



## DAY ONE (November 4, 2009)

07:30 – 08:30

### CONFERENCE REGISTRATION

The Fairfax at Embassy Row Hotel  
2100 Massachusetts Avenue, NW  
Washington, DC 20008

08:30 – 08:40

### *Welcoming Remarks*

Ballroom

**Nicole Lurie, M.D., M.S.P.H.**

Assistant Secretary for Preparedness and Response  
Rear Admiral, U.S. Public Health Service  
Department of Health & Human Services, United States

08:40 – 10:25

### *Plenary Session: A Sustainable Global Infrastructure for MCM*

Ballroom

**Moderator: Mary Mazanec, M.D., J.D.**

Deputy Assistant Secretary  
Director, Office of Medicine, Science, and Public Health  
Office of the Assistant Secretary for Preparedness and Response  
Department of Health & Human Services, United States

08:40 – 08:55

### *GHSI and the Need for a Sustainable Global Infrastructure for MCM*

**Professor Nigel Lightfoot, CBE**

Chief Advisor and Chair  
GHSI Risk Management and Communications Working Group  
Health Protection Agency, United Kingdom

08:55 – 09:15

### *The French MCM Research and Development Program*

**François Salicis, M.S.**

Project Manager for CBRN Issues  
Public Health Emergency Preparedness and Response Division  
General Directorate of Health  
Ministry of Health, France

09:15 – 09:35

### *Medical Countermeasures Programs on Biodefense, Radiological/Nuclear, and Chemical Threats at the National Institute of Allergy and Infectious Diseases (NIAID)*

**Michael G Kurilla, M.D., Ph.D.**

Director, Office of Biodefense Research Affairs  
Associate Director for Biodefense Product Development Director  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health  
Department of Health & Human Services, United States



09:35 – 09:55

***The U.S. Public Health Medical Countermeasures Enterprise***

**Robin A. Robinson, Ph.D.**

Deputy Assistant Secretary

Director, Office of Biomedical Advanced Research and Development Authority (BARDA)  
Office of the Assistant Secretary for Preparedness and Response  
Department of Health & Human Services, United States

09:55 – 10:15

***The Canadian MCM Consortium***

**R. Kent Harding, Ph.D.**

Chief Scientist

DRDC-Suffield

Defence Research and Development Canada, Canada

10:15 – 10:25

***Questions and Answers***

10:25 – 10:40

**BREAK**

10:40 – 11:00

***The World Health Organization (WHO)  
Smallpox Vaccine Bank***

**Cathy Roth, M.B., B.Chir., F.R.C.Path.**

Coordinator

Biorisk Reduction for Dangerous Pathogens  
Epidemic and Pandemic Alert and Response  
World Health Organization

11:00 – 11:20

***The World Health Organization Coordination Efforts to Make 2009 H1N1 Vaccine Available Globally***

**Cathy Roth, M.B., B.Chir., F.R.C.Path.**

Coordinator

Biorisk Reduction for Dangerous Pathogens  
Epidemic and Pandemic Alert and Response  
World Health Organization

11:20 – 11:40

***The Mexican Joint Venture to Build Domestic Vaccine Manufacturing Capacity***

**Hugo Lopez-Gatell, M.D., Ph.D.**

Director General of Epidemiology

Ministry of Health, Mexico

11:40 – 12:00

***MCM Markets and Sustainability: The National Biodefense Science Board Approach***

**Patrick J. Scannon, M.D., Ph.D.**

Member, MCM Markets and Sustainability Working Group

National Biodefense Science Board

Office of the Assistant Secretary for Preparedness and Response  
Department of Health & Human Services, United States



12:00 – 12:20

***Legal and Liability Issues Associated With International Sharing of MCM***

**John Clerici**

Partner and Chair

Life Sciences and Public Health Preparedness Practice  
McKenna Long & Aldridge LLP, United States

12:20 – 12:30

***Questions and Answers***

12:30 – 14:00

**LUNCH ON YOUR OWN**

14:00 – 15:30

**BREAKOUT SESSION I: MCM RESEARCH AND DEVELOPMENT**

***Pandemic Influenza (Agenda A)***

Salon Room

***Biological Threats (Agenda B)***

Balcony Room

***Radiological/Nuclear Threats (Agenda C)***

Whitehall Room

***Chemical Threats (Agenda D)***

Churchill Room

15:30 – 15:50

**BREAK**

15:50 – 17:30

**BREAKOUT SESSION I (Continued)**

***Pandemic Influenza (Agenda A)***

Salon Room

***Biological Threats (Agenda B)***

Balcony Room

***Radiological/Nuclear Threats (Agenda C)***

Whitehall Room

***Chemical Threats (Agenda D)***

Churchill Room

17:30 – 18:00

**GHSI GOVERNMENT MEMBERS CLOSED SESSION**

Whitehall Room

18:00 – 20:00

**POSTER SESSION AND RECEPTION**

Sponsored by the Foundation for the National Institutes of Health (NIH)  
and the Centers for Disease Control and Prevention (CDC) Foundation

Ballroom



## DAY TWO (November 5, 2009)

09:00 – 10:40

### **Policy Session I: *Stockpile Management and Shelf-Life Extension***

**Moderator: Professor Walter Biederbick, Ph.D.**

Center for Biological Safety  
Robert Koch-Institute  
Ministry of Health, Germany

09:00 – 09:20

### ***Stockpile Management and Shelf-Life Extension in France***

**Claude-Olivier Martin**

Head Manager  
Health Reserve Services  
French Agency for Preparedness and Response of Health Emergencies (EPRUS), France

09:20 – 09:40

### ***The U.S. Strategic National Stockpile***

**Greg Burel**

Director  
Strategic National Stockpile  
Coordinating Office for Terrorism Preparedness and Emergency Response  
Centers for Disease Control and Prevention  
Department of Health & Human Services, United States

09:40 – 10:00

### ***Shelf-Life Extension for Drugs and Biologics: Cost/Benefit Analysis***

**Susan E. Gorman, Pharm.D., M.S., DABAT**

Associate Director for Science  
Strategic National Stockpile  
Coordinating Office for Terrorism Preparedness and Emergency Response  
Centers for Disease Control and Prevention  
Department of Health & Human Services, United States

10:00 – 10:20

### ***Shelf-Life Extension: An Industry Perspective***

**Alan Goldhammer, Ph.D.**

Scientific and Regulatory Affairs  
Pharmaceutical Research and Manufacturers of America (PhRMA), United States

10:20 – 10:40

### ***Questions and Answers***

10:40 – 11:00

**BREAK**



11:00 – 12:30

**POLICY SESSION II: *Regulatory Approval and Use of MCM***

**Moderator: Maria Julia Marinissen, Ph.D.**

Acting Team Leader

International Partnerships and Initiatives

Office of Medicine, Science, and Public Health

Office of the Assistant Secretary for Preparedness and Response

Department of Health & Human Services, United States

11:00 – 11:20

***Regulatory Procedures in the European Union for the Authorization of Vaccines***

**Sabine Atzor**

Policy Officer

Consumer Goods, Unit F2 Pharmaceuticals

Enterprise and Industry Directorate-General

European Commission

11:20 – 11:40

***Emergency Use of Medical Countermeasures***

**Cynthia L. Kelley, M.S.**

Senior Advisor for Counterterrorism/Medical Countermeasures

Center for Biologics Evaluation and Research (CBER)

U.S. Food and Drug Administration

Department of Health & Human Services, United States

11:40 – 12:00

***Animal Models for Assessing Countermeasures to Bioterrorism Agents***

**Lida Anestidou, D.V.M., Ph.D.**

Program Officer

Institute for Laboratory Animal Research

The National Academies, United States

12:00 – 12:20

***Prospects for International Harmonization of the Regulatory Processes for MCM***

**David Wood, Ph.D.**

Coordinator

Quality Assurance and Standards

Immunization, Vaccines, and Biologicals

World Health Organization

12:20 – 12:30

***Questions and Answers***

12:30 – 14:00

**LUNCH ON YOUR OWN**



14:00 – 15:30

**BREAKOUT SESSION II: MCM RESEARCH AND DEVELOPMENT**

***Pandemic Influenza (Agenda A)***

Salon Room

***Biological Threats (Agenda B)***

Balcony Room

***Radiological/Nuclear Threats (Agenda C)***

Whitehall Room

***Chemical Threats (Agenda D)***

Churchill Room

15:30 – 15:50

**BREAK**

15:50 – 16:50

**BREAKOUT ROUNDTABLES**

***Pandemic Influenza (Agenda A)***

Salon Room

***Biological Threats (Agenda B)***

Balcony Room

***Radiological/Nuclear Threats (Agenda C)***

Whitehall Room

***Chemical Threats (Agenda D)***

Churchill Room

16:50 – 17:00

**BREAK**

17:00 – 17:45

**PLENARY ROUNDTABLE: GUIDELINES TO INTEGRATING POLICY AND RESEARCH  
AND DEVELOPMENT FOR MCM**

Ballroom

**Moderator: Monique K. Mansoura, Ph.D.**

Director for Medical Countermeasure Policy, Planning, and Requirements  
Office of the Biomedical Advanced Research & Development Authority (BARDA)  
Office of the Assistant Secretary for Preparedness and Response  
Department of Health & Human Services, United States

17:45 – 17:55

**CLOSING REMARKS**

Ballroom

**Mary Mazanec, M.D., J.D.**

Deputy Assistant Secretary  
Director, Office of Medicine, Science, and Public Health  
Office of the Assistant Secretary for Preparedness and Response  
Department of Health & Human Services, United States



**17:55 – 18:00**

**BREAK**

**18:00 – 18:45**

**GHSI GOVERNMENT MEMBERS CLOSED ROUNDTABLE**

Whitehall Room