Cambridge Healthtech Institute’s
Second Annual

Immunogenicity Summit

October 19-21, 2010
Loews Philadelphia Hotel
Philadelphia, Pennsylvania

PART ONE:
Immunogenicity Assessment and Clinical Relevance
October 19-20

PART TWO:
Immunogenicity Prediction and Control
October 20-21

PRE-CONFERENCE SHORT COURSES
October 18
1: Technical Advice on Assay Development, Validation and Sample Analysis
2: Development of Cell-Based Neutralizing Antibody Assays

Course Leaders
Arno Kromminger, Ph.D., Professor & CEO, Immunology, IPM Biotech
Lakshmi Amaravardi, Ph.D., Director, Pre-clinical & Clinical Development Sciences, Biogen Idec, Inc.
Shobha Purushothama, Ph.D., Scientist, Bioanalytical R&D, Pfizer, Inc.
Immunogenicity Summit
October 19-21

Following inaugural success, Cambridge Healthtech Institute presents the Second Annual Immunogenicity Summit 2010. This case study-rich event is designed to provide an update on advances in immunogenicity assays and their application to pre-clinical and clinical development. It presents expert experiences on dealing with the challenges, and advice on risk assessment, regulatory guidance and white papers. In addition, factors affecting immunogenicity together with means of predicting and controlling immunogenicity will be presented. Excellent networking and discussion opportunities are an integral part of the meeting.

Distinguished Faculty List:
- Jack Ragheb, M.D., Ph.D., Principal Investigator, Laboratory of Immunology, Therapeutic Proteins, OBP, CDER, FDA
- Valerie Quarmby, Ph.D., Director and Principal Scientist, Analytical R&D, Genentech, Inc.
- Margot O’Toole, Ph.D., Director, Translational Medicine, BioTherapeutics Research, Pfizer, Inc.
- Lakshmi Amaravardi, Ph.D., Director, Pre-clinical & Clinical Development Sciences, Biogen Idec, Inc.
- Michele Fiscella, Ph.D., Associate Director, Clinical Immunology, Human Genome Sciences
- Arno Kromminga, Ph.D., Professor, CEO, Immunology, IPM Biotech
- Jaya Goyal, Ph.D., Principal Investigator, Clinical Science and Technology, Biogen Idec, Inc.
- Frank J. Carr, Ph.D., Director, Biologics Research, Antitope Ltd.
- Donald Bennett, Ph.D., Director, Biostatistics, Biogen Idec, Inc.
- Matthew Seefeldt, Ph.D., Vice President, Research, BaroFold, Inc.
- Matthew Baker, Ph.D., Chief Scientific Officer, R&D, Antitope Ltd.
- Stephen Lee, Ph.D., Associate Professor, Biomedical Engineering, Ohio State University
- Christoph Giese, Ph.D., Director, Probiogen GmbH
- Masanori Onda, Ph.D., Staff Scientist, Laboratory of Molecular Biology, NCI/NIH
- Shobha Purushothama, Ph.D., Scientist, Bioanalytical R&D, Pfizer, Inc.
PART ONE:

Immunogenicity Assessment and Clinical Relevance

Tuesday, October 19

WHITE PAPERS & CURRENT CONCERNS
Update on Guidance and White Papers
Lakshmi Amaravardi, Ph.D., Director, Pre-clinical & Clinical Development Sciences, Biogen Idec, Inc.

CASE STUDIES: PRE-CLINICAL DEVELOPMENT
Assessment of Immunogenicity and Relevance to Clinical Observations
Frank J. Carr, Ph.D., Director, Biologics Research, Antitope Ltd.

ASSAY DEVELOPMENT AND VALIDATION
Case Study on Strategy for Dealing with Drug Interference
Michele Fiscella, Ph.D., Associate Director, Clinical Immunology, Human Genome Sciences

CASE STUDIES: CLINICAL DEVELOPMENT
Analytical Support of Clinical Development
Valerie Quarmby, Ph.D., Director and Principal Scientist, Analytical R&D, Genentech, Inc.

An ex vivo Gene Expression Assay with Blood from Non-Human Primates Treated with a Candidate Therapeutic Antibody
Margot O’Toole, Ph.D., Director, Translational Medicine, BioTherapeutics Research, Pfizer, Inc.

Measurement and Clinical Impact of IgE Anti-Drug Antibodies
Arno Kromminga, Ph.D., Professor, CEO, Immunology, IPM Biotech

Experiences with Fluorometric and Electrochemiluminescence-Based Blocking/Neutralizing Assays During the Clinical Development of a Biotherapeutic
Jaya Goyal, Ph.D., Principal Investigator, Clinical Science and Technology, Biogen Idec, Inc.

INTERPRETING DATA
Inducing Tolerance to Statisticians: Cut Point Determination Made Easier with Statistics
Donald Bennett, Ph.D., Director, Biostatistics, Biogen Idec, Inc.

Additional presentations to include:
- Case Studies on Assays for Neutralizing Antibodies
- A Case Study on Means of Blocking False Positivity
- Immunogenicity Testing in Animals
- Pre-Clinical Assay Development and Implementation
- Additional Clinical Case Studies
- Immune Responses to Novel Antibody Products
- A Post Marketing Immunogenicity Case Study

COMBINED SESSION: PARTS ONE AND TWO

Wednesday, October 20
1:30 – 5:00 pm

RISK ASSESSMENT AND REGULATORY CONCERNS
Sub-Visible Particles and Immunogenicity
Jack Ragheb, M.D., Ph.D., Principal Investigator, Laboratory of Immunology, Therapeutic Proteins, OBP, CDER, FDA

Additional presentations to include:
- Practical Application of Immunogenicity Pre-Clinical Risk Assessment
- Update on EU Regulatory Guidance
- Update on US Regulatory Guidance
- Immunogenicity Regarding Comparability / Biosimilars
PART TWO: Immunogenicity Prediction and Reduction

Thursday, October 21

FACTORS AFFECTING IMMUNOGENICITY

High Pressure Dissociation of Aggregate Structure and Resulting Decreased Immunogenicity
Matthew Seefeldt, Ph.D., Vice President, Research, BaroFold, Inc.

PREDICTIVE IMMUNOGENICITY TOOLS

Human Artificial Lymph Nodes for Predictive Immunogenicity and Selection of a Non-Immunogenic Biotherapeutic
Christoph Giese, Ph.D., Director, Probiogen GmbH

APPLICATION OF PREDICTIVE METHODS TO GENERATE NON-IMMUNOGENIC PROTEINS

Reducing the Immunogenicity of the Pseudomonas Exotoxin-Based Immunotoxins by Modification of B Cell Epitopes
Masanori Onda, Ph.D., Staff Scientist, Laboratory of Molecular Biology, NCI/NIH

Generation of Therapeutic Proteins Against Inflammatory Disease and Cancer Targets with a Low Risk of Clinical Immunogenicity
Matthew Baker, Ph.D., Chief Scientific Officer, R&D, Antitope Ltd.

Design Space Available for Non-Immunogenic Proteins
Stephen Lee, Ph.D., Associate Professor, Biomedical Engineering, Ohio State University

Additional presentations to include:
- Immune Tolerance Mechanisms in Animal Models
- Predictive Immunogenicity and Immune Modulation of a Novel Product
- Clinical Benefits of Correlating T Cell Epitopes and the HLA Haplotype
- Demonstration of the Value of in silico Prediction of Immunogenicity
- Influence of Route of Delivery / Formulation on Immunogenicity
**HOTEL and TRAVEL INFORMATION**

Loews Philadelphia Hotel  
1200 Market Street  
Philadelphia, PA 19107  
Phone: 215-627-1200  
Fax: 215-231-7305  
Discounted Room Rate: $179 s/d  
Discounted Room Rate Cut-off Date: September 19, 2010

To reserve your accommodation, call the hotel directly, and to receive your discounted room rate, identify yourself as a Cambridge Healthtech Institute conference attendee. 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:**
To receive a 5% or greater discount on all American Airline flights please use one of the following methods:

- Call 1-800-433-1790 (authorization code A48H0AP).
- Go online at www.aa.com (enter A4819SS in promotion discount box).
- Contact our designated travel agent, Wendy Levine, at 1-800-336-5248 ext. 137.

**Car Rental Discounts:**
Special discount rentals have been established with Hertz for this conference. Call Hertz directly at 800-654-3131 and reference our Discount Number 04KL0001

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**SPONSORSHIP and EXHIBIT INFORMATION**

Showcase your company’s expertise, brand your solutions and develop revenue opportunities with qualified decision-makers by becoming an Exhibitor or Sponsor!

**Sponsored Presentation Opportunities**
Speak to a captive audience about your latest product or service for 15 or 30 minutes as part of the conference program, ensuring your audience is seated and ready to listen.

**Breakfast or Luncheon Presentations** - Invite session delegates to enjoy breakfast or lunch on your company’s behalf while you give a 30-minute presentation. Your presentation is concluded with 15 minutes of Q&A, allowing you to interact with your customer base.

**Invitation Only Networking Receptions** - CHI will invite delegates that you select to a private reception at the host hotel. Cocktails and hors d’oeuvre’s will be served in a setting conducive to networking. These receptions are available on a first-come, first served basis.

**Additional Networking & Promotional Opportunities**
- Refreshment Breaks
- Exhibit Hall Reception
- Tote Bags
- Tote Bag Insert
- Conference Padfolios
- Attendee Coffee Mugs
- Badge Lanyards and more!

**Exhibitor Information**
The exhibit hall presents an excellent opportunity to network with prominent scientists and executives who attend the event to learn about cutting edge research and technologies in their field. Exhibiting will allow your company to meet hard to reach prospects face to face, and pave the way for future sales.

We can CUSTOMIZE any opportunity to meet your current MARKETING OBJECTIVES and BUDGET.

To find out more about our comprehensive sponsorship and exhibit packages, please contact:

Ilana Quigley  
Manager, Business Development  
781-972-5457  
iguigley@healthtech.com

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Online: [ImmunogenicitySummit.com](http://www.immunogenicitysummit.com)  
Email: reg@healthtech.com  
Fax: 781-972-5425
Immunogenicity
Summit
October 19-21, 2010
Loews Philadelphia Hotel
Philadelphia, Pennsylvania

$q$ Yes! Please register me for Immunogenicity Summit

REGISTRATION INFORMATION
$q$ Mr.  $q$ Ms.  $q$ Mrs.  $q$ Dr.  $q$ Prof.

Name ____________________________________________  Div./Dept. ___________________________
Company ________________________________________
Address _________________________________________
City/State/Postal Code _____________________________
Country _________________________________________
Telephone ________________________________________

How would you prefer to receive notices from CHI?  $q$ Yes $q$ No
Email*: __________________________________________ Fax:  $q$ Yes $q$ No

Email is not a mandatory field. However, by excluding your email you will not receive notification about online access to
pre-conference presenter materials, conference updates, networking opportunities and requested eNewsletters.

CONFERENCE PRICING

PRE-CONFERENCE SHORT COURSES - OCTOBER 18

1 Short Course

COMMERCIAL: $695  ACADEMIC, GOVERNMENT, HOSPITAL-RELATED: $395

2 Short Courses

COMMERCIAL: $995  ACADEMIC, GOVERNMENT, HOSPITAL-RELATED: $695

$q$ SC1: Technical Advice on Assay Development, Validation and Sample Analysis
$q$ SC2: Development of Cell-Based Neutralizing Antibody Assays

SUMMIT PRICING - OCTOBER 19-21 BEST VALUE

Early Registration Deadline until July 30, 2010

COMMERCIAL: $1845  ACADEMIC, GOVERNMENT, HOSPITAL-RELATED: $875

Advance Registration Deadline until September 17, 2010

COMMERCIAL: $1995  ACADEMIC, GOVERNMENT, HOSPITAL-RELATED: $945

Registrations after September 17, 2010 and on-site

COMMERCIAL: $2195  ACADEMIC, GOVERNMENT, HOSPITAL-RELATED: $995

INDIVIDUAL CONFERENCE PRICING

Early Registration Deadline until July 30, 2010

COMMERCIAL: $1295  ACADEMIC, GOVERNMENT, HOSPITAL-RELATED: $695

Advance Registration Deadline until September 17, 2010

COMMERCIAL: $1445  ACADEMIC, GOVERNMENT, HOSPITAL-RELATED: $775

Registrations after September 17, 2010 and on-site

COMMERCIAL: $1645  ACADEMIC, GOVERNMENT, HOSPITAL-RELATED: $875

Please select which part you will be attending:

$q$ Part 1: Immunogenicity Assessment and Clinical Relevance (October 19-20)
$q$ Part 2: Immunogenicity Prediction and Control (October 20-21)

POSTER DISCOUNT

$q$ $50 off

$q$ $50 off

REGISTRATION INFORMATION

$q$ Yes! I would like to receive a FREE eNewsletter subscription to:

Weekly Update
A series of diverse reports designed to keep life science professionals informed of the latest trends in pharmaceutical technology, business, clinical development, and therapeutic disease markets. For a detailed list of reports, visit InsightPharmaReports.com or contact Rosa LaRotta at rlarotta@healthtech.com, 781-972-5444.

eCliniqua
Innovative management is critical.

CHI Insight Pharma Reports
A series of diverse reports designed to keep life science professionals informed of the latest trends in pharmaceutical technology, business, clinical development, and therapeutic disease markets. For a detailed list of reports, visit InsightPharmaReports.com or contact Rosa LaRotta at rlarotta@healthtech.com, 781-972-5444.

Barnett Educational Services
Barnett is a recognized leader in clinical education, training, and reference guides for life science professionals involved in the drug development process. For more information, visit www.barnettinternational.com.

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 22, 2010.

Register online, or by phone, fax, or mail. Indicate that you would like to present a poster and you will receive abstract submission instructions via email.

I am interested in presenting a poster at
$q$ Immunogenicity Summit

Title ____________________________________

Individuals must register for the same conference or conference combination and submit completed registration forms together for discount to apply. Please reproduce this registration form as needed.

GROUP DISCOUNTS AVAILABLE! Special rates are available for multiple attendees from the same organization. For more information on group discounts contact David Cunningham at 781-972-5472.

$50 off

$50 off

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.

Substitution/Cancellation Policy
In the event that you need to cancel a registration, you may:
$q$ Transfer your registration to a colleague within your organization.
$q$ Credit your registration to another Cambridge Healthtech Institute program.
$q$ Request a refund minus the cost ($50) of making a copy of the CD.

NOTE: Cancellations will only be accepted up to two weeks prior to the conference. Program and speakers are subject to change.

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