



United States Department of

**Health & Human Services**

Office of the Assistant Secretary for Preparedness and Response



## Centers for Innovation in Advanced Development & Manufacturing (CIADM)

### BARDA Industry Day

**October 15, 2014**

**Joe Figlio**

*Senior Project Officer*

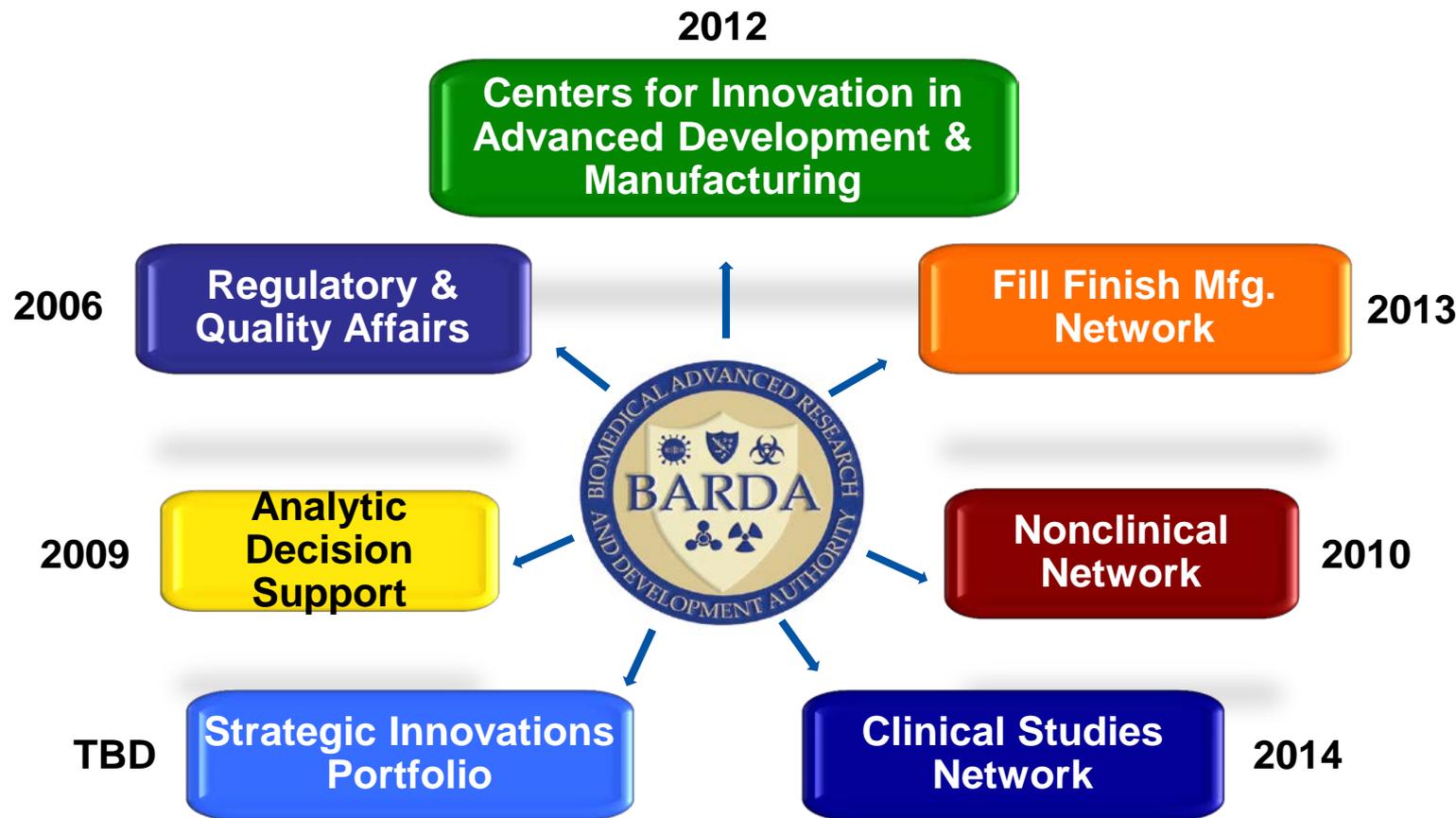
Manufacturing, Facilities & Engineering Division

BARDA





# BARDA's Core Service Programs





# CIADM Program Objectives



- Establish public-private partnerships to construct/retrofit U.S.-based, commercial-scale, biopharmaceutical facilities that support advanced development and manufacturing of MCMs
- Provide core services, on a routine basis, for the advanced development and manufacturing of CBRN biopharmaceuticals supported by the U.S. Government
- Provide, in an emergency, necessary U.S.-based surge capacity to respond to an emerging infectious disease, pandemic influenza, and currently known or unknown threats
- Provide biopharmaceutical oriented workforce development through training programs aligned with current regulatory guidelines



# CIADM Award Details



The three (3) CIADM Contractors are:

- **Texas A&M University System (TAMUS)** – Facilities in College Station, TX & Marietta, PA

BASE Period of Performance:

- Duration: 5-years
- Funding: \$176 million



**THE TEXAS A&M CENTER FOR INNOVATION**  
in Advanced Development & Manufacturing

- **Emergent Manufacturing Operations Baltimore LLC** – Facilities in Baltimore & Gaithersburg, MD

BASE Period of Performance:

- Duration: 8-years
- Funding: \$163 million



- **Novartis** – Facility in Holly Springs, NC

BASE Period of Performance:

- Duration: 4-years
- Funding: \$60 million



# HHS CIADM – LOCATIONS





# HHS CIADM Capability Matrix



Platform Expression Systems	Bacterial	✓	✓	✓
	Yeast		✓	
	Insect Cell	✓		
	Avian Cell	✓	✓	✓
	Mammalian Cell	✓	✓	✓
	Plant Cell	✓		
Product Classes	Recombinant Proteins	✓	✓	✓
	Therapeutic Proteins	✓	✓	✓
	(Monoclonal) Antibodies	✓	✓	✓
	(Polyclonal) Antibodies			✓
	Antibody-like Biologics		✓	✓
	Bacterial Vaccines			✓
	Inactivated Viral Vaccines	✓	✓	✓
	Live Viral Vaccines	✓	✓	✓
	Virus Like Particles	✓	✓	✓
	Cell Therapeutics / Stem Cells	✓		
	Adjuvants	✓	✓	✓
	Blood/Plasma-Derived	✓		✓
	RNA based Vaccines		✓	
	Personalized Vaccines	✓	✓	✓
Viral Vectored Vaccines	✓	✓	✓	



# HHS CIADM Program Health

## *Year 2 Key Accomplishments*



### **EXTERNAL**

- HHS CIADM Base Period activities w/in budget; however, specific items experiencing schedule slip
- CLIN 0001 Completed – Securing Influenza Vaccine Candidate
- Limited ADM Core Services available for use
- Two (2) Task Orders Issued to HHS CIADMs [Anticipate awards Oct 2014]

### **INTERNAL**

- HHS CIADM Governance Plan Approved
- HHS ADM Steering Committee [HHS-ASC] Established
- 1<sup>st</sup> Data Call & HHS-ASC Meeting Conducted in Jan 2014
- 2<sup>nd</sup> Project Data Call – Jun & Jul 2014
- 2<sup>nd</sup> HHS ASC Meeting – held in August 2014

*Now let's review each HHS CIADM Contractor...*



# HHS CIADM Program Health

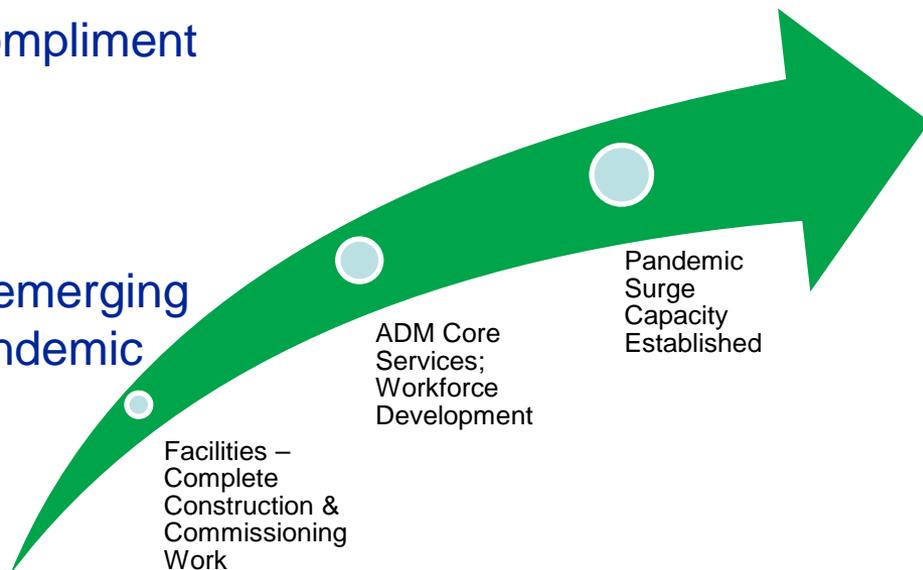


The March 2014 GAO report title sums it up...

*“HHS has Funded Flexible Manufacturing Activities for Medical Countermeasures, but it is too soon to Assess their Effect” [GAO-14-329]*

HHS CIADM Contractors are still in the ‘Base Period of Performance’; primarily working to...

- Infrastructure to establish the full compliment of ADM Core Services
- Workforce Training & Development Program(s)
- Surge capability for MCMs against emerging infectious diseases (specifically, pandemic influenza)







# Novartis CIADM Key Items & Capacity



## Construction in progress

- CTM retrofit 44% complete
- TSB (new building) 70% complete
- Warehouse Expansion 100% complete

## Surge Capacity/Modified Bulk Manufacturing

- Studies progressing on: alternate media, method transfer/execution, other potential process improvements

## Major equipment procurement:

- Washer & Autoclave (received)
- Vial Line, Syringe Line & Lyo (in progress)



# Novartis CIADM TSB building



# Novartis CIADM CTM Renovation



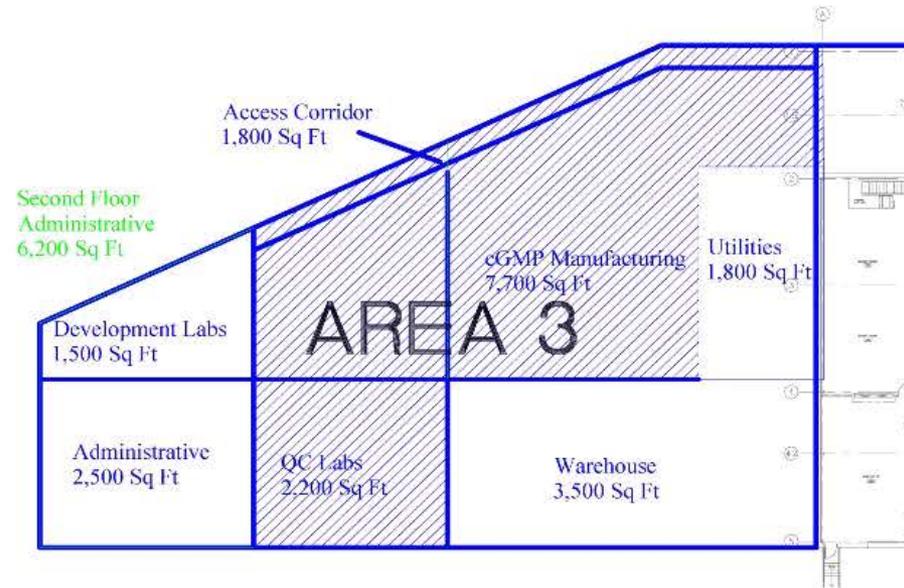
# Emergent CIADM



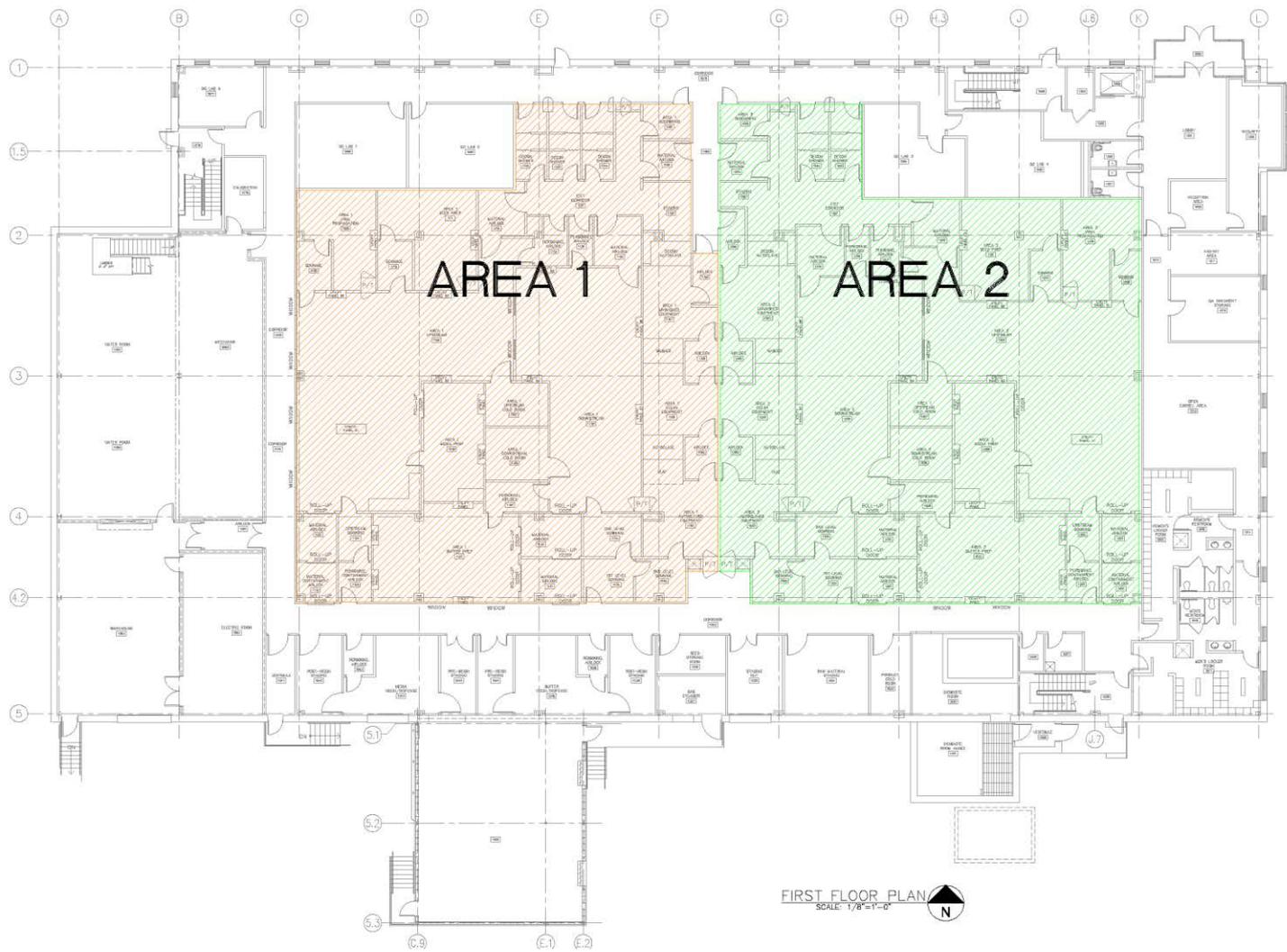


# Emergent CIADM Key Items & Capacity

- Site Security activities near completion- target year end 2014
- Detailed Design in progress for new Area 3 Manufacturing Suite, QC Labs & Warehouse at the Baltimore Facility
- HOLD: Pilot Plant in Gaithersburg retrofit; Pending analysis of additional capacity Cangene acquisition.

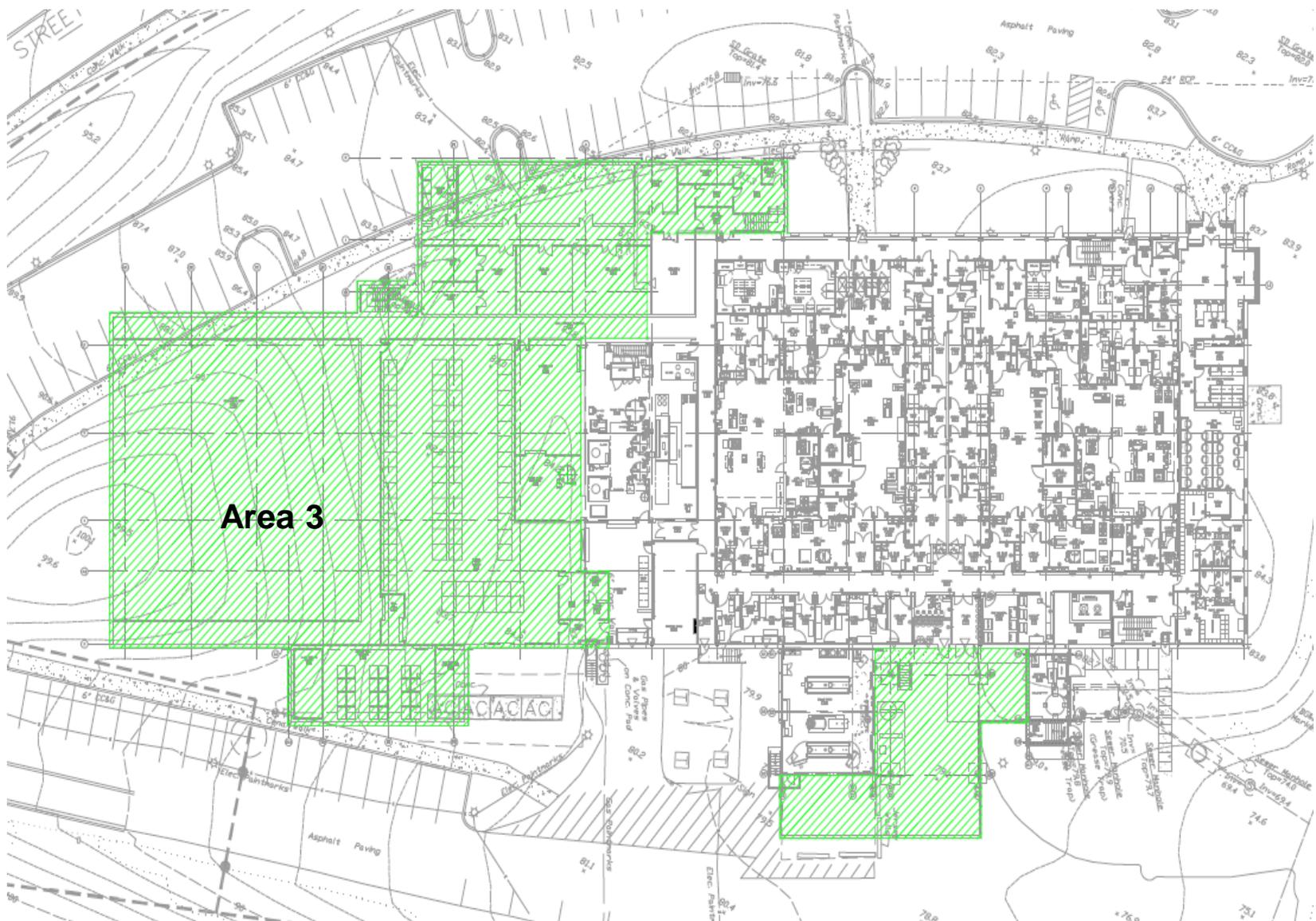


# Design Layout of Manufacturing Areas 1 and 2



# Emergent CIADM

## Area 3: 1<sup>st</sup> Level Concept Drawing



**Buffer/Media Prep**

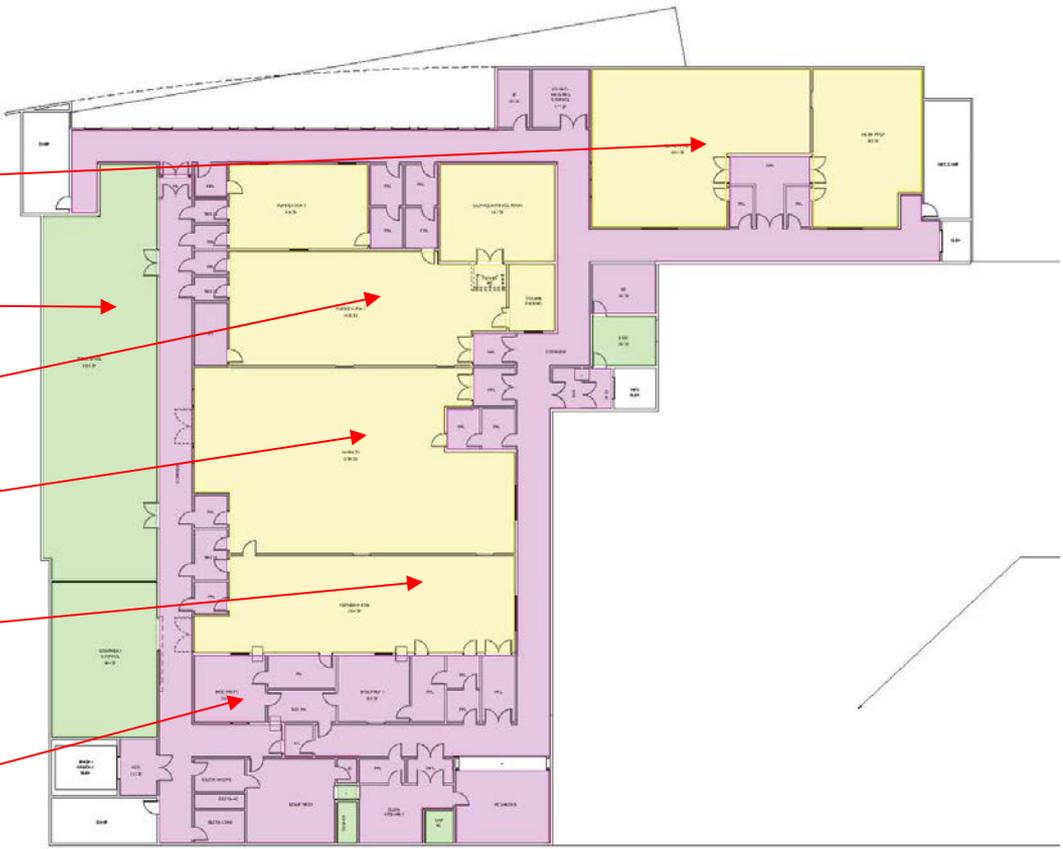
**Flex Area**

**Purification**

**Harvest**

**Fermentation**

**Seed Expansion**







# Emergent CIADM

## Influenza Vaccine Candidate Story



- VaxInnate signed as influenza candidate Dec 2012
- Proof of Concept studies completed at the Gaithersburg Development Lab for converting the target influenza vaccine process from traditional stainless steel reactors to disposables- scaled to 200L and 500L- very successful!
- Currently Clinical Study in progress - final report expected 4Q2014
- Pandemic influenza program - pending results of clinical study, adjuvant selection, additional commercial manufacturing process development, and completion of IPR
- Detailed design of Influenza Mfg area (Suite3) is still pending

In April 2014, House and Senate Staffers visited the Emergent facility in Baltimore for a tour and overview of the CIADM program.





# Texas A&M University System (TAMUS) CIADM



ASPR: Resilient People. Healthy Communities. A Nation Prepared.



# TAMUS CIADM

## Key Items & Capacity



## CORE SERVICES

### — Development Services

- Most are Currently Available in the NCTM

### — Manufacturing Services - phase-in/ ramp-up as capacity is brought online

- 4Q2014 – NCTM Core Retrofitted [College Station, TX] & Ready for Service
- TBD – Adjuvant Facility Retrofitted [Marietta, PA] & Ready for Service
- 1Q2016 – Live Virus Vaccine Pilot Facility [Bryan, TX] Ready for Service
- 1Q2018 – Pandemic Influenza Facility [Bryan, TX] Ready for Production

### — Workforce Training Capabilities

- Now available



# TAMUS CIADM: The “NCTM” – Innovative & Flexible



## *National Center for Therapeutics Manufacturing*





# TAMUS CIADM: The “NCTM” – Innovative & Flexible



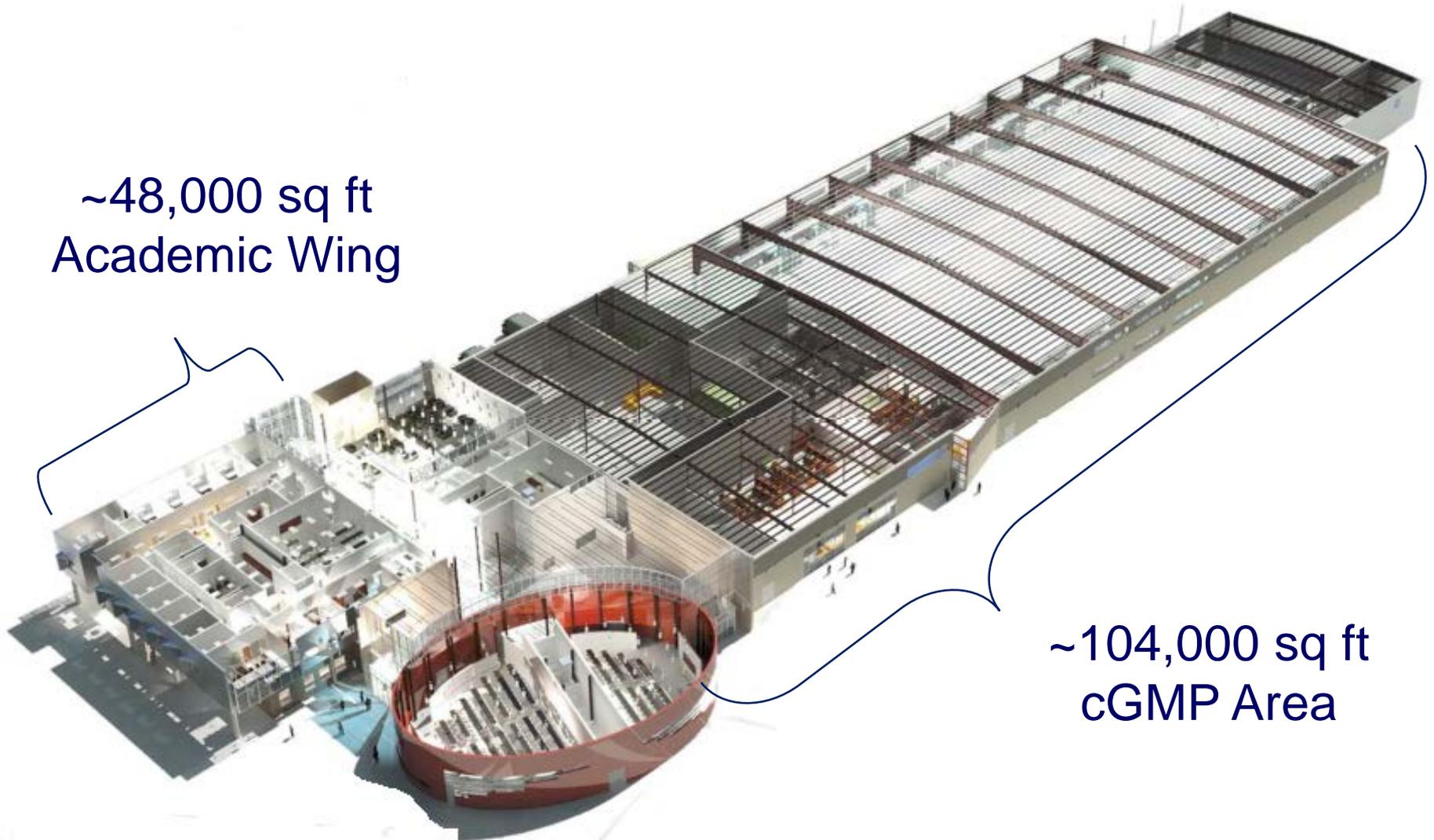
The NCTM is...

TAMUS-owned, operated by KALON, biopharmaceutical process development and manufacturing facility that is a prototype for a flexible multiproduct, multi-technology strategic biosecurity facility.

- Initially funded by a \$50M competitive award from the *State of Texas Emerging Technology Fund* (January 27, 2009)
- Further supported with +\$60M by BARDA & TAMUS Cost Share under the CIADM contract award (June 15, 2012)
- Flexible-by-design, multi-product, multi-technology architecture
- Accommodating most proven flexible bioprocess technologies
- Facilitate surge or product changeover
- Focus: Phase 1, Phase 2 & Phase 3 transition studies
- Support educational programs for workforce training



# TAMUS CIADM: The “NCTM” – Innovative & Flexible



~48,000 sq ft  
Academic Wing

~104,000 sq ft  
cGMP Area

# NCTM: Multi-product Flexibility Modular Cleanrooms (MCR)

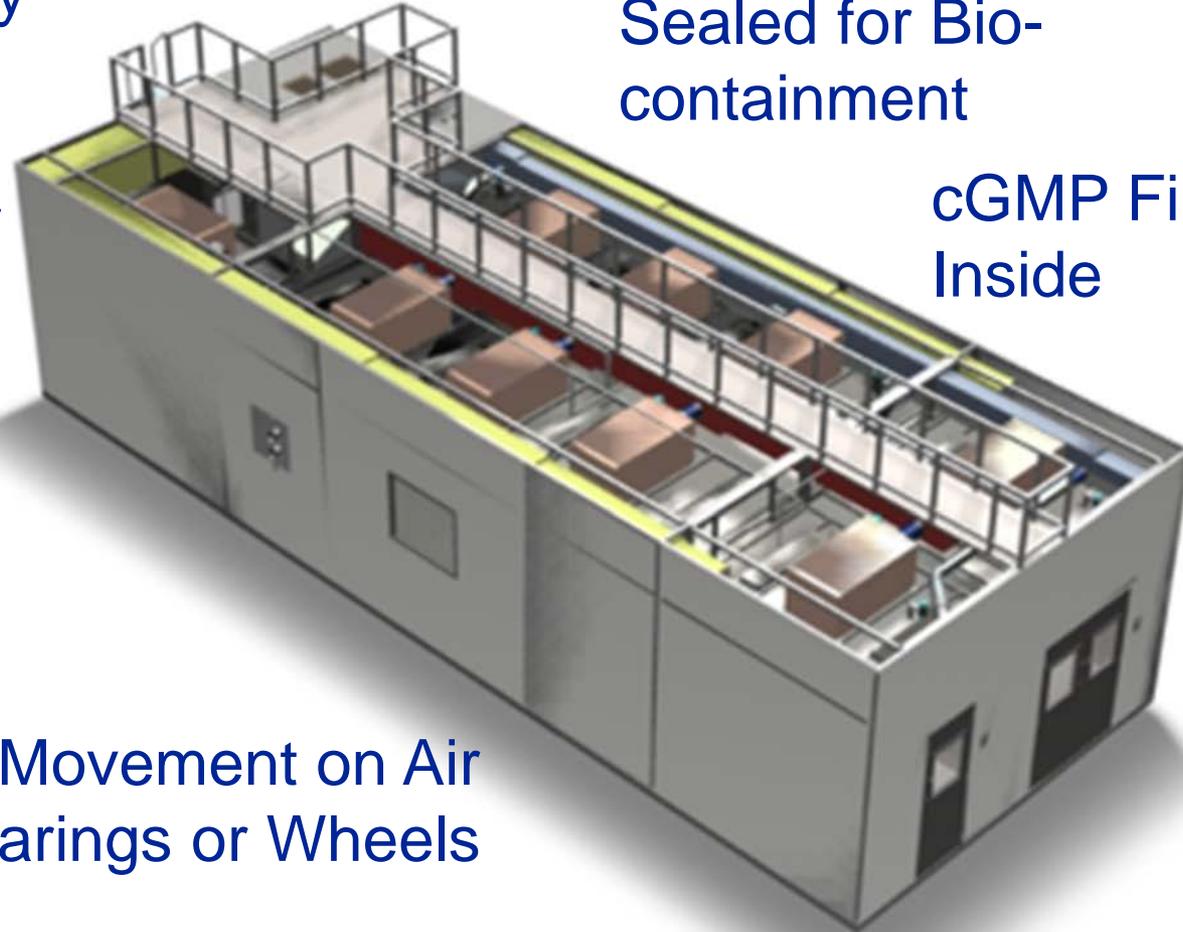
Common Utility  
Hook-up

- Electric
- Chilled Water

Sealed for Bio-  
containment

cGMP Finishes  
Inside

Movement on Air  
Bearings or Wheels



# NCTM MCRs Arrive

*Through April 2014*



**1<sup>st</sup> Mobile Cleanroom (MCR) under HHS CIADM Contract arriving in College Station, TX.**

*MCR designed and constructed by Walker Barrier Systems of Lisbon, WI.*



**New MCR being attached to clean corridor in the NCTM...**



# NCTM: Multi-product Flexibility

## *MCR's In Place & Commissioned*





# Demonstration of Capability



## Process Development & Validation Plans (PDVPs)

- Being executed by KALON at the NCTM
- Proposed/Approved biological production platforms:
  - PDVP for E. coli-based plasmid DNA Vaccine (*Done*)
  - PDVP for Live Virus Vaccine (*In Process*)
    - GSK's EB66 cell-based influenza vaccine technical transfer
  - PDVP for Microbial (*On Deck*)
  - PDVP for Insect Culture VLP Vaccine (*Being Assessed*)
  - PDVP for Mammalian (*Being Assessed*)



# TAMUS CIADM – NCTM

## Single Use Technologies Employed





# TAMUS CIADM

## Cell-based Influenza Vaccine Facility



Design Complete  
Construction Underway

4Q15 – Construction Ends  
2016 to 2017 – CQV  
2018 – Pandemic Ready



*ASPR: Resilient People. Healthy Communities. A Nation Prepared.*

# TAMUS CIADM

## Live Virus Vaccine Facility & Capability

**Cell-based Influenza Vaccine Facility**

**Live Virus Vaccine Facility**

