Innovative Technologies, Products & Platforms

Rapid Vaccine & Therapeutic Response Platforms

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BARDA Industry Day

ASPR: Saving Lives... Protecting America
Vision & Strategy

Agile, robust and sustainable U.S. manufacturing infrastructure capable of rapidly producing vaccines and other biologics against pandemic influenza and other emerging threats… and

…responsive and nimble programs and capabilities to address novel and emerging threats… and

…a ready capability to develop, manufacture and facilitate distribution of medical countermeasures during public health emergencies.

BARDA Strategic Plan 2011-2016, Goals 3, 4 & 5
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BARDA Strategic Plan 2011-2016, Goals 3, 4 & 5
Rapid...? Platforms...?

- Rapid Response
  Days, Weeks, Months, a few Years

- Vaccine & Therapeutic
  Primarily biologics

- Platforms
  Multi-purpose technology
  Proven vs. Unproven
Innovation Mandate

…reminder…

“Advanced Research & Development”
Innovation Mandate

...reminder...

Centers for Innovation in Advanced Development & Manufacturing

“CIADM Program”
CIADM Program

01 Public-Private Partnerships
Establish public-private partnerships to construct or retrofit U.S.-based, commercial-scale, biopharma facilities that support advanced development and manufacturing of MCMs.

02 Core Services
Provide core services, on a routine basis, for the advanced development and manufacturing of CBRN biopharmaceuticals supported by the U.S. Government.

03 Emergency Capacity
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.

04 Biopharma Workforce
Provide biopharma-oriented workforce development through training programs aligned with current regulatory guidelines.
Domestic Capacity

Holly Springs, NC

1st “cell-based” influenza vaccine manufacturing facility in the U.S.
Domestic Capacity

Baltimore, MD
Ribbon Cutting May 2017
Three ~9,000 sq-ft cGMP suites
Domestic Capacity

College Station, TX

National Center for Therapeutics Manufacturing [NCTM]

Texas Biomanufacturing Facility [TBF]
Flexible Biomanufacturing Facility [FBF]
Domestic Capacity

Department of Defense’s (DoD) Advanced Development & Manufacturing (ADM) facility is “Open for Business” for MCM development & manufacturing.
Coordinated Approach

**DoD ADMC**
- Focused on global threats
- Supports 1.4M service members – 18 to 55 years old
- Works toward a state of good health
- Maintains broad product portfolio to protect service members
- Produces small force to full force scale depending on threat

**HHS CIADM**
- Focused on threats to the homeland
- Supports U.S. population – pediatrics to geriatric
- Works on the entire health continuum
- Maintains a biological-focused & pandemic influenza
- Produces relatively large scale to support the entire U.S. population.
BARDA has invested to bolster Domestic Infrastructure [Capacity]

+ True Partnership Model
+ Skilled Workforce
+ Proven Technologies/Platforms
+ Innovative Culture
+ Sustained Funding Commitment

...to get closer to the CIADM Vision!
Platforms for Rapid Integrated Solutions of Medical countermeasures

Streamline generation of a portfolio of MCM candidates
• Reduce developmental risk
• Shorten timelines
• Reduce costs

Develop a DoD capability to support MCM rapid response
• novel threats
• emerging threats

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