MEDICAL COUNTERMEASURES INITIATIVE
REGULATORY SCIENCE SYMPOSIUM

FDA Headquarters, Silver Spring, MD
June 5 & 6, 2012

SCIENTIFIC PROGRAM

TUESDAY, JUNE 5, 2012

8:30 AM WELCOME
Margaret Hamburg, M.D., Commissioner, U.S. Food & Drug Administration

8:35 AM INTRODUCTORY REMARKS
Lisa Hensley, Ph.D., M.S.P.H., Director, MCMi Regulatory Science, Office of Counterterrorism & Emerging Threats, FDA/OC

8:40 AM CONTINUING EDUCATION ANNOUNCEMENT
Bernadette Williamson-Taylor, M.Ed., Lead Regulatory Health Education Specialist, Office of Scientific & Professional Development, FDA/OC

SESSION 1: ANIMAL MODELS: ADVANCING REGULATED STUDIES

Moderators: Jerry Davis, D.V.M., Ph.D. & Estella Jones, D.V.M.

8:45 AM GETTING TO THE ANIMAL RULE
Judy Hewitt, Ph.D., Chief, Research Resources Section, Office of Biodefense Research Affairs, National Institute of Allergy & Infectious Diseases, NIH

9:15 AM DEVELOPING ELECTRONIC DATA STANDARDS FOR USE IN PRODUCT DEVELOPMENT UNDER THE ANIMAL RULE
Susan McDermott, M.D., Medical Officer, Office of Counterterrorism & Emergency Coordination, FDA/CDER

9:30 AM IMAGING APPLICATIONS IN ANIMAL MODELS OF INFECTION
Dima Hammoud, M.D., Neuroradiologist/Tenure Track Investigator, NIH Center for Infectious Disease Imaging

10:00 AM WHOLE BODY BIOIMAGING FOLLOWING VACCINA INFECTION FOR BETTER EVALUATION OF NEW VACCINES & ANTIVIRALS
Marina Zaitseva, Ph.D., Staff Scientist, Division of Viral Products, Office of Vaccine Research & Review, FDA/CBER

10:15 AM CONDUCT OF ANIMAL RULE STUDIES IN HIGH & MAXIMUM BIOCONTAINMENT AT UTMB
Trevor Brasel, Ph.D., Study Director, Regulated Studies, University of Texas Medical Branch at Galveston

10:45 AM NATURAL DISEASE PROGRESSION OF FILOVIRUSES IN RHESUS MACAQUES
Anna Honko, Ph.D., Microbiologist, U.S. Army Medical Research Institute of Infectious Diseases

11:15 AM BIODEFENSE VACCINES, ANIMAL RULE & COLLABORATIONS
Nicole Kilgore, M.S., Deputy Joint Product Manager, Joint Vaccine Acquisition Program, Chemical Biological Medical Systems, U.S. Department of Defense

11:45 AM LUNCH
11:45 AM POSTER SESSION 1 (CONCURRENT)

SESSION 2: BIOMARKERS & OTHER CORRELATES

Part 1 – Moderator: Gene Olinger, Ph.D.

1:30 PM TRANSLATIONAL MEDICINE FOR MEDICAL COUNTERMEASURE DEVELOPMENT
Giora Feuerstein, M.D., M.Sc., Chief Medical & Technical Officer,
Chemical & Biological Technologies Directorate, Defense Threat Reduction Agency

2:15 PM SEARCHING FOR BIOMARKERS OF HEMORRHAGIC FEVER INFECTION IN THE CIRCULATING IMMUNE SYSTEM
John Connor, Ph.D., Assistant Professor of Microbiology, Boston University School of Medicine

2:45 PM RESCUE OF VACCINE MEMORY RESPONSES IN THE AFTERMATH OF IONIZING RADIATION EXPOSURE
Hugh McFarland, Ph.D., Staff Scientist, Laboratory of Immunology, Division of Therapeutic Proteins,
Office of Biotechnology Products, FDA/CDER

3:00 PM DEVELOPING A NEW ANIMAL MODEL & NOVEL BIOMARKERS FOR ANTHRAX INFECTION: A BASIS FOR ENHANCING THE REGULATORY REVIEW OF MEDICAL COUNTERMEASURES
David Frucht, M.D., Chief, Laboratory of Cell Biology, Division of Monoclonal Antibodies,
Office of Biotechnology Products, FDA/CDER

3:15 PM INNATE IMMUNE RESPONSE MODULATORS CONTROL INFLAMMATION & IMPROVE SURVIVAL IN VIRAL ENCEPHALITIS
Daniela Verthelyi, M.D., Ph.D., Chief, Laboratory of Immunology, Division of Therapeutic Proteins,
Office of Biotechnology Products, FDA/CDER

3:30 PM BREAK

SESSION 2: BIOMARKERS & OTHER CORRELATES (continued)

Part 2 – Moderator: Tracy MacGill, Ph.D.

3:45 PM DISCOVERY, GLOBAL SURVEILLANCE & IMPLICATION OF NOVEL AGENTS IN EMERGING INFECTIOUS DISEASES
Thomas Briese, Ph.D., Associate Professor of Clinical Epidemiology,
Columbia University, Mailman School of Public Health

4:15 PM PANDEMIC INFLUENZA VACCINES: NEW TOOLS TO EXPLORE ADJUVANT IMPACT ON IMMUNE RESPONSE & CROSS-CLADE PROTECTION FOR HUMAN, SWINE & AVIAN INFLUENZA
Surender Khurana, Ph.D., Visiting Scientist, Division of Viral Products, Office of Vaccine Research & Review, FDA/CBER

4:30 PM IDENTIFYING NEW BIOMARKERS OF IMMUNE RESPONSE TO PANDEMIC INFLUENZA TO IDENTIFY NEW APPROACHES TO EVALUATE VACCINES: SUBTYPES OF INTERFERON-ALPHA & INTERFERON-LAMBDA IN RESPONSE TO SEASONAL & PANDEMIC STRAINS OF INFLUENZA A
Ronald Rabin, M.D., Chief, Laboratory of Immunobiochemistry, Division of Bacterial, Parasitic & Allergenic Products, Office of Vaccines Research & Review, FDA/CBER

5:00 PM LEARNING FROM THE 2009 INFLUENZA PANDEMIC TO PREPARE FOR THE NEXT: DO HUMANS HAVE IMMUNE CROSS-PROTECTION TO PANDEMIC FLU?
Suzanne Epstein, Ph.D., Associate Director for Research, Office of Cellular, Tissue & Gene Therapies, FDA/CBER

5:15 PM CLOSING REMARKS: ALWAYS START WITH THE END IN MIND
George Korch, Ph.D., Senior Science Advisor to the Assistant Secretary for Preparedness & Response, U.S. Dept. of Health & Human Services

WEDNESDAY, JUNE 6, 2012

8:25 AM CONTINUING EDUCATION ANNOUNCEMENT
Bernadette Williamson-Taylor, M.Ed., Lead Regulatory Health Education Specialist, Office of Scientific & Professional Development, FDA/OC

SESSION 3: SURVEILLANCE, DETECTION & DEVELOPMENT OF NEW DIAGNOSTIC STRATEGIES

Moderator: Jens Kuhn, M.D., Ph.D.

8:30 AM LINKING CLINICAL DIAGNOSTICS & SURVEILLANCE – CHALLENGES & OPPORTUNITIES
Lt. Col. Dan Wattendorf, M.D., Program Manager, Defense Sciences Office, Defense Advanced Research Projects Agency

9:00 AM NEW OPPORTUNITIES FOR TRANSLATIONAL RESEARCH THROUGH SCIENTIFIC ENGAGEMENT & MEDICAL DIPLOMACY
Joseph Fair, Ph.D., M.P.H., Corporate Vice President, Global Viral Forecasting, Inc.

9:30 AM DEVELOPING STANDARDS TO AID IN THE EVALUATION OF THE SAFETY & EFFECTIVENESS OF *IN VITRO* DIAGNOSTIC TESTS FOR BIOTHREAT AGENTS
Sally Hojvat, Ph.D., Director, Division of Microbiology Devices, Office of In Vitro Diagnostic Device Evaluation & Safety, FDA/CDRH

9:45 AM GENOMIC PLASTICITY AS A MARKER OF FILOVIRUS NATURAL HISTORY AND THERAPEUTIC SUCCESS
Gustavo Palacios, Ph.D., Director, Center for Genomic Sciences, U.S. Army Medical Research Institute for Infectious Diseases

10:15 AM BREAK

SESSION 4: POSTMARKET SURVEILLANCE

Moderator: Sally Hojvat, Ph.D.

10:30 AM DEVICE SURVEILLANCE IN THE EVENT OF AN EMERGENCY
Douglas Wood, Associate Director, Office of Surveillance & Biometrics; Mary Beth Ritchey, Ph.D., Associate Epidemiology Division Director, FDA/CDRH

11:00 AM CHANGING THE LANDSCAPE FOR POSTMARKET SURVEILLANCE OF MEDICAL DEVICES: THE CRITICAL ROLE OF THE MEDICAL DEVICE EPIDEMIOLOGY NETWORK (MDEpiNet)
Danica Marinac-Dabic, M.D., Ph.D., Director, Division of Epidemiology, Office of Surveillance & Biometrics, FDA/CDRH

11:30 AM MONITORING A NEW VACCINE DURING A PUBLIC HEALTH EMERGENCY: CANADA'S EXPERIENCE
Carole Légaré, M.D., Manager, Medical Section (Marketed Biologicals & Biotechnology Products), Health Canada

12:00 PM LUNCH
12:00 PM POSTER SESSION 2 (CONCURRENT)

SESSION 5: PRODUCT QUALITY & SAFETY

Moderators: Pam Chamberlain, D.V.M., D.A.B.T., Ph.D. & Jean Hu-Primmer, M.S.

1:30 PM DETECTION OF ADVENTITIOUS AGENTS IN VACCINES & CELL SUBSTRATES
Philip Krause, M.D., Acting Deputy Director, Office of Vaccines Research & Review, FDA/CBER

1:45 PM ENABLING AN INTEGRATED WORKFLOW FOR NON-CLINICAL RESEARCH SUPPORTING THE EVALUATION & PREDICTION OF MEDICAL COUNTERMEASURE SAFETY, EFFICACY & PHARMACOKINETICS
Rodney Rouse, D.V.M., M.B.A., Ph.D., Research Veterinary Medical Officer, Division of Drug Safety Research, Office of Testing & Research, FDA/CDER

2:00 PM INFLUENCE OF HIGH-TEMPERATURE STORAGE & VARIOUS FORMULATION, PROCESSING & PACKAGING VARIABLES ON THE PHYSICAL STABILITY OF OSELTAMIVIR PHOSPHATE CAPSULE SHELLS USED TO TREAT INFLUENZA
Mansoor Khan, Ph.D., Director, Division of Product Quality Research, Office of Testing & Research, Office of Pharmaceutical Science, FDA/CDER

2:15 PM OPTIMIZATION OF MEDICAL COUNTERMEASURES FOR THE TREATMENT OF INTERNAL RADIOACTIVE METAL CONTAMINATION
Patrick Faustino, Ph.D., Acting Deputy, Division of Product Quality Research, Office of Testing & Research, FDA/CDER

2:30 PM TACI AS A DETERMINANT FOR PEDIATRIC VACCINE POTENCY
Mustafa Akkoyunlu, M.D., Ph.D., Senior Investigator, Laboratory of Bacterial Polysaccharides, Office of Vaccines Research & Review, FDA/CBER

2:45 PM DEVELOPING NEW METHODS FOR SAFETY EVALUATION OF NEXT GENERATION INFLUENZA VACCINES INCLUDING NOVEL VACCINE ADJUVANTS: USE OF RABBIT MODEL & HUMAN CELL-BASED ASSAYS FOR PRE-CLINICAL EVALUATION OF SAFETY OF ADJUVANTED INFLUENZA VACCINES
Marina Zaitseva, Ph.D., Staff Scientist, Division of Viral Products, Office of Vaccines Research & Review, FDA/CBER

3:00 PM IMPROVED METHODS FOR THE CHARACTERIZATION OF IV VANCOMYCIN PRODUCTS
Michael Boyne, Ph.D., Chemist, Division of Pharmaceutical Analysis, Office of Testing & Research, FDA/CDER

3:15 PM THE EFFECT OF SUBSTITUTION OF DEAMIDATION-SUSCEPTIBLE ASPARAGINE RESIDUES WITH GLUTAMINE ON ANTHRAX PROTECTIVE ANTIGEN
Drusilla Burns, Ph.D., Deputy Director, Division of Bacterial, Parasitic & Allergenic Products, Office of Vaccines Research & Review, FDA/CBER

3:30 PM BREAK

SESSION 6: THE CHANGING LANDSCAPE OF REGULATORY SCIENCE

Moderator: Rakesh Raghuwanshi, M.P.H.

3:45 PM ETHICAL & SCIENTIFIC CHALLENGES IN PEDIATRIC MCM DEVELOPMENT
Jason Gerson, Ph.D., Commissioner's Fellow, Office of Pediatric Therapeutics, FDA/OC

4:15 PM CAN WE RE-ENGINEER MEDICAL COUNTERMEASURES?
Jason Paragas, Ph.D., Senior Advisor for Science, Chemical & Biological Technologies Directorate, Defense Threat Reduction Agency

4:45 PM KEYNOTE: ORGANS ON CHIPS
Donald Ingber, M.D., Ph.D., Founding Director, Wyss Institute for Biologically Inspired Engineering; Professor of Vascular Biology, Harvard Medical School/Children's Hospital Boston; Professor of Bioengineering, Harvard School of Engineering & Applied Sciences

5:15 PM CLOSING REMARKS
Luciana Borio, M.D., Assistant Commissioner for Counterterrorism Policy; Director, Office of Counterterrorism & Emerging Threats, FDA/OC