Introduction to the Division of Manufacturing, Facilities and Engineering

Biomedical Advanced Research and Development Authority (BARDA)

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HHS/ASPR/BARDA
Division of Manufacturing, Facilities and Engineering (MFE)

Mission
Provide advanced development, manufacturing capabilities and production surge capacities and plans as core service to medical countermeasure programs to address national security and to augment public health needs on a cost-effective, reliable, and sustainable basis.

Goal
Enhance all-hazards MCM readiness posture through innovative production and acquisition partnerships and process re-engineering.
MFE Contract Overview

Total Number of Contracts

<table>
<thead>
<tr>
<th>Service Type</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Egg Supply</td>
<td>1*</td>
</tr>
<tr>
<td>Retrofit (Egg-Based Flu)</td>
<td>2</td>
</tr>
<tr>
<td>Cell-Based Flu Facility</td>
<td>1</td>
</tr>
<tr>
<td><strong>TOTAL Contracts:</strong></td>
<td><strong>4</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Service Type</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>sanofi Egg Supply #2</td>
<td>$57 M*</td>
</tr>
<tr>
<td>sanofi Retrofit</td>
<td>$105 M</td>
</tr>
<tr>
<td>MedImmune Retrofit</td>
<td>$55 M**</td>
</tr>
<tr>
<td>NVD Flu Facility</td>
<td>$487M</td>
</tr>
<tr>
<td><strong>TOTAL:</strong></td>
<td><strong>$704 M</strong></td>
</tr>
</tbody>
</table>
Matrix Organization to Support the Influenza and CBRN Divisions

- Process Development
- Process Scale-up and Manufacturing
- New Facilities Design & Construction
- Facilities Renovation and Improvements
- Facilities Inspections/Audits
- BARDA Response Plans
  - Pandemic Influenza Response
  - CBRN Response
- BARDA Logistical Support
- International Program Support
## Manufacturing, Facilities & Engineering

<table>
<thead>
<tr>
<th>Funding: $5.1 B Awarded 41 contracts/ 3 grants for $4.9 B</th>
<th>Vaccines</th>
<th>Antivirals</th>
<th>Diagnostics/ Respiratory Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Advanced Development</strong></td>
<td>Cell-based Antigen-sparing Next Generation Recombinant</td>
<td>Peramivir AV MedKits</td>
<td><strong>Diagnostics</strong>&lt;br&gt;Point of Care Clinical Lab Simple Ventilators Next Generation</td>
</tr>
<tr>
<td><strong>Stockpile Acquisitions</strong></td>
<td>H5N1 Pre-Pandemic Vaccine Stockpiles</td>
<td>Tamiflu &amp; Relenza Federal Stockpiles State Stockpiles</td>
<td><strong>Masks &amp; Respirators</strong></td>
</tr>
</tbody>
</table>
Egg Supply Contract

sanofi pasteur
Retrofitting Contracts

MedImmune Facilities Retrofit
Retrofitting Contracts

sanofi pasteur Bldg 37 Retrofit
Facility Construction Contract

Novartis Vaccines & Diagnostics
BARDA Response

2009 H1N1 Pandemic Influenza
H1N1 Vaccine Manufacturing Process

Current Egg-based Vaccine Technology

Eggs

Virus

Inoculate Eggs

Production Challenges

Poor Virus Growth

Decayed Seasonal Vaccine Completion

Processing

Testing: Bulk Product

Testing: Formulated Product

Testing: Final Product

Filling Capacity Limits may Constrict Gains in Productivity

Formulation

Testing: Formulated Product

Filling

Packaging

QA Lot Release

QA Lot Release

Syringes

CDC Distribution to States

Eggs

Prepare Virus Seed (CDC) (4-6 weeks)

Incubation

Formulation

Testing: Bulk Product

Testing: Final Product

Testing: Formulated Product

Fill Virus Seed Stock

Isolate Virus

Grow Virus Seed Stock

Inoculate Eggs

Production

Testing: Bulk Product

Testing: Formulated Product

Testing: Final Product

Start up Issues with New Lines

Sanofi Retrofit (2007)

MedImmune Retrofit (2007)

Production

Testing: Final Product

Filling

Packaging

On-going

Eggs

Incubation

Isolate Virus

Prepare Virus Seed (CDC) (4-6 weeks)

Grow Virus Seed Stock

Inoculate Eggs

Production

Testing: Bulk Product

Testing: Final Product

Testing: Formulated Product

Formulation

Testing: Formulated Product

Filling

Packaging

QA Lot Release

Ship to Distribution Centers

CDC Distribution to States

Future Vaccine Technologies

Cell-based (2006)

Recombinant (2009)

Recombinant Technology

Novartis Cell Mfg Facility (2009)

Cell Culture

HHS Flu Vaccine Contracts (2004-09)

Prepare Virus Seed (CDC) (4-6 weeks)

Start up Issues with New Lines

Delayed Seasonal Vaccine Completion

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Delayed Seasonal Vaccine Completion

HHS Flu Vaccine Contracts (2004-09)
BARDA Response

H1N1 Ancillary Supplies & Kitting
H1N1 Distribution Scheme

Vaccine Manufacturers

Consolidation & Distribution

Ancillary Suppliers

Ancillary Kitting and Repackaging

CA

GA

OH

TN

TX

FL

MD

OH
International Capacity Building
Centers for Innovation in Advanced Development and Manufacturing

Michael Angelstro
Questions?