



7TH ANNUAL BIODEFENSE VACCINES & THERAPEUTICS

June 15-17, 2009 | Almas Temple Club | Washington DC

Pre-Conference Symposium

Monday, June 15, 2009 * 9:00AM-12:30PM

Regulatory Symposium: Animal Rule Licensure and Emergency Use Authorization

About the Symposium

This symposium is designed to address some of the unique challenges that relate to achieving licensure of medical countermeasures under the Animal Rule; such as the development of appropriate animal models, designing appropriate pivotal animal efficacy trials, and bridging animal data to humans. The symposium will facilitate discussion among government agencies supporting development portfolios, companies engaged in MCM development, and the FDA. Symposium participants will share lessons learned and discuss the practical aspects of biodefense product development, such as managing risk in critical path development activities or delivering products to stockpiles.

Monday, June 15, 2009

9:00 – 9:10

Welcome and Introduction by the Chair

Boris Lushniak, M.D., MPH, *Assistant Commissioner, Counterterrorism Policy, Office of Counterterrorism Policy & Planning, Office of the Commissioner, U.S. Food and Drug Administration (invited)*

9:10 – 10:10

Session I: Developing Appropriate Animal Models for Disease

This session will provide government and commercial perspectives on animal model development. Panelists will discuss experience and current efforts by government agencies and industry, as well as approaches to coordinating animal model development activities across organizations.

Moderator:

Panelists:

Gigi Gronvall, Ph.D., *Senior Associate, Center for Biosecurity of UPMC and Assistant Professor of Medicine, University of Pittsburgh*

Judith Hewitt, Ph.D., *Chief, Biodefense Research Resources Section, Office of Biodefense Research Affairs, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, NIH*

Valerie Riddle, M.D., FACP, *Vice President and Medical Director, PharmAthene, Inc.*

John Wade, DVM, Ph.D., *Vice President and Manager, Battelle National Security Global Business*

10:10-11:30

Session II: Achieving Product Licensure/Approval Under the Animal Rule

Panelists will discuss experience in designing appropriate animal efficacy studies, bridging animal data to humans, and achieving appropriate safety database for vaccines and therapeutics

Moderator:

Brad Leissa, M.D., MPH, *Deputy Director and CDER Emergency Coordinator, Office of Counter-Terrorism and Emergency Coordination, Center for Drug Evaluation and Research, U.S. Food and Drug Administration*

Panelists:

Kathleen Berst, *Director, Developmental Program Integration, Chemical Biological Medical Systems – Joint Vaccine Acquisition Program (CBMS-JVAP)*

Sally Bolmer, Ph.D., *Senior Vice President, Development and Regulatory Affairs, Human Genome Sciences*

Paul Chaplin, Ph.D., *Executive Vice President and CSO, Bavarian Nordic GmbH*

Dennis Hruby, Ph.D., *Chief Science Officer, SIGA Technologies*

Gary Nabors, Ph.D., *Vice President, Product Development & Site Operations, Emergent BioSolutions, Inc.*

11:30-11:45

Morning Refreshment Break

11:45-12:30

Session III: Emergency Use Authorization

This session will provide FDA perspective on Emergency Use Authorizations, including discussion of common misconceptions about EUA. Panelist will offer perspectives on seeking EUA, stockpiling decisions and post licensure commitments.

Moderator:

CDR Carmen Maher, RN RAC, *Policy Analyst, Office of Counterterrorism & Emerging Threats, Office of the Commissioner, U.S. Food and Drug Administration*

Panelists:

Sally Bolmer, Ph.D., *Senior Vice President, Development and Regulatory Affairs*, Human Genome Sciences

Debra Yeskey, *Director, Regulatory and Quality Affairs, Biomedical Advanced Research & Development Authority, Office of Assistant Secretary for Preparedness and Response*, Department of Health and Human Services