

AGENDA

13 July 2009

10:00 – 13:00 REGISTRATION & LUNCH (11:00 – 12:45)

13:00 – 13:10 Opening Remarks

Judy Hewitt, *Chief, Biodefense Research Resources Section
OBRA/DMID/NIAID.*

**13:10 – 13:40 Integrated National Biodefense Medical Countermeasures (MCM)
Portfolio**

Carol Linden, *Principal Deputy Director, BARDA.*

13:40 – 14:00 Transformation of Fort Detrick.

COL Judith Robinson, *Commander, U.S. Army Garrison, Fort Detrick.*

Session 1: Facilities

Chair: Jean P (Fred) Khoshbin, *NIAID, NIH.*

14:00 – 14:35 The Impact of the Facility on the Science

Jean P (Fred) Khoshbin, *NIAID, NIH.*

14:35 – 15:10 Hydrogen Peroxide Vapor Decontamination

Martin Orłowski, *BioQuell.*

15:10 – 15:30 BREAK

**15:30 – 15:55 Challenges and Lessons Learned: Aerobiology in an Academic Setting
at the MU RBL**

Paul Anderson, *Missouri University.*

**15:55 – 16:20 Construction and Commissioning of the U. of Pittsburgh Aerobiology
Core Facility**

Dan Fisher / Kelly Cole, *University of Pittsburgh.*

**16:20 – 16:45 Aerobiology Core in Support of the National Center for Biodefense
and Infectious Diseases**

Calvin Carpenter, *George Mason University.*

**16:45 – 17:10 Infectious Disease Aerobiology at Tulane National Primate Research
Center**

Chad Roy, *Tulane University.*

**17:10 – 17:30 Challenges and Lessons Learned Bringing Down an Enhanced
Animal BSL-3 Facility for Annual Maintenance and Verification**

Debra Sharpe, *Southern Research Institute.*

17:30 – 18:30 POSTER SESSION

- 1. Overcoming Challenges Associated with Conducting GLP-Regulated Studies in BSL-3 and BSL-4 Containment Facilities.**
Beth Incao, Donna Hering, Carolyn Mentzer, USAMRIID.
- 2. GLP and GCLP Comparison for Management Evaluation at USAMRIID, Ft. Detrick, MD.**
Lucinda Leaman, Carolyn Mentzer, USAMRIID.
- 3. Standardization and Characterization of *Francisella tularensis* Aerosols for Experimental Infection of Animals.**
Douglas Reed, Seth Faith, University of Pittsburgh.
- 4. Vaporized Hydrogen Peroxide Decontamination of a Class III Biosafety Cabinet and Mobile Transfer Cart.**
Lesley Homer, Daniel Fisher, Douglas Reed, Kelly Stefano Cole, University of Pittsburgh..
- 5. Decontamination of Spores with Aqueous Chlorine Dioxide Solutions.**
Johnny Peterson, B. Chatuey, Galveston National Laboratory.
- 6. Preparation and Characterization of *Francisella tularensis* DVC SCHU S4 Aerosol Material.**
H. Carl Gelhaus, Hank Lockman, Kevin Sayers, Amber Lindsay, Brock Miniard, Shannon Martin, Jessica Price, Lawrence Wolfrain, Battelle Biomedical Research Center.
- 7. Impact of *Bacillus anthracis* Spore Preparation on Aerosol Performance.**
Jamie Austin, Roy Barnewall, Daniel Sanford, Gregory Stark, Battelle Biomedical Research Center.
- 8. Effects of Aerosolization and Heat-Shocking on *B. anthracis* Spores.**
David Dyer, Richard Washington, Paul Dabisch, Louise Pitt, USAMRIID.
- 9. The Effects of Growth Media on the Virulence of Aerosolized *Francisella tularensis* in BALB/C Mice.**
Seth Faith, Gerard Nau, Douglas Reed, University of Pittsburgh.
- 10. Challenges Facing Sponsors Seeking Licensure of Vaccines using the Animal Rule (21 CFR 601.90).**
Mary Kate Hart, DVC.
- 11. Graduate Course in Aerosol biology.**

USAMRIID and George Mason University.

19:00 DINNER

14 July 2009

Session 2: Overcoming Aerosol Challenges

Chair: Judy Hewitt, NIAID, NIH.

08:30 – 09:15 FDA Draft Guidance on the Essential Elements of Animal Models.
Susan McCune, FDA.

09:15 – 09:45 The Alliance for Biosecurity's Work on Animal Model development Issue.
Valerie Riddle, Alliance for Biosecurity.

09:45 – 10:15 The Importance of Standardized Reagents for Animal Models.
Melissa Willis, BEI.

10:15 – 10:35 BREAK

10:35 – 11:05 Preparation and Characterization of Aerosol Challenge Material.
Jamie Austin, Battelle Biomedical Research Center.

11:05 – 11:35 Bioassays in Support of Aerosol Challenge Animal Studies.
Frejya Lynn, NIAID, NIH.

11:35 – 12:05 Pharmacokinetics in Aerosol Efficacy Studies.
Blaire Osborn, NIAID, NIH.

12:05 – 13:15 LUNCH

Session 3: BioAccountability

Chair: Jim Estep, Battelle

13:15 – 13:25 Bioaccountability - The Roles, Responsibility and Personnel Reliability Requirements of Researcher and Facility Operations Personnel Involved in Biological Defense and Select Agent Research.
Jim Estep, Battelle

13:25 – 13:50 Strengthening Laboratory Biosecurity.
Carol Linden, Principal Deputy Director, BARDA.

13:50 – 14:15 Regulatory Compliance for DHS S & T Directorate.

Brandt Pasco, DHS.

**14:15 – 14:50 Biosecurity, Biosurety, BSAT Inventory Control and Accountability:
New Requirements and New Challenges.**

David Shoemaker, USAMRIID.

**14:50 – 15:05 New Challenges in Biosecurity and Biosurety: How to Take a Rational
Approach to Ensure Compliance.**

Debra Sharpe, Southern Research Institute.

15:05 – 15:20 Battelle's Approach to Implementing the BPRP.

Robert Hunt, Battelle Biomedical Research Center.

15:20 – 15:40 BREAK

15:40 – 16:00 Export Control Regulation – Application to Research.

Kimberley Orr, U.S. Department of Commerce

16:00 – 16:20 Introduction to U.S. Export Controls.

Johanna Reeves, Law Office of Johanna Reeves.

**16:20 – 16:40 The National Biosafety and Biocontainment Training Program:
Culturing a New**

Generation of Biosafety Professionals.

Debbie Hunt, Duke University

16:40 – 17:00 Implementation of NBBTP.

J. Craig Reed, Frontline Foundation

17:00 – 17:20 Why Should You Develop a Training Program for Your Institution.?

Sophie Brocard, University of Texas Medical Branch.

17:40 – 18:40 POSTER SESSION

1. Infectious Large Particle Aerosols.

Richard J. Thomas, Dstl.

**2. Biological Aerosol Background Characterization and Aerosol Collection
Methods.**

*Charles Merritt, Cathy Sotto, Horn-Bond Lin, Vasanthi Sivaprakasam,
Jay Eversole. NRL.*

**3. Deposition of Airborne Chemical and Biological Agents in the Lungs of Humans
and Animals.**

Bahman Asgharian, Applied Research Associates.

- 4. Characterization of a Head-Only Aerosol Exposure Chamber for Non-human Primates.**
Paul A Dabisch, Jamie Kline, John Yaeger, Nick Johnson, Andrew Beck, Carlton Lewis, Neal Batdorf, USAMRIID.
- 5. Calibration and Verification of an Exposure System for *Yersinia pestis* CO92 in a BSL-3 Facility.**
John E Trombley, Jeremy Boydston, J. Kyle Bohannon, Zara Llewellyn, Larry Bowen, Peter Silvera. Southern Research Institute.
- 6. Performance of the Southern Research Nonhuman Primate Plethysmography System.**
Jordan Bohannon, Z. Llewellyn, J. Trombley, J. Boydston, L Bowen. Southern Research Institute.
- 7. Extracting Real-Time Respiratory Parameters from Existing Head-only Aerosol Exposure Chamber.**
Jamie Kline, Paul Dabisch, John Yeager, Andrew Beck. USAMRIID.
- 8. Assessment of the Dose-response of Aerosolised Monkeypox in *Cynomolgus* Macaques.**
Graham Hatch, J. Vipond, G. Funnell, D. Hopkins, D. Roberts. HPA.
- 9. Characterization of a Nonhuman Primate Aerosol Exposure System for Generation Delivery and Collection of *Francisella tularensis* DVC SCHU S4.**
Roy Barnewall, Dave Fisher, Edward Heller, Robert Krile, Amber Lindsay, Dennis Pak, Gary Sparks, Jessica Price, Lawrence Wolfrain Battelle Biomedical Research Institute and Dynport Vaccine Company.
- Aerobiological Characteristics of Multisized Mycobacterial Bioaerosols in a Nonhuman Primate Model Pulmonary Tuberculosis.**
Sathseesh Sivasubrahmani, Deepak Kaishal, Noton Dutta, Stephanie Killeen, Chad Roy, Tulane National Primate Center.
- 11. Qualification of a Nose-Only Inhalation Exposure System for Inhalation Challenge of *Yersinia pestis* in vivo.**
Shu-Chieh Hu, Winston Lin, Narayanan Rajendranm Patricia Fellows, Mark Bolanowski, Louis Holland, IIT Research Institute and DVC.
- 12. Validation of Sampling Devices for a Non-Human Primate Aerosol Exposure Chamber.**
John Yaeger, Nick Johnson, Jamie Kline, Paul Dabisch, USAMRIID.

13. Validation of a Chamber for Whole-Body Dispersion of Infectious Bioaerosols.
Andrew Beck, Jamie Kline, Resse Baker, Paul Dabisch, USAMRIID.

14. Qualification of Bacterial Bioaerosols for Use in GLP Exposure Studies.
Trevor Brasel, Krystle Agans, Edward Barr, Andrew Cawthon, Joan Gallis, Veronica Gonzales, Felisha Romero, Steven Storch, Alicia Weldon, Robert Sherwood, Lovelace Respiratory Research Institute.

Development of Nonhuman Primate and Rodent Aerosol Systems for Generation, Delivery and Collection of Botulinum Neurotoxins A1 and B1.

Roy Barnewall, Edward Heller, Patricia Reuther, Gary Sparks, Jeffrey Shearer, Battelle Biomedical Research Institute.

19:00 DINNER

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Session 4: Modeling

Chair: Michael Kuhlman, NBACC.

08:30 – 09:00 An Improved Model of Human Response to Aerosol Chemical and Biological Agent Hazards.

Gene McClellan, ARA.

09:00 – 09:30 TBD

09:30 – 10:00 TBD

10:00 – 10:30 TBD

10:30 – 10:50 BREAK

Session 5: Aerosol Science and Technologies

Chair: Louise Pitt, USAMRIID.

10:50 – 11:10 Development of an ABSL-3 Nose-Only Bioaerosol Exposure System.
Richard Tuttle, Midwest Research Institute.

11:10 – 11:30 Use of Aerosol Delivery System Inside of a Flexible Film Isolator.
Rigoberto Sanchez, University of Maryland.

11:30 – 11:50 Development of a New Test Chamber for Large Item Testing with BSL-3 Agents.
Kevin Hommema, Battelle Memorial Institute.

11:50 - 12:10 Inhalation Dosimetry in Murine Bioaerosol Challenge Models.
Larry E Bowen, Southern Research Institute

12:10 – 12:30 LRRI Whole-Body Plethysmography Exposure Systems.
Edward Barr, Lovelace Respiratory Research Institute.

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12:30 – 12:50 Survival of Zaire Ebolavirus, Reston Ebolavirus and Lake Victoria Marburgvirus in Aerosols
Mark Lever, Dstl

12:50 – 14:00 LUNCH

Session 6: Animal Models
Chair: Elizabeth Leffel

14:00 – 14:20 Different Clinical Outcomes following Aerosol or Intranasal Exposure to Influenza H5N1 Virus in the Ferret.
John Lednicky, Midwest Research Institute.

14:20 – 14:40 Development of a Non-Traditional Pregnant Animal Model for Aerosol Infection of Influenza.
Richard Beigi, University of Pittsburgh.

14:40 – 15:00 Development of an Inhalational *Bacillus anthracis* Therapeutic Model in Cynomolgus Macaques.
Gabriel Meister, Battelle Biomedical Research Center.

15:00 – 15:20 Aerosol Infection of Mice with *Brucella Melitensis* 16M.
Roy Barnewall, Battelle Biomedical Research Center.

15:20 – 15:40 BREAK

15:40 – 16:00 Comparison of Aerosolized *F. tularensis* in Three Species of Nonhuman Primates.
Aysegul Nalca, USAMRIID.

16:00 – 16:20 Development of a Bioaerosol Model for Pneumonic Plague in Swiss Webster Mice.
Winston Lin, IIT Research Institute.

16:20 – 16:40 Aerosol Models for Emerging Infections and Biodefense.
Divey Saini, Duke Human Vaccine Institute.

16:40 – 17:00 Analysis of Telemetry Data from Non-human Primates Exposed to Aerosolized Ebola Sudan Boniface.

Matt Lackemeyer, USAMRIID.

17:00 – 17:20 Development of Mouse and Rhesus Macaque Models for Evaluation of Recombinant Botulinum Vaccine Efficacy.

Daniel Sanford, Battelle Memorial Institute.

17:20 – 18:30 POSTER SESSION

1. Evaluation of Large Particle vs Small Particle Aerosolized Rabbitpox Virus in Rabbits.

Virginia Livingston, Justin Hartings, Nicole Garza, Josh Hatkin, Aysegul Nalca, USAMRIID.

Development of the Mouse Aerosol Challenge Model for Evaluation of Recombinant Botulinum Vaccine Efficacy.

Michelle Vassar, Roy Barnewall, Michael Babin, Nancy Niemuth, Karen Metcalfe, Ian Henderson, Jeffry Shearer, Battelle Biomedical Research Center and DVC.

3. Development of the Rhesus Macaque Aerosol Challenge Model for Evaluation of Recombinant Botulinum

Vaccine Efficacy.

Daniel Sanford, Roy Barnewall, Michelle Vassar, Nancy Niemuth, Karen Metcalfe, Ian Henderson, Jeffry Shearer, Battelle Biomedical Research Center and DVC.

4. Major Recall Expansion of Vaccine-Elicited CD4+CD25+Foxp3+ T cells and Homeostatic Protection against

Lymphoid Destruction in Monkeypox.

Zheng W Chen, Dan Huang, Crystal Chen, Richard Wang, Jeff Fortman, Lingyun Shoa, University of Illinois College of Medicine

5. Development of Francisella tularensis SCHU S4 Aerosol Challenge Model in the Rhesus Macaque.

Jessica Price, Carl Gelhaus, David Fisher, Robert Krile, Hank Lockman, Lawrence Wolfrain, Dynport Vaccine Company and Battelle Biomedical Research Center.

6. Host Immune Responses to Aerosolized Staphylococcus Enterotoxin B (SEB) in African Green Monkeys.

Rebecca Erwin-Cohen, Dianna Blau, Aimee Porter, Micheal West, Luis DaSilva, USAMRIID.

7. **Effects of Aerosolized F+ vs F- Strains of Yersinia pestis on African Green Monkeys.**
Aimee Porter, Rebecca Erwin-Cohen, Lara Chuvala, Nancy Twenhafel, Luis DaSilva, Dianna Blau, USAMRIID.
8. **Clinical Data of Aerosolized Monkeypox Virus Infection in Cynomolgus Macaques.**
Aysegul Nalca, Virginia Livingston, Nicole Garza, Ondraya Espinshade, Jennifer Chapman, Justin Hartings, USAMRIID.
9. **Cynomolgus Macaque Model for Pneumonic Plague.**
Richard Warren, Hank Lockman, Roy Barnewall, Robert Krile, Oscar Bermeo Bianco, Daphne VAsconcelos, Jessica Price, Mark Bolanowski, Patrica Fellows, Battelle Biomedical Research Center.
10. **A comparison of the Host Responses between Humans and Nonhuman Primates to Francisella tularensis.**
Aimee Porter, Dianna Blau, Phillip Pittman, Chrysanthi Paranavitana, Thomas Downey, Rebecca Erwin-Cohen, Michael West, Luis DaSilva. USAMRIID.

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11. **Exposure of Swiss Webster Mice to Aerosolized Francisella tularensis SCHU S4.**
Kristopher Van Zandt, Carl Gelhaus, Dennis Pak, Amber Lindsay, Jennifer Cross, Joe Hying, Kristin Battles, Robert Krile, Roy Barnewall, Hank Lockman, Battelle Biomedical Research Center.
12. **Exposure of Cynomolgus Macaques to Aerosolized Francisella tularensis SCHU S4.**
Carl Gelhaus, Dennis Pak, Amber Lindsay, Jennifer Cross, Joe Hying, Kristin Battles, Robert Krile, Roy Barnewall, Kris Van Zandt, Hank Lockman, Battelle Biomedical Research Center.

Body Temperature Analysis in Three Species of Nonhuman Primates Following Exposure to Aerosolized Bacillus anthracis.
Scott Willens, Steven Yee, Jessica Reinhardt, Elizabeth Zumbrun, Louise Pitt, USAMRIID.

The Temporal Relationship between Bacteremia, Toxemia and Body Temperature in the New Zealand White Rabbit Model of Inhalational Anthrax.
Jason Comer, J Schmidt, E Johnson, A Wasko, J Wickham, F Robin, B. Miniard, G Stark, G Meister,

Battelle Biomedical Research Center.

15. The Antibody Levels to the *Yersinia pestis* F1-V Vaccine in Cynomolgus Macaques at the Time of Challenge do not

Necessarily Indicate the Possible Outcome.

Kei Amemiya, Sylvia Trevino, Christopher Bolt, Diana Fisher, Bradford Powell, Jeffrey Adamovicz, USAMRIID.

Use of Marmosets as Models for Inhalational BW Infection

Michelle Nelson, Dstl

18:45 – 19:30 PRE DINNER SOCIAL

19:30 BANQUET

Guest Speaker: Anna Johnson-Winegar

16 July 2009

Session 7: Animal Models – Countermeasures

Chair: Ed Nuzum, NIAID, NIH.

08:30 – 09:00 Transformational Medical Technologies Initiative.

Heather Wargo, TMTI, DTRA.

09:00 – 09:20 Dual Antibody Approach for the Treatment of Anthrax.

Kristopher Van Zandt, Battelle Biomedical Research Institute.

09:20 – 09:40 Determination of the Pulmonary Mean Deposited Dose, Onset of Bacteremia, and Efficacy of Levofloxacin in New Zealand White Rabbits following *Bacillus anthracis* Ames Inhalation Exposure.

Jeremy Boydston, Southern Research Institute.

09:40 – 10:00 Antimicrobial Peptide Response of Human Lung Epithelial Cells to *Francisella tularensis* Live Vaccine Strain Infection.

Tony Pierson, George Mason University.

10:00 – 10:20 BREAK

10:20 – 10:40 Evaluation of IMVAMUNE (Modified Vaccinia Virus Ankara Vaccine) for Time to Protection Against Aerosolized Rabbitpoxvirus.

Ondraya Espenshade, USAMRIID.

10:40 – 11:00 Evaluation of the Immunogenicity and Efficacy of Inactivated VEEV Vaccine Candidates in BALB/C Mice.

Shannon Martin, DVC.

11:00 – 11:20 Anthrax Vaccine Adsorbed (AVA) Demonstrates Long Term Efficacy against Inhalation Anthrax following a Modified Regimen and Route of Immunization in Rhesus Macaques.

Carol Sabourin, Battelle Memorial Institute.

11:20 – 11:40 Augmentation of the Murine Immune Response to the Plague F1-V Vaccine by Activation of Endosomal Expressed Toll-like Receptors.

Kei Amemiya, USAMRIID.

11:40 – 12:00 WRAP UP

LUNCH TO GO