Centers of Innovation for Advanced Development and Manufacturing

Biomedical Advanced Research and Development Authority (BARDA)

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HHS/ASPR/BARDA

Centers: HHS Needs

- **HHS needs are following:**
  - U.S.-based Centers for Innovation in Advanced Development and Manufacturing (the “Centers”) as public-private partnerships
  - Greater assistance in the development and manufacture of CBRN medical countermeasure (MCM) product candidates
  - Secure, robust, & nimble domestic vaccine and other biopharmaceutical manufacturing surge capacity in an emergency
  - Training of next generation of operators with workforce development training programs.

CIADM Synopsis

- **HHS released a synopsis on March 2, 2011 for the Centers for Innovation in Advanced Development and Manufacturing (CIADM).**

- **Solicitation Number: 11-100-SOL00011**

- **Available online at www.fedbizopps.gov**

1. Establish Center Facilities

- **Construction new or retrofit existing facilities in the U.S. utilize state-of-the art flexible manufacturing approaches for platform vaccine and biopharmaceutical product technologies**
- **Facility design, construction, commissioning, and validation are cost-shared between HHS and Offeror**
  - New facilities: Maximum HHS contribution - 49%
  - Retrofitted facilities: Maximum HHS contribution – 75%

2. Provide ADM Core Services for CBRN MCMs

- **Provide primarily, on a routine basis, core services that include the advanced development and manufacturing of chemical, biological, radiological, and nuclear (CBRN) medical countermeasures.**
  - Medical countermeasures will include vaccines and well-characterized biological products
  - Candidate products receiving core service assistance will be from USG-supported developers and assigned by USG
  - ADM Core Services include, but are not limited, to following:
    - Upstream & downstream process development, optimization, scale up, and validation
    - Manufacturing process validation
    - Product formulation chemistry
    - Lot release & clinical testing assay development, optimization, and validation
    - Quality systems (Control & Assurance – GMP & GLP compliance)
    - Regulatory affairs (IND, EUA, BLA, NDA submissions & strategy)
    - Clinical investigational lot manufacturing (pilot scale)
    - Commercial scale manufacturing
    - Program management
  - All ADM core service must be performed in-residence or subcontracted to domestic, cGMP facilities.
- **Offeror must provide at least 6 months of core services per annum.**
- **USG will pay operational & maintenance costs for services rendered with 6 months/annum guaranteed.**

3. Provide Emergency Flexible Vaccine Manufacturing for Pan Flu & Other Threats

- Provide rapid & nimble commercial scale manufacturing surge capabilities for vaccine & biological product production in an emergency
- Manufacturing facilities will utilize state-of-the-art flexible and innovative manufacturing processes combined with new cell, recombinant & molecular platform technologies
- Produce vaccines & biologicals for pandemic influenza, emerging infectious diseases, & other unknown threats
- Pandemic influenza vaccine manufacturing capacity should be at least 50 million doses within four (4) months and first dose available within 12 weeks on pandemic onset
- Pandemic vaccine candidates will be assigned to Centers based on technology capabilities at contract awarding or afterwards

4. Workforce Development Training Program

- **Establish a workforce development training program to enhance and maintain the U.S.-based personnel ability to produce these medical countermeasures**
- **Bring technology and innovation into the American job market is a critical element of these Centers**
- **Training programs will need to align with FDA training requirements and current best practices in commercial industry**
- **Partnership with accredited U.S.-based universities will be a pre-requisite for these programs**

Statement of Objectives (SOO)

- **Our solicitation will include a Statement of Objectives, not a Statement of Work**
- **Offerors will be required to submit a detailed Statement of Work to address these Objectives as part of their submission**
- **HHS SOO is asking Offerors to prescribe creative & innovative solutions to HHS stated needs & objectives**
  - Provides basic, top-level needs & objectives in a solicitation
  - Provides Offerors with flexibility to develop cost-effective and alternative solutions

Mandatory Criteria for Evaluation

- **HHS solicitation will have five (5) mandatory evaluation criteria:**

1. Experience with FDA approval process
   - Offeror or subcontractor must have sponsored successfully BLA or NDA in last ten (10) years
2. U.S. Biopharmaceutical Manufacturing commitment
   - Core services & mfg capability must be maintained through the lifetime of the facility in the U.S.
3. Cost Sharing – Facility Construction
   - Offeror Minimum: 51% of the total cost of new construction
     25% of the total cost to retrofit an existing facility
4. Surge Manufacturing Capacity for Pandemic Influenza Vaccine Production
   - Offeror 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

Questions and Clarifications

1. What is the primary mission of the proposed Centers?

The primary mission of the Centers is to provide core advanced development and manufacturing services for CBRN medical countermeasures through public-private partnerships on a day-to-day basis. HHS/BARDA will coordinate and integrate these ADM core services for CBRN MCMs with those offered by other federal agencies (e.g., clinical studies at NIAID).

Questions and Clarifications

2. What are other missions of the proposed Centers?

The other purposes of the proposed Centers are:

(1) increase domestic vaccine and other biologicals manufacturing capacity by building new, or retrofitting existing pharmaceutical facilities for pandemic influenza & other threats in an emergency

(2) provide workforce development programs to foster and advance the next generation of domestic biopharmaceutical manufacturers.

In regard to pandemic influenza vaccines, the requirement for each Center will be to make first doses available within 12 weeks of receipt of the virus reference strain, for a total of 50 million doses of vaccine within four months.

Questions and Clarifications

3. Is the development of pandemic influenza vaccines a requirement of these Centers?

No. The USG, through NIAID and HHS/BARDA, has other existing contracts in place for the development of vaccines for seasonal and pandemic influenza.

Questions and Clarifications

4. In the event of an influenza pandemic requiring vaccine surge capacity, how will pandemic vaccine be assigned to Centers?

HHS will assign Centers task orders to manufacture pandemic influenza vaccines based on technology compatibility and readiness of the Centers for the pandemic influenza vaccine and its technology. If a Center has a cell-, recombinant,- or molecular-based pandemic influenza vaccine available, it will be considered.

Questions and Clarifications

5. Are the Centers required to make commercial products?

No, the Centers are NOT required by HHS to make commercial products in these facilities. Core advanced development and manufacturing services for USG-designated CBRN MCMs are required for at least six (6) months per year; greater consideration will be given to those Offerors who can provide more than the minimum. However, the Centers are required to stay in compliance with all federal and other governmental regulatory guidelines.

Questions and Clarifications

6. How will the USG provide for the construction, operation and maintenance costs for the Centers?

Construction costs for the building of new or retrofitting of existing pharmaceutical facilities will be shared between HHS and the Centers with HHS supporting 49% and 75% respectively.

Core Services and Readiness: The costs associated with operation and maintenance of the Centers will be provided by the USG.

Questions and Clarifications

7. How will CBRN MCMs entering the Centers for assistance be prioritized & managed?

The Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) is the USG governance framework for national medical countermeasure requirements, development, acquisition, stockpiling, distribution, and utilization. The PHEMCE is comprised of agencies from HHS, DoD, DHS, and VA. The PHEMCE Product Advisory Committee (PAC) comprised of HHS and DoD agencies reviews routinely the MCM development portfolios across the USG for CBRN threats.

- The PAC will perform a needs assessment of MCMs that could benefit through Center assistance.
- The PAC will recommend a prioritized MCM list to PHEMCE senior leaders for final approval.
- PHEMCE will assign the CBRN medical countermeasure to the Center having the best fit with that specific medical countermeasure.
- HHS/BARDA will manage directly the HHS-sponsored Centers and coordinate activities between the pharmaceutical companies and the Centers.
- HHS/BARDA will provide periodic reports to PHEMCE senior leaders and an outside Advisory Board (TBD) on progress, challenges, and other issues in the construction, operation, and maintenance of the Centers.
- In an emergency, PHEMCE will confer on the best usage of these facilities for the given threat.

Questions and Clarifications

8. Can the Centers be located outside of the U.S.?

No. The Centers and their activities must be conducted in the U.S.

Next Steps and Points of Engagement

- **On or about 15-30 days from the posting of the synopsis, HHS/BARDA intends to release the request for proposal (RFP)**
  - Offerors will have a 90-day period in which to submit their proposal to the Contracting Officer
- **During the RFP window, HHS/BARDA will hold two (2) pre-proposal conferences**
  - First: on or about 30 days after release of the RFP
  - Second: on or about 30 days prior to receipt of proposals

For Additional Follow-Up

- **Public information will be posted on www.medicalcountermeasures.gov**
- **Replays of this session will be available using the conference link**
- **All correspondence/communications shall be directed to the attention of the Contracting Officer or Contract Specialist listed below. Communications with any other Government official regarding this RFP is strictly prohibited and may disqualify potential Offeror's proposal for consideration.**

Contracting Officer: Linda Luczak
linda.luczak@hhs.gov

Contract Specialist: Kyle Roberts
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