IMVACs
THE IMMUNOTHERAPEUTICS & VACCINE SUMMIT
August 17-19, 2010 • Royal Sonesta Hotel • Cambridge, MA

Preliminary Agenda

FIFTH ANNUAL
NOVEL VACCINES: Design & Development
August 17-18, 2010

SECOND ANNUAL
PRODUCTION & MANUFACTURING OF VACCINES
August 17-18, 2010

SECOND ANNUAL
NOVEL VACCINES: Adjuvants & Delivery Systems
August 18-19, 2010

THIRD ANNUAL
CHALLENGES IN PRE-CLINICAL & CLINICAL DEVELOPMENT
TOP 5 Challenges in Vaccines & Immunotherapies
August 18-19, 2010

Corporate Sponsor:

Keynotes:

David Cho, Ph.D., M.P.H., Senior Scientist for Emerging and Pandemic Threat Preparedness, Office of the Director, Center for Biologics Evaluation and Research (CBER), FDA

Norman Baylor, Ph.D., Director, Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, FDA

Jay Berzofsky, M.D., Ph.D., Chief, Vaccine Branch, Center for Cancer Research, National Cancer Institute (NCI), National Institutes of Health

George Siber, Ph.D., Director, Selecta Biosciences, and Executive Chairman, Genocea Biosciences

Monday, August 16
Pre-Conference Short Courses:

SC1 Vaccines Business Opportunities: Collaborations, Mergers And Acquisitions

SC2 Single-Use Systems (Disposables) For Vaccine Manufacture

Event Highlights:

• 4 Conferences, ONE Location!
• Over 60 Presentations
• Panel Discussions
• Exhibit & Poster Viewing

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REGISTER BY MAY 14 AND SAVE UP TO $400
SC1: VACCINES BUSINESS OPPORTUNITIES: COLLABORATIONS, MERGERS AND ACQUISITIONS
2:00 – 5:00pm

Examination of Global Opportunities in the Vaccine Industry
Clement Lewin, Head, Strategic Immunization Planning, Novartis, Inc.

Current Business Strategies of the Major Players
Douglas J. Pon, Ph.D., Assistant Vice President, World Wide Business Development Strategy and Innovation, Pfizer, Inc.

Positioning your Product to take Advantage of Business Opportunities in the Vaccine Market
Alan R. Shaw, Ph.D., Chairman and CEO, VaxInnate Corporation

Experiences of a Recent Collaboration between Small and Large Players
Speaker to be Announced

Critical Skills for Effective Alliance Management
Speaker to be Announced

Additional Confirmed Speaker:
Harold Kleanthous, Head, Discovery US, Sanofi-Pasteur, Inc.

SC2: SINGLE USE SYSTEMS (DISPOSABLES) FOR VACCINE MANUFACTURE
2:00 - 5:00pm

• Industry Case Study on Comparison between Disposables and Conventional Methods
• Regulatory Authority Experiences and Expectations Regarding the Use of Single Use Systems
• How Single Use Systems Lend Themselves to Management of Multi-Product Facilities
• Application of Single Use Systems for Pandemic Preparedness or for Biodefence Vaccines

HOTEL & TRAVEL INFORMATION

Conference Venue and Hotel:
Royal Sonesta Hotel
40 Edwin Lane Blvd
Cambridge, MA 02142
T: 617-806-4200
F: 617-806-4232

Discounted Room Rate: $185 s/d
Discounted Room Rate Cut-off Date: July 21, 2010

Please call the hotel directly to reserve your sleeping accommodations. Identify yourself as a Cambridge Healthtech Institute conference attendee to receive the reduced 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:
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 4680AA).
• Go online at www.aa.com (enter 4680AA in promotion discount box).
• Contact our designated travel agent, Wendy Levine, 1-800-336-5248 ext. 137.

Car Rental Discounts:
Special discount rentals have been established with AVIS for this conference. Please call AVIS directly at 800-331-1600 and you must reference our Avis Worldwide Discount (AWD) Number J868190.

SPONSORED PRESENTATION OPPORTUNITIES

Agenda Presentations: Includes a 15 or 30-minute presentation during a conference program of your choice, ensuring your audience is seated and ready to hear your talk.

Breakfast or Luncheon Workshops: Includes a 30-minute presentation given over breakfast or lunch, which is served on behalf of your company. Workshop is concluded with a 15-minute Q&A session, allowing further interaction with your customer base.

CHI can customize a sponsorship to meet your needs and budget. We offer comprehensive packages that give your company exposure before, during and after the event. Sponsorships include an agenda presentation, exhibit space, conference registrations, wide-ranging branding opportunities, use of event mailing lists and more.

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• Invitation-Only VIP Functions
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• Branded badge lanyards
• Branded conference tote bags
• Branded attendee coffee mugs
• Branded padfolios

For more information please contact:
Suzanne Carroll
Manager, Business Development
781.972.5452
scarroll@healthtech.com
INFLUENZA & PANDEMICS

Opening Keynote Presentation: FDA’s Approach Towards Pandemic Vaccine Preparedness
David S. Cho, Ph.D., M.P.H., Senior Scientist, Emerging and Pandemic Threat Preparedness, Office of the Director, Center for Biologics Evaluation and Research (CBER), FDA

Influenza Virus-Like Particle Vaccine Produced in Insect Cells Elicits Hemagglutination and Neuraminidase Inhibiting Antibodies in Immunized Healthy Adults
Steven Pincus, Ph.D., Executive Director, Analytical Operations, Novavax, Inc.

PNEUMONIA

New Pneumococcal Vaccines: Protein, Conjugate and Hybrid Vaccine Strategies
Mark Alderson, Ph.D., M.B.A., Director, Pneumococcal Vaccine Project, PATH

HIV

Removing the Roadblock to an HIV Vaccine
Philip R. Johnson, M.D., Professor of Pediatrics, Director, Joseph Stokes Research Institute, The Children’s Hospital of Philadelphia, CSO & Executive VP, The Children’s Hospital of Philadelphia

Development of an HIV Vaccine: Challenges and Successes
Indresh Srivastava, Ph.D., Associate Director, Vaccines Research, Protein Biochemistry, Novartis Vaccines & Diagnostics, Inc.

MALARIA

Live Attenuated Pre-Eythrocytic Malaria Vaccines
Sebastian A. Mikolajczak, Ph.D., Staff Scientist, Malaria Program, Seattle Biomedical Research Institute

Development of a Metabolically Active Non-Replicating Sporozoite Vaccine to Prevent Malaria Caused By Plasmodium Falciparum
Peter Billingsley, Ph.D., Senior Director, Entomology and Quality Systems, Sanaria

TUBERCULOSIS

TB Vaccine Development
Jerald C. Sadoff, M.D., President and CEO, Aeras Global TB Vaccine Foundation

DENGE FEVER

Talk Title to be Announced
Beth-Ann Coller, Ph.D., Senior Vice President, Research and Development, Hawaii Biotech, Inc.

CANCER

Immunotherapy for Prostate Cancer: Explaining the Conundrum of Improved Survival without Improvement in Time to Progression
James Gulley, M.D., Ph.D., Director, Clinical Trials Group, Laboratory of Tumor Immunology and Biology, The Center for Cancer Research (CCR), National Cancer Institute, NIH

Carbohydrate Tumor Antigen Vaccines Using Unique Strategies
Kate Rittenhouse-Olson, Ph.D., Professor, Director, Biotechnology Program, Biotechnical and Clinical Laboratory Sciences, The University at Buffalo

INNOVATING DESIGN & STRATEGIES

Novel Strategies for Synthetic Vaccines by Mimicry of Discontinuous Epitopes and Multivalency
Rob M.J. Liskamp, Ph.D., Professor, Medicinal Chemistry and Chemical Biology, Utrecht University

Filamentous Phage as a Carrier for Conjugate Vaccines
Jamie Scott, Ph.D., Professor, Molecular Biology & Biochemistry, Simon Fraser University

“Universal” Influenza Vaccine: Progress and Challenges
Hersh Mehta, Ph.D., Head, Product Conception and Development, Sanofi Pasteur Biologics

Epitope-Based Immunome-Derived Vaccines: A Strategy for Improved Design and Safety
Annie De Groot, Ph.D., CEO, Immunology, EpiVax, Inc.

On the Path to the Clinic: Rapid Discovery of Protective T Cell Antigenic Targets from Naturally Infected Humans
Mojca Skoberne, Ph.D., Head, Cellular Immunology, Genocea Biosciences

Development of a New Generation of Adenovirus (Ad5) Vaccines
Raj Dua, Ph.D., VP, Operations, Product Development, Etubics Corporation

How to overcome Cold Chain Challenges
Tim Redmond, Director, Regional Accounts, World Courier, Inc.
WORKING WITH REGULATORY AUTHORITIES

Opening Keynote Presentation: Regulatory Authority Perspective on Handling Vaccine Production, Manufacturing and Process Change
Norman Baylor, Ph.D., Director, Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, FDA

Industry Perspective on Handling the Complex and Sometimes Undefined Regulatory Requirements
Michael L. Dekleva, Director, Worldwide Regulatory Affairs, Merck, Inc.

SCALE-UP AND RAPID RESPONSE TO PANDEMCICS

Scale-Up of an Intensified Process for Rad35 Adenovirus Production Using the PER.C6 Cell Substrate
Alfred Luitjens, Senior Scientist, New Technology, Crucell

Technical Challenges and Solutions for Development, Manufacturing Scale-Up and Management of Seasonal Strain Changes for Recombinant Influenza Vaccine
Albert Price, Ph.D., Technical Director, Influenza, Protein Sciences Corporation

Case Study on Scale-Up of Production from Bench to Commercialization
Rinaldo Zurbriggen, Ph.D., Senior Program Manager, Lonza AG (Formerly CSO of Pevion Biotech)

Staying Live: Scale-Up of an Attenuated Respiratory Syncytial Virus (RSV) Vaccine
Mark W. Thompson, R.Ph., Ph.D., Director, Vaccine Process Biochemistry, Vaccine Development, MedImmune, Inc.

PROCESS DEVELOPMENT AND OPTIMIZATION FOR VACCINE MANUFACTURE

Gaining Control and Determining Specifications of the Process
Speaker to be Announced

Designing and Validating a Manufacturing Process
Trevor Deeks, Ph.D., Senior Director, Manufacturing Support Group, Contract Manufacturing Group, Emergent BioSolutions, Inc.

Advances in Purification Technology
Speaker to be Announced

Manufacturing a Sterile, Autologous Colon Tumor Derived Vaccine for a Patient-Specific Immunotherapeutic Treatment
Michael Hanna, Ph.D., Chairman and CEO, Vaccinogen, Inc.

Managing Aggregation of VLP and Viral Vaccines
Speaker to be Announced

Measures to Reduce Cost of Goods in Vaccine Manufacturing Particularly in Implementing Change
Speaker to be Announced

Production of Influenza Vaccines Using a Fungal Production Platform
Debbie Higgins, Ph.D., Vice President, Vaccine Development, Neugenesis Corporation

Spray Drying in Vaccine Manufacturing for Improved Stability
Tom Jin, M.D., Scientist, Principal Investigator, Technique Operations & Manufacturing, Aeras Global TB Vaccine Foundation

QUALITY ISSUES & COMPARABILITY

Quality by Design for Maintaining Quality and Potency of the Product and for Risk Analysis
Speaker to be Announced

Change Control Assays to Ensure Consistent Antigen and Product Characteristics
Speaker to be Announced

After the License Approval - What Can Analytics Do?
Robert D. Sitrin, Ph.D., Executive Director, GVTE-Bioanalytics, Merck Manufacturing Division

Characterization of the Product to Satisfy the Regulatory Authorities
Jonathan Liu, D.V.M., Ph.D., Director, R&D, Vaccine Development, MedImmune, Inc.
Adjuvants and novel delivery systems hold the promise of innovating vaccines by enhancing the immune response, decreasing dosage requirements, and overcoming cold chain challenges. More than just a tool for vaccine developers, Adjuvants have become an integral part of the solution for fighting disease. Lack of FDA approval for new Adjuvants presents a major hurdle for vaccine developers, as do the pressing concerns for undesirable side effects.

In the Novel Vaccines’ “Adjuvants & Delivery Systems” meeting, vaccine leaders will discuss their promising work that is leading the way to Next Generation Vaccines.

**INNOVATIONS & SAFETY**

**Opening Keynote Presentation:**
Cytokines and Toll-Like Receptor Ligands as Adjuvants to Improve the Quality as well as Quantity of T Cell Immune Responses
J. A. Berzofsky, M.D., Ph.D., Chief, Vaccine Branch, Center for Cancer Research, National Cancer Institute (NCI), National Institutes of Health

**Adjuvantation of a Vaccine without Adjuvant Injection**
Mei X. Wu, M.D., Ph.D., Associate Professor, Wellman Center for Photomedicines, MGH/ Harvard Medical School

**Clinical Safety of the ISCOMATRIX Adjuvant**
Marli Watt, M.D., Clinical Safety Physician, Clinical Safety, CSL Limited

**ENHANCING THE IMMUNE RESPONSE**

**Enhancement of Response to Vaccines with the Use of an Immune Modulating Peptide, Thymosin Alpha 1**
Israel Rios, M.D., CMO & Senior VP, SciClone Pharmaceuticals, Inc.

**Vaccine Immune-Enhancing Delivery Systems: From Danger Signals to a Nutritive Approach in Vaccine and Adjuvant Design**
Michael Vajdy, Ph.D., CEO, EpitoGenesis, Inc.

**TOLL-LIKE RECEPTORS**

**Harnessing Toll-Like Receptor Agonists to Enhance Vaccine Efficacy**
Speaker to be Announced

**MODES OF DELIVERY**

**Mucosal Immunization against Vaginal Candida Infections Using Sap2 Recombinant Protein Delivered by Influenza Virosomes**
Rinaldo Zurbriggen, Ph.D., Senior Program Manager, Biopharma Manufacturing, Lonza AG

**Intranasal Nanoemulsion Adjuvanted Influenza Vaccine – Dose Range Efficacy and Toxicity Studies**
Tarek Hamouda, M.D., Ph.D., M.B.A., Director of Vaccines, NanoBio Corp.

**PARTICULATE DELIVERY**

**How VLPs Develop Their Efficacy**
Thomas Stauffer, Ph.D., CEO, Pevion Biotech

**Synthetic Virus-Like Particle (SVLP) Technology in Synthetic Vaccine Design**
Arin Ghasparian, Ph.D., CSO, Virometix AG

**Lecithin Nanoparticles as an Adjuvant for Vaccines**
Zhengrong Cui, Ph.D., Associate Professor, College of Pharmacy, The University of Texas at Austin

**Enhancing Vaccine Uptake through Manipulating Surface Properties**
Speaker to be Announced

**DNA VACCINES**

**Heterologous Prime-Boost Vaccines for HIV Vaccine Development**
Shan Lu, M.D., Ph.D., Professor, Medicine, University of Massachusetts Medical School

**Designing Smarter Adenoviral Vector Delivery of Vaccines: What Has Translated Successfully into Humans**
Alfredo Nicosia, Ph.D., CSO, Okairos

**SynCon DNA Vaccines for Emerging Infectious Diseases**
Niranjan Y. Sardesai, Ph.D., Senior VP, Research & Development, Inovio Biomedical Corporation
Cambridge Healthtech Institute’s Third Annual “Challenges in Pre-Clinical & Clinical Development” conference will focus on the top 5 challenges facing vaccine and immunotherapy developers in 2010. Hear case studies from across a wide range of target areas, both therapeutic and prophylactic, including HIV/AIDS, tuberculosis, RSV, infectious disease, cancer and influenza.

Regulatory requirements, advancements in pre-clinical animal models, and biomarkers for determining immune response, including identifying non-responders, will be addressed. Experts in the fields of immunogenicity and biomarkers will describe movements toward standardization to better improve lab-to-lab correlations. Learn new risk management strategies focused on post-market surveillance and epidemiology from industry leaders.

**SELECTING THE BEST PRE-CLINICAL ANIMAL MODELS**

**Engineering T cells for Cancer Therapy**
Robert Hawkins, Ph.D., Professor, Medical Oncology, University of Manchester, and Coordinator, ATTACK Project

**Strategies for the Nonclinical Safety Assessment of Vaccines**
Jayanthi Wolf, Ph.D., Associate Director, Safety Assessment, Merck & Co., Inc.

**Evaluation of the Safety and Efficacy of a Novel RSV F Particle Vaccine in the Cotton Rat**
Ramadevi Raghunandan, Ph.D., Senior Scientist, Immunology, Novavax

**IDENTIFYING BIOMARKERS FOR IMMUNE RESPONSE**

**An Integrative Paradigm for Biomarker Development in Immunotherapy Clinical Trials-Lessons Learned and Future Directions**
Michael Kalos, Ph.D., Director, Translational and Correlative Studies Laboratory, University of Pennsylvania Medical School

**Identify Correlates of Protection Biomarker in Vaccine Development**
Yiwu He, Ph.D., Senior Program Officer, Global Health, Bill & Melinda Gates Foundation

**Talk Title to be Announced**
Danilo Casimiro, Ph.D., Director, Vaccine Basic Research, Merck Research Labs

**STANDARDIZING IMMUNOGENICITY TESTING**

**Standardization of Immunogenicity Testing Across Species**
Travis Harrison, Ph.D., Associate Director, SRI International

**Navigating Changing Regulatory Requirements**
Scott R. Burger, M.D., Principal, Advanced Cell & Gene Therapy

**ANALYZING POST-MARKETING SURVEILLANCE AND EPIDEMIOLOGY**

**Risk Management Strategies for Immunotherapeutics Pre- and Post-Approval**
Michael Forstner, Ph.D., Manager, Integrated Safety Risk, PDS, F. Hoffmann-La Roche

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HOW TO REGISTER: Online: www.imVacs.com

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Yes! Please register me for The Immunotherapeutics & Vaccine Summit 10990.00

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Yes 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.

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Production & Manufacturing of Vaccines AND Novel Vaccines: Adjuvants & Delivery Systems

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Production & Manufacturing of Vaccines AND Pre-Clinical / Clinical Development of Vaccines

$2195 $995

SINGLE CONFERENCE PRICING

Early Registration Deadline until May 14, 2010

Advance Registration Deadline until July 16, 2010

Registrations after July 16, 2010 and on-site

Early Registration Deadline until May 14, 2010

Advance Registration Deadline until July 16, 2010

Registrations after July 16, 2010 and on-site

PRE-CONFERENCE SHORT COURSES Monday, August 16 • 2:00-5:00 PM

SC1: Single-Use Systems (Disposables) for Vaccine Manufacture

$1245 $625

SC2: Vaccines Business Opportunities: Collaborations, Mergers & Acquisitions

$1495 $695

SC3: Vaccines Development for Commercial Hospital-affiliated

$1695 $795

POSTER DISCOUNT

$50 off $50 off

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Individuals must register for the same conference or conference combination and submit completed registration form 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

I cannot attend but would like to purchase the ImVacs conference CD for $350 (plus shipping). Massachusetts delivery will include 6.25% sales tax.

I would like to receive a copy of this conference brochure by mail.

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Enclosed is a check or money order payable to Cambridge Healthtech Institute, drawn on a U.S. bank, in U.S. currency.

I invoice me, but reserve my space with credit card information listed below. Invoices unpaid two weeks prior to conference will be billed to credit card at full registration rate. Invoices must be paid in full and checks received by the deadline date to retain registration discount. If you plan to register on site, please check with CHI beforehand for space availability.

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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 July 21, 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.

Yes, I am interested in presenting a poster at ImVacs

Title

CHI Insight Pharma Reports

A series of diverse reports designed to keep life science professionals informed of the salient trends in pharmaceutical technology, business, clinical development, and therapeutic disease markets.

For a detailed list of reports, visit InsightPharmaReports.com or contact Rose LaRia, rlaria@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.

Additional Registration Details

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

Group Discounts

Special rates are available for multiple attendees from the same organization. Contact David Cunningham at 781-972-5472 to discuss your options and take advantage of the savings.

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:

Transfer your registration to a colleague within your organization.

Credit your registration to another Cambridge Healthtech Institute program.

Request a refund minus the cost ($350) of order and processing fees.

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.