



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



BARDA INDUSTRY DAY

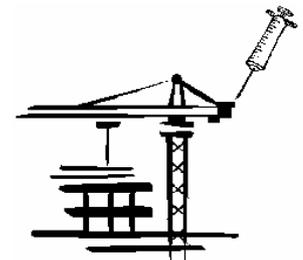
Core Service Support for MCM Advanced Development & Manufacturing

R. Thomas Warf, Director

Division of Manufacturing, Facilities & Engineering

HHS/OS/ASPR/BARDA

Monday, December 10, 2012





Division of Manufacturing, Facilities & Engineering (MFE)



Office of the
Director

Division of:

**Chemical Biological Radiological & Nuclear
(CBRN)**

Strategic Science & Technology

Influenza Division

Manufacturing, Facilities & Engineering (MFE)

Analytical Decision Support (ADS)

Regulatory & Quality Affairs (RQA)

Clinical Studies



MFE Mission



Provide advanced development, manufacturing capabilities and production surge capacity as core services for medical countermeasure (MCM) programs to address national security and to augment public health needs on a **cost-effective, reliable, and sustainable** basis.



MFE Capabilities/ SMEs



SUBJECT MATTER EXPERTISE

- Large & Small Molecule Manufacturing
- Process Development
- Logistics & Readiness
- Cold Chain



MFE Capabilities The 'Flu' Contracts



OVERSEE BARDA'S CAPACITY BUILDING INVESTMENTS:



MedImmune / Philadelphia, PA
Double LAIV Filling Capacity

Novartis Vaccines Division / Holly Springs, NC
U.S.-Based Flu Cell Culture Facility (USFCC)

sanofi pasteur / Swiftwater, PA
Retrofit of Egg-based



MFE Capabilities CIADM Contracts



CIADM =

***Centers for Innovation in
Advanced Development and Manufacturing***

3 Awards on June 15, 2012



**THE TEXAS A&M
UNIVERSITY SYSTEM**





MFE Capabilities

CIADM Contracts *cont.*



Establish public-private partnerships to construct/retrofit U.S.-based, commercial-scale, biopharmaceutical facilities that support advanced development and manufacturing of Medical Countermeasures (MCMs) to provide...

...core services, on a routine basis, for the advanced development and manufacturing of biopharmaceutical MCMs supported by the U.S. Government;

...in an emergency, necessary U.S.-based surge capacity to respond to an emerging infectious disease, pandemic influenza, and currently known or unknown threats;

...biopharmaceutical oriented workforce development through training programs aligned with current regulatory guidelines.



MFE Capabilities FFMN Solicitation



FFMN =

Fill Finish Manufacturing Network

Solicitation 12-100-SOL-00010

Proposals Due - September 27, 2012

Task I: Augment Current U.S.-based Fill & Finish Manufacturing Capacity

Task II: Provide Fill & Finish Manufacturing 'Core Services'

Task III: Provide Biopharmaceutical Production Surge Capacity