Click Here to Register Online!
ImmunogenicitySummit.com

Cambridge HEALTHTECH Institute

250 First Avenue
Needham, MA 02494
www.healthtech.com

Register by **August 5** and save up to **$400!**

Eighth Annual

Immunogenicity AND Bioassay Summit

Technologies and Strategies for Safe and Efficacious Products in the Clinic

Hyatt Regency Baltimore, MD — October 26–28, 2016

Conferences:

- **Immunogenicity Assessment & Clinical Relevance**
- **Immunogenicity Prediction & Control**
- **Optimizing Bioassays for Biologics**

Plus! 4 Short Courses

Keynote Speakers:

João Pedras-Vasconcelos, Ph.D., Biotech Quality and Immunogenicity Reviewer, Biotechnology Products, CDER-FDA

Susan Richards, Ph.D.
Presidential Scientific Fellow, Translational Medicine Early Development, Sanofi R&D

Melody Sauerborn, Ph.D.
Head, Research and Development, Mymetics BV

Perceval Sondag
Senior Statistician, Non-Clinical Statistics, Arlenda

"Program and participants, first class."
– Associate Director, Novo Nordisk

Join **250+** of Your Peers!

Click Here to Register Online!
Immunogenicity Summit.com

Cambridge HEALTHTECH Institute
250 First Avenue
Needham, MA 02494
www.healthtech.com

Eighth Annual

Immunogenicity AND Bioassay Summit

Technologies and Strategies for Safe and Efficacious Products in the Clinic

October 26–28, 2016

Join us at the #1 Immunogenicity & Bioassay Event
Bringing Together Industry, Academia, & Regulatory Authorities

Dear Colleague,

Following record attendance last year, Cambridge Healthtech Institute presents its eighth annual Immunogenicity and Bioassay Summit with NEW speakers, NEW case studies and NEW ways of overcoming immunogenicity and bioassay challenges. We hope you will join us in Baltimore on October 26-28, 2016.

The first conference on **Immunogenicity Assessment & Clinical Relevance** features regulatory perspectives, neutralizing antibody assays, pre-existing antibodies, and managing drug tolerance and target interference. It also provides case studies on TNF inhibitors, proteins with endogenous counterparts, ADCs, enzyme replacement therapies and recombinant Factor VIIa.

Immunogenicity Prediction & Control examines factors that contribute to immunogenicity, and presents immunogenicity predictive studies, correlations between predictive immunogenicity and the clinical outcome, measures to control immunogenicity, and means of overcoming immunogenicity with deimmunization and tolerance-inducing approaches.

"Interesting new data; very relevant to the field."
- Senior Scientist, Process Development, Amgen, Inc.

"Congratulations on a very well put together conference."
- Assistant Vice President, Pfizer

Optimizing Bioassays for Biologics presents expert advice and case studies on assay bridging, transfer and validation, bioassays for multi-specific antibodies, emerging bioassay formats and technologies, and statistical tools for bioassays.

The summit features FDA presentations and discussions from Drs. Kathleen Clouse, João Pedras-Vasconcelos, Will Hallett, and Zuben Sauna. Hear academic experiences from the Universities of California, Massachusetts, and Pennsylvania, from the NIH, ENS Cachan, and a clinical perspective from the Mayo Clinic.

We showcase industry case studies from Pfizer, GSK, Biomarin, Allergan, Genentech, Amgen, Sanofi, BMS, EMD Serono, uniQure, Alexion, Novo Nordisk, Selecta Biosciences, Mymetics, Arlenda, Precision Bioassay, and Exponent.

We hope you will enjoy the summit and that your experience at CHI's event is personally rewarding. On behalf of CHI, we extend our gratitude to all the speakers, sponsors, exhibitors, and alumni for making this event happen.

We hope to see you this Fall in Baltimore.

Sincerely,

Nicole Lyscom, Ph.D.
Senior Conference Director & Team Lead
Cambridge Healthtech Institute (CHI)

Samantha Drinkwater
Senior Conference Director
Cambridge Healthtech Institute (CHI)

Cambridge HEALTHTECH Institute
250 First Avenue
Needham, MA 02494
www.healthtech.com

Sponsorship, Exhibit, and Lead Generation Opportunities

CHI offers comprehensive sponsorship packages which include presentation opportunities, exhibit space, branding and networking with specific prospects. Sponsorship allows you to achieve your objectives before, during, and long after the event. Any sponsorship can be customized to meet your company's needs and budget. Signing on early will allow you to maximize exposure to qualified decision-makers.

Podium Presentations — Available within Main Agenda!

Showcase your solutions to a guaranteed, targeted audience through a 15- or 30-minute presentation during a specific conference program, breakfast, lunch, or separate from the main agenda within a pre-conference workshop. Package includes exhibit space, on-site branding, and access to cooperative marketing efforts by CHI. For the luncheon option, lunches are delivered to attendees who are already seated in the main session room. Presentations will sell out quickly, so sign on early to secure your talk!

Breakfast & Luncheon Podium Presentations

Opportunity includes a 30-minute podium presentation. Boxed lunches are delivered into the main session room, which guarantees audience attendance and participation. A limited number of presentations are available for sponsorship and they will sell out quickly. Sign on early to secure your talk!

Invitation-Only VIP Dinner/Hospitality Suite

Sponsors will select their top prospects from the conference pre-registration list for an evening of networking at the hotel or at a choice local venue. CHI will extend invitations and deliver prospects, helping you to make the most out of this invaluable opportunity. 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 facilitated networking opportunities with qualified delegates. Speak face-to-face with prospective clients and showcase your latest product, service, or solution.

One-on-One Meetings

Select your top prospects from the pre-conference registration list. CHI will reach out to your prospects and arrange the meeting for you. A minimum number of meetings will be guaranteed, depending on your marketing objectives and needs. A very limited number of these packages will be sold.

Additional branding and promotional opportunities are available, including:

- Conference Tote Bags
- Literature Distribution (Tote Bag Insert or Chair Drop)
- Badge Lanyards
- Padfolios
- Program Guide Advertisement

Looking for additional ways to drive leads to your sales team?

CHI's Lead Generation Programs will help you obtain more targeted, quality leads throughout the year. We will mine our database of 800,000+ life science professionals to your specific needs. We guarantee a minimum of 100 leads per program! Opportunities include:

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

FOR SPONSORSHIP AND EXHIBIT INFORMATION, PLEASE CONTACT:

Carolyn Benton
Business Development Manager
781-972-5412 | cbenton@healthtech.com

Corporate Sponsors

ABZENA
Enabling better biopharmaceuticals

charles river

DiscoverX

eurofins | Bioanalytical Services

PROIMMUNE
www.proimmune.com

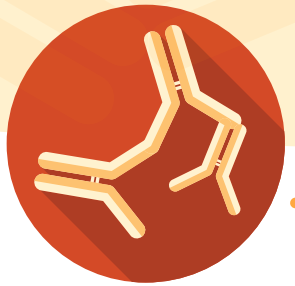
Corporate Support Sponsors

PRECISION FOR MEDICINE
THE FUTURE OF MEDICINE IS PRECISION

BDS
ImmunoAssay Services

Click Here to Register Online!
Immunogenicity Summit.com

Cambridge HEALTHTECH Institute
250 First Avenue
Needham, MA 02494
www.healthtech.com



Immunogenicity Assessment & Clinical Relevance

October 26 – 27, 2016

Overcoming Challenges for Reliable Immunogenicity Evaluation

WEDNESDAY, OCTOBER 26

7:30 am Registration and Morning Coffee

8:30 Chairperson's Opening Remarks
Boris Gorovits, Ph.D., Senior Director, PDM, Pfizer, Inc.

Regulatory and Industry Perspectives on Immunogenicity Assessment for Innovators and Biosimilars

8:35 KEYNOTE PRESENTATION: FDA REGULATORY PERSPECTIVES ON IMMUNOGENICITY - AN UPDATE

João Pedras-Vasconcelos, Ph.D., Biotech Quality and Immunogenicity Reviewer, Biotechnology Products, CDER-FDA
The cost to the biotechnology industry of developing a biologic from early stage all the way to licensing is very high, and many factors can impinge upon approval, particularly the occurrence of immune responses against the biologic. Immunogenicity can impact product efficacy and safety depending on patient-related and product-related factors. This presentation will provide an updated overview of the FDA regulatory perspective to immunogenicity risk management for innovator and biosimilar biologics including risk assessment and mitigation, and anti-drug antibody detection.

9:05 Challenges in Assessing Relative Immunogenicity for Biosimilars and for Manufacturing Change
Paul Chamberlain, NDA Advisory Board
This presentation will reflect on how the extent of the evaluation of relative immunogenicity of closely related therapeutic proteins is strongly dependent on the nature of the product and the regulatory purpose. Directly comparative clinical evaluation is normally required for biosimilars, whereas a requirement for clinical data is exceptional in the case of manufacturing process changes for authorized products. The importance of minimization of bioanalytical bias, sensitivity of the clinical population, and duration of interventional monitoring for building an effective strategy will be highlighted.

9:35 Creating Reference Sera and Standardized Antibody Panels to Assist Standardization of ADA Assays for Therapeutic Proteins
Kimberly Florence, MS, Investigator, Immunogenicity and Clinical Immunology, GlaxoSmithKline
As biopharmaceuticals revolutionize patient care, safety issues may arise through drug/anti-drug antibody interactions. How do we ensure that immunogenicity testing post licensing in routine clinical practice is standardized and fit for purpose? Although there is no "perfect" ADA assay, can universal standards be implemented in the ADA sphere? This presentation will focus on newly developed approaches to use reference standards in the assessment of immunogenicity.

10:05 Presentation to be Announced

Sponsored by: eurofins | Bioanalytical Services

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

Application and Significance of Neutralizing Antibody Assays

11:15 Challenges in Developing Neutralizing Antibody Assays for Antibody Drug Conjugates
Shan Chung, Ph.D., Senior Scientist, BioAnalytical Sciences, Genentech, Inc.
Antibody Drug Conjugates (ADCs) are a new class of anti-cancer medicines consisting of a tumor-specific antibody, a cytotoxic toxin, and a linker. Each of these components either by itself or in combination with the others can induce immune responses in patients including generation of antibodies (NAbs) capable of neutralizing the therapeutic effects of the ADC. This presentation will describe technical challenges and potential solutions in development of NAb assays for ADCs.

11:45 Neutralizing Antibody Titers Measured with a Cell-Based Flow Cytometry Assay Show No Association with Reduced Efficacy or Pharmacodynamic Effect in Elosulfase Alfa Treated Subjects
Andrew C. Melton, Ph.D., Scientist II, Bioanalytical R&D, BioMarin Pharmaceutical, Inc.
Many enzyme replacement therapies (ERTs) utilize the cation-independent mannose-6-phosphate receptor (CI-M6PR) to target lysosomal delivery of ERTs. However, patients receiving ERTs may produce neutralizing antibodies that interfere with CI-M6PR binding. We validated a cell-based flow cytometry assay that detects antibodies capable of interfering with uptake of elosulfase alfa. Consistent with earlier findings, no correlations were observed between NAb titers and the clinical outcomes of elosulfase alfa-treated patients with Morquio A.

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

12:45 Luncheon Presentation *(Sponsorship Opportunity Available)*

1:15 Session Break

Managing Drug and Target Interference

2:15 Chairperson's Remarks
Shan Chung, Ph.D., Senior Scientist, BioAnalytical Sciences, Genentech, Inc.

2:20 New Method for Overcoming Drug and Target Interference in ADA Assays
Jad Zoghbi, MSc, Senior Scientist, Biomarkers and Clinical Bioanalyses, Sanofi
I will describe a novel method that is effective at solving interference problems in immunogenicity assays. I will outline the principles behind the Precipitation and Acid (PandA) approach developed by Sanofi for detecting free and drug-bound ADA in the presence of high levels of circulating drug and drug target in patient samples. Case studies demonstrating superiority over other methods will be presented.

2:50 Practical Approaches to Improving Drug Tolerance in ADA Assays: Impact of Assay Format and Platform
Mitra Azadeh, Ph.D, Principal Scientist, Bioanalytical & Biomarker Development, Nonclinical Development, R&D, Shire
Drug intolerance in ADA assays remains a significant bioanalytical challenge as it interferes with the proper assessment of immunogenicity. This presentation is aimed at providing practical approaches to reducing drug interference in ADA

Click Here to Register Online!
Immunogenicity Summit.com

Cambridge HEALTHTECH Institute
250 First Avenue
Needham, MA 02494
www.healthtech.com

assays. Case studies where changes to either assay format or platform as well as specific examples in which simple modifications to assay parameters and reagents resulted in ten-fold or higher increase in drug tolerance will be presented.

3:20 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 Method to Improve the Recovery of pH Labile Anti-Drug Antibodies during Acid Dissociation and Extraction
Weifeng Xu, Ph.D., Senior Research Investigator, Bioanalytical Science-Biologics, BMS
When large amounts of biotherapeutic drug are present in clinical samples, these drugs have to be dissociated and removed from anti-drug antibodies (ADA) so that ADAs can be detected by either ligand-binding assays or cell-based bioassays. By screening a panel of more than 20 ADA positive control (PC) Abs, we found that the current widely used acid dissociation method followed by biotinylated-drug extraction led to low recovery of more than 40% of these ADA PCs, due to sensitivity to low pH and denaturation. Here we discuss the alternative methods for ADA extraction so that pH labile species can be maximally recovered. This will increase the sensitivity of immunogenicity testing.

4:30 Problem Solving Roundtable Discussions

Table 1: Meeting Regulatory Expectations Regarding Immunogenicity Assessment
Kathleen A. Clouse, Ph.D., Director, Division of Biotechnology Review and Research 1, OBP/OPQ/CDER/FDA

Table 2: Challenges in Developing Neutralizing Antibody (NAb) Assays
Shan Chung, Ph.D., Senior Scientist, BioAnalytical Sciences, Genentech, Inc.

Table 3: Overcoming Drug Interference in ADA Assays
Melissa R. Snyder, Ph.D., Laboratory Director, Antibody Immunology Laboratory, Pathology and Laboratory Medicine, Mayo Clinic

Table 4: Critical Issues in ADA Assay Validation
Jim McNally, Ph.D., Associate Director and Immunogenicity Expert, Global Early Development, Quantitative Pharmacology & Drug Disposition, EMD Serono

Table 5: Practical Application of Immunogenicity Preclinical Risk Assessment
Boris Gorovits, Ph.D., Senior Director, PDM, Pfizer, Inc.

Table 6: Focus on Immunogenicity of Biosimilars
Paul Chamberlain, NDA Advisory Board

Table 7: Dealing with Pre-Existing Positive ADA Activity in Study Patients
Li Xue, Ph.D., Principal Scientist, Pharmacokinetics Dynamics & Metabolism, NBE, Pfizer, Inc.

5:30 Welcome Reception in the Exhibit Hall with Poster Viewing

6:30 End of Day One

THURSDAY, OCTOBER 27

7:30 am Registration and Morning Coffee

8:00 Chairperson's Remarks
João Pedras-Vasconcelos, Ph.D., Biotech Quality and Immunogenicity Reviewer, Office of Biotechnology Products, CDER-FDA

Clinical Relevance of Drug Target Interference

8:05 Impact and Challenges of Drug Target Interference on Immunogenicity Assessment: Perspectives from a Clinical Laboratory
Melissa R. Snyder, Ph.D., Laboratory Director, Antibody Immunology Laboratory, Pathology and Laboratory Medicine, Mayo Clinic
Assessment of immunogenicity is increasingly becoming the standard of care for patients being treated with monoclonal antibody therapeutics, particularly for evaluation of loss of response. However, a significant challenge is the potential for drug target interference. In this session, methods for assessment of anti-drug antibodies to adalimumab and infliximab will be discussed, with a focus on the analytical impact and clinical relevance of drug target interference.

Pre-Existing Antibodies

8:35 Determination of the Clinical Significance of Pre-Existing Antibodies
Li Xue, Ph.D., Principal Scientist, Pharmacokinetics Dynamics & Metabolism, NBE, Pfizer, Inc.
Therapeutic reactive pre-existing antibodies have been widely detected during clinical immunogenicity evaluation and have received growing attention in the past decade. The related clinical significance ranges from severe adverse safety findings to no impact at all. This talk will provide an overview of the known clinical impact of pre-existing antibodies and discuss the clinical risk assessment and management strategies.

Case Studies

9:05 FEATURED PRESENTATION: RELATIONSHIP BETWEEN IMMUNOGENICITY, DRUG CONCENTRATION, EFFICACY, SAFETY AND HOW THIS CORRELATES WITH TESTS/METHODS FOR TNF INHIBITORS

Boris Gorovits, Ph.D., Senior Director, PDM, Pfizer, Inc.
This presentation will focus on reported immunogenicity data for anti-TNF mAb and similar compounds with the goal to link with PK, efficacy and other clinical observations. Also, to understand whether the methods applied to evaluate immunogenicity responses had any influence on the outcome of the correlation to determine relevance of immunogenicity assays.

9:35 Immunogenicity Strategy for a Multidomain Protein Containing Endogenous Counterparts
Jim McNally, Ph.D., Associate Director and Immunogenicity Expert, Global Early Development, Quantitative Pharmacology & Drug Disposition, EMD Serono
This talk will describe the ongoing immunogenicity risk assessment, strategic planning and bioanalytical assay development to support a novel biotherapeutic containing multiple effector domains each with an endogenous counterpart. In addition to the need to closely monitor anti-drug antibody responses due to the potential cross reactivity against the endogenous counterparts, the biotherapeutic also has soluble targets that have the possibility of generating false positives in screening ADA assays using the bridging format. The goal will be to present the case for early assessment of immunogenicity risk to drive the generation of the numerous reagents and associated procedures to support the clinical development of this molecule.

10:05 Sponsored Presentation *(Opportunity Available)*

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

11:10 Application of a Cell-Based Neutralizing Antibody Assay for Botulinum Neurotoxin ADA
Samuel Pine, Ph.D., Principal Scientist, Immunology, Allergan
Immunogenicity measurements for anti-botulinum neurotoxin serotype A (BoNT/A) antibodies have historically relied on mouse protection bioassays. We devised a cell-based method that captures the complexity of all three biologically relevant steps of BoNT/A activity – receptor binding, translocation and target cleavage – to assess human serum samples for anti-BoNT/A neutralizing antibodies. Method validation results indicate the assay detects clinically relevant neutralizing antibodies similarly to the currently accepted mouse protection assay.

Click Here to Register Online!
Immunogenicity Summit.com

Cambridge HEALTHTECH Institute
250 First Avenue
Needham, MA 02494
www.healthtech.com

11:40 Implementation of Therapeutic Drug Monitoring in Clinical Practice as a Reactive or Proactive Tool to Optimize Treatment Outcomes of Biologics
Niels Vande Casteele, Pharm.D., Ph.D., Postdoctoral Fellow, Gastroenterology, University of California, San Diego
Anti-drug antibodies (ADA) can impair the treatment effect of biologics and have been associated with adverse events. However, it is important to distinguish transient from persistent ADA and how this covariate (continuous or categorical) is included in pharmacological models. ADA are typically used in a reactive setting to support treatment decisions, whereas drug concentrations can be used in a proactive setting to guide dosing based on exposure.

12:10 pm rFVIIa Analog Clinical Trial Including 3-Year Follow Up Study in Patients with Anti-Drug Antibodies
Karin Nana Weldingh, Ph.D., Principal Scientist, Immunogenicity Assessment, Novo Nordisk
A FVIIa analogue with 3 amino acid mutations compared to the native molecule was developed to improve the treatment of bleeds in hemophilia patients. In the Phase III trial, 8/72 (11%) of the treated patients developed anti-drug antibodies (ADAs). The presentation will describe the characterisation and consequences of these ADAs. Furthermore, data from a 3 year follow-up study of the ADA positive patients will be presented.

12:40 End of Conference

Lead Sponsoring Publications

American Laboratory
American Pharmaceutical Review
Biocompare The Buyer's Guide for Life Scientists
nature
Pharmaceutical Outsourcing
The Scientist Exploring Life, Inspiring Innovation
Science AAAS

Sponsoring Publications

Human Immunology News
Immunology of Infectious Disease News
Immune Regulation News
Insight Pharma Reports
mAbs
PharmaVOICE

Web Partners

antibodies-online.com
BioSpace
DNAvaccine.com

Click Here to Register Online!
Immunogenicity Summit.com

Cambridge HEALTHTECH Institute
250 First Avenue
Needham, MA 02494
www.healthtech.com

Immunogenicity Prediction & Control

October 27 – 28, 2016

Identifying Causes, Pre-empting, and Management

THURSDAY, OCTOBER 27

1:00 pm Conference Registration

2:00 Chairperson's Opening Remarks
Susan Richards, Ph.D., Presidential Scientific Fellow, Translational Medicine Early Development, Sanofi R&D

Risk Factors that Contribute to Immunogenicity

2:05 FEATURED PRESENTATION: UNDERSTANDING THE IMPACT OF IMMUNOGENICITY ON QUALITY BY DESIGN

Valerie Quarmby, Ph.D., Staff Scientist, BioAnalytical Sciences, Genentech, Inc.
The incorporation of Quality by Design (QbD) principles into biotherapeutic development means that product quality must be closely linked to product safety. Since it is not possible to predict whether a biotherapeutic will elicit immune responses, it is important to monitor immunogenicity during clinical trials. At the same time, any putative critical quality attributes (pCQAs) which could affect immunogenicity must be identified and tracked in the manufacturing control system.

2:35 Impact of Aggregates on Immunogenicity of Protein Therapeutics: A Regulatory Perspective
Will Hallett, Ph.D., Product Quality and Immunogenicity Reviewer, CDER/FDA
Aggregates of protein therapeutics may impact a product's immunogenicity. Aggregated protein therapeutics can promote immunogenicity through multiple mechanisms. Risk factors to consider when assessing aggregates include a product's tendency to form aggregates during manufacturing and storage, the ability to adequately monitor and characterize aggregate species, and the potential clinical consequences that may occur. This presentation discusses the regulatory perspective on aggregates and their impact on immunogenicity.

3:05 Robust Immune Response to a Product-Related Impurity and Impact on Immunogenicity Rate of an Antibody Therapeutic
Sally Fischer, Ph.D., Principal Scientist & Group Leader, Assay Development & Technology (ADT), Genentech, Inc.
A product-related impurity was identified in the material used in the clinical study. To assess the potential ability of patients to develop an immune response to the impurity and the impact on immunogenicity of the therapeutic, two bridging ELISA were developed and validated. Samples from treated subjects were evaluated in both assays. This presentation will discuss the results of the immunogenicity assessment to the impurity and observed immunogenicity rate of the antibody therapeutic.

3:35 Sponsored Presentation *(Opportunity Available)*

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

Immunogenicity Predictive Studies

4:30 Benefits of Humanized Mouse Models for the Study of Immunogenicity
Michael Brehm, Ph.D., Associate Professor, Molecular Medicine, University of Massachusetts Medical School
The development of severely immunodeficient IL2rγ^{null} mice that support engraftment of functional human immune systems has enabled the *in vivo* study of human immunity. This presentation will include a general overview of these humanized mouse models, describing currently available strains, the protocols to generate humanized mice, the strengths of each system and a discussion of the application of these models to study immunogenicity.

5:00 Working with Protein Engineers to Predict and Pre-Empt Immunogenicity of Biotherapeutics
Tim Hickling, Ph.D., Immunogenicity Sciences Lead, Biomedicine Design, Pfizer, Inc.
Pfizer has developed a model for predicting clinical immunogenicity based upon the known processes of the immune system and *in vitro* assay data. Immune system parameters including danger signals and immune epitopes will be discussed, as will the effect of ADA on the PKPD relationship. In describing this approach, I will highlight the importance of designing out immunogenicity risk early during lead development and the necessity of refining parameters as development progresses.

5:30 Immunogenicity Risk-Assessment Based on Computer Algorithms in Conjunction with *in vitro* and *ex vivo* Assays
Zuben Sauna, Ph.D., Principal Investigator, Division of Hematology Research and Review, FDA/CBER
There have been considerable improvements in the predictive performance of preclinical assessments of immunogenicity. These assessments however focus on specific steps of the immune response, not on the clinical manifestation of immunogenicity. Properly used and interpreted, these tools can be used to formulate a comprehensive strategy for the risk-assessment for immunogenicity. The presentation will discuss the various computational, *in vitro* and *ex vivo* tools and their proper use and interpretation.

6:00 End of Day One

6:30-9:30 Dinner Short Course: Advice on Putting Together an Integrated Summary of Immunogenicity
See page 10 for details; separate registration required.

FRIDAY, OCTOBER 28

Correlation between Predictive Immunogenicity and the Clinical Outcome

7:30 am Registration and Morning Coffee

8:00 Chairperson's Remarks
Ronit Mazor, Ph.D., Post-Doctoral Fellow, Molecular Biology, National Cancer Institute, National Institutes of Health

Click Here to Register Online!
Immunogenicity Summit.com

Cambridge HEALTHTECH Institute
250 First Avenue
Needham, MA 02494
www.healthtech.com

8:05 Determination of Clinical Relevance of Predictive Immunogenicity
Vibha Jawa, Ph.D., Principal Scientist, Clinical Immunology, Amgen, Inc.
Predictive tools can be used during early development to decrease the likelihood of risk, and during process development for de-risking attributes that change from process to process. The next step to gain more value from these tools would be to understand their predictive accuracy as they apply in clinic. This talk will attempt to discuss new clinical data and the different approaches and challenges involved in the clinical validation of these tools.

8:35 Retrospective Immunogenicity Risk Prediction of Bioengineered Factor VIIa
Kasper Lamberth, Ph.D., Manager, Immunogenicity Prediction & Tolerance, Novo Nordisk A/S
The development of a bioengineered recombinant Factor VIIa (rFVIIa) analog was discontinued in Phase III trials due to development of ADAs. The FVIIa analog has three mutations compared to the unmodified parent molecule rFVIIa. By using computational and experimental methods we demonstrate that the observed ADAs could have been elicited by neo-epitopes in the engineered-protein. In addition, we show that the Human Leucocyte Antigen (HLA) type of the patients who developed ADAs is consistent with this hypothesis of a neo-epitope driven immune response.

9:05 An Integrated Approach to Managing Immunogenicity Risk and Drug Immune Modulation
Sponsored by: PROIMMUNE www.proimmune.com
Emilee Knowlton, D. Phil., Immunology Sales Specialist, ProImmune
Immunogenicity is one of the most complex issues to address in drug design and development. I will provide an overview of the best tools to mitigate immunogenicity risk, including Mass Spectrometry antigen presentation assays, DC-T and T cell proliferation assays for biologic lead selection/optimization, HLA-peptide binding assays to characterize individual epitopes, as well as undiluted whole blood cytokine storm assays.

9:35 Problem-Solving Roundtable Discussions

Table 1: Product Quality Attributes and Immunogenicity
Valerie Quarmby, Ph.D., Staff Scientist, BioAnalytical Sciences, Genentech, Inc.

Table 2: Current and Emerging Predictive Tools: Selecting Candidates and Predicting Clinical Outcome
Vibha Jawa, Ph.D., Principal Scientist, Clinical Immunology, Amgen, Inc. and Tim Hickling, Ph.D., Immunogenicity Sciences Lead, Biomedicine Design, Pfizer, Inc.

Table 3: Protein Design Tools for Biotherapeutic Deimmunization
Zuben Sauna, Ph.D., Principal Investigator, Division of Hematology Research and Review, FDA/CBER

Table 4: Progress towards Inducing Immunological Tolerance to Biotherapeutics
Ronit Mazor, Ph.D., Post-Doctoral Fellow, Molecular Biology, National Cancer Institute, National Institutes of Health

Table 5: Development of Mouse Models for Predictive Studies
Michael Brehm, Ph.D., Associate Professor, Molecular Medicine, University of Massachusetts Medical School

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

Measures to Control Immunogenicity

11:15 How Do T Regulatory Cells (Treg) Suppress Immune Responses?
Ethan Shevach, M.D., Senior Investigator, Immunology, National Institute of Allergy and Infectious Diseases, National Institutes of Health
Treg play critical roles in the control of all aspects of immune function including autoimmunity, transplantation, and tumor immunity. Modulation of Treg function with biologics and small molecules requires a detailed understanding of the mechanisms used by Treg to mediate their suppressive function. I will review the current status of the proposed suppressive pathways used by both polyclonal and antigen-specific Treg with a focus on preclinical *in vivo* models.

11:45 Immunogenicity of Immuno-Gene Therapy Products: Current State of Affairs and Future Developments
J. Joseph (Jos) Melenhorst, Ph.D., Director, Product Development & Correlative Sciences, Center for Cellular Immunotherapies, University of Pennsylvania
Over the past few decades, patients with various disorders have received gene therapy products to treat various disorders such as hematopoietic solid tumors. The potency of such products, driven largely by expansion and persistence, partly depends on "acceptance" of the infused cells by the host. In my talk I will describe such key learning moments in this relatively young field and provide concrete examples and how this changed the way we treat patients. I will also highlight new developments in the chimeric antigen receptor field where we wish to de-personalize the therapy.

12:15 pm Influence of Aggregates on *in vitro* T Cell Responses
Gary Bembridge, Ph.D., Director, Scientific Affairs, Abzena
Protein aggregates can trigger innate responses leading to distinct antigen-presenting cell phenotypes which enhance T-cell activation, a significant risk factor in the development of anti-drug antibodies (ADAs). This presentation will describe methods to measure the effects of aggregates on drug immunogenicity.

12:45 Luncheon Presentation *(Sponsorship Opportunity Available)*

1:15 Awarding of Poster Prize PLUS Coffee and Cupcakes in the Exhibit Hall

Means of Overcoming Immunogenicity / Deimmunization Approaches / Tolerance

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

2:05 KEYNOTE PRESENTATION: INDUCTION OF IMMUNE TOLERANCE IN POMPE DISEASE

Susan Richards, Ph.D., Presidential Scientific Fellow, Translational Medicine Early Development, Sanofi R&D
This presentation will describe how immunogenicity can be mitigated in Pompe disease using low dose methotrexate immune tolerance induction and propose mechanisms for how this is achieved. I will discuss the challenges encountered, including determining which patients to consider for this approach, the translatability shown between mouse and man and the challenges with determining the clinical threshold. Clinical data on tolerance induction will be discussed.

2:35 The Human Immune System: A Challenge for Successful AAV-Based Gene Therapy
Harald Petry, Ph.D., CSO, Research and Development, uniQure
The application of AAV-based gene therapy in the clinic is facing different types of immune responses that are either directed against the delivery vehicle AAV or the transgene product, which is either a natural protein or a related variant. Strategies to overcome neutralizing antibodies as the initial hurdle to achieve successful transduction as well as the impact of T-cell activation on long term activity of the gene therapy product will be discussed.

Click Here to Register Online!
Immunogenicity Summit.com

Cambridge HEALTHTECH Institute
250 First Avenue
Needham, MA 02494
www.healthtech.com

3:05 Strategies to Reduce Immune Responses to Immunotoxins
Ira Pastan, M.D., Co-Chief, and Ronit Mazor, Ph.D., Post-Doctoral Fellow, Molecular Biology, National Cancer Institute, National Institutes of Health
Recombinant immunotoxins are anti-cancer agents composed of an Fv targeting a protein on a cancer cell fused to a bacterial toxin. They have good anti-cancer activity in hematologic malignancies, where the immune system is suppressed and neutralizing antibodies do not develop. SS1P is an immunotoxin targeting mesothelin expressing tumors. It is composed of an anti-mesothelin Fv attached to a fragment of Pseudomonas exotoxin A. Its anti-tumor activity is limited by its immunogenicity in patients with normal immune function. We have pursued several strategies to reduce the immunogenicity of SS1P, which include identification and removal of B and T cell epitopes and the induction of tolerance using novel approaches.

3:35 Tolerogenic Immunotherapy for Pegsiticase, a Pegylated Uricase for the Treatment of Refractory Gout
Kei Kishimoto, Ph.D., CSO, Selecta Biosciences
Refractory gout is a painful and debilitating disease due to deposition of uric acid crystals in joints and soft tissues. The current therapy for refractory gout is a pegylated uricase that is highly immunogenic, resulting in loss of efficacy and risk of anaphylaxis. We describe here the preclinical and early clinical development of an immunotherapy to induce antigen-specific immune tolerance to pegsiticase, a pegylated uricase.

4:05 End of Conference

PRESENT A POSTER AND SAVE $50!

Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions. To secure a poster board and inclusion in the conference materials, your abstract must be submitted, approved and your registration paid in full by **September 23, 2016.**

Reasons you should present your research poster at this conference:

- Your poster will be seen by our international delegation, representing leaders from top pharmaceutical, biotech, academic and government institutions
- Receive $50 off your registration
- Your poster abstract will be published in our conference materials
- Automatically entered in the Poster Competition, where two winners will each receive an American Express Gift Card.

Click Here to Register Online!
Immunogenicity Summit.com

Cambridge HEALTHTECH Institute
250 First Avenue
Needham, MA 02494
www.healthtech.com

Optimizing Bioassays for Biologics

October 27 – 28, 2016

Merging Biology & Statistics for Successful Biological Assay Development

THURSDAY, OCTOBER 27

Assay Bridging, Transfer and Validation

2:00 pm Chairperson's Remarks
Melody Sauerborn, Ph.D., Head, Research and Development, Mymetics BV

2:05 From Cell Line to Qualified/Validated Bioassay
Melody Sauerborn, Ph.D., Head, Research and Development, Mymetics BV
Cells are the pivotal part of any bioassay, being a Nab assay or a potency assay. But they are also a source of great variability. This presentation will focus on how to develop a cell line into an acceptable bioassay. We will look at early, intermediate and late cell responses, matrix effects and monitoring bioassay performance over time.

2:35 Essentials in Bioassay Design, Relative Potency Determination and Validation
Thomas Little, Ph.D., President, Bioassay Sciences, Thomas A. Little Consulting
This presentation covers essential concepts in bioassay design and validation. Topics include data transformation, curve fitting, weighting, masking, outlier detection and removal. A framework to control standards and reference standard stability will be presented including assay design space. Parallel line analysis for PLA linear models and 4PL Models will be discussed including equivalence testing, ratios and statistical tests will be compared. Acceptance criteria for bioassay validation will be discussed with rationale following USP 1033 and other guidance. A platform approach to bioassays will also be discussed to simplify development and validation.

3:05 Binding Assay as a Surrogate Assay for Functional Assay in Lot Release and Stability Testing: A Case Study
Ravish Patel, Ph.D., Scientist, Analytical Development Lab, EPR Centre for Cancer Research & Bioinformatics Pvt. Ltd. (A Vitane Group company)
Potency is considered a CQA for any biological product. The biological activity is the link between clinical response and activity measured in a bioassay. Functional assays vary in their underlying technology, their design and their complexity. Binding assays may be used as a surrogate for mAb potency testing if binding (Fab) is enough for MoA and if no effector functions (Fc) are involved in the antibody's biological effect/binding activity.

3:35 Optimizing and Qualifying Bioassays for Biosimilars, Biobetters, and Innovator Drugs
Sponsored by: DiscoverX
Abhi Saharia, Ph.D., Director, Cell-Based Assays & Biologics, DiscoverX Corporation
Developing robust cell-based bioassays for potency testing of biologic drugs is challenging due to the development and optimization required for each assay. We will discuss and demonstrate how DiscoverX cell-based assays accelerate the development of accurate and reproducible bioassays for biosimilar candidates and molecules with novel mechanisms of action.

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

Working with Multi-Specific Antibodies: ADCs, Bispecifics, and Beyond

4:30 Two Case Studies: Picking the Best Potency Assay for a Bispecific Antibody
Peter Day, Ph.D., Scientist, Genentech
Consideration of mechanism of action (MOA) is central to the design of any potency assay but the importance of MOA is multiplied in the case of bispecific antibodies. There are several factors, unique to bispecifics, which need to be considered when developing the potency assay(s). Does the MOA require bridging of the two targets? Is the binding cooperative or independent? Are the affinities for the targets similar? Here, we present two case studies on the unique challenges inherent in the development of potency assays for bispecifics.

5:00 A High Throughput Platform for the Quantification of the Potency of Multifunctional Biologics
Michael Tovey, Ph.D., INSERM Director, Research, Laboratory of Biotechnology & Applied Pharmacology, Ecole Normale Supérieure de Cachan
Multifunctional biologics including bispecific monoclonal antibodies, antibody-drug conjugates (ADCs), & pegylated trans-signaling fusion proteins have been developed that have several functional epitopes and/or a multifunctional action. Such products present significant challenges for the development of assays that can assess the potency of each component. A novel molecular engineering approach has been used to resolve these challenges.
A high throughput platform has been established based on the use of 384-well microtiter plates and unique multiple readout reporter gene assays for products including trans-signaling fusion proteins and bi-functional monoclonal antibodies that target FGF21, Her2, VEGFR2, and that exhibit ADCC activity.

5:30 The Development of LC-MS Based Bioassays for a Novel Class of Payloads
Raymond Xu, Ph.D., Associate Director, Clinical Pharmacology, Immunogen Inc.
Antibody–drug conjugates (ADCs) represent an increasingly important approach to cancer treatment by targeting the delivery of cytotoxic agent to tumor cell type of interest. ADCs are generally complex heterogeneous mixtures of multiple in-vivo drug species and present unique challenges to bioassay development. We will present some examples from our experience in the development of LC-MS based quantitative bioassays for the measurement of a new class of payloads from biological matrices.

6:00 End of Day One

6:30-9:30 Dinner Short Course: Strategic Bioassay Design and Analysis
See page 10 for details; separate registration required.

FRIDAY, OCTOBER 28

8:00 am Chairperson's Remarks

Click Here to Register Online!
Immunogenicity Summit.com

Cambridge HEALTHTECH Institute
250 First Avenue
Needham, MA 02494
www.healthtech.com

Emerging Formats and Technologies

8:05 Something Old, Something New: Strategies for Challenging Biological Assay Development
Matthew Roberts, Ph.D., Investigator, Biopharmaceutical Analytical Sciences, GlaxoSmithKline
Implementing assay formats that appropriately represent the mechanism of action or binding modality of recent biologic molecules poses many challenges to development. This is due to the increasingly complex biologic modalities under development and the biological processes these molecules affect. Non-cell based assay formats utilizing classic ELISA readout in combination with innovative commercial technologies are being used to overcome these challenges. Representative case studies highlighting recent progress will be presented.

8:35 *In vitro* Functional Bioassays for Immune Checkpoint and Immune Cell Metabolism Screening
Sofie Pattijn, CTO, ImmunXperts
With the new wave of candidate cancer therapies acting mainly on the immune system via immune checkpoint blockade and immune cell metabolism, the demand for *in vitro* characterization of these molecules has significantly increased. This presentation will give a technical overview of a series of *in vitro* assays using human primary cells used for the characterization of new leads. Also, the major benefits, limitations and challenges will be discussed.

9:05 Sponsored Presentation *(Opportunity Available)*

9:35 Breakout Discussions

Design of Experiments (DOE) for Product and Process Development
Moderator: Martin Kane, Managing Data Scientist, Statistical and Data Sciences, Exponent

Potency Assays for Bispecific Antibodies
Peter Day, Ph.D., Scientist, Genentech

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

11:15 Talk Title to be Announced
Tara Stauffer, Senior Scientist, Bristol-Myers Squibb

11:45 Design of Experiment to Expedite Potency Assay Development for Biologics
Ashley Mullan, Associate Scientist I, MedImmune

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

12:45 Luncheon Presentation to be Announced

1:15 Awarding of Poster Prize PLUS Coffee and Cupcakes in the Exhibit Hall

Sponsored by:
charles river

Statistical Tools for Bioassays

2:00 Chairperson's Remarks
David Lansky, Ph.D., President, Precision Bioassay, Inc.

2:05 Using Simulation to Derive Acceptance Criteria for Parallelism Tests in Bioassays
Perceval Sondag, Ph.D., Senior Statistician, Non-Clinical Statistics, Arlenda
Both US and European Pharmacopeia require that parallelism be shown to compute relative potency. Classic tests (Chi-squared, F-ratio) are known to have poor performance, while computation of equivalence margins can be both difficult and costly, due to the need for sufficient reference product data. A case study will be presented that describes the use of simulation to derive the equivalence margin without sacrificing accuracy, while substantially reducing the need for reference product experimentation.

2:35 Good Bioassay Designs: Practical, Statistically Sound, and Ready for DOE
David Lansky, Ph.D., President, Precision Bioassay, Inc.
Biologists and statisticians have different criteria for 'simple' bioassay design. Common laboratory practices (i.e.; multichannel pipettes) induce statistically complex designs. Good compromise designs and their statistically sound analyses are presented. Equivalence testing for similarity brings new performance requirements. Modular designs allow protocol adjustments to achieve adequate precision for equivalence tests, adequate precision of potency for various intended uses of the assay, or to meet block size requirements for DOE.

Design-of-Experiment in Support of Antibody Product Development

3:05 Accelerating the Speed of Optimization and Validation through Design of Experiments
Martin Kane, Managing Data Scientist, Statistical and Data Sciences, Exponent
Design of Experiments (DOE) are a powerful set of statistical tools that can be used in product and process development to increase knowledge, reduce waste, and innovate at an accelerated pace. This presentation will outline general DOE concepts for factorial and fractional factorial DOE's and describe several DOE's that were used in a biopharmaceutical product. It will demonstrate how the DOE tool will enable the acceleration of getting product out of the lab and into clinical trials.

3:35 Applying Stepwise DOE Method to Optimize Neutralizing Antibody Bioassay with Different Formats
Jenny Hu, Scientist, PKDM, Amgen, Inc.
The design-of-experiment method has been adopted in the development and optimization of neutralizing antibody bioassays. Due to the complex nature of bioassays, many critical factors are involved and need to be assessed. In this presentation, two case studies representing two different assay formats will be presented to show how stepwise DOE helps to accelerate the optimization process of all critical factors to achieve the desired assay sensitivity.

4:05 Close of Conference

Click Here to Register Online!
Immunogenicity Summit.com

Cambridge HEALTHTECH Institute
250 First Avenue
Needham, MA 02494
www.healthtech.com

Short Courses*

Training to enrich your conference experience

TUESDAY, OCTOBER 25

1:30–4:30 pm SC1: Basics of Immunogenicity Testing

Instructors:

» *Jim McNally, Ph.D., Associate Director, PDM Immunogenicity Expert, EMD Serono*

» *Jad Zoghbi, MSc, Senior Scientist, Biomarkers and Clinical Bioanalyses, Sanofi*

This interactive session will enable attendees to work out a basic immunogenicity pre-clinical and clinical testing strategy for various molecules including bi-functional and other novel scaffolds. Areas of difficulty will be discussed with specific case studies. Attendees are encouraged to contribute with their own experiences and to bring questions for discussion or submit to the meeting organizers in advance.

THE FOLLOWING TOPICS WILL BE COVERED:

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

5:30–8:30 pm Dinner SC2: Challenges of Immunogenicity Assessment

Instructors:

» *Jim McNally, Ph.D., Associate Director, PDM Immunogenicity Expert, EMD Serono*

» *Jad Zoghbi, MSc, Senior Scientist, Biomarkers and Clinical Bioanalyses, Sanofi*

This interactive session of intermediate level will focus on the potential challenges of immunogenicity testing in pre-clinical and clinical development and present case studies demonstrating how they can be handled. Attendees are encouraged to contribute with their own experiences and to bring questions for discussion or submit to the meeting organizers in advance.

THE FOLLOWING TOPICS WILL BE COVERED:

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

**Separate registration is required.*

THURSDAY, OCTOBER 27

6:30–9:30 pm Dinner SC3: Advice on Putting Together an Integrated Summary of Immunogenicity

Instructors:

» *João Pedras Vasconcelos, Ph.D., Biotech Quality and Immunogenicity Reviewer, Biotechnology Products, CDER-FDA*

» *Paul Chamberlain, NDA Advisory Board*

PURPOSE

The purpose of this workshop is to share experience gained in preparing and reviewing the "Integrated Summary of Immunogenicity", with case examples to illustrate the multi-disciplinary information that is most useful for the regulator assessing the scale of risk of undesirable immunogenicity for overall clinical benefit vs. risk.

BACKGROUND

Information relevant for the assessment of the impact of undesirable immunogenicity of therapeutic proteins on overall clinical benefit vs. risk balance is distributed across many different sections of the regulatory dossier. This can make it difficult for regulatory reviewers to locate the requisite data. Moreover, essential background information to describe the intrinsic immunogenic potential of the molecule, and how extrinsic factors (product quality, patient variables, dose regimen, etc.) might interact to influence clinical manifestations, is often missing. Although there might be valid reasons for applying a particular strategy for evaluating immunogenicity, the Sponsor's rationale is often not clearly explained. For this reason, the recent draft revision to the main EU immunogenicity guideline has formally endorsed the concept of including a summary document in the MAA dossier, with the objective of collating the essential information required by the regulatory assessor.

WHO SHOULD ATTEND?

This workshop is relevant to anyone who is involved in generating and compiling the input data for immunogenicity-related sections of regulatory dossiers, including CMC, bioanalytical, non-clinical, clinical and regulatory specialists.

6:30–9:30 pm Dinner SC4: Strategic Bioassay Design and Analysis

Instructor:

» *Liming Shi, MS, MA, Senior Group Leader, Bioassay Development, Hospira, a Pfizer Company*

This course will focus on the fundamentals of statistics and simple methodology that are routinely applied in bioassay laboratories. Covered topics will include review of statistical concepts and calculations, study design, assessing bioassay measurement quality and comparative studies.

THE FOLLOWING TOPICS WILL BE COVERED:

- Uniqueness of bioassay, especially cell-based potency assay
- Considerations in bioassay development and validation
- Bioassay measurements and calculations
- Quality control of bioassay performance
- Comparative studies for bioassay development and transfer

Click Here to Register Online!
Immunogenicity Summit.com

Cambridge HEALTHTECH Institute
250 First Avenue
Needham, MA 02494
www.healthtech.com

Hotel & Travel

Conference Hotel:
Hyatt Regency Baltimore
300 Light Street
Baltimore, MD 21202
Phone: 410-528-1234

Reservations: Go to the travel page of www.ImmunogenicitySummit.com

Discounted Room Rate: $199 s/d

Discounted Room Rate Cut-Off Date: September 27, 2016

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

Car Rental Discounts are Available:
For details, visit **www.ImmunogenicitySummit.com**

Click Here to Register Online!
Immunogenicity Summit.com

Cambridge HEALTHTECH Institute
250 First Avenue
Needham, MA 02494
www.healthtech.com

Eighth Annual

Immunogenicity AND Bioassay Summit 2016

October 26–28

Technologies and Strategies for Safe and Efficacious Products in the Clinic

Hyatt Regency Baltimore, MD

SHORT COURSES

	Commercial	Academic, Government, Hospital-affiliated
One short course	$699	$399
Two short courses	$999	$699
Three short courses	$1,299	$899

Tuesday, October 25th		Thursday, October 27th	
1:30-4:30 PM	SC1: Basics of Immunogenicity Testing	6:30-9:30 PM	Dinner SC3: Advice on Putting Together an Integrated Summary of Immunogenicity
5:30-8:30 PM	Dinner SC2: Challenges of Immunogenicity Assessment	6:30-9:30 PM	Dinner SC4: Strategic Bioassay Design and Analysis

CONFERENCE PRICING

SUMMIT – BEST VALUE! (Includes access to all conference days, Wednesday–Friday, excludes short courses)

Early Registration Discount until August 5, 2016	$2,599	$1,199
Advance Registration Discount until September 23, 2016	$2,849	$1,299
Registration after September 23, 2016 and on-site	$2,999	$1,399

SINGLE CONFERENCE (Includes access to Wed.–Thu. AM conference or Thu. PM–Fri. concurrent conferences, excludes short courses)

Early Registration Discount until August 5, 2016	$1,699	$899
Advance Registration Discount until September 23, 2016	$1,899	$949
Registration after September 23, 2016 and on-site	$2,099	$1,049

	Wednesday, October 26th	Thursday, October 27th		Friday, October 28th	
AM	Immunogenicity Assessment & Clinical Relevance	Immunogenicity Assessment & Clinical Relevance		Immunogenicity Prediction & Control	Optimizing Bioassays for Biologics
PM		Immunogenicity Prediction & Control	Optimizing Bioassays for Biologics		

CONFERENCE DISCOUNTS

Poster Submission ($50 Off): Poster abstracts are due by September 23, 2016. 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.

Alumni Discount: Cambridge Healthtech Institute (CHI) appreciates your past participation at Immunogenicity and Bioassay Summit. 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 Bill Mote at 781-972-5447 or bmote@healthtech.com.

If you are unable to attend but would like to purchase the Immunogenicity and Bioassay Summit 2016 CD for $550 (+ shipping), please visit ImmunogenicitySummit.com.

How to Register: ImmunogenicitySummit.com

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

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 healthtech.com/regdetails

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