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

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
- 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