



*United States Department of*

# **Health & Human Services**

**Office of the Assistant Secretary for Preparedness & Response (ASPR)  
Biomedical Advanced Research & Development Authority (BARDA)**



# **Centers for Innovation in Advanced Development & Manufacturing**

**-or-**

## **CIADM**

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Project Officer

Division of Manufacturing, Facilities & Engineering

BARDA Industry Day

*Contracting for Countermeasures*

October 17, 2011



# HHS MCM Enterprise Review: August 2010



U.S. Department of Health and Human Services  
Assistant Secretary for Preparedness and Response

## The Public Health Emergency Medical Countermeasures Enterprise Review

*Transforming the Enterprise  
to Meet Long-Range National Needs*

August 2010

## Key Initiatives

1. Expand Product Pipeline through Concept Acceleration Program (CAP) at NIAID
2. Establish a Strategic Investment (SI) Fund to increase investments in commercial ventures with multi-use potential (BARDA & NIAID)
3. Establish Centers for Innovation in Advanced Development and Manufacturing (BARDA)
4. Optimize influenza vaccine development and manufacturing (BARDA, NIAID, FDA, CDC)
5. Investment in upgrading science capacity at FDA



# Outreach to Potential Performers



SEP 15, 2010	'DRAFT' Solicitation [DRAFT-AMCG-10-39]
OCT 5-8, 2010	One-on-one Meetings
OCT 29, 2010	Questions/Comments Received
JAN 25, 2011	Responses Posted (~242)
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MAR 02, 2011	Synopsis Posted [11-100-SOL-00011]
MAR 30, 2011	Solicitation Issued
APR 15, 2011	Round 1 Questions/Comments Received
APR 25, 2011	1 <sup>st</sup> Pre-proposal Conference
MAY 05, 2011	Amendment #1 & Round 1 Responses (~122) Posted
MAY 18, 2011	Round 2 Questions/Comments Received
JUN 01, 2011	2 <sup>nd</sup> Pre-proposal Conference
JUN 06, 2011	Amendment #2 & Round 2 Responses (~153) Posted
JUN 28, 2011	Round 3 Questions/Comments Received
JUN 28-29, 2011	One-on-one Communication Sessions
JUL 07, 2011	Amendment #3 & Round 3 Responses (~22) Posted
JUL 13, 2011	Amendment #4 Posted
JUL 21, 2011	PROPOSALS DUE



# Objectives of the RFP



- Establish public-private partnerships to construct/retrofit U.S.-based, commercial-scale, biopharmaceutical facilities that support advanced development and manufacturing of MCMs
- Provide core services, on a routine basis, for the advanced development and manufacturing of CBRN biopharmaceuticals supported by the U.S. Government
- Provide, in an emergency, necessary U.S.-based surge capacity to respond to an emerging infectious disease, pandemic influenza, and currently known or unknown threats
- Provide biopharmaceutical oriented workforce development through training programs aligned with current regulatory guidelines



# The Buzzwords!



Sustainable, domestic-based medical countermeasure manufacturing capabilities require innovative solutions!

**Speedy**

**Multi-product Facility**

**Nimble / Adaptable**

**Flexible Manufacturing**

**Single-use / Disposables**



# Mandatory Elements for Offeror



1. FDA Licensure of a Biopharmaceutical Product within the Last Ten (10) Years
2. U.S. Biopharmaceutical Manufacturing commitment
  - Core services through the lifetime of the facility
3. Cost Sharing
  - USG / Contractor Minimums:  
49% / 51% of the total cost of new construction *-and/or-*  
75% / 25% of the total cost to retrofit an existing facility
4. Surge Manufacturing Capacity for Pandemic Influenza Vaccine Production & Other Threats
  - Minimum: 50 million finished doses within four (4) months of task order receipt
5. Training Commitment
  - Biopharmaceutical-oriented program provided in conjunction with an accredited U.S. academic institution or other reputable organization(s)



# The Procurement Process Presses Forward



*Dates on this slide are tentative, of course.*

## **OCT 2011 – Competitive Range Determination**

- After the technical and business evaluation of Offerors' proposal(s), the Contracting Officer determines the competitive range

## **OCT/ NOV 2011 – Pre-Award Site Visits**

- Pre-award site visits are conducted for those Offeror(s) in the competitive range

## **NOV 2011 to JAN 2012 – Discussions**

- Negotiations will be conducted with all Offeror(s) in the competitive range

## **JAN/ FEB 2012 – Final Proposal Revisions (FPR):**

- Upon completion of negotiations, the Offeror(s) will be requested to submit their FPR

## **MAR 2012 – FPR Evaluations:**

- The FPRs are evaluated in the similar manner in which the original evaluations were conducted focusing on the areas within the proposal that were revised

## **MAR/ MAY 2012 – Source Selection:**

- Upon final review of the FPR, the Source Selection Evaluation Board (SSEB) Chairperson with the Contracting Officer will brief the Source Selection Authority (SSA) who will make the final decision on this Source Selection