Introduction to the Division of Manufacturing, Facilities and Engineering

Biomedical Advanced Research and Development Authority (BARDA)

Tom Warf
Director, MFE
HHS/ASPR/BARDA
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
### Funding: $5.1 B
Awarded 41 contracts/ 3 grants for $4.9 B

<table>
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<tr>
<th>Vaccines</th>
<th>Antivirals</th>
<th>Diagnostics/ Respiratory Devices</th>
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| **Advanced Development** | Cell-based Antigen-sparing Next Generation Recombinant | Peramivir AV MedKits | **Diagnostics**  
**Point of Care**  
**Clinical Lab**  
**Simple**  
**Ventilators**  
**Next Generation** |
| **Stockpile Acquisitions** | H5N1 Pre-Pandemic Vaccine Stockpiles | Tamiflu & Relenza Federal Stockpiles State Stockpiles | **Masks & Respirators** |

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MedImmune Facilities Retrofit
Sanofi Pasteur Bldg 37 Retrofit
Manufacturing, Facilities & Engineering

Retrofit Contract
• sanofi pasteur - $105 M
• MedImmune - $55 M Completed

Egg Supply Contracts
• sanofi pasteur – $44 M Completed
  • sanofi pasteur – $57 M

New Facilities Construction
• Novartis FCC - $486 M
Manufacturing, Facilities & Engineering

Novartis New Facility Construction
Centers for Innovation in Advanced Development and Manufacturing

BARDA Response – Pandemic Influenza H1N1
H1N1 Vaccine Manufacturing Process

Current Egg-based Vaccine Technology


1. Begin
2. 2 wks
3. 4 wks
4. 6 wks
5. 8 wks
6. 10 wks
7. 12 wks
8. 14 wks
9. 16 wks
10. 18 wks

HHS Flu Vaccine Contracts (2004-09)

Cell-based (2006)
Recombinant (2009)

Novartis Cell Mfg Facility (2009)

Filling
Testing: Final Product
Packaging
QA Lot Release
QA Lot Release

Testing: Formulated Product
Testing: Bulk Product
Formulation
Testing: Formulated Product

Start up Issues with New Lines
Delayed Seasonal Vaccine Completion
Decisions by Home Country
Production Challenges
Poor Virus Growth

Prepare Virus Seed (CDC) (4-6 weeks)
Grow Virus Seed Stock
Inoculate Eggs
Incubation

Isolate Virus
Incubation
Incubation

Future Vaccine Technologies

MedImmune Retrofit (2007)
Sanofi Retrofit (2007)

Sanofi Retrofit (2007)

CDC Distribution to States

Syringes

Cell Culture
Recombinant Technology


On-going
Eggs
Incubation

MedImmune Retrofit (2007)


Eggs
Incubation
H1N1 Ancillary Supplies & Kitting
Questions