

Program

Vaccine Technology

June 25-30, 2006

Casa Magna Marriott Puerto Vallarta Resort

Puerto Vallarta, Mexico

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Jerald C. Sadoff, M.D.

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ECI

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Sunday, June 25, 2006

01:30 pm – 05:30 pm	Registration
05:30 pm – 06:00 pm	Welcome
06:00 pm – 07:30 pm	Keynote: Adel Mahmoud , Chief Med Advisor-Vaccine & Infectious Disease, Merck & Co., Inc. <i>"A New Era for Immunization in Public Health"</i>
07:30 pm – 08:30 pm	Reception
08:30 pm – 11:00 pm	Dinner

NOTES FOR CONFERENCE PARTICIPANTS

- Participants should observe no smoking at ECI technical and social events.
- During technical sessions please keep cell phones on vibrate or shut off. Take any telephone conversations out of the session room.
- All breakfasts will be located in the La Estancia Restaurant.
- All dinners will be outside (weather permitting) with the Vallarta IV as back up.
- All lunches are in Vallarta IV
- All general sessions are in Vallarta V-VIII
- All poster sessions are in Vallarta I-III

Monday, June 26, 2006

- 07:00 am – 08:30 am Breakfast
- 08:30 am – 10:45 am **Session I: Virus and Replicon Vectors & Production**
Session Chair: Phil Gomez, Director, Vaccine Production, NIH
- 08:30 am – 8:45 am *Phil Gomez, Director, Vaccine Production, NIH*
"Introduction to session"
- 08:45 am – 9:15 am *John A. Lewis, Aecselabiologics*
"Using Automation and QPCR to Develop Highly Precise Potency Assays for BioProcess Development and Adenovirus Product Release"
- 09:15 am – 9:45 am *Maria Grazia Pau, Project Director R&D, Crucell*
"Development of Vaccines Based on Human Adenovirus Serotype 35"
- 09:45 am – 10:15 am *John Konz, Senior Research Fellow, Merck & Co., Inc.*
"Development and Scaleup of a Platform Adenovector Production Process"
- 10:15 am – 10:45 am *Bryan Butman, Vice President, Vector Operations, Gen Vec, Inc.* *"Manufacture and Testing of a Multi-Clade HIV Recombinant Adenovirus Vaccine"*
- 10:45 am – 11:15 am Break
- 11:15 am – 12:30 pm Keynote: **Seth Berkley**, President & CEO, International AIDS Vaccine Initiative
"Innovative Alliances Towards Accelerating the Development of Vaccines: The Example of an AIDS Vaccine"
- 12:30 pm – 01:30 pm Lunch
- 01:30 pm – 03:50 pm **Session II: Nucleic Acid Vectors & Production**
Session Chairs: David Kaslow, Chief Scientific Officer, Vical
M. Susana Levy, Lecturer, UCL
- 01:30 pm – 1:50 pm *John Ward, Reader in Molecular Microbiology, UCL*
"Host Cell Engineering and Fermentation for Changing Process Design Rules"

Monday, June 26, 2006 (continued)

- 01:50 pm – 02:20 pm *Anthony Green, Distinguished Scientist, Scientific Affairs
Puresyn
"Analytical and Biological Characterization of Supercoiled Plasmids
by Various Chromatographic Techniques"*
- 02:20 pm – 02:50 pm *Markus Müller, Director R&D, Nucleic Acid Preparation
Research, Qiagen, GmbH
"A Ready-to-Use Process for Large-Scale Plasmid DNA
Manufacturing"*
- 02:50 pm – 03:20 pm *Russ Middaugh, Takeru and Aya Higuchi Distinguished
Professor, Department of Pharmaceutical Chemistry,
University of Kansas – "Stabilization of Vaccines"*
- 03:20 pm – 03:50 pm *Alain Rolland, Sr. Vice President of Product Development, Vical
"Development of Potency Assays for Release of Plasmid-based
Vaccines"*
- 03:50 pm – 08:00 pm Free Time
- 08:00 pm – 09:00 pm Dinner
- 09:00 pm – 11:00 pm Poster Reception

Tuesday, June 27, 2006

- 07:00 am – 08:30 am Breakfast
- 08:30 am – 12:30 pm **Session III: Immune System Function and its Quantitation**
Session Chair: Mark Feinberg, Vice President, Policy, Public Health & Medical Affairs, Merck & Co., Inc
- 08:30 am – 08:35 am *Mark Feinberg, Vice President, Policy, Public Health & Medical Affairs, Merck & Co., Inc*
"Introduction to session"
- 08:35 am – 09:10 am *Bali Pulendran, Emory Vaccine Center, Emory University School of Medicine*
"Modulating Vaccine Responses with Dendritic Cells and Toll-Like Receptors"
- 09:10 am – 09:45 am *John Wherry, Assistant Professor, The Wistar Institute*
"CD8 T-cell Differentiation and its Relationship to Immune Protection"
- 09:50 am – 10:20 am Mario Roederer, Section Chief Vaccine Research, NIH
"Flow Cytometric Evaluation of Vaccine Immunogenicity: Quality vs. Quantity"
- 10:20 am – 10:55 am Break
- 10:55 am – 11:30 am *Michael Robertson, Director, HIV Vaccines Clinical Research, Merck & Co., Inc.*
"Immune Monitoring in HIV Vaccine Clinical Trials"
- 11:30 am – 12:00 pm *Sergei Spitsin, Biotechnology Foundation Laboratories at Thomas Jefferson University*
"Immunological Assessment of Plant-Based Recombinant Vaccine Against Smallpox"
- 12:00 pm – 12:30 pm *Daniel Rivera, EpiVax, Inc.*
"High Throughput Validation of Predicted T-Cell Epitopes in F. Tularensis; The Development of a Novel T-Cell Epitope Based Tularemia Vaccine"
- 12:30 pm – 01:30 pm Lunch

Tuesday, June 27, 2006 (continued)

01:30 pm – 04:00 pm	Session IV: Adjuvants & Formulation Session Chair: Nathalie Garçon, Vice President, Head of Research and North America R&D, GlaxoSmithKline Biologicals
01:30 pm – 02:00 pm	<i>Derek O'Hagan, Director Vaccine Adjuvants & Delivery Systems, Chiron</i> <i>"New Generation Vaccine Adjuvants and Delivery Systems"</i>
02:00 pm – 02:30 pm	<i>Prof. David Weiner, University of Pennsylvania, School of Medicine</i> <i>"Cytokine Adjuvanted DNA Vaccines for Improved In-Vivo Immunity"</i>
02:30 pm – 03:00 pm	<i>Debbie Drane, Director Project & Portfolio Management R&D, CSL limited</i> <i>"ISCOMATRIX® Adjuvant Technology"</i>
03:00 pm – 03:30 pm	<i>Robert Evans, Sr. Director and Head of Product Development, VaxInnate Corporation</i> <i>"Formulation Development of a Pam3Cys-lipidated M2e Peptide-Based Influenza Vaccine Candidate"</i>
03:30 pm – 04:00 pm	<i>Nathalie Garçon, Vice President, Head of Research and North America R&D, GlaxoSmithKline Biologicals</i> <i>"The Challenge to Developing Adjuvant System: AS04 and AS02 as an Example"</i>
04:00 pm – 08:00 pm	Break
08:00 pm – 09:00 pm	Dinner
09:00 pm – 11:00 pm	Poster Reception

Wednesday, June 28, 2006

- 07:00 am – 08:30 am Breakfast
- 08:30 am – 11:00 am **Session V: Cell Substrates & Regulatory Issues**
Session Chair: Captain Rebecca Sheets, Vaccine Scientific & Regulatory Specialist, NIH/NIAID
- 08:30 am – 09:00 am *Phil Minor, NIBSC*
"New and Old Regulatory Issues for Novel Cell Substrates"
- 09:00 am – 09:30 am *Philip Krause, Deputy Director, Division of Viral Products, Office of Vaccines Research and Review, FDA/CBER*
"Finding Scientific Pathways to Address Regulatory Issues Associated with Introductions of Novel Cell Substrates for Viral Vaccine Manufacture"
- 09:30 am – 10:00 am *Volker Sandig, VP Molecular Biology & Virology, ProBioGen*
"Development of Avian Cell Lines for Vaccine Manufacture"
- 10:00 am – 10:30 am Break
- 10:30 am – 11:00 am *Majid Mehtali, Vivalis SA*
"Embryonic Stem Cell-Derived Substrates for the Industrial Production of Viral Vaccines and Therapeutic Proteins"
- 11:00 am – 11:30 am *Prof. Jaap Goudsmit, Chief Scientific Officer, Crucell*
"Mass Vaccination and Vaccine Production Technology"
- 11:30 am – 12:30 pm Lunch
- 12:30 pm – 04:00 pm Free Time
- 04:00 pm – 07:30 pm **Session VI: Development & Technologies for Emergent/Emergency Vaccines**
Session Chair: Kathrin Jansen, Senior Vice President, Research and Development & Chief Scientific Officer, Vaxgen
- 04:00 pm – 04:30 pm *Manon Cox, COO, Protein Sciences*
"A Recombinant Hemagglutinin Protein Vaccine for Influenza"
- 04:30 pm – 05:00 pm *Jonathan Smith, Chief Scientific Officer, AlphaVax*
"Alphavirus Replicon Vaccines for Emerging Diseases and Biodefense Indications"
- 05:00 pm – 05:30 pm *Kathrin Jansen, Senior Vice President, Research and Development & Chief Scientific Officer, Vaxgen*
"rPA Anthrax Biodefense Program at Vaxgen"

Wednesday, June 28, 2006 (continued)

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| 05:30 pm– 06:00 pm | Break |
| 06:00 pm – 06:30 pm | <i>Christopher Dale, VP of Technology, Cambrex Biopharma
"Outsourcing of Vaccine Development and Production:
Development of a Cost-Effective and Portable Manufacturing
Process for the Production of a Ricin Vaccine (RiVax)"</i> |
| 06:30 pm – 07:00 pm | <i>Bernd Kalbfuß, Bioprocess Engineering, Max-Planck-Institute for
Dynamics of Complex Technical Systems
"A Generic Purification Scheme for the Production of Human
Influenza Vaccines Derived from Serum-Free Mammalian Cell
Culture"</i> |
| 07:00 pm – 07:30 pm | <i>Michael Meagher, Director, UN-L Biological Process Development
Facility, University of Nebraska-Lincoln
"Development of a Fermentation Process for a Recombinant
Vaccine Candidate Against Botulinum Neurotoxin Serotype F
(rBoNTF(H_c))"</i> |
| 07:30 pm | Dinner – on your own and out on the town |

Thursday, June 29, 2006

07:00 am – 08:30 am	Breakfast
08:30 am – 12:15 pm	<u>Session VII: Manufacturing Issues</u> Session Chairs: Barry Buckland, Vice President, Bioprocess R&D, Merck & Co., Inc. John Auniņš, Executive Director, Fermentation & Cell Culture, Merck & Co., Inc.
08:30 am – 10:00 am	<u>Disposable Technologies:</u>
08:30 am – 09:00 am	<i>Vijay Singh, President, Wave Biotech, LLC</i> <i>"Disposable Manufacturing Technologies for Vaccine Production"</i>
09:00 am – 09:30 am	<i>Yvonne Genzel, Max Planck Institute for Dynamics of Complex Technical Systems</i> <i>"High Cell Density Microcarrier Process in a Wave Bioreactor for the Production of Influenza A Virus"</i>
09:30 am – 10:00 am	<i>Hélène Pora, Pall Life Sciences</i> <i>"Implementing Single Use Technologies in Vaccine Manufacturing: Practical and Validation Aspects"</i>
10:00 am – 10:30 am	Break
10:30 am – 12:15 pm	<u>Manufacturing Issues:</u>
10:30 am – 11:05 am	<i>Rahul Singhvi, President & CEO, Novavax, Inc.</i> <i>"Comprehensive Solution for an Influenza Pandemic"</i>
11:05 am – 11:40 am	<i>James Swartz, Professor, Stanford University</i> <i>"Rapid Vaccine Production for Personal and Pandemic Protection"</i>
11:40 am – 12:15 pm	<i>Michel Chartrain, Distinguished Sr. Investigator, Merck & Co., Inc.</i> <i>"Development of a Productive and Scalable Plasmid DNA Up-stream Production Platform"</i>
12:15 pm - 01:00 pm	Keynote: Michael Hoare , Professor, University College London <i>"Bioprocess Engineering Issues to be Faced for Large-Scale Production of a DNA Vaccine for an Influenza Pandemic"</i>
01:00 pm – 02:00 pm	Lunch
02:00 pm - 05:00 pm	Free Time

Thursday, June 29, 2006 (continued)

- 05:00 pm – 07:30 pm **Session VIII: Characterization of Complex Biologicals**
Session Chair: Michael Washabaugh, Sr. Director,
Bioprocess & Bioanalytical Research, Merck & Co., Inc.
- 05:00 pm – 05:40 pm *Natarajan Sethuraman, Associate Director of Preclinical Development, Glycofi*
"Production of Complex Human Glycoproteins in Yeast and Fungi"
- 05:40 pm – 06:20 pm *Robert Sitrin, Executive Director, Bioprocess & Bioanalytical Research, Merck & Co., Inc.*
"Characterization of a Recombinant Human Papillomavirus Vaccine, Gardasil®"
- 06:20 pm – 06:55 pm *Clint Potter, Associate Professor, Scripps*
"Characterization of Viruses & Virus-Like Particles Using Automated CryoEM"
- 06:55 pm – 07:30 pm *Derek O'Hagan, Director Vaccine Adjuvants & Delivery Systems, Chiron*
"The Challenge with Novel Vaccine Adjuvants: From Empirism to Molecular Mechanisms"
- 08:00 pm – 11:00 pm Banquet and Closing

Friday, June 30, 2006

- 07:00 am – 8:30 am Breakfast and departure
(Hotel check-out time is Noon)