BARDA Core Service Overview

2013 BARDA Industry Day

Centers for Innovation in Advance Development & Manufacturing (CIADM)

Fill and Finish Manufacturing Network (FFMN)

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Director, MFE

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The CIADMs and FFMN are BARDA Core Services

- Centers for Innovation in Advanced Development & Manufacturing (2012)
- Nonclinical Network (2010)
- Strategic Innovations Portfolio (TBD)
- Clinical Studies Network (2014)
- ADS Modeling Hub (2009)

These public-private partnerships will provide advanced development and manufacturing capabilities as core service assistance to medical countermeasure developers for CBRN threats to augment national health security on a cost-effective, reliable and sustainable basis.

The Centers will also contribute to U.S. emergency preparedness by providing vaccine and biological product manufacturing surge capacity for pandemic influenza and other public health events.
CIADM Capabilities

- Pandemic influenza surge inventory (50M doses/center)
- CBRN Medical Countermeasures
- Regulatory support
- Analytical development
- Clinical trial and commercial scale lots
- Live virus vaccines
- 23 core services
CIADM Stakeholders

- **CIADM will provide core services and pandemic surge capability by coordinating with:**
  - Pandemic influenza vaccine manufacturers
  - Universities
  - MCM developers and manufacturers

- **CIADM supports:**
  - Pandemic influenza vaccine manufacturing
    - Development and response
  - NIH
  - DoD
  - BARDA existing CBRN MCM contractors
  - Emerging infectious diseases
Novartis CIADM

- Detailed design nearing completion
- NVD internal capital approved
- Long lead-time procurement in process
- Tech Services Building groundbreaking – Oct 2013
CORE SERVICES

— ‘Development Services’
  • Most are currently available in the NCTM

— ‘Manufacturing Services’ phase-in/ ramp-up as capacity is brought online
  • 4Q2013 – Adjuvant Facility Retrofitted [Marietta, PA] & Ready for Service
  • 2Q2015 – NCTM Core Retrofitted [College Station, TX] & Ready for Service
  • 4Q2015 – Live Virus Vaccine Pilot Facility [Bryan, TX] Ready for Service
  • 1Q2018 – Pandemic Influenza Facility [Bryan, TX] Ready for Production

— ‘Workforce Training Capabilities’ are ready by 3Q2014
NCTM Flexibility
Mobile Bioprocessing Units
Emergent CIADM

- VaxInnate signed as influenza candidate December 2012
- Conceptual design in progress for new Area 3 Manufacturing Suite, QC labs and Warehouse at the Baltimore facility
- Proof of Concept studies in progress at the Gaithersburg Development Lab for converting the VaxInnate process from traditional stainless steel reactors to disposables
CIADM Trajectory for the Future

- Complete Core Services capabilities
- Establish Workforce Development
- Complete Construction/Renovations
- Establish Pandemic Surge
Establishes a network of existing facilities that are pre-qualified and under contract to fill and finish vaccine for U.S. Government-contracted vaccine manufacturers in a public health emergency.
Fill and Finish expertise in the following:

- Pandemic Influenza Surge Inventory (16M – 50M doses per Contract)
- CBRN Medical Countermeasures
- Regulatory Support
- Analytical Development
- Clinical Trial and Commercial Scale lots
- Labeling & Packaging
- Storage and Distribution
- Lyophilization
FFMN Stakeholders

- FFMN will provide filling and finishing capabilities by coordinating with:
  - Pandemic influenza vaccine manufacturers
  - Contract Manufacturing Organizations (Bulk CBRN MCMs)

- FFMN supports:
  - Pandemic influenza vaccine manufacturers
  - FDA (drug shortage)
  - Existing BARDA CBRN contractors
  - New CBRN MCM innovators
  - DoD
  - NIH
### FFMN Contractors

<table>
<thead>
<tr>
<th>Offeror</th>
<th>Potential Influenza Vaccine Candidate</th>
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<tbody>
<tr>
<td>Cook Pharmica</td>
<td>GSK *</td>
</tr>
<tr>
<td>JHP</td>
<td>CSL Biotherapies *</td>
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<tr>
<td>DSM</td>
<td>Novartis *</td>
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<tr>
<td>Nanotherapeutics partnered with Baxter Pharmaceutical Solutions (BPS)</td>
<td>Protein Sciences Corp (PSC) or Baxter Healthcare or Other</td>
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* BARDA Stockpile Contract company

**Awarded Contracts on Sep 27, 2013 !!!**
Fill and Finish Manufacturing Network
Fill and Finish Manufacturing Network (FFMN)

Contract Awardees:
- Cook Pharmica LLC
- DSM Pharmaceuticals
- JHP Pharmaceuticals
- Nanotherapeutics

• Confirm Pandemic Influenza Partner
• Tech Transfer Pandemic Candidate
• Establish Pandemic Surge Capacity