

*Our vision is a U.S. Military Force that has a full medical countermeasure capability to fight and win in any CBRN battlespace worldwide.*

# Overview of the Department of Defense's (DoD) Advanced Development and Manufacturing (ADM) Facility and Capabilities

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**ADVANCED DEVELOPMENT &  
MANUFACTURING CAPABILITIES**

# Bottom Line Up Front (BLUF)



**The DoD ADM is “Open for Business” for medical countermeasure development and manufacturing**

# Challenges in Medical Countermeasure Development



- **“Big Pharma” is unwilling to develop DoD MCMs**
  - Low profitability/return on investment, lack of long term DoD commitment
  - Intellectual Property concerns
  - Federal Acquisition Regulations (FAR)
- **DoD relies on small innovator companies**
  - Restarts a steep learning curve with each new product
    - Lack FDA regulatory experience, especially ‘animal rule’
    - Lack GMP process development/scale-up experience
  - Typically, product has a unique development path and manufacturing process
  - Limited access to stable manufacturing infrastructure
- **Manufacturing issues a major cause of delays and cost increases**
- **Impact: Extended development schedules, increased costs**

**Solution: A dedicated, flexible and agile  
Advanced Development and Manufacturing (ADM) capability**

# DoD ADM Contract



- **Contract awarded to Nanotherapeutics, Inc., in Alachua, FL**
  - Base Period (Establishment)
  - Four 2-Year Option Periods (Sustainment)
  - Options for up to 3 additional manufacturing suites
- **Purpose-built biomanufacturing facility featuring:**
  - 180,000 ft<sup>2</sup> of development, manufacturing, laboratory, warehousing, and support space.
  - Biosafety Level 3 (BSL-3) manufacturing
  - Capability to support development from research through licensure and fielding
  - Capable of manufacturing scales from bench to large scale, including horizontal scaling for surge events



# DoD ADM Facility From Concept to Reality



# DoD ADM Facility Highlights



- **State-of-the-art Bio-manufacturing facility:**

- cGMP and BSL-3 compliant manufacturing
- Four, independent manufacturing suites, segregated by dedicated HVAC systems
  - Allows for concurrent projects
  - Provides unidirectional flow of people & materials
  - Horizontal scaling
- Utilizes stainless steel and single-use manufacturing technologies
- Supports pilot through large-scale cGMP manufacturing
  - Up to 300L fermenter or 2,000L single-use bioreactor
- All support capabilities “under one roof”
  - Process development, cell banking, and laboratory testing
  - 25,000 square feet of active GMP manufacturing space
- Over 100 full time employees

# Current DoD ADM Pipeline



- **Ricin vaccine (RVEc)**
  - Technology transfer, process development and engineering run production
- **Venezuelan Equine Encephalitis vaccine**
  - Assay and Manufacturing Technology transfer, Engineering runs
- **Tularemia Vaccine**
  - Process development and product manufacturing
- **Scopolamine**
  - Fill/finish product for clinical trial
- **Autoinjectors**
  - Development of alternative autoinjectors for 2-PAM and/or atropine
  - Regulatory assistance
- **Platform Technologies**
  - Technologies that can counter a variety of threat agents using standardized discovery, design, manufacturing, and/or testing processes to accelerate MCM delivery to the Warfighter

# Summary



- **DoD ADM is “Open for Business” to support DoD’s MCM requirements**
- **DoD ADM is a state-of-the-art development and manufacturing capability**
  - Contractor-owned, contractor operated facility
  - Provides a full array of development and production services
  - Designed to support a wide range of product types at scales to meet DoD requirements
  - Multi-product, BSL-3 capable, hybrid manufacturing concept leverages single-use systems
- **DoD ADM will implement lessons learned on each additional DoD product**
  - Advancing new regulatory science, platforms, and manufacturing processes
  - Shortened development cycles and reduced life cycle costs
- **Product development efforts underway at new facility**
  - BOT A/B mAbs, and vaccines against ricin, WEVEE and Tularemia





# Contact Us



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