Centers for Innovation in Advanced Development & Manufacturing (CIADM)

BARDA Industry Day

October 15, 2014

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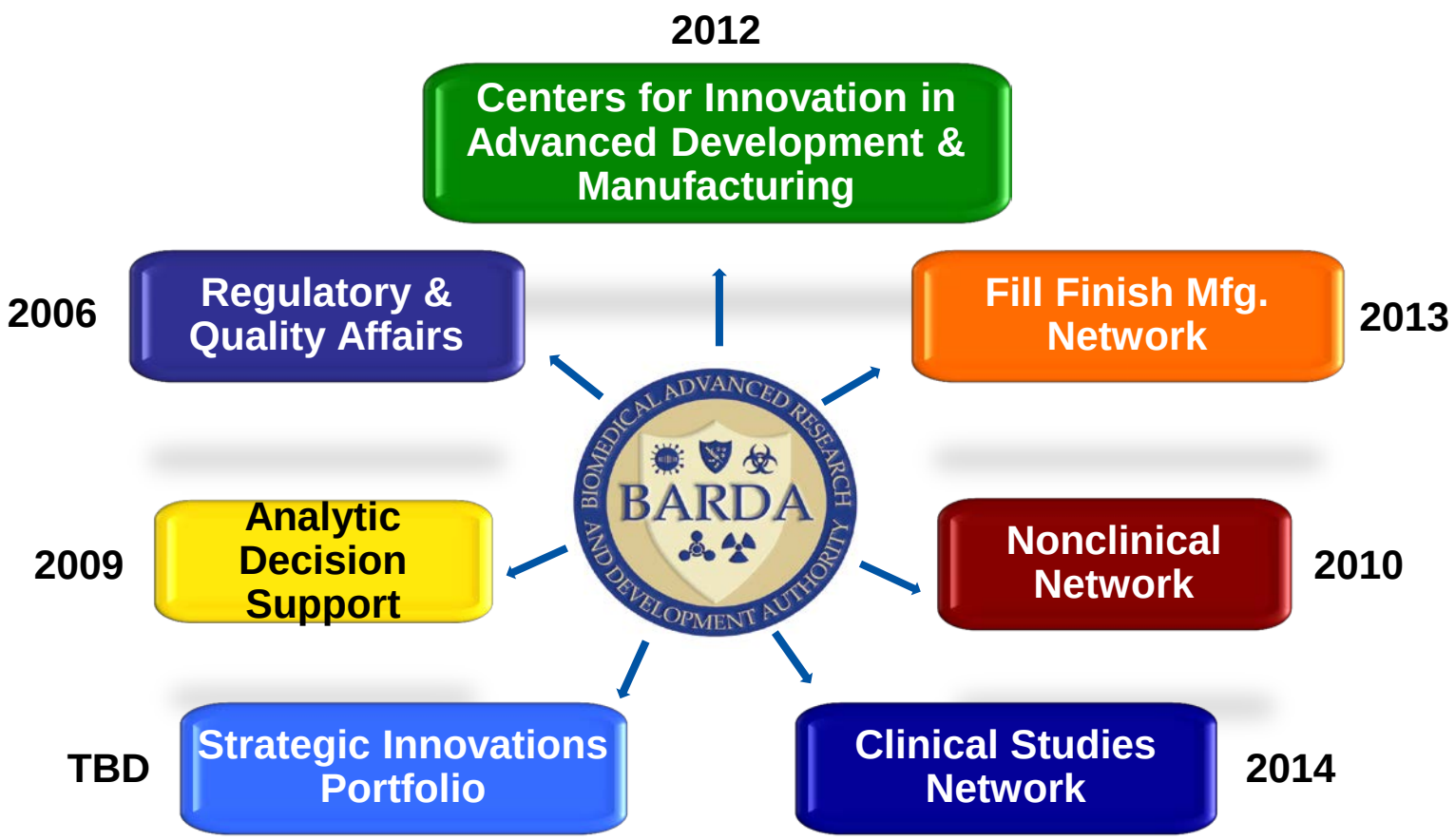
BARDA

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

- **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

		THE TEXAS A&M UNIVERSITY SYSTEM	NOVARTIS	emergent biosolutions™
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
- 1st Data Call & HHS-ASC Meeting Conducted in Jan 2014
- 2nd Project Data Call – Jun & Jul 2014
- 2nd HHS ASC Meeting – held in August 2014

Now let's review each HHS CIADM Contractor…

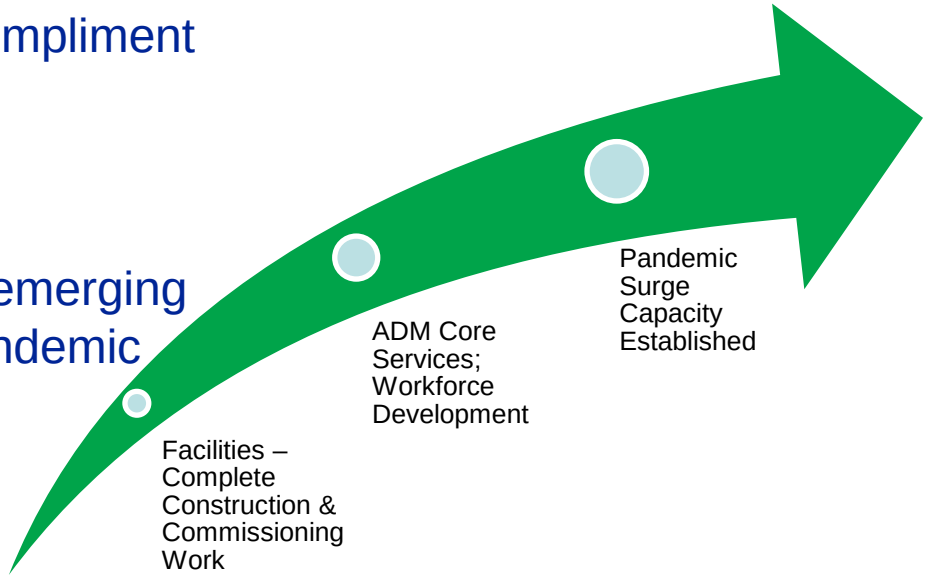
HHS CIADM Program Health

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

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)

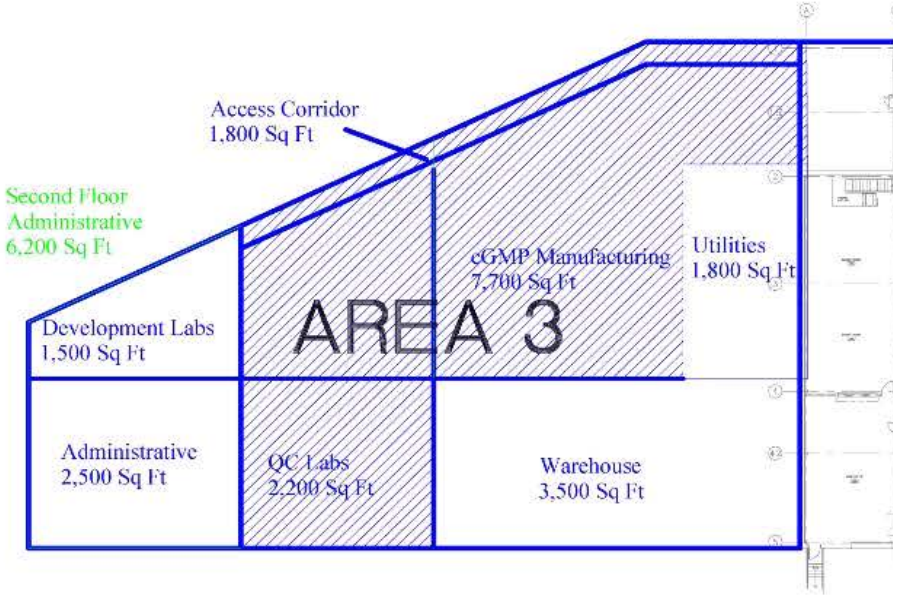
Novartis CIADM
TSB building

Novartis CIADM
CTM Renovation

Emergent CIADM

Emergent CIADM
Key Items & Capacity

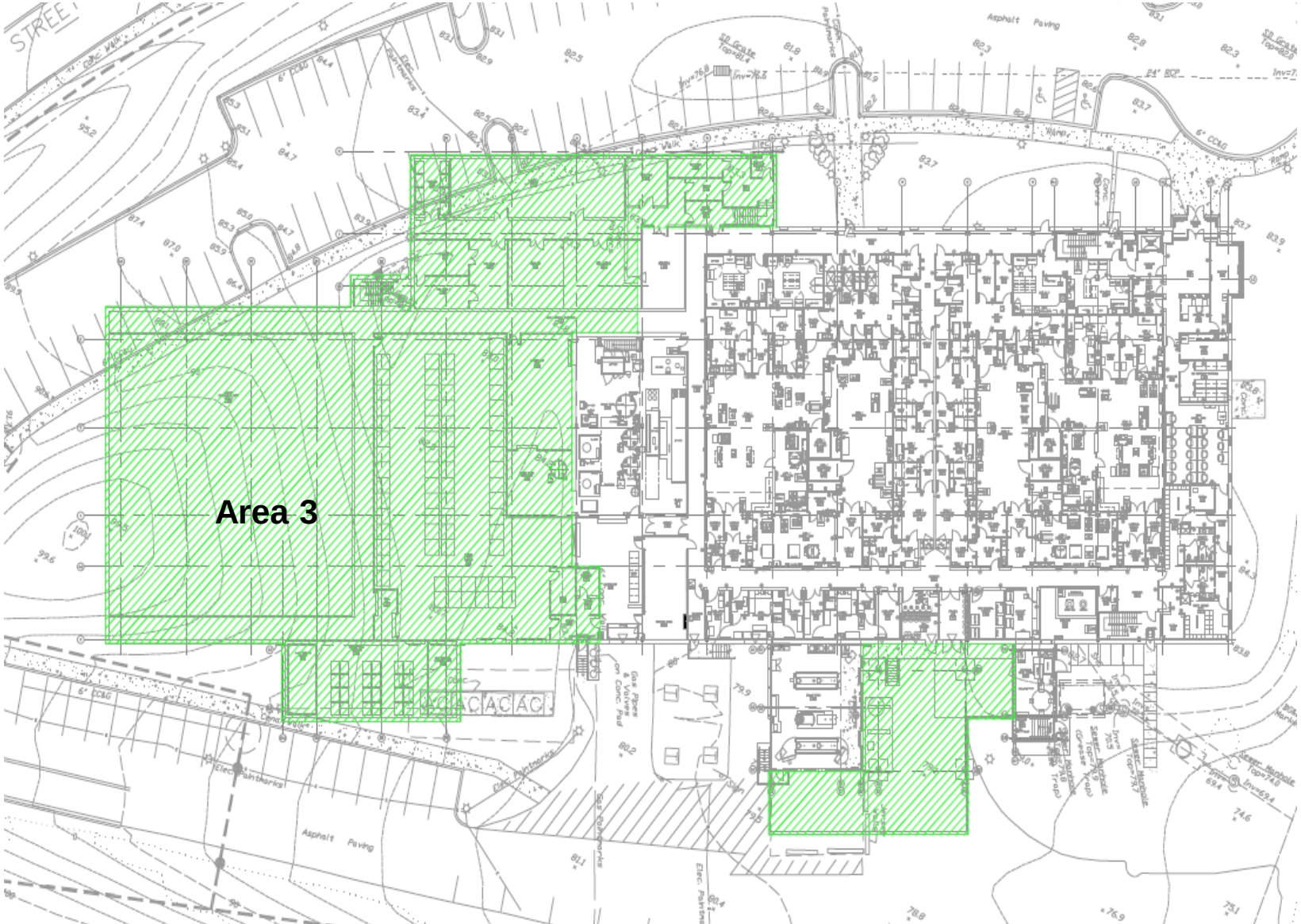
- Site Security activities near completion- target year end 2014
- Detailed Design in progress for new Area 3 Manufacturing Suite, QC Labs & Warehouse at the Baltimore Facility
- HOLD: Pilot Plant in Gaithersburg retrofit; Pending analysis of additional capacity Cangene acquisition.



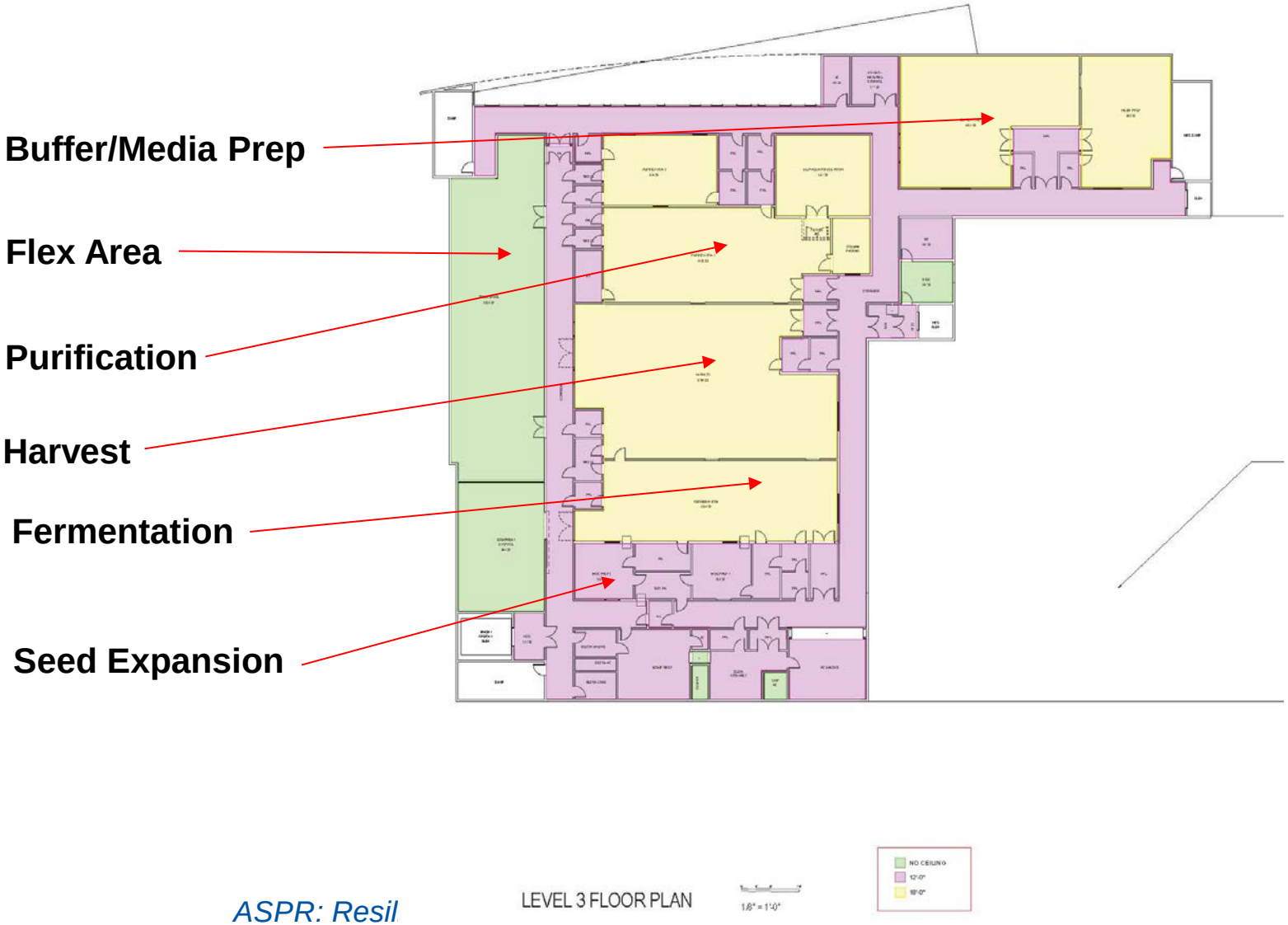
Design Layout of Manufacturing Areas 1 and 2

Emergent CIADM

Area 3: 1st Level Concept Drawing



Conceptual Design - Manufacturing



Single-use Bioreactor Platform (50-2000 L)

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

Emergent CIADM

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

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

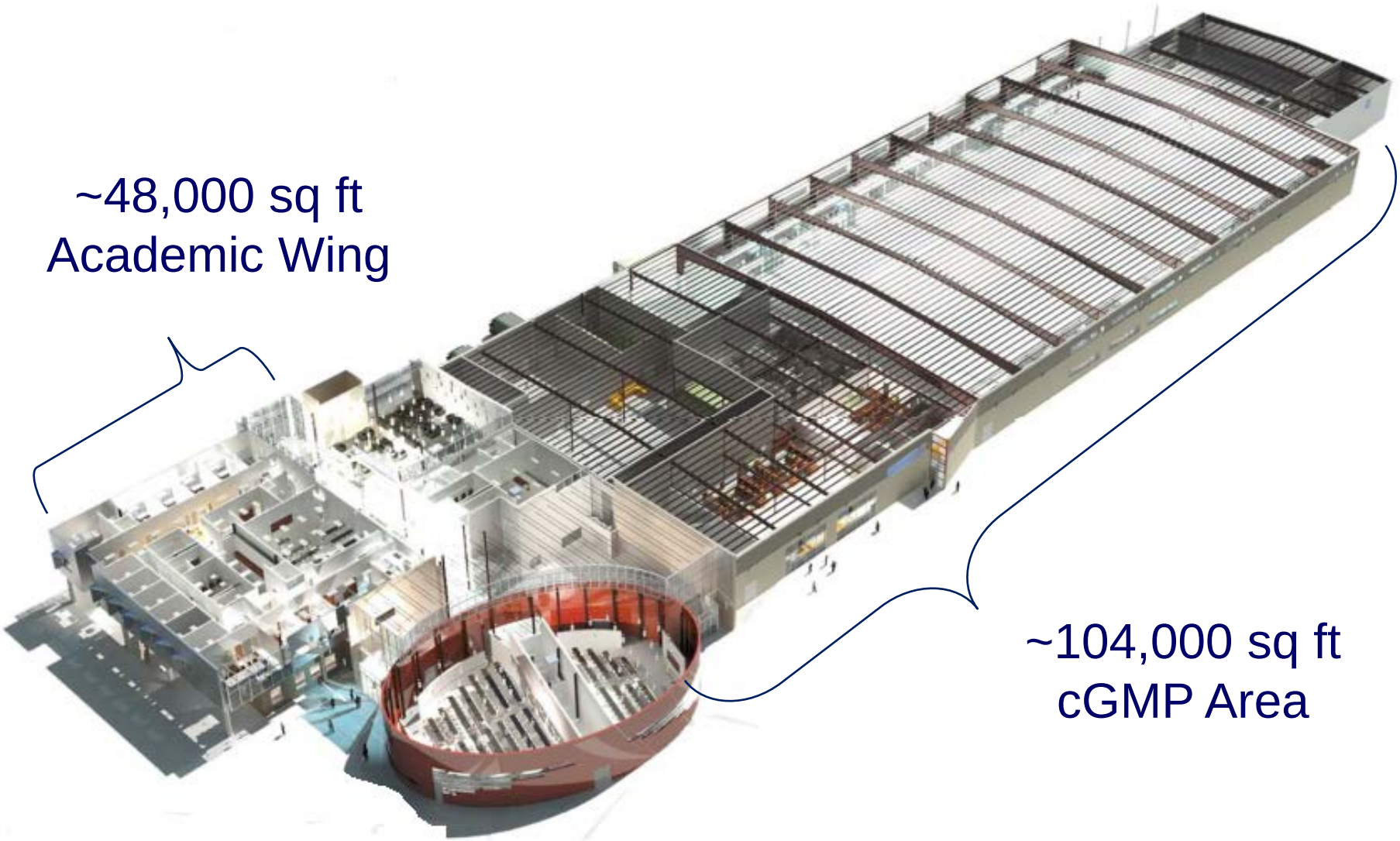
TAMUS CIADM: The "NCTM" – Innovative & Flexible

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

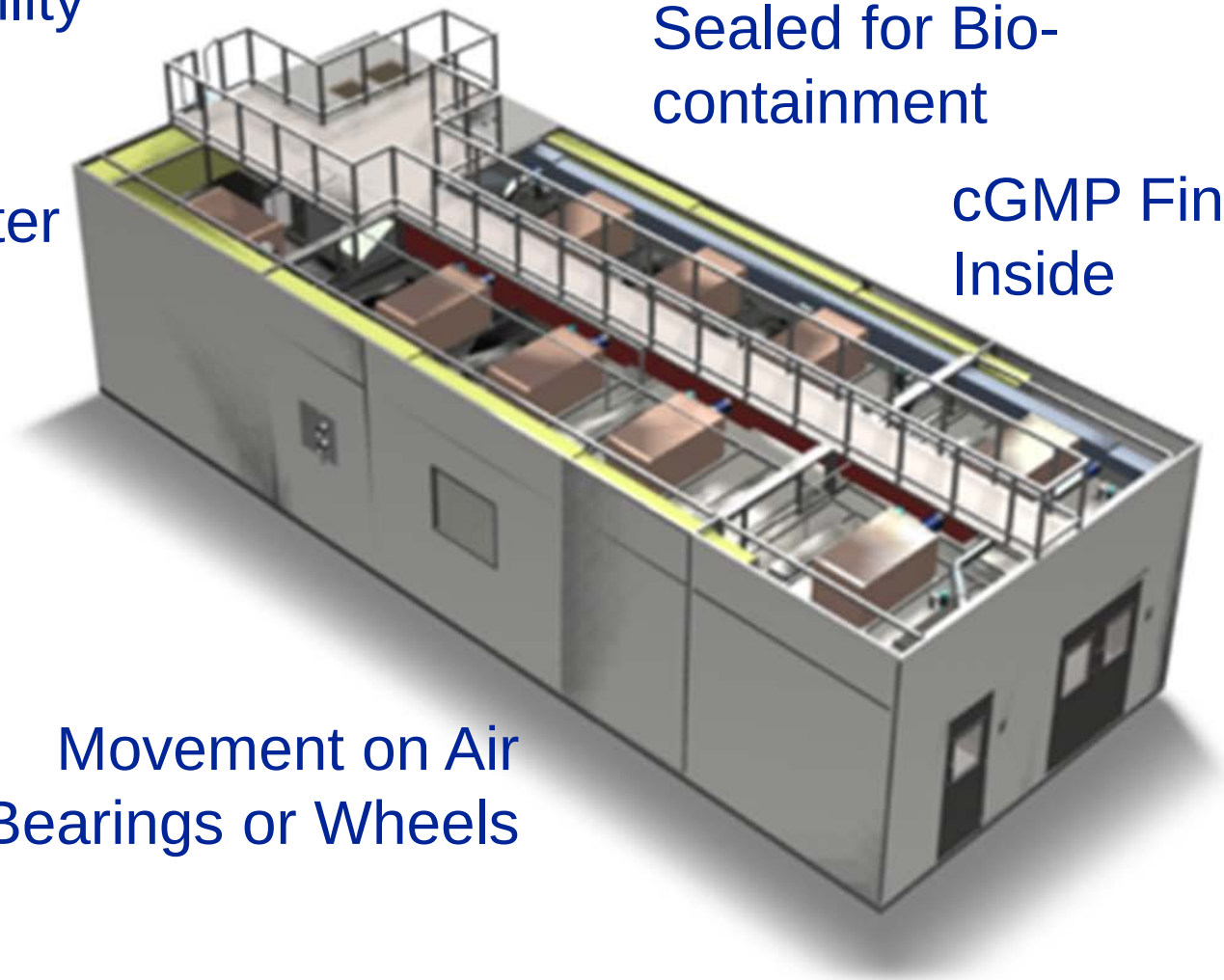


NCTM: Multi-product Flexibility Modular Cleanrooms (MCR)

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

1st 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

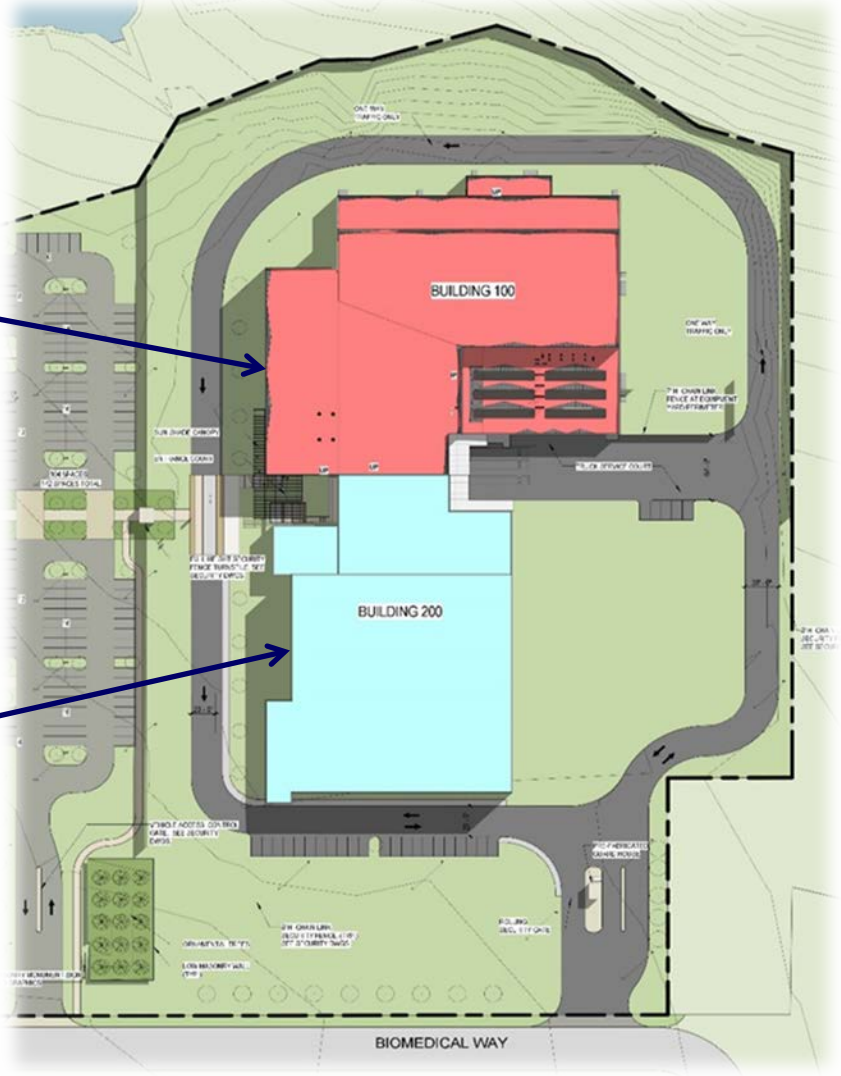
Cell-based Influenza Vaccine Facility

Design Complete
Construction Underway

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

TAMUS CIADM

Live Virus Vaccine Facility & Capability

Cell-based Influenza Vaccine Facility

Live Virus Vaccine Facility