



CBRN Medical Countermeasures Workshop 2009



**June 25-26, 2009
Hyatt Regency Bethesda
1 Bethesda Metro Circle
Bethesda, Maryland 20814**

AGENDA

Goals and Anticipated Outcomes

- The Office of the Biomedical Advanced Research and Development Authority (BARDA) Divisions of Chemical, Biological, Radiological, and Nuclear (CBRN) Countermeasures and Acquisitions Management Systems (AMS) will host a two-day informational workshop for Industry and Academic stakeholders on medical countermeasure requirements generation, responding to a solicitation, constraints governing product use under public health emergency conditions, interacting with FDA, and product development funding.
- Our goal is to help stakeholders better understand BARDA, and provide guidance on how to best engage with us.

Format

- This Workshop will take place over two days, with morning and afternoon plenary sessions.
- Day 1 will comprise of information sessions sponsored by the BARDA Division of CBRN Countermeasures.
- Day 2 will comprise of information sessions sponsored by the BARDA Division of AMS.

Day One: June 25th

Interactive Information Sessions with CBRN Division

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| 8:30 – 8:40 am | Welcome and Opening Remarks – Dr. Carol Linden
HHS, Principal Deputy Director of the Biomedical Advanced Research and Development Authority (BARDA) |
| 8:40 – 8:50 am | Overview of BARDA and the CBRN Division – Dr. Gary Disbrow
Deputy Director, BARDA/CBRN Division of Countermeasures |
| 8:50 – 9:00 am | Overview of CBRN Strategic Plan – Dr. Gerald Kovacs
Director, BARDA/CBRN Division Countermeasures |

- 9:00 – 10:00 am** **Programmatic Presentations by BARDA Staff**
- **Anthrax Vaccines** – Dr. Narayan Iyer, Chief Anthrax Vaccines
 - **Antitoxins** – Dr. Stephen Morris, Chief, Anthrax Therapeutics
 - **Chem/Rad/Nuc** – Dr. Ronald Manning, Chief Chemical Radiological Nuclear Countermeasures
 - **Smallpox** – Dr. Dawn Myscofski, Chief Smallpox Vaccines
 - **SSTD** – Dr. Jerome Donlon, Director Strategic Science and Technology Division
- 10:00 – 10:15 am** **Panel Q&A with Directors and Branch Chiefs**
- 10:15 – 10:30 am** **BREAK**
- 10:30 – 10:40 am** **Overview of Medical Countermeasures Website and Navigation –**
Ms. Elizabeth Jarrett, Program Analyst, BARDA
- 10:40 – 11:15 am** **Requirements Generation**
- **Department of Homeland Security** – Dr. Diane Berry
Chief Scientist, DHS Office of Health Affairs
 - **Policy Planning and Requirements (BARDA)** – Dr. Joanna Prasher
Chief, Rad/Nuc Policy Planning and Requirements
 - **BARDA Modeling Group** – Ms. Mary Beth Hill-Harmon
Program Analyst, Modeling, BARDA
- 11:15 – 11:30 am** **Panel Q & A with Presenters**
- 11:30 – 12:30 pm** **Overview of Integrated National Biodefense Portfolio –** Dr. Carol Linden
Principal Deputy Director, BARDA
- Funding Mechanisms and Roles in Development of Medical Countermeasures**
- Dr. Michael Kurilla, Director, Office of BioDefense Research Affairs
Associate Director for BioDefense Product Development, DMID,
NIAID, National Institutes of Health
 - Dr. Albert Churilla, Chief, Medical Science and Technology Division,
Chemical / Biological Technologies Directorate, Joint Science &
Technology Office Defense Threat Reduction Agency
- 12:30 -12:45 pm** **Q & A**
- 12:45 – 2:00 pm** **LUNCH** **(PLEASE SEE LIST OF NEARBY RESTAURANTS)**
- 2:00 – 3:00 pm** **Regulatory Issues, Critical Path and Lessons Learned**
- **Animal Rule** – Dr. Rosemary Roberts
Director, Office of Counterterrorism and Emergency Coordination

- Food and Drug Administration, CDER
- **EUA and Contingency Use** – Dr. Debra Yeskey
Director, Regulatory and Quality Affairs Division, BARDA
- **SNS and Their Role in Stockpiling & Deployment** –
Dr. Susan Gorman Associate Director for Science,
Division of Strategic National Stockpile, Centers for Disease Control
and Prevention
- **Critical Path and Lessons Learned** –
Dr. Thomas Dreier – Subject Matter Expert, BARDA/CBRN
Dr. Michael Merchlinsky – Subject Matter Expert, BARDA/CBRN
Mr. David Aglow – Subject Matter Expert, BARDA/CBRN

3:00 – 3:15 pm **Panel Q & A**

3:15 – 3:30 pm **Closing Remarks and Wrap Up** – Dr. Gerald Kovacs

Day Two: June 26th
Interactive Information Sessions with AMS

8:30 – 8:35 am **Opening Remarks & Introduction of AMS** – Dr. Michael A. Balady
Director, BARDA Acquisition Management Systems (AMS) Division and Head
of Contracting Activity (HCA)

8:35 – 8:55 am **AMS Organizational Review and Overview Acquisition Process,
RFP to Award** – Mr. Brian Goodger
Senior Contracting Officer & Deputy Director BARDA/AMS

8:55 – 9:05 am **Q & A**

9:05 – 9:25 am **Overview of Broad Agency Announcements (BAA)** – Ms. Glynis Fisher
Senior Contracting Officer and Section Chief BARDA/AMS

- What is the BAA Process?
- How do they differ from RFP?
- What’s appropriate to acquire under a BAA vs a RFP?

9:25 – 9:35 am **Q&A**

9:35 – 9:55 am **BREAK**

9:55 – 10:00 am **Panel Discussion** – Moderator: Mr. Schuyler Eldridge
Chief Contracting Officer, BARDA/AMS

10:00 – 10:20 am **Types of Contracts Used in BARDA** – Mr. Jake Lewis
Contracting Officer BARDA/AMS

- Cost Reimbursement vs Fixed Price – Use of incentives
- Risks associated with each type

- 10:20 – 10:40 am** **How to Respond to a BARDA Solicitation** – Mr. Andre Early
Senior Contracting Officer BARDA/AMS
Ms. Alice Roache, Small Business Specialist Office of Small
Disadvantaged Business Utilization, HHS
- Key contract terms
 - Socio-Economic small business concerns
 - How BARDA evaluates IAW Section M
- 10:40 -10:50 am** **Q & A**
- 10:50 – 11:30 am** **Mock Technical Evaluation Panel (TEP) Review**
Dr. Michael A. Balady, Director, AMS
Mr. Brian Goodger, Deputy Director & Sr. Contracting Officer, AMS
Ms. Trang Gisler, Project Officer, BARDA/CBRN
- Technical Evaluation
 - Cost Evaluation
 - Past Performance Evaluation
 - Technical Evaluation Report
- 11:30 – 11:45 am** **Q & A**
- 11:45 – 1:00 pm** **LUNCH** **(PLEASE SEE LIST OF NEARBY RESTAURANTS)**
- 1:00 – 1:20 pm** **Earned Value Management (EVM)** – Mr. Carl Ruggiero
EVM Subject Matter Expert (SME), BARDA/AMS
- 1:20 – 1:30 pm** **Q & A**
- 1:30 – 1:50 pm** **Data Rights, Patents** – Dr. Dale Berkley
Office of General Counsel, National Institutes of Health (NIH)
- Who owns the data made under a contract?
 - Who owns inventions made under a contract?
- 1:50 – 2:00 pm** **Q & A**
- 2:00 – 2:20 pm** **Ethics/Conflicts of Interest** – Mr. Michael Goulding
Office of General Counsel, HHS
- Ethics Do's and Don'ts for Industry
 - PREP Act
- 2:20 – 2:30 pm** **Q & A**
- 2:30 – 2:40 pm** **Closing Remarks** – Dr. Michael A. Balady