STRATEGIES FOR SUCCESS IN THE CLINIC AND WITH THE REGULATORS

6th Annual
Immunogenicity for Regulatory Success

Inaugural
Immunogenicity Prediction & Mitigation

Inaugural
PK/PD of Antibody-Derived Molecules

PEGSummit.com

PLENARY KEYNOTE PANEL

Conventional vs. Non-Conventional Formats

Moderator:
Janice Reichert, Editor-in-Chief, mAbs

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

Ninth Annual
PEGS

April 29 - May 3, 2013
SEAPORT WORLD TRADE CENTER
BOSTON, MA

the essential protein engineering summit

PREMIER SPONSORS

Blue Sky BioServices
Pathways to Productivity

Lonza Vivalis®

Organized by
Cambridge Healthtech Institute

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

SPONSORS

PREMIER SPONSORS

Blue Sky BioServices
Pathways to Productivity

Lonza

Vivalis®

CORPORATE SPONSORS

accelrys®

arGEN-X

BioInvent

Bio-Rad

Catalent

Chemical Computing Group

DNA 2.0

Dyax

forteBIO
A Division of Pall Life Sciences

GE Healthcare

Genedata
solutions in silico

GYROS

isogenica

Lucigen®
Simplifying Genomics

Malvern

MaxCyte®

morphosys

OMT

Particle Sizing Systems
PSS

PerkinElmer
For the Better

Pfenex Inc.

Polyplus
transfection

PROIMMUNE
www.proimmune.com

ProteoNic

Quanta BioDesign
Limited

RETROGENIX™
SPOTTING YOUR TARGET.

scil
proteins

SCHRÖDINGER.

sdix

SELEXIS

WACKER

WYATT
TECHNOLOGY

X-BODY
BIOSCIENCES

CORPORATE SUPPORT SPONSORS

GENEWIZ®
Solid science. Superior service.

intellicyt
screening solutions for life

LATHROP & GAGE LLP

proteinsimple

Sutro
Biopharma

zymeworks
BUILDING BETTER BIOLOGICS™

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 lists.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!

Agenda Presentations

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.

Luncheon Presentations

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!

User Group Meetings

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

Invitation-Only VIP Dinner/Hospitality Suite

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

Looking for additional ways to drive leads to your sales team?
Cambridge Healthtech Institute can help!

We offer clients numerous options for custom lead generation programs to address their marketing and sales needs. Some of our programs include: live webinars, white papers, market surveys, podcasts, and more!

Benefits of working with Cambridge Healthtech Institute for your lead generation needs:

- Your campaign will receive targeted promotion to Cambridge Healthtech Institute's unparalleled database of over 800,000 individuals, all of which are involved in all sectors of the life sciences – lists can be segmented based on geography, research area, title and industry.
- 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

CURRENT EXHIBITORS *As of 12/12/12

Accelagen
Aldevron
AllCells
Antibody Solutions
Aragen Bioscience
Asahi Kasei Bioprocess
Bioneer
BiOptix, Inc.
Blue Sky Bioservices, Inc.
Catalent Pharma Solutions
Chemical Computing Group
Cisbio US
Core Informatics
DNA 2.0
Emerald Bio
ExSAR
ForteBio, A division of Pall Life Sciences
Genewiz
GenScript
Gyros
Intellicyt
Isogenica
KBI Biopharma, Inc.
Lonza
Lucigen
m2p-labs
Malvern Instruments
MaxCyte
Molecular Devices
NanoSight
New England Biolabs
Paragon Bioservices, Inc.
Pfenex
Precision Antibody
Premas Biotech
ProteinSimple
ProteoNic
Proteos
Quanta BioDesign, Ltd.
RheoSense, Inc.
Sapidyne Instruments
Schrodinger
SDIX
Selexis
SensiQ
Soluble Therapeutics
Tecan
Teknova
Thomson Instrument Company
Wasatch Microfluidics

HOTEL + TRAVEL

CONVENTION VENUE:

The Seaport World Trade Center
200 Seaport Boulevard | Boston, MA 02210
Telephone: 617-385-5049

HOST HOTEL

Seaport Hotel
One Seaport Lane | Boston, MA 02210
Telephone: 617-385-4500

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.

FLIGHT DISCOUNTS:

Special discounts have been established with American Airlines for this conference.

- Call American Airlines 1-800-433-1790 and use Conference code 9243BM.
- Go to www.aa.com/group and enter Conference code 9243BM in promotion discount box.
- Contact our dedicated travel agent, Wendy Levine at 1-877-559-5549 or wendy.levine@protravelinc.com.

CAR RENTAL DISCOUNTS:

Special rental discounts have been established with Hertz for this conference.

- Call Hertz 1-800-654-3131 and use our Hertz Convention Number (CV): 04KL0004
- Go to www.hertz.com and use our Hertz Convention Number (CV): 04KL0004

Reserve your hotel room and SAVE $100 off your conference registration*

*You must book your reservation under the Cambridge Healthtech/PEGS room block for a minimum of four nights at the Seaport Hotel. The $100 discount is per room.

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, MB, BS, 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, SK_D 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

** Separate Registration Required*

(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

(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

Instructors: Kathleen Clouse, Ph.D., Director, Division of Monoclonal Antibodies FDA/CDER

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.

- 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

(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., Pharmacology, Director, 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*

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.

This presentation discusses factors considered in an Immunogenicity Risk Assessment, how the outcome affects decisions through all phases of drug development, and the importance of communication of the risk decision across internal components and external regulators to ensure a cohesive strategy for immunogenicity characterization and mitigation.

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

Immunogenicity risk assessment must be performed early in the development of a biotherapeutic. However, as the molecule progresses through development and additional data is collected, the risk should be re-evaluated periodically. Thus, immunogenicity risk assessment is an iterative process. There are various factors to consider with regards to the assessment of immunogenicity risk. Based on careful consideration of the risk factors, a program-specific risk mitigation and / or risk management strategy needs to be defined. These factors and strategies can be categorized into three areas – clinical, CMC-related and bioanalytical. Examples of some factors and potential mitigation strategies will be discussed in the context of the phase of development. Phase-appropriate risk management strategies are critical to minimize immunogenicity-related concerns from regulatory agencies.

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.

Anti-Drug Antibody (ADA) responses occur even when patients are administered biotherapeutics which are fully human monoclonal antibodies. Evaluating the impact of these ADA on the efficacy of the biotherapeutics can be challenging, particularly if observed drug and biomarker levels in the ADA negative patients are variable. A case study highlighting this issue will be presented.

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* ProImmune

Nikolai Schwabe, Ph.D., CEO, ProImmune Inc

ProImmune has developed a comprehensive suite of *in vitro* assays that characterize DC, T cell, B cell and innate immune responses. Antigen presentation assays using mass spectrometry, dendritic cell - T cell assays and physical HLA-peptide binding assay can be combined to provide a broad picture of protein antigenicity. Data from these assays can help inform improved drug design and lead selection through a clearer understanding of the mechanisms that drive immune responses.

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

A robust assay is essential for monitoring neutralizing antibody (NAb) in rhGM-CSF treated patients. In collaboration with Michael Tovey (Institute Andre Lwoff, France), a GM-CSF specific luciferase reporter-gene cell line was generated. The 1-day luciferase NAb assay showed significant improvement over the 4-day cell-proliferation based methodin assay performance and meets the current standard.

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

This presentation will discuss a case study on developing a cell-based assay for detection of neutralizing antibodies and will discuss challenges related to inherent sensitivity, drug interference and clinical study design that limit the utility of the assay in a clinical program. Alternative approaches to address these issues will be presented.

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

Humanized mice represent a new animal model that may benefit preclinical and drug discovery research. This presentation will review of a variety of humanized mouse models with discussion of the applicability, advantages and disadvantages of each. Examples of the challenges encountered employing this animal model for immunogenicity drug testing will be presented.

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

This presentation discusses the recent push by regulatory agencies to address ADA method drug tolerance limitations and explores whether improved drug tolerance actually leads to a better understanding of the clinical impact of ADA on safety and efficacy.

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

6:45 End of Day

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
Numerous protein therapeutics in development including bi-specifics, ADCs, or pegylated fusion proteins have several functional epitopes and/or a multifunctional action that present significant challenges for the development of assays for immunogenicity of each component including pre-existing or drug induced IgE, and NAbs. A cell engineering approach has been used to resolve these challenges.

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., Senior Scientist, Group Leader, Bioanalytical R&D, Genentech, Inc.
To improve the effectiveness of antibody therapeutics, a variety of antibodies with engineered features have been generated. These engineered features are designed to improve various characteristics of the molecules. This presentation will focus on a case study where a mutation intended to increase FcRn binding affinity caused unforeseen challenges in the immunogenicity evaluation of the molecule.

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.
Anti-drug antibodies often develop in response to enzyme replacement therapy. Related hypersensitivity is common, but can often be controlled with concomitant medication and temporary reductions in exposure. Transient IgM can play a significant role in early hypersensitivity, suggesting that the IgG isotype switch may partially explain why protein therapy is better tolerated over time.

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
Successful AAV-mediated gene delivery to the liver through the intravascular space must overcome barriers imposed by the human immune response. This presentation will review state-of-the-art approaches to avoiding the neutralizing effects of pre-existing antibodies to AAV, present in up to 50% of the adult population, and managing the T cell response to AAV capsid, which if unchecked can result in loss of transgene expression.

11:15 Pre-Existing Anti-Drug Antibody, Related Reactivity and Risk Mitigation
Boris Gorovits, Ph.D., Director, PDM, Pfizer, Inc.
An increased frequency of observed pre-existing reactivities to various types of biotherapeutics in development have been observed which leads to a discussion of causes and the need for a risk-based mitigation plan. This presentation will focus on a brief overview of the topic and present several case studies.

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.
During the development of an ATA assay for a F(ab')2, we noted the presence of extensive pre-existing antibodies (PEA) that required a unique bioanalytical approach to assess an immunogenic response. The existence of these PEAs suggest the need for modified immunogenicity strategies when developing drugs that might contain neoepitopes of endogenous homologues of proteins such as IgGs, and also awareness of the immunogenic potential of these neoepitopes.

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
Unwanted immunogenicity of biological medicines continues to be a serious problem and can have serious clinical consequences. It is a concern for regulators assessing biological products and the EU CHMP was the first regulatory agency to publish a guideline on the subject in 2008. Since then further guidance has been drafted and a new guideline on immunogenicity assessment of monoclonal antibodies intended for *in vivo* clinical use came into effect in December 2012. This presentation will provide an update on unwanted immunogenicity and the status and interpretation of existing EU guidelines. Considerations relevant to the immunogenicity assessment of biosimilars will also be discussed.

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

6:00 - 8:00 Dinner Short Courses - see page 5 for details

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
A clearer understanding of immunogenic risk throughout the drug development process could reduce development time and cost while helping to ensure lead candidates with more favorable immunogenic profiles. This presentation will provide an overview of the current tools available for immunogenicity risk prediction and management. Examples will be provided illustrating the use of these tools at various stages of drug development.

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
ADA measurement and characterization tools are highly valuable in assessing immunogenicity potential, yet they are applied after decisions are made about selection of candidate molecules, formulations, and dosing regimens. This presentation will overview risk assessment tools that are being applied earlier, and discuss limitations that should be addressed to increase their reliability.

9:40 An Overview of the ABIRISK Initiative
Dan Sikkema, Ph.D., Head, BioPharma Clinical Immunology, GlaxoSmithKline
ABIRISK (www.abirisk.eu), is a €35M Public-Private partnership (35 partners in 13 countries) receiving support from the Innovative Medicines Initiative and EFPIA. The program will investigate mechanisms of anti-drug immune response, technologies for predicting immunogenicity, and establish an immunogenicity databank to identify common and disease-specific/drug-specific variables.

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
Immunogencity assessment with *in silico* tools and *in vitro* T cell-based assays open the possibility to change the human immune response to therapeutic proteins by protein engineering. Here we will discuss the use of these tools in discovering Adnectins with low immunogenicity.

11:40 XTEN: A Protein-Based, Biodegradable PEG Alternative with Low Immunogenicity
Beth Pei-Yun Chang, Ph.D., Associate Director, Cell Biology, Amunix, Inc.
XTEN represents a family of unstructured polypeptides that extends the half-life of an attached therapeutic. Biopharmaceuticals fused with XTEN displayed excellent serum half-life extension and good efficacy. Preclinical and clinical studies on the immunogenicity of XTEN fusions will be discussed.

12:10 pm Developability: Predicting, Avoiding and Reducing Immunogenicity and the Risk of Failure of Biotherapeutics
Sponsored by Lonza
Yvette Stallwood, Ph.D., Head, Applied Protein Services, Lonza Biologics
Development risk, attrition and saftey remain some of the key challenges to a successful biopharmaceutical and vaccine pipeline. To help our customers streamline drug development, Lonza offers Applied Protein Services, a platform of *in silico* and *in vitro* tools for a multidisciplinary approach to risk assessment and product design. Our services incorporate immunogenicity, stability and aggregation assessment along with chemical and glycosylation assessment as well as small scale protein production services.

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.
Using artificially modified and/or stressed proteins as model antigens, *in vitro* and new *in vivo* models can provide informative data for risk assessments and help to support risk mitigation plans. A case study will be presented to show the benefit and limitations of preclinical tools for immunogenicity assessment.

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
This lecture describes the nature of light and reactive chemicals, which protein pharmaceuticals are exposed to during production, purification, formulation and storage, and delineates pathways by which these factors can impact drug substance and drug product. It will focus specifically on chemical pathways leading to aggregation, and summarize *in vivo* studies testing the immunogenicity of chemically modified proteins.

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
Humanized mice are chimeric animal models containing both murine and human components. This presentation will address recent progress in testing human biologic drug products in this model. Discussion will focus on the use of commercial assays designed for human samples and results from our ongoing studies.

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.

There is a potential immunogenicity risk associated with administration of fully human based biotherapeutics in clinic. A proactive assessment of such risk in early stage candidate development can help mitigate the risk. This talk provides a strategy encompassing these factors that can be implemented at early stages of biotherapeutic development.

9:35 Immunogenicity Studies Using Immune Tolerant Mice

Vera Brinks, Ph.D., Utrecht Institute for Pharmaceutical Sciences, Department of Pharmacy, Utrecht University

In order to minimize immunogenicity of therapeutic proteins better insight into the underlying mechanisms is needed. Using immune tolerant mice we (i) study which types of protein aggregates are immunogenic and (ii) assess which immune responses protein aggregates induce.

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

Because CD4 T lymphocytes specific for therapeutic proteins play a major role in the initiation of the antibody response, we estimated their number in the blood of healthy donors. This approach was applied to therapeutic proteins and antibodies. Relationship with their immunogenicity is discussed.

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

We are developing recombinant immunotoxins that contain a portion of Pseudomonas Exotoxin A (PE38) to treat cancer. The toxin moiety induces neutralizing response and limits the number of treatment cycles. This talk will describe identification and elimination of T cell epitopes in PE38.

12:05 Close of Conference

Poster Discount

Gain further exposure by presenting your work in the poster sessions.

- Your poster will be exposed to our international delegation
- Receive $50 off your registration
- Your poster abstract will be published in our conference materials
- Your research will be seen by leaders from top pharmaceutical, biotech, academic and government institutes
- Poster competition

To secure a poster board and inclusion in the conference materials, your abstract must be submitted, approved and your registration paid in full by **March 22, 2013**.

Alumni Discount

Cambridge Healthtech Institute (CHI) appreciates your past participation at the PEGS Summit. Through support like yours, CHI has been able to build this event into a must attend for senior level decision makers. **As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate.** Just check off the box marked Alumni Discount on the registration form to receive the discount! Please note: Our records must indicate you were an attendee of the PEGS Summit in the past in order to qualify.

CHI's INTRONET Networking at its Best

The Intro-Net offers you the opportunity to set up meetings with selected attendees before, during and after this conference, allowing you to connect to the key people that you want to meet. This online system was designed with your privacy in mind and is only available to registered session attendees of this event.

MEDIA PARTNERS

Sponsoring Society

The Protein Society

Lead Sponsoring Publications

Bio-IT World, BioProcess, Insight, nature, Science, The Scientist

Sponsoring Publications

BioPharm, ddn, Genome Technology, Drug Discovery, mAbs, Pharma Voice

Media Partners

CenBiotech, Oxford University Press, Springer

Web Partners

genomeweb

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
PK, PD and potential immunogenicity (IG) of therapeutic proteins cannot be investigated in isolation. An integrated approach is needed which takes into account the interdependency of PK/PD/IG assays. This presentation will focus on the use of an integrated bioanalytical strategy to effectively interpret the behaviour of protein therapeutics.

2:10 Immunogenicity of Therapeutic Proteins: Strategies for Assessing Antidrug Antibodies and Their Impact
Theresa J. Goletz, Ph.D., Director, Clinical Immunology, Amgen, Inc.
The presentation will provide an overview of the interactions of therapeutic proteins with anti-therapeutic antibodies. Examples will illustrate challenges encountered during various stages of drug.

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

5:30 - 7:30 Dinner Short Courses - see page 5 for details

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
Pharmacometrics is a discipline with a net worth of at least $250 million. Its applications aided decisions pertaining to go/no-go, dose selection, trial design, endpoint selection, surrogacy designation, labeling and drug approval. A business case will be made on why industry and academia should invest in pharmacometrics will be made with case studies.

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
Designing optimal dosing regimens for targeted biologic therapies is an open problem in translational oncology. In this talk I will present how we developed a multi-scale mathematical model of the mechanism of action of MM-111, a bispecific antibody designed to treat ErbB2/ErbB3 positive tumors, and other ErbB family targeted therapies. Using the model, we designed optimal dosing schedules for MM-111 based combination therapies, and validated the predictions *in vivo*. We found that by integrating PK/PD and mechanistic biochemical models, we are able to rationally design combination dosing strategies to maximize therapeutic synergy.

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
Pharmacokinetic/pharmacodynamic (PK/PD) modeling and simulation provides important information for the development of therapeutic antibodies. The success of modeling approach highly depends on the quality of PK and PD measurements. In this presentation, approaches to the selection and development of PK and PD assays for therapeutic antibodies as well as the application of the assay results in PK/PD models are discussed.

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
The neonatal Fc receptor (FcRn) is is responsible for the extended half-lives of IgG in circulation. Significant species differences in FcRn make standard rodents a poor model for studying mAb half-life. Genetically engineered mouse models expressing human FcRn will be presented and their use for preclinical mAb development and evaluation will be discussed.

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 Blotherapeutics
Using Eleven's proprietary AMP-Rx protein design and engineering platform, human serum albumin (HSA) variants were selected with improved binding to human FcRn at pH 5.5. These variants have extended plasma half-life relative to wild-type albumin in both mouse and primate preclinical models.

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.
T-DM1 is an antibody–drug conjugate in development for the treatment of human epidermal growth factor receptor 2 (HER2)–positive cancers. Thrombocytopenia is the dose-limiting toxicity. A semimechanistic population pharmacokinetic-pharmacodynamic model was developed to characterize the effect of T-DM1 on platelet counts in clinical studies and to predict platelet response to T-DM1.

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

The presentation will layout a step by step approach to build and validate a novel, multiscale, mechanism-based PK/PD model for ADCs. The model is designed to integrate preclinical biomeasures and PK/PD data for preclinical to clinical translation of ADC efficacy. The presentation will highlight that it is essential to understand and characterize the disposition of ADC and payload, at cellular and physiological level, to better predict the clinical outcome of ADCs.

2:40 ADME of Antibody-Maytansinoid Conjugates

Xiuxia Sun, Ph.D., Scientist, ADC Biochemistry, ImmunoGen, Inc.

The concept of treating cancer with antibody-drug conjugates (ADCs) has gained momentum with the favorable activity and safety of several ADCs in clinical trials. Characterizing the absorption, distribution, metabolism, and excretion (ADME) of these ADCs in rodent models is important to understanding their efficacy and safety. We examine the ADME properties of several antibody-maytansinoid conjugates.

3:10 Design Concepts for Antibody-Drug Conjugates

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

With the increase in worldwide approvals for antibody therapeutics, much attention has been drawn to novel antibody engineering approaches such as development of antibody-drug conjugates (ADCs). The ability of ADCs to specifically prolong drug exposure at the effect site by targeted bio-distribution enables the use of drugs that may otherwise have increased toxicity or not been commercially viable. In this work, we theoretically compare the rates of payload delivery and elimination into the site of effect.

Improving Performance

3:40 Optimizing Pharmacokinetic Stability of Protein Therapeutics

Josh Pearson, Ph.D., Senior Scientist, Biochemistry & Biophysics Group, Department of Pharmacokinetics & Drug Metabolism, Amgen, Inc.

For protein therapeutic candidates beyond antibodies, structural integrity is paramount for desired pharmacokinetic and pharmacodynamic effect. The scope of this presentation will cover techniques and strategies to characterize the integrity of the candidate therapeutics.

4:10 Close of Conference

Pricing & Registration Information

EVENT SHORT COURSE AND PARTNERING FORUM PRICING

	Commercial	Academic, Government, Hospital-affiliated
Partnering Forum	$1395	
One short course	$695	$395
Two short courses	$995	$595
Three short courses	$1195	$695

CONFERENCE PRICING

PREMIUM PACKAGE *BEST VALUE*

(Includes access to all conferences Monday-Friday. Excludes short courses and Partnering Forum.)

	Commercial	Academic, Government, Hospital-affiliated
Advance Registration Discount until March 29, 2013	$2945	$1545
Registrations after March 29, 2013, and on-site	$3095	$1645

STANDARD PACKAGE

(Includes access to 2 conferences. Excludes short courses and Partnering Forum.)

Advance Registration Discount until March 29, 2013	$2425	$1245
Registrations after March 29, 2013, and on-site	$2625	$1325

BASIC PACKAGE

(Includes access to 1 conference. Excludes short courses and Partnering Forum.)

Advance Registration Discount until March 29, 2013	$1575	$825
Registrations after March 29, 2013, and on-site	$1745	$895

CONFERENCE DISCOUNTS

POSTER DISCOUNT ($50 Off) Poster abstracts are due by March 22, 2013. Once your registration has been fully processed, we will send an email containing a unique link allowing you to submit your poster abstract. If you do not receive your link within 5 business days, please contact jring@healthtech.com.
** CHI reserves the right to publish your poster title and abstract in various marketing materials and products.*

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.

PROTEIN SOCIETY DISCOUNT 20%
CHI is pleased to offer all Protein Society Members a 20% discount to attend. Records must indicate you are a Protein Society member at time of registration. Please Note - Discounts may not be combined.

ALUMNI DISCOUNT: Cambridge Healthtech Institute (CHI) appreciates your past participation at PEGS. As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate.

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

**Alumni, Protein Society Member, Twitter, LinkedIN, Facebook or any other promotional discounts cannot be combined. Discounts not applicable on Event Short Courses.*

April 29 - 30 (Monday - Tuesday)	May 1 - 2 (Wednesday-Thursday AM)	May 2 - 3 (Thursday PM-Friday)
Phage and Yeast Display	Engineering Antibodies	Engineering Bispecific Antibodies
Antibodies for Cancer Therapy	Advancing Bispecific Antibodies to the Clinic for Oncology	Antibody-Drug Conjugates
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

ADDITIONAL REGISTRATION DETAILS

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

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

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

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

How to Register: **PEGSummit.com**

reg@healthtech.com • P: 781.972.5400 or Toll-free in the U.S. 888.999.6288

Please use keycode **PEGS F5** when registering!

Please refer to the Registration Code below:

Cambridge Healthtech Institute
250 First Avenue, Suite 300, Needham, MA 02494
www.healthtech.com • Fax: 781-972-5425