Joint Program Executive Office for Chemical and Biological Defense

Medical, Biomedical & Biodefense Support to the Warfighter Symposium

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WARFIGHTER NEEDS

Requirements Identified

Acquisition Documents
- Initial Capabilities Document (ICD)
- Capabilities Development Document (CDD)
- Capabilities Production Document (CPD)
- Key Performance Parameter = FDA Licensure

Science & Technology (S&T) Development

Advanced Development

FDA Licensure Process

Portfolio of Safe & Effective CBRN Medical Countermeasures

Warfighter Requirements JRO Requirements Documents S & T JPEO-CBMS

CBRN Threat

Protecting the warfighter

ICD CDD CPD

20160603 Bio Med Def JPEO v2
CHEMICAL AND BIOLOGICAL DEFENSE PROGRAM

Areas of Responsibility

- Vaccines
- Decontamination
- Biosurveillance
- Individual/Collective Protection
- Chemical & Biological Agent Detection
- Weapons of Mass Destruction
- Information Systems
- Installation/Force Protection
- Diagnostics
- Treatments
- Weapons of Mass Destruction Civil Support

Under Secretary of Army for AL&T

Assistant Secretary of Defense for NCB

Deputy Assistant Secretary of Defense NCB/CBD

Under Secretary of Defense for AT&L

Force Structure, Resources & Assessment, The Joint Staff (J8)

Acquisition Authority

Oversight & Governance of CBDP

Requirements

Technology

Capability Solutions

UNCLASSIFIED

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JPEO-CBD: CURRENT MAJOR INITIATIVES

- **Biosurveillance**
  - Joint US Forces Korea Portal and Integrated Threat Recognition
  - Biosurveillance Portal

- **Global Crisis Response**
  - Diagnostics/Critical Reagents Program
  - Therapeutics/Vaccines
  - Force Protection Systems
  - Deployable CWMD Destruction Capability

- **Emerging Threats**
  - NTA capabilities to WMD Civil Support Teams/active components

- **Installation & Force Protection** *(Installation as a System)*

- **Radiological/Nuclear**
  - Joint Personal Dosimeter Program
  - Radiological Detection System

- **Long term planning and Analysis** *(30yr Plan)*

- **Advanced Technology Demonstrations**
No Single Agency has Visibility into the Entire Development Portfolio

Basic Research
- Preclinical Development
  - In Vitro & Animal Models
  - Animal Testing
  - Lab-Scale Production
- Clinical/Non-clinical Development
  - Human & Animal Efficacy, Dose, & Safety Testing
  - Formulation
  - Production of Clin. Supplies
- Filing & Launch Preparation
  - Regulatory Submission
  - Manufacturing Scale-Up
- Commercialization & Procurement
  - Full-Scale Production
  - Safety Follow-Up
- Readiness & Stockpiling
  - Warm base production

Civilian Programs
- NIH
- BARDA
- OPEO
- CDC

Military Programs
- DARPA
- DTRA-JSTO
- Joint Program Executive Office - CBD
- Individual Services
UNITY OF EFFORT AND PURPOSE
Requirements – Unique and Common

DoD-Unique
- Brucellosis VAC
- WEVEE/MEE VAC & Tx
- Plague VAC
- Botulism VAC
- SEB VAC & Tx
- Tularemia VAC
- Ricin VAC & Tx
- (other, unfunded)

Common
- Anthrax VAC & Tx
- Smallpox VAC & Tx
- Ebola/Marburg VAC & Tx
- Tularemia Tx
- Botulism Tx
- Radiation Tx
- Nerve agent VAC & Tx

HHS-Unique
- Smallpox VAC for special populations
- Burkholderia sp. Tx
- Junin Tx
- Plague Tx

VAC = Vaccine  Tx = Therapeutic

DoD Focus is on Protecting Forces Prior to Exposure. HHS Focus is on Response to Threats to General Civilian Population After Exposure.
The Complexity of Medical Acquisition
Integration of DODi 5000.02 Defense Acquisition Management Framework and 21 CFR FDA Regulatory Process

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**DOD**
- Materiel Solution Analysis
- Technology Development

**Research/Discovery**
- Pre-Clinical/Clinical Development

**FDA**
- Clinical Development
- Regulatory Submission
- Post Licensure

**Legend:**
- MRL = Manufacturing Readiness Levels
- TRL = Technology Readiness Levels

**Medical Acquisition Programs must be Compliant with DoD 5000, FAR, and 21 CFR FDA Regulatory Process**

- Development timelines are in line with industry standard
- The product sponsor is the only direct interface with the FDA
- DoD has no special relationship with the FDA
- TRLs, MRLs agreed among DoD and HHS; UK/CAN/AS

**Reference:** DODi 5000.02 & FDA 21 CFR
• Contracting with JPEO-CBD


• DTRA BAA Portal

https://www.dtrasisubmission.net/portal/
The BEST Technology and Equipment
At the RIGHT PLACE
At the RIGHT TIME
At the RIGHT COST

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www.jpeocbd.osd.mil