Program

VACCINE TECHNOLOGY II

June 1-6, 2008

Grande Real Santa Eulalia Resort
Albufeira, Algarve, Portugal

Co-Chairs:

Barry C. Buckland, Ph.D.
Research Vice President, Bioprocess R&D, Merck & Co., Inc.

John G. Auniņš, Ph.D.
Executive Scientific Director, Bioprocess R&D, Merck & Co., Inc.

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Organizing Committee

Manuel Carrondo, Professor and CEO, IBET, Portugal

Manon Cox, COO, Protein Sciences Corp., USA

Matthew Croughan, Professor, Keck Graduate Institute, USA

Anne De Groot, CEO, EpiVax, Inc., USA

Emilio Emini, Executive Vice President, Wyeth Pharmaceuticals, USA

Nathalie Garçon, Vice President, GlaxoSmithKline Biologicals, Belgium

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Jerald Sadoff, CEO, Aeras Global TB Vaccine Foundation, USA

Volker Sandig, Vice President, ProBioGen AG, Germany

George Siber, Consultant, USA

John Vose, Consultant, France

David Weiner, Professor, University of Pennsylvania School of Medicine, USA
**Sunday, June 1, 2008**

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<tr>
<td>03:30 pm – 05:30 pm</td>
<td><strong>Registration</strong></td>
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<tr>
<td>05:30 pm – 06:00 pm</td>
<td><strong>Welcome and conference overview</strong></td>
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| 06:00 pm – 07:00 pm| **The Challenge of Providing an Effective, but Technically Complex, Vaccine to the Developing World**  
Emilio Emini, Wyeth Pharmaceuticals, USA |
| 07:00 pm – 08:00 pm| **Reception**                                                |
| 08:00 pm – 10:00 pm| **Opening Dinner and entertainment**                         |

**IMPORTANT ANNOUNCEMENTS**

- Audiotaping, videotaping and photography of presentations are strictly prohibited.
- Speakers – Please leave at least 5 minutes for questions and discussion.
- Please do not smoke at any conference functions.
- Turn your cellular telephones to vibrate or off during technical sessions.
- Be sure to make any corrections to your name/contact information on the Master Participant List or confirm that the listing is correct. A corrected copy will be sent to all participants after the conference.
Monday, June 2, 2008

07:00 am – 08:30 am  Breakfast

08:30 am – 10:30 am  Session I: Immune System Function and Its Quantitation  
(Sponsored by Merck & Co., Inc.)  
Session Chair:  
David Weiner, University of Pennsylvania School of Medicine

08:30 am – 09:00 am  Human Monoclonal Antibodies and Analytic Vaccinology  
Antonio Lanzavecchia, Institute for Research in Biomedicine, Switzerland

09:00 am – 09:30 am  Utilizing Influenza Vaccination to Rapidly Clone High Affinity Human  
Monoclonal Antibodies and to Test the Concept of Original Antigenic  
Sin  
Jens Wrammert, Emory University School of Medicine, USA

09:30 am – 10:00 am  Anti-viral Immune Responses in Lymph Nodes  
Ulrich H. von Andrian, Harvard Medical School, USA

10:00 am – 10:30 am  Immunological Response to new DNA vaccines  
David Weiner, University of Pennsylvania School of Medicine, USA

10:30 am – 11:00 am  Break  
(Sponsored by Bioreliance)

11:00 am – 11:30 am  The First Clinical Efficacy Trial of an Adenovirus Type 5-Based HIV-1  
Vaccine: The STEP Study  
Danilo Casimiro, Merck & Co., Inc., USA

11:30 am – 12:00 pm  Quality Issues: The Good-Enough Vaccine  
Phil Minor, NIBSC, UK

12:00 pm – 12:45 pm  New Methods for Detecting Adventitious Agents  
David Onions, BioReliance Corporation, USA

12:45 pm – 01:30 pm  Lunch

01:30 pm – 03:30 pm  Ad hoc sessions, free time

03:30 pm – 06:00 pm  Session II: Virus and Replicon Vectored Vaccines  
(Sponsored by GE Healthcare - WAVE Products Group)  
Session Chairs:  
Manuel Carrondo, IBET  
Alexander von Gabain, Intercell AG

03:30 pm – 04:00 pm  Towards a Therapeutic Hepatitis C Vaccine – a Preclinical and Clinical  
Learning Curve  
Alexander von Gabain, Intercell AG, Austria

04:00 pm – 04:30 pm  Delivery Devices and Approaches for Pre-Clinical and Clinical HIV  
Immunization  
Britta Wahren, Karolinska Institute and Swedish Institute for Infectious  
Disease Control (SMI), Stockholm, Sweden

04:30 pm – 05:00 pm  Flavivirus Capsid Deletion Mutants as a New Vaccine Approach  
Christian Mandl, Medical University Vienna, Austria
Monday, June 2, 2008 (continued)

05:00 pm – 05:30 pm  Viral Vectors – Coupling Innate Signals to Antigen Expression and Presentation  
Peter Liljestrom, Karolinska Institute Stockholm, Sweden

05:30 pm – 06:00 pm  VEEV Replicon-Based Vaccines used in Heterologous Prime Boost Strategies Induce Lifelong Protection from Prostate Cancer and Therapy of Cervical Cancer in Mice and Robust Cell-Mediated Immunity in Rhesus Macaques  
W. Martin Kast, University of Southern California, USA

06:00 pm – 06:30 pm  Break  
(Sponsored by Pall Life Sciences)

06:30 pm – 08:30 pm  Session III: Emergent & Emergency Vaccines  
Session Chair:  
Manon Cox, Protein Sciences Corp.

06:30 pm – 07:00 pm  Efficient and Economical Influenza Vaccines  
Alan Shaw, VaxInnate, USA

07:00 pm – 07:30 pm  Flublok, A High Dose Recombinant Influenza Vaccine  
Manon Cox, Protein Sciences, USA

07:30 pm – 08:00 pm  Challenges and Solutions for the Next Generation of Vaccines: Development of Cell Culture-based Live Attenuated Influenza Vaccine  
Jonathan Liu, MedImmune, Inc., USA

08:00 pm – 08:30 pm  Toward the Development of a SARS Vaccine  
Jeffrey Ulmer, Novartis Vaccines and Diagnostics, USA

08:30 pm – 09:30 pm  Dinner

09:30 pm – 11:00 pm  Poster Reception
Tuesday, June 3, 2008

07:00 am – 08:30 am  Breakfast

08:30 am – 10:30 am  Session IV: Conjugate Vaccines
Session Chair: George Siber, Consultant

08:30 am – 09:00 am  Analytical and Manufacturing Challenges in Preparation of Bacterial Polysaccharide Conjugates
Carl Frasch, Frasch Biologics Consulting, USA

09:00 am – 09:30 am  Development of Validated Assays for Measuring the Human Antibody Response to Polysaccharide Conjugate Vaccines
Helena Käyhty, National Public Health Institute, Finland

09:30 am – 10:00 am  The Human Immune Response to Polysaccharides and Conjugates
David Goldblatt, University College London, UK

10:00 am – 10:30 am  The Impact of Polysaccharide Conjugate Vaccines
George Siber, Consultant, USA

10:30 am – 11:00 am  Break
(Sponsored by Artelis)

11:00 am – 11:30 am  Regulatory Issues Associated with the Development of a Comprehensive Meningococcal Vaccine
Ian Feavers, NIBSC, UK

11:30 am – 12:00 pm  TB Vaccine Development and Manufacturing
Jerald Sadoff, Aeras Global TB Vaccine Foundation, USA
(Being presented by Walter Kallaur)

12:00 pm – 12:30 pm  Evaluating Novel Cell Substrates for use in Vaccine Manufacture
Phil Krause, FDA/CBER, USA

12:30 pm – 01:00 pm  Epitope Driven GAIA HIV Vaccine Development: An Update
Annie De Groot, EpiVax, Inc., USA

01:00 pm – 02:00 pm  Lunch

02:00 pm – 04:00 pm  Session V: Adjuvants & Formulation
Session Chair: Nathalie Garçon, GlaxoSmithKline Biologicals

02:00 pm – 02:30 pm  The Improved ISCOMATRIX® Adjuvant
Debbie Drane, CSL Ltd., Australia

02:30 pm – 03:00 pm  Adjuvanted Plasmid DNA-Based Vaccines
Alain Rolland, Vical Inc., USA

03:00 pm – 03:30 pm  Exploiting Glycoengineered Yeast for the Development of Next Generation Vaccines
Robert Davidson, GlycoFi, USA

03:30 pm – 04:00 pm  Enhancing Vaccine Immunogenicity Through use of CpG TLR9 Agonists and Other Adjuvants
Risini Weeratna, Coley Pharmaceutical Group, Canada
**Tuesday, June 3, 2008 (continued)**

04:00 pm  
*Ad hoc sessions, free time* for those not going on optional excursion. Those going on optional excursion should meet at 4:20 in hotel lobby for 4:30 departure.

04:30 pm  
**Optional Excursion/Dinner** to Tavira where one can visit the medieval castle and old Moorish town. Dinner will be on your own and the buses will return to the hotel after dinner. Participants not going on the optional excursion will have dinner on their own either at the hotel or in a local restaurant.
**Wednesday, June 4, 2008**

07:00 am – 08:30 am  
**Breakfast**

08:30 am – 11:00 am  
**Session VI: Characterization of Complex Biologicals**  
Session Chairs:  
Robert Sitrin, Merck & Co., Inc.

08:30 am – 09:00 am  
**Quality Assessment of Cervarix™, GSK’S Cervical Cancer Vaccine, Manufactured with the Baculovirus Expression Vector System (BEVS)**  
Marguerite Deschamps, GlaxoSmithKline, Belgium

09:00 am – 09:30 am  
**Characterization of Conjugate Vaccines**  
Rasappa Arumugham, Wyeth Vaccines R&D, USA

09:30 am – 10:00 am  
**Characterization of Adenoviral Vector-Based Vaccines**  
Katey Einterz Owen, Merck & Co., Inc., USA

10:00 am – 10:30 am  
**Focus on Aggregation: Causes, Impact & Characterization**  
John Philo, Alliance Protein Laboratories, USA

10:30 am – 11:00 am  
**Developing In-Vitro Potency Assays to Monitor Process Development and Stability for Subunit Vaccine**  
Ying Zhang, Wyeth Vaccines R&D, USA

11:00 am– 11:30 am  
**Break**  
(Sponsored by GlaxoSmithKline Biologicals)

11:30 am – 12:00 pm  
**Challenge of Filing 4 New Vaccines at Once**  
Keith Chirgwin, Merck & Co., Inc., USA

12:00 pm – 12:30 pm  
**PATH: Narrowing the Immunization Gap**  
John Boslego, PATH, USA

12:30 am – 01:00 pm  
**Viral Vectors for Genetic Vaccination: Strategies, Vector Design and Production**  
Juan Asenjo, University of Chile, Chile

01:00 pm – 02:00 pm  
**Lunch**

02:00 pm – 04:00 pm  
**Ad hoc sessions, free time**

04:00 pm – 06:10 pm  
**Session VII: VLP’s & Inactivated Vaccines**  
(Sponsored by Probiogen)  
Session Chairs:  
Octavio Ramirez, UNAM, Mexico  
Kathrin U. Jansen, Wyeth Vaccine Research

04:00 pm – 04:30 pm  
**Controlling in vitro Assembly of Virus-like Particles: From Theory to Example(s)**  
Adam Zlotnick, University of Oklahoma Health Sciences Center, USA

04:30 pm – 05:00 pm  
**Virus-Like Particles as Vaccine Platforms**  
Bryce Chackerian, University of New Mexico, USA

05:00 pm – 05:30 pm  
**Alternate Rotavirus Vaccines: Inactivated Virus and VLPs**  
Margaret Conner, Baylor College of Medicine, USA
05:30 pm – 05:50 pm  
**Towards a Respiratory Syncytial Virus Vaccine Using Recombinant F Protein Transiently Expressed in Mammalian Cells**  
Sophie Nallet, École Polytechnique Fédérale de Lausanne (EPFL), Switzerland

05:50 pm – 06:10 pm  
**A Selective Recovery Methodology for the Clarification of Lipid-Envelope Virus-like Particles from S. Cerevisiae**  
Gaik Sui Kee, University College London, UK

06:10 pm – 06:40 pm  
**Break**

06:40 pm – 07:10 pm  
**Considerations for use of the “Animal Efficacy Rule”**  
Karen Goldenthal, Consultant, USA

07:10 pm – 07:40 pm  
**De-risking Vaccine Development: Correlates of Success**  
Fiona MacLaughlin, The Wellcome Trust, UK

07:40 pm – 08:00 pm  
**AGE1.CR – A Well Characterized Cell Substrate Designed for Production Vector Based Vaccines**  
Volker Sandig, ProBioGen AG, Germany

08:00 pm – 09:15 pm  
**Dinner**

09:15 pm – 11:00 pm  
**Poster Reception**
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<td>07:00 am – 08:30 am</td>
<td>Breakfast</td>
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| 08:30 am –10:30 am | **Session VIII: Veterinary Vaccines: Lessons to Learn for Human Vaccine Development**  
(Sponsored by Merial Ltd.)  
Session Chair:  
**Robert Nordgren**, Merial Limited |
| 08:30 am –09:00 am | **Emerging Diseases, Zoonoses and Vaccines to Control Them**  
Paul-Pierre Pastoret, World Organization for Animal Health, France |
| 09:00 am –09:30 am | **Avian Influenza Vaccine Development: Application Technology Platforms, Field Use and Predictors of Protection**  
David E. Swayne, US Department of Agriculture, USA |
| 09:30 am –10:00 am | **Use of Alternate Hosts in the Modeling of Immune Profiling and Vaccine Recognition**  
Lorne Babiuk, University of Saskatchewan, Canada |
| 10:00 am –10:30 am | **Use of Plasmid DNA Vaccine to Treat Melanoma in Dogs**  
Jedd Wolchok, Memorial Sloane Kettering Cancer Center, USA  
(Being presented by Robert Nordgren, Merial Limited) |
| 10:30 am– 11:00 am | **Break**                                                              |
| 11:00 am– 01:00 pm | **Session IX: Manufacturing of Vaccines**  
Session Chairs:  
**John G. Auniņš**, Merck & Co., Inc.  
**Paula Marques Alves**, ITQB/IBET |
| 11:00 am– 11:30 am | **Process Intensification for Large Scale Manufacturing Issues**  
Jose Castillo, Arteilis, Belgium |
| 11:30 am– 12:00 pm | **Multivalent Vaccines for Control and Eradication of FMD**  
M. Susana Levy, Biogenesis-Bago S.A., Argentina |
| 12:00 pm– 12:30 pm | **Manufacturing and Regulatory Challenges During the Approval of the First Gene Therapy for Food Animals**  
Henry Hebel, VGX Pharmaceuticals, USA |
| 12:30 pm– 12:50 pm | **Intensifying the Productivity of a Recombinant AD35 Manufacturing Process Using the PER.C6® Cell Substrate**  
Alfred Luitjens, Crucell, Netherlands |
| 12:50 pm– 01:10 pm | **Affinity Chromatography of Cell Culture Derived Vaccinia Virus**  
Michael Wolff, Max Planck Institute for Dynamics of Complex Technical Systems, Germany |
| 01:10 pm – 02:10 pm | **Lunch**                                                              |
| 02:10 pm – 04:10 pm | **Ad hoc sessions, free time** |

*Note: The session times and events are approximate and subject to change.*
Thursday, June 5, 2008 (continued)

04:10 pm – 05:30 pm  
**Session IX: Manufacturing of Vaccines (cont’d)**

04:10 pm – 04:30 pm  
**Trouble-Shooting Fermentation and Primary Recovery Manufacturing Issues in Order to Optimize Antigen Expression Used as Vaccine Candidates Against Infectious Diseases**
Timothy Lee, Sanofi Pasteur, Canada

04:30 pm – 04:50 pm  
**Technology Transfer and Process Scale-Up**
Bo Arve, Wyeth Pharmaceuticals, USA

04:50 pm – 05:10 pm  
**Predictive Modeling in Rotavirus-like Particles Production: Improving Upstream and Downstream Processing Design**
Tiago Vicente, IBET, Portugal

05:10 pm – 05:30 pm  
**Implementation of Disposable Technology in Vaccines Manufacturing: An Approach to Extractables/Leachables Studies**
Hélène Pora, Pall Life Sciences, France

05:30 pm – 06:00 pm  
**Break**

06:00 pm – 08:00 pm  
**Session X: Vaccines in Developing Countries**
Session Chair:  
**Barry Buckland**, Merck & Co., Inc.

06:00 pm – 06:30 pm  
**The Development of an Inactivated JE Vaccine for Endemic Countries**
Mahima Datla, Biological E, India

06:30 pm – 07:00 pm  
**Chickenguniya incidence and Vaccine Technology**
Krishna Ella, Bharat Biotech, India

07:00 pm – 07:30 pm  
**Vaccine Development for Developing Countries – Regulatory Approach in the European Union**
Manfred Haase, Consultant, Germany

07:30 pm – 08:00 pm  
**Developing Vaccines for Neglected Diseases**
Douglas Holtzman, Bill & Melinda Gates Foundation, USA

08:30 pm – 11:00 pm  
**Banquet & Closing**
Friday, June 6, 2008

07:00 am – 10:00 am  Breakfast and departure  
(hotel check-out is noon)
Poster Presentations

1. Metabolism of avian designer cells during influenza and MVA production
   Verena Lohr, Max Planck Institute for Dynamics of Complex Technical Systems, Germany

2. Capturing of cell culture derived influenza viruses by sulphated cellulose membranes – A promising pseudo-affinity method for influenza vaccine production
   Lars Opitz, Max Planck Institute for Dynamics of Complex Technical Systems, Germany

3. Anti-apoptotic action of one protein isolated from Lononlia Obliqua and the mitochondrial participation
   Ronaldo Zucatelli Mendonca, Instituto Butantan, Brazil

4. Influenza A virus-like particles as vaccine: comparison and evaluation of different strategies
   Florian Krammer, Institute for Applied Microbiology, Austria

5. Rabies virus glycoprotein (RYGP) expression in drosophila S2 cells and in BHK-21 cell infected by recombinant semliki forrest virus for vaccine purpose
   Pereira CA, Instituto Butantan, Brazil

6. Towards a recombinant vaccine for heartwater
   Nontobeko Thema, Agricultural Research Council - Onderstepoort Veterinary Institute, South Africa

7. Cryo-electron microscopy as a tool for imaging, characterization and structural analysis of biological solutions
   Clint Potter, NanolImaging Services, USA

8. Insect cells as an efficient platform for the production of AAV-based vaccines
   Marc G. Aucoin, University of Waterloo, Canada

9. Engineering of an E. coli host for production of plasmid biopharmaceuticals
   Diana M. Bower, Massachusetts Institute of Technology, USA

10. Rapid deployment plasmid production: combining inducible high yield fermentation process with novel autolytic plasmid DNA purification
    Aaron E. Carnes, Nature Technology Corporation, USA

11. Modified E. Coli B, A superior producer of plasmid DNA compared with E. Coli K
    Joseph Shiloach, Biotechnology Lab NIDDK, USA

12. Immunogenic display of diverse peptides on virus-like particles of RNA phage Ms2
    David S Peabody, University of New Mexico School of Medicine, USA

13. Novel techniques for characterization of double and triple-layered rotavirus-like particles
    Maria Candida M. Mellado, IBET/ITQB-UNL, Portugal

14. Host strain influences on supercoiled plasmid DNA Production in E. Coli; implications for efficient design of Large scale processes
    Sin Yee Yau, The Advanced Centre for Biochemical Engineering, UK

15. Insights into the effects of culture media and metabolites on adenovirus production
    Chun Fang Shen, Biotechnology Research Institute, Canada

16. Novel adenovirus 5 vaccine delivery platform which overcomes pre-existing immunity to AD
    Frank R. Jones, Etubics Corporation, USA

17. Fermentation strategies for the production of recombinant protein antigens in E. Coli
    Willie Sun, Wyeth Pharmaceuticals, USA
18. Critical process parameter to control productivity in helper-dependent adenoviral vector production
   Amine Kamen, Biotechnology Research Institute, Canada

19. Production of yellow fever virus in vero cells grown in serum-free medium
   Leda R. Castilho, Federal University of Rio de Janeiro, Brazil

20. Screening of DNA vaccines prototypes encoding antigen targeting sequences against sleeping sickness
   Gabriel A. Monteiro, Institute for Biotechnology and Bioengineering, Portugal

21. On the design and production of more stable and efficient plasmid DNA vectors
   Duarte Miguel F Prazeres, IBB-Institute for Biotechnology and Bioengineering, Portugal

22. Vp7 and Vp4 genotyping of bovine group a rotavirus in México. Towards the development of a recombinant vaccine
   William A. Rodríguez-Limas, Universidad Nacional Autónoma de México, México

23. 293 cells: An alternative cell line for PPRV production
   Paula Marques Alves, ITQB-UNL/IBET, Portugal

24. Assessment of the thermal stability of Cervarix ™
   Diane Doucet, GlaxoSmithKline Biologicals, Belgium

25. The influence of elevated oxygen partial pressure on specific virus productivities in an influenza vaccine process
   Andreas Bock, Max Planck, Germany

26. Rotavirus-Like Particle Production: Mathematical Modeling Rational Approach for Process Development
   António Roldão, IBET/ITQB-UNL, Portugal

27. Development of a cell culture production platform for cold-adapted live attenuated influenza vaccine (CAIV) strains of Flumist®: effects and interactions of medium components, trypsin, and different influenza viruses in process productivity
   Luis Maranga, MedImmune Vaccines, USA

   Luis Maranga, MedImmune Vaccines, USA

29. Capillary electrophoresis for the differentiation of double-layered and triple-layered rotavirus-like particles
   Laura A. Palomares, Instituto de Biotecnología. Universidad Nacional Autónoma de Mexico, Mexico

30. Differential expression and functional analysis of e. ruminantium proteins: identification of potential antigens for a subunit heartwater vaccine
   Isabel Marcelino, ITQB/IBET, Portugal

31. Characterization of a cancer vaccine based on very small size proteoliposome (VSSP) obtained by different formulation processes.
   Vladimir Peña, Center of Molecular Immunology, Cuba

32. The Silver Anniversary of Clinical Protein production from recombinant CHO cell culture
   Matt Croughan, Rathmann Professor, Keck Graduate Institute, USA

33. A cell-culture-based platform for viral vaccine production for humans
   Marina Etcheverrigaray, Universidad Nacional del Litoral, Argentina
34. Rapid mycoplasma testing: The HYMY™ assay combines amplification of viable mycoplasmas in broth culture with signal detection by quantitative polymerase chain reaction (QPCR)
   David Onions, BioReliance Corporation, USA

35. Comparison of dengue-2 virus production in vero cells under serum-free and serum-containing conditions
   Erica A. Schulze, Federal University of Rio de Janeiro, School of Chemistry, Brazil

36. Perfusion process for human and animal viral vaccine production in a single use stirred tank bioreactor
   Nicholas Havelange, Artelis, Belgium

37. Exploiting lymphatic transport and complement activation in Th1 stimulating nanoparticle vaccines
   Jeffrey A. Hubbell, Melody A. Swartz, Ecole Polytechnique Fédérale de Lausanne (EPFL), Switzerland

38. MDCK-based influenza production using Cytodex 3 in a wave bioreactor
   Johanna Norberg, GE Healthcare Bio-Sciences AB, Sweden

39. Protection induced by pneumococcal surface protein a (pspa) is enhanced by conjugation to a streptococcus pneumoniae capsular polysaccharide
   Luciana C.C. Leite, Instituto Butantan, Brazil

40. Biodistribution and toxicological safety evaluation of adenovirus type 5 vectored vaccines against ebola and marburg viruses
   Rebecca L. Sheets, Vaccine Research Center, NIAID/NIH, USA

41. Development of a universal influenza vaccine
   Walter E. Manger, Merck & Co., Inc., USA

42. Purification of retrovirus vector particles and identification of host-associated proteins by proteomic analysis
   Maria Mercedes Segura, Center of Animal Biotechnology and Gene Therapy (CBATEG), Spain

43. SPR Technology as a Powerful Tool to Accurately Determine Influenza Virus Concentration
   Camilla Nilsson, GE Healthcare Bio-Sciences AB, Sweden
   (presented by Johanna Norberg, GE Healthcare Bio-Sciences AB)

44. Protective Immune Responses to Pathogenic Influenza Using Consensus DNA Immunogens and Constant Current Electroporation
   Henry Hebel, VGX Pharmaceuticals, USA

45. Development of a BioVeris-based, Quantitative Immunoassay for Assessing the Quality of a Conjugate Vaccine Candidate
   Charlie Chen, Wyeth Research, USA