

United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response (ASPR)



Introduction to the Division of Manufacturing, Facilities and Engineering

Biomedical Advanced Research and Development Authority (BARDA)

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Director, MFE

HHS/ASPR/BARDA



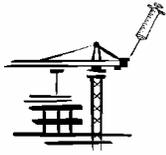
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Matrix Organization to Support the Influenza and CBRN Divisions

- 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

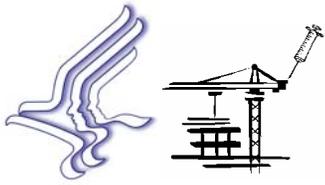




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<p>Funding: \$5.1 B Awarded 41 contracts/ 3 grants for \$4.9 B</p>	<p>Vaccines</p>	<p>Antivirals</p>	<p>Diagnostics/ Respiratory Devices</p>
<p>Advanced Development</p>	<p>Cell-based Antigen-sparing Next Generation Recombinant</p>	<p>Peramivir AV MedKits</p>	<p><u>Diagnostics</u> Point of Care Clinical Lab Simple <u>Ventilators</u> Next Generation</p>
<p>Stockpile Acquisitions</p>	<p>H5N1 Pre-Pandemic Vaccine Stockpiles</p>	<p><u>Tamiflu & Relenza</u> Federal Stockpiles State Stockpiles</p>	<p>Masks & Respirators</p>
<p>Infrastructure Building</p>	<p>Retrofit Existing Mfg Facilities Build New Cell-based Mfg Facilities Egg-based Supply Intl. Vaccine Cap.</p>	<p></p>	<p></p>

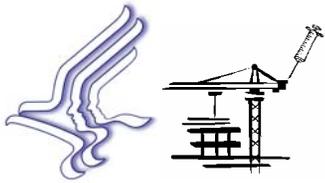


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Egg Supply

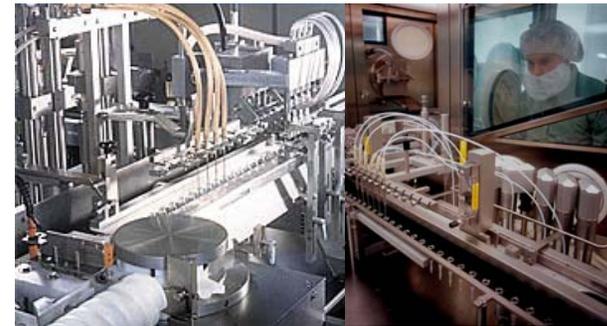


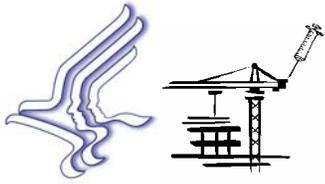


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MedImmune Facilities Retrofit



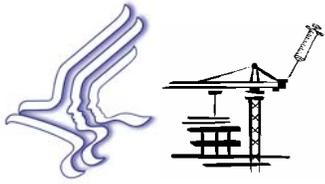


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Sanofi Pasteur Bldg 37 Retrofit





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RetroFit Contract

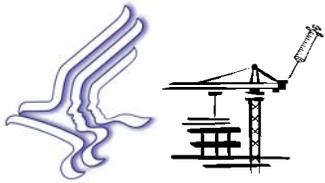
- sanofi pasteur - \$105 M
- MedImmune - \$55 M Completed

Egg Supply Contracts

- sanofi pasteur \$ 44 M Completed
 - sanofi pasteur – \$57 M

New Facilities Construction

- Novartis FCC - \$ 486 M

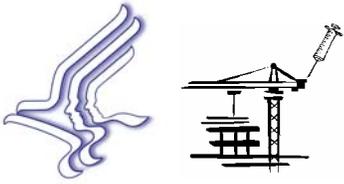


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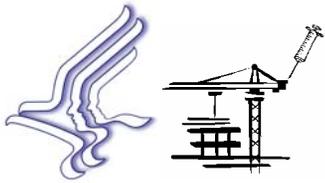
Novartis New Facility Construction





Centers for Innovation in Advanced Development and Manufacturing

<https://www.fbo.gov/spg/HHS/OOS/OASPHEP/11-100-SOL-00011/listing.html>



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BARDA Response – Pandemic Influenza H1N1





H1N1 Vaccine Manufacturing Process



Current Egg-based Vaccine Technology

Egg Supply Contract (2004)



HHS Flu Vaccine Contracts (2004-09)

Sanofi Retrofit (2007)

Medimmune Retrofit (2007)

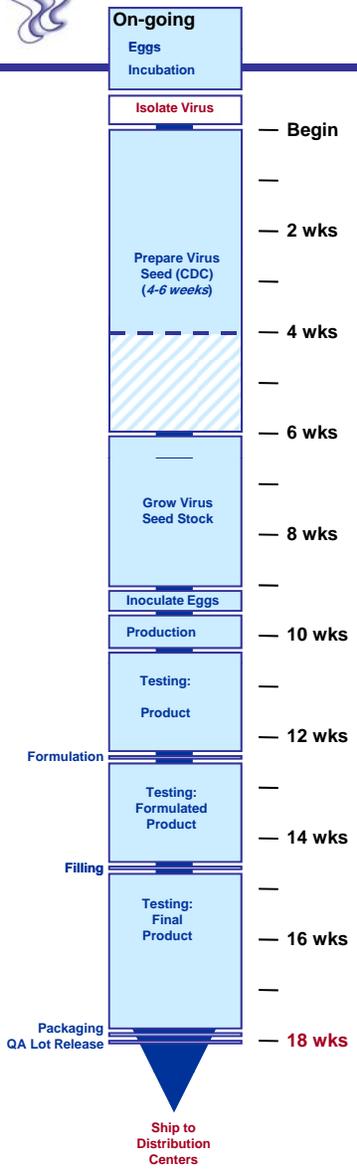
Future Vaccine Technologies



Cell-based (2006)

Recombinant (2009)

Novartis Cell Mfg Facility (2009)



Poor Virus Growth

Production Challenges

Decisions by Home Country

Delayed Seasonal Vaccine Completion

Start up Issues with New Lines

Formulation

Filling Capacity Limits may Constrict Gains in Productivity

QA Lot Release



Testing: Bulk Product



Testing: Formulated Product

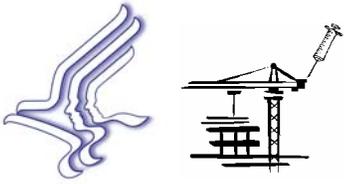


Testing: Final Product



QA Lot Release





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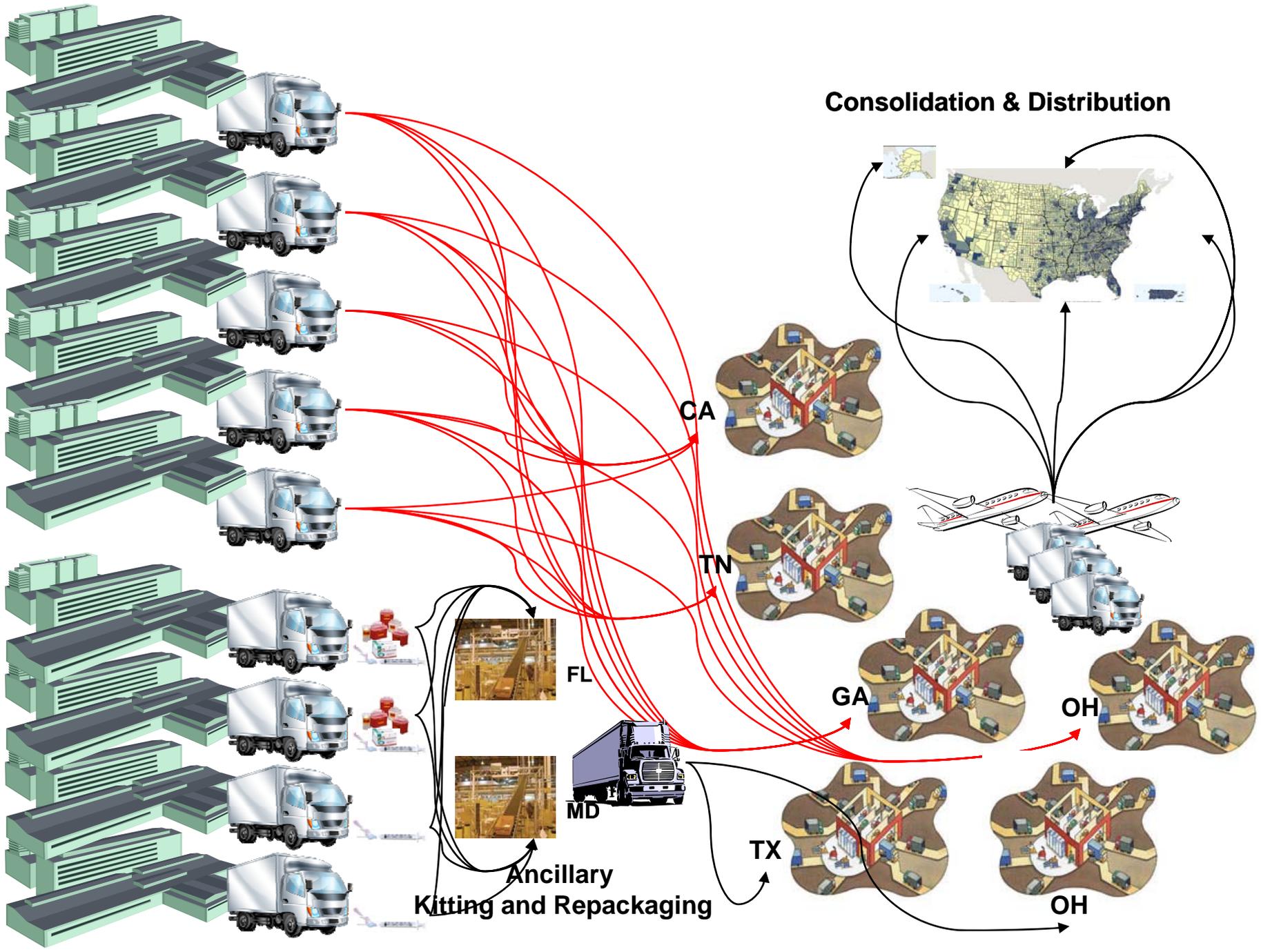
H1N1 Ancillary Supplies & Kitting



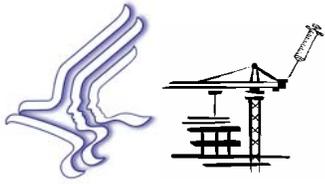
Vaccine Manufacturers

Ancillary Suppliers

Consolidation & Distribution



Ancillary Kitting and Repackaging

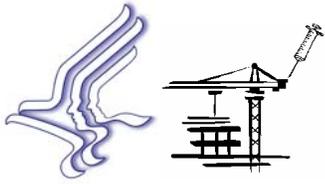


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International Capacity Building





Questions

