

United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness & Response (ASPR)
Biomedical Advanced Research & Development Authority (BARDA)



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



Division of Manufacturing, Facilities and Engineering (MFE)

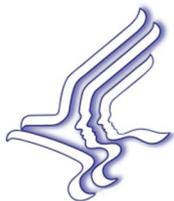


Mission

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

Egg Supply	1*
Retrofit (Egg-Based Flu)	2
Cell-Based Flu Facility	1
TOTAL Contracts:	4

sanofi Egg Supply #2	\$57 M*
sanofi Retrofit	\$105 M
MedImmune Retrofit	\$55 M**
NVD Flu Facility	\$487M
TOTAL:	\$704 M



Manufacturing, Facilities & Engineering



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



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

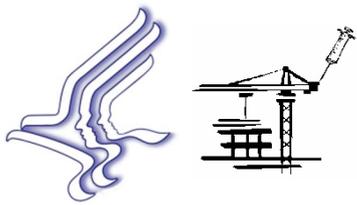


Egg Supply Contract



sanofi pasteur

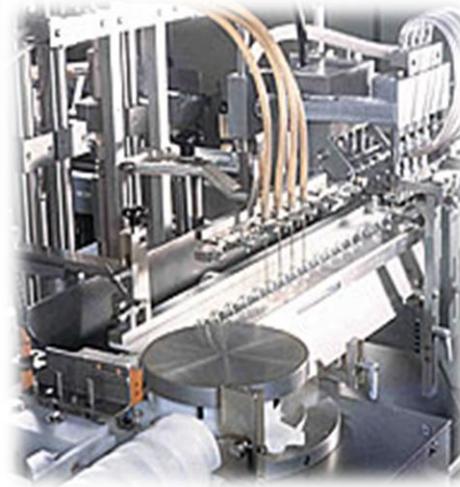


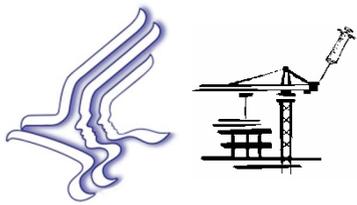


Retrofitting Contracts



MedImmune Facilities Retrofit



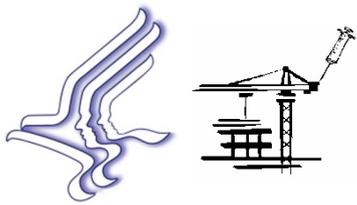


Retrofitting Contracts



sanofi pasteur Bldg 37 Retrofit



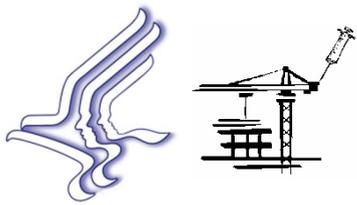


Facility Construction Contract



Novartis Vaccines & Diagnostics





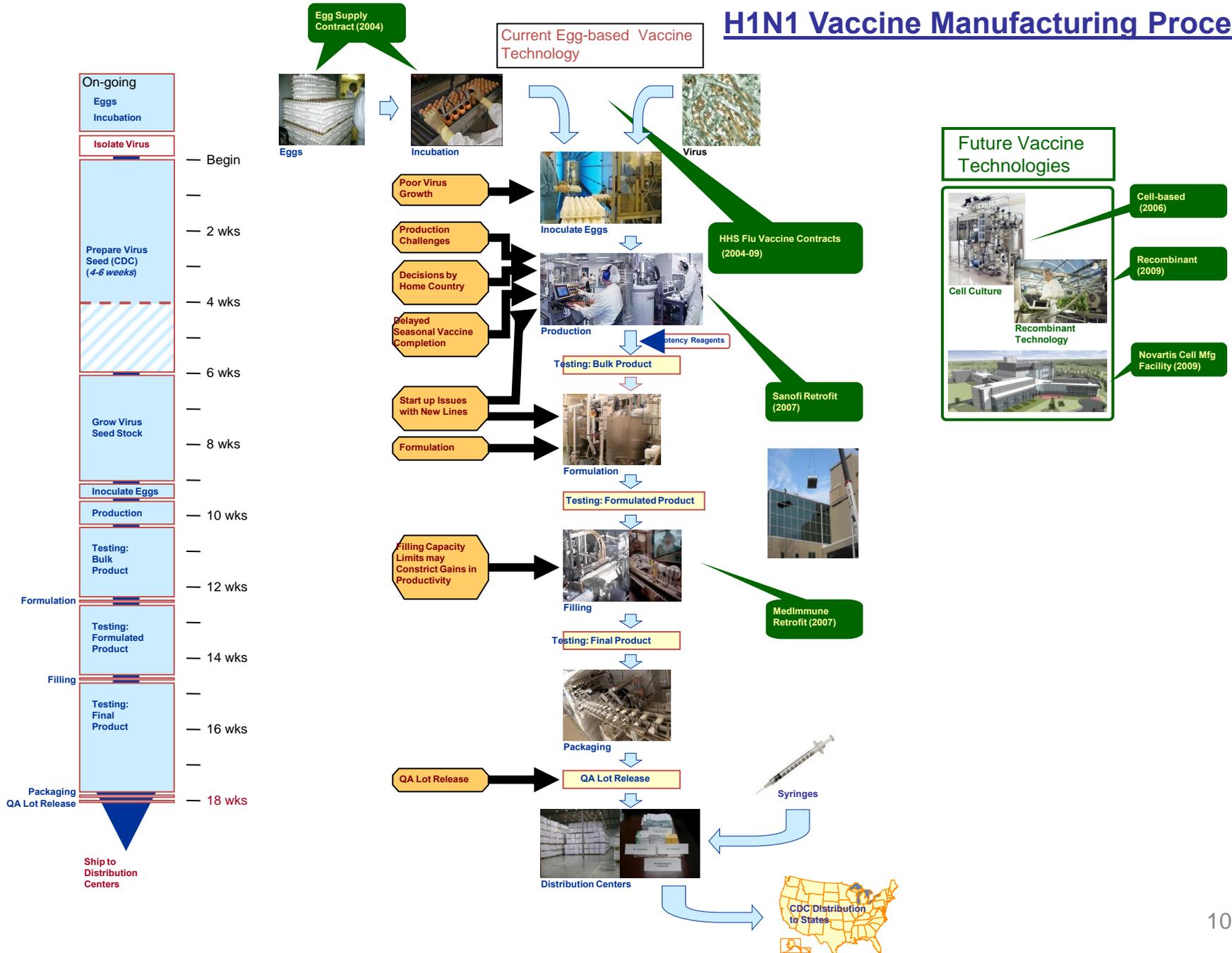
BARDA Response

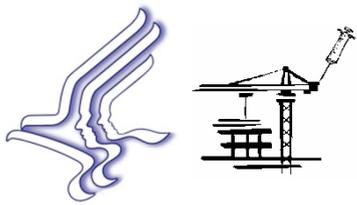


2009 H1N1 Pandemic Influenza



H1N1 Vaccine Manufacturing Process

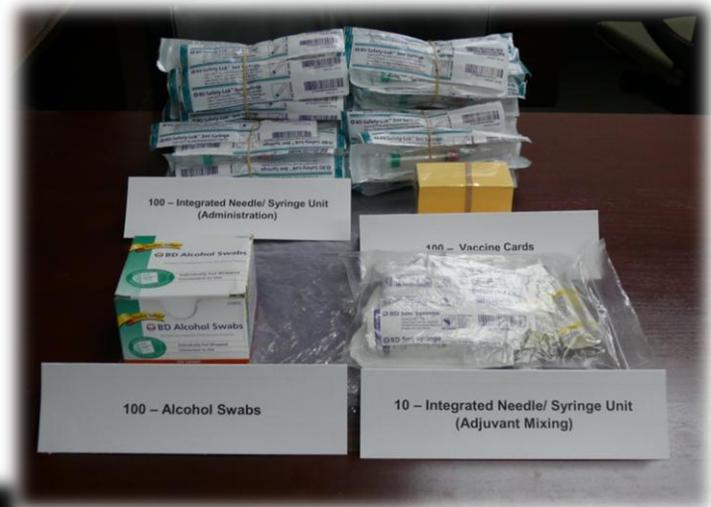




BARDA Response



H1N1 Ancillary Supplies & Kitting

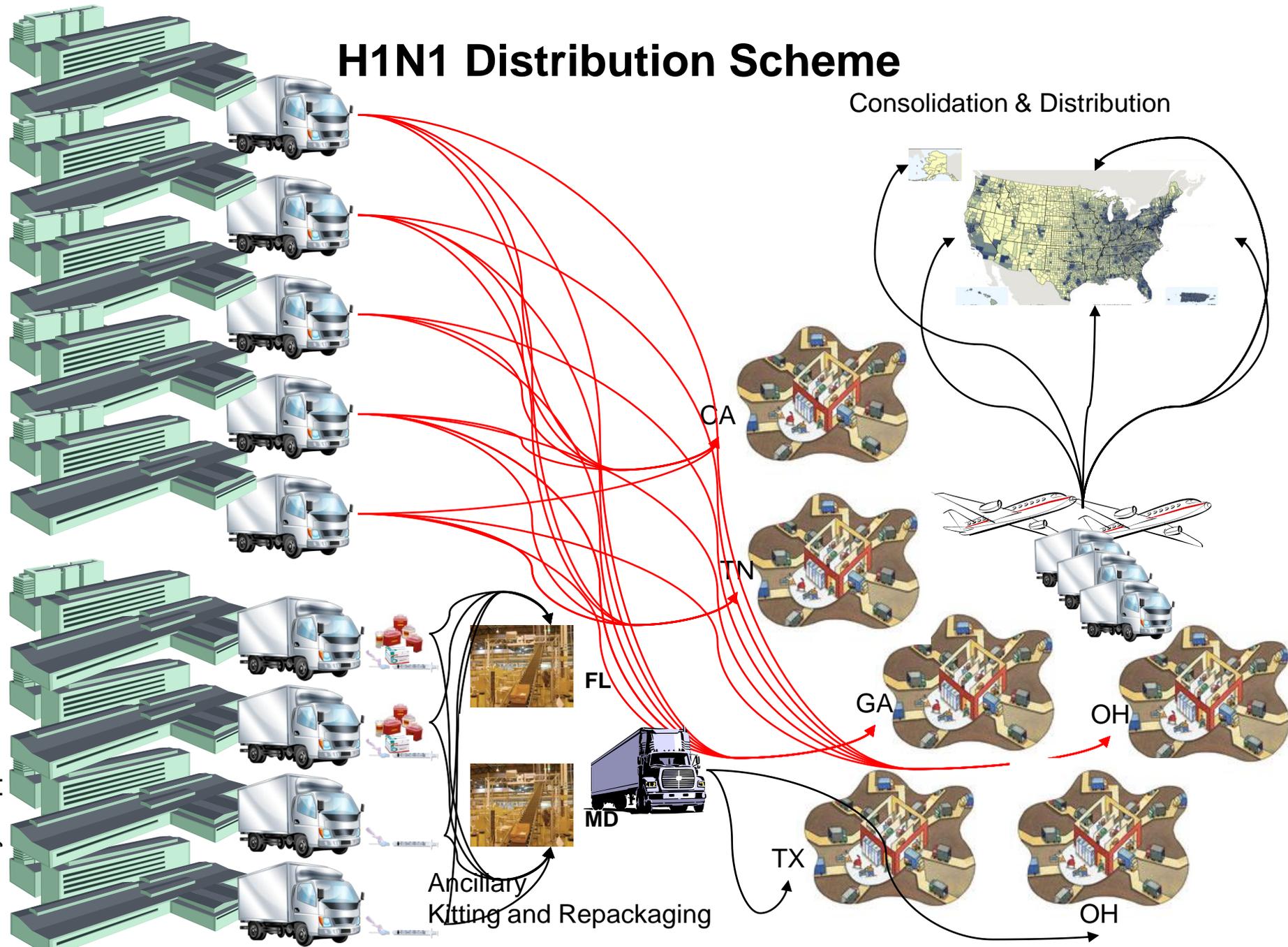


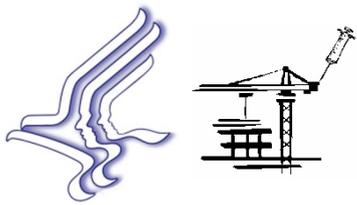
H1N1 Distribution Scheme

Vaccine Manufacturers

Ancillary Suppliers

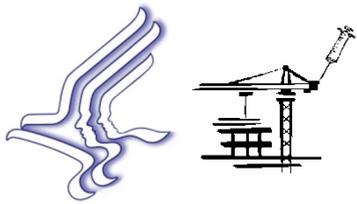
Consolidation & Distribution





International Capacity Building



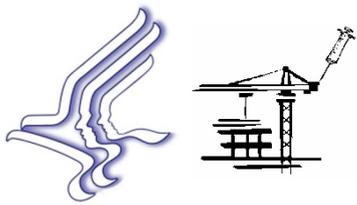


Core Services & Surge Capacity



Centers for Innovation in Advanced Development and Manufacturing

Michael Angelstro



Manufacturing, Facilities & Engineering



Questions?

