in silico* Prediction Algorithms for the Design of Stable Biologics
Francisco G. Hernandez-Guzman, Ph.D., Senior Product Manager, Accelrys, Inc.

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12:20 pm Luncheon Presentation
Counting and Sizing Protein Aggregates Down to 150nm Using New Focused Beam Light Scattering Technology
David F. Nicoli, Ph.D., Vice President, Research & Development, Particle Sizing Systems LLC

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1:05 Session Break

Biophysical Methodologies: Uncovering Critical Aspects of Protein Stability

1:35 Chairperson's Opening Remarks
Danny Chou, Ph.D., Senior Research Scientist, Biologics Development, Gilead Sciences, Inc.

1:40 Electrostatic Modeling and Native State Aggregation
Paul Dubin, Ph.D., Professor, Chemistry, University of Massachusetts-Amherst

2:10 Dual Variable Domain Igs: Considerations during Early Molecule Selection and Formulation Development
Sonal Saluja, Ph.D., Senior Scientist, Preformulations, AbbVie

2:40 The Effect of Protein Charge Landscape on Conformational and Colloidal Stability
Henryk Mach, Ph.D., Principal Scientist, Vaccine Drug Product Development, Merck

3:10 Thioflavin-S Staining Coupled to Flow Cytometry: A Screening Tool to Detect *in vivo* Protein Aggregation
Salvador Ventura, Ph.D., Full Professor, Institute of Biotechnology and Biomedicine, Universitat Autònoma de Barcelona

3:40 Elucidating the Effect of Protein Desorption on Biotherapeutics Aggregation
Tatiana Perevozchikova, Ph.D., Researcher, nSoft Consortium, National Institute of Standards and Technology

4:10 Close of Conference

SPONSORSHIP + EXHIBIT

CHI offers comprehensive sponsorship packages which include presentation opportunities, exhibit space, branding, as well as the use of the pre and post-show delegate list. Sponsorships allow you to achieve your objectives before during and long after the event. Any sponsorship can be customized to meet with your company's needs and budget. Signing on earlier will allow you to maximize exposure to hard-to-reach decision makers!

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Showcase your solutions to a guaranteed, highly-targeted audience in the session room. 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.

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Presentations are held in the main session room & flow directly from the morning talks into lunch. Attendees from the morning sessions are already seated and lunch is delivered to the room, resulting in longer talks with plenty of time for Q&A. During this time, you can distribute literature and drive traffic to your booth resulting in maximum exposure and a high ROI!

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Co-locate your user-group meeting with PEGS 2013. CHI will help market the event, manage logistical operations, develop the agenda, and more.

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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. Evening will be customized according to sponsor's objectives (i.e. purely social, focus group, reception style, plated dinner with specific conversation focus).

Exhibit

Exhibitors will enjoy face-to-face networking with 1,200+ qualified end-users. PEGS is the perfect place to launch a new product to your target audience, the PEGS delegates! Showcase your latest technologies or solutions and walk away with new business leads!

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- All custom lead generation programs are promoted through our experienced marketing team that will develop and drive targeted campaigns to drive awareness and leads to your lead generation program.
- For our webinar programs, we offer assistance in procuring speakers for your web symposia through our extensive roster of industry recognized speakers across multiple disciplines within life sciences, as well as provide an experienced moderator and dedicated operations team will coordinate all efforts.
- If choosing a white paper program, we can offer editorial experience and provide an industry recognized author to write your white paper.

Additional promotional opportunities are available, including the conference tote bag distributed to all delegates.

To customize your sponsorship or exhibit package, please contact:

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

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Discounted Room Rate: $239 s/d
Discounted Room Rate Cutoff: March 25, 2013

Please visit PEGSsummit.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 attendee to receive the discounted room rate. 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.

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- Call American Airlines 1-800-433-1790 and use Conference code 9243BM.
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How to Register: PEGSummit.com

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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.

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CONFERENCE TRACKS

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Phage and Yeast Display	Engineering Antibodies	Engineering Bispecific Antibodies
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Difficult to Express Proteins	Optimizing Protein Expression	High-Throughput Protein Expression
Characterization of Biotherapeutics	Biophysical Analysis of Biotherapeutics	Protein Aggregation and Stability
Immunogenicity for Regulatory Success	Immunogenicity Prediction and Mitigation	PK/PD of Antibody-Derived Molecules
	Purifying Antibodies & Recombinant Proteins	Protein Aggregation and Stability

CONFERENCE SHORT COURSES

April 28 10:00am - 1:00pm	April 28 2:00 - 5:00pm	April 30 6:00 - 8:00pm	May 2 5:30 - 7:30pm
SC1: Antibody Humanization via One Hot Homology Model	SC5: Biosimilars & Biobetters: Development, Regulation and Prospects	SC10: Immunogenicity Risk Assessment and Regulatory Strategy	SC13: Cancelled
SC2: Basics of Immunogenicity	SC6: Overcoming the Challenges of Immunogenicity Testing	SC11: Boosting Anti-Tumor Immunity with Monoclonal Antibodies	SC14: Antibody-Drug Conjugate Therapeutics: Potential and Challenges
SC3: Phage and Yeast Display Libraries	SC7: Alternate Display Technologies	SC12: How to Obtain Reliable Information from Light Scattering	
SC4:Translational Considerations for Development of Monoclonal Antibodies Part I: Focus on Early Discovery	~~SC8: Automated Antibody Sequencing Using Mass Spectrometry~~ CANCELLED		
	SC9: Translational Considerations for Development of Monoclonal Antibodies Part II: Focus on Nonclinical Development to Clinic		