

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

# Medical Countermeasure Systems (MCS)

*Command Overview Briefing*

*Presented to:*

**Advanced Planning Briefing  
to Industry**

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**November 7, 2015**



**MCS**  
MEDICAL COUNTERMEASURE SYSTEMS



# WHO WE ARE



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# Medical Countermeasure Systems (MCS)



## ■ VISION

A U.S. military force that has a full medical countermeasure capability to fight and win in any CBRN battlespace worldwide

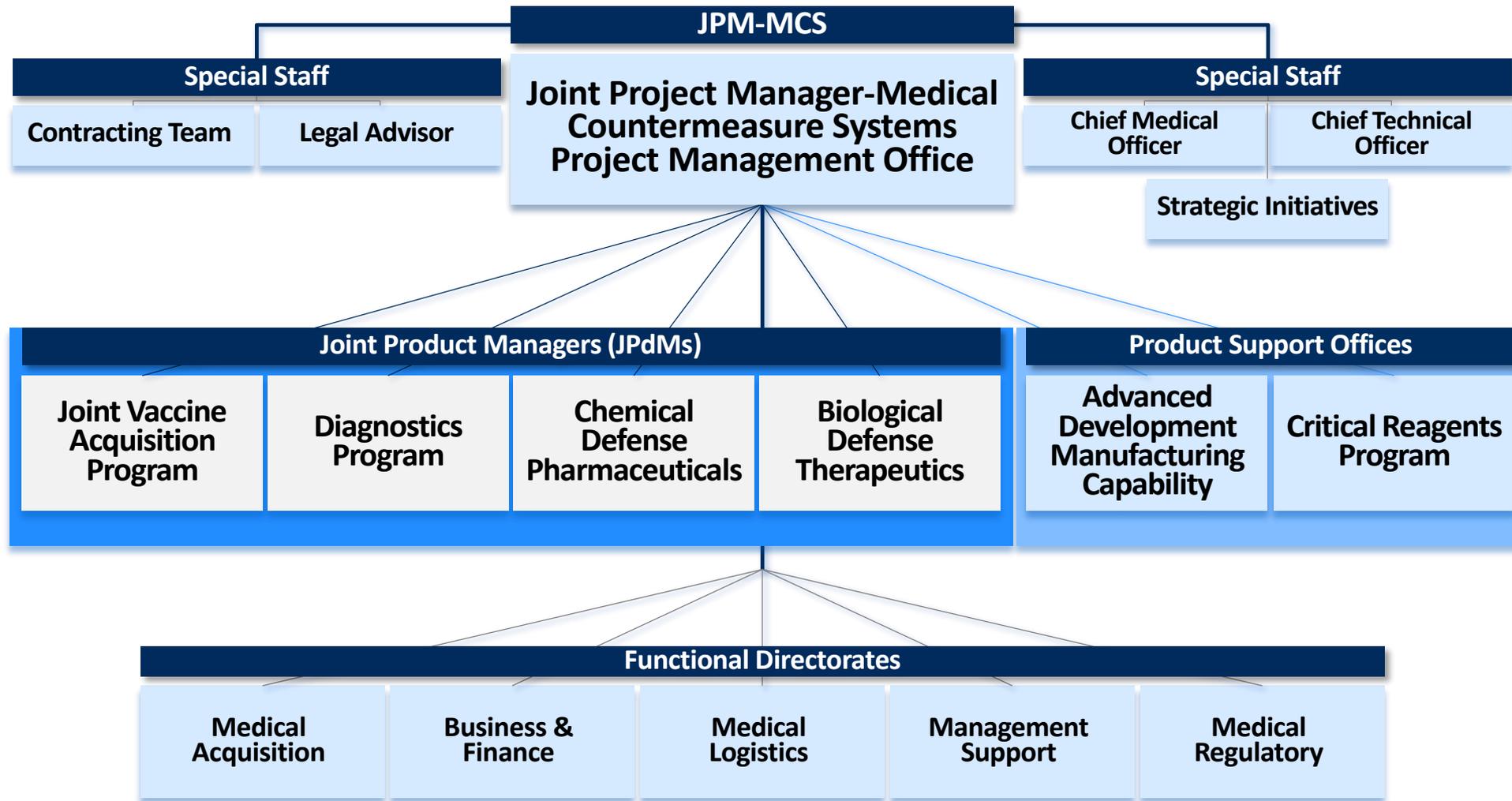
## ■ MISSION

To provide U.S. military forces and the nation safe, effective, and innovative medical solutions to counter CBRN threats





# MCS Organizational Structure





# HOW WE DO IT



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# DoD: Meeting the Needs of the Warfighter



## CAPABILITY DOCUMENTS

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

## TRANSLATIONAL TEAMING

- Capability Technology Agreement (CTA)
- Technology Transition Agreement (TTA)

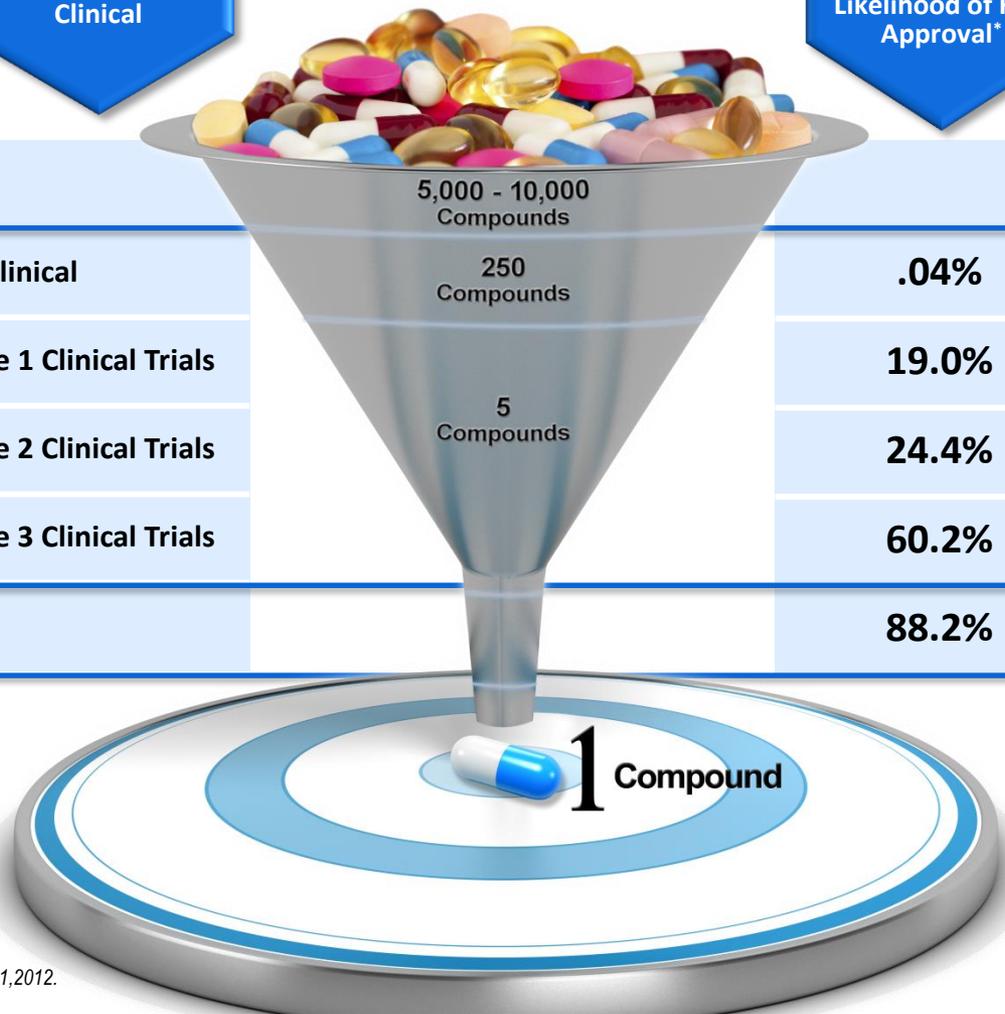
**SAFE & EFFECTIVE FDA APPROVED PRODUCTS**



# FDA: Developing a safe and effective MCM



Drug Discovery				
Lab scale	Proof of Concept	Pre Clinical	5,000 - 10,000 Compounds	
Pilot Lot	Dose, Schedule, Safety	Phase 1 Clinical Trials	250 Compounds	.04%
Validation/Demo	Pivotal	Phase 2 Clinical Trials	5 Compounds	19.0%
Consistency Lots	Pivotal	Phase 3 Clinical Trials		24.4%
FDA Review				60.2%
				88.2%



**Industry Average: \$1B per Drug/Vaccine and 10-15 years**

*\*Source: BioMedTracker (Feb 2013) Clinical Development Success Rates Jan 1, 2003-Dec 31, 2012. Uses of Secondary Data to Drive Primary Strategy*



# WHAT ARE WE DOING TO IMPROVE



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# Enhancing Stakeholder Partnerships



## 1 INDUSTRY

- Experienced Pharma
- Dedicated Prime Contractors
- Small Biotechnology Companies
- Others

## 2 INTERAGENCY

- Health and Human Services
- Department of Homeland Security
- Food & Drug Administration
- Centers for Disease Control

## 6 ACADEMIA

- Academic Labs and Research Institutions
- University-led Drug Discovery Centers and Programs

## 3 INTRA-AGENCY

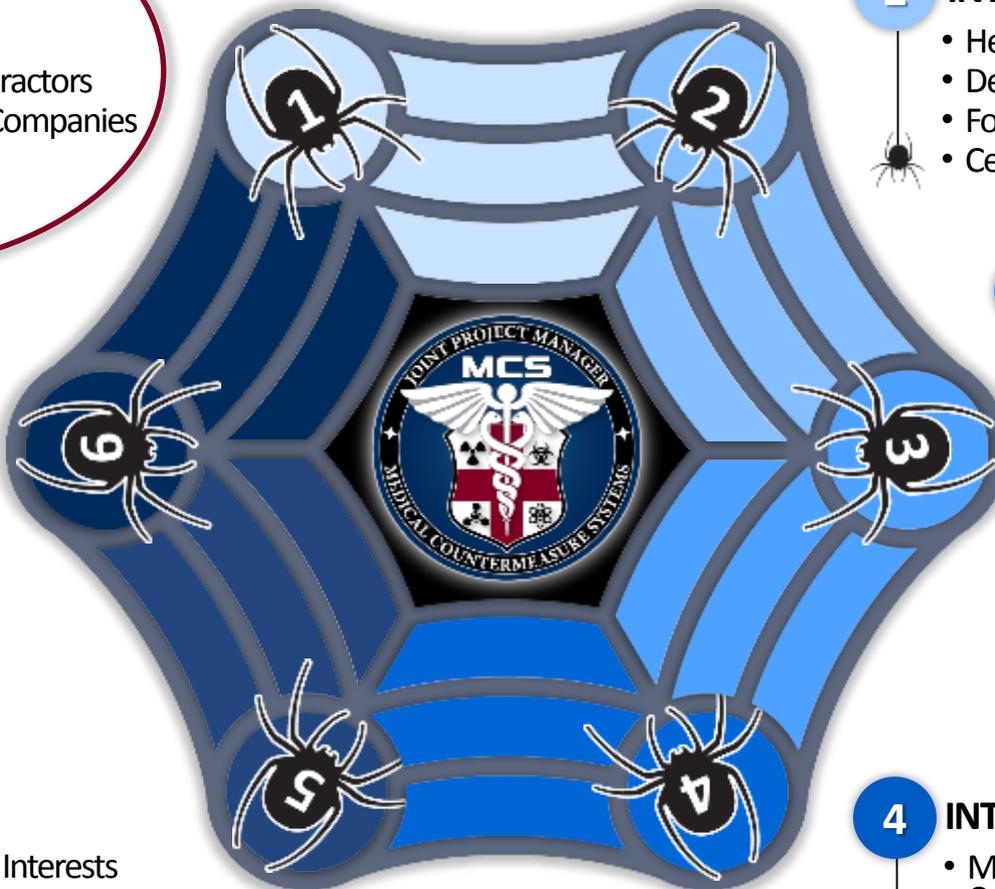
- OTSG-U.S. Army
- ASD-Health Affairs
- DTRA-JSTO
- USAMRMC
- AFRR
- U.S. AFHS
- Service Laboratories
- Service Hospitals
- DARPA

## 5 CONGRESS

- Congressional Special Interests
- University Affiliated Research Centers

## 4 INTERNATIONAL

- Medical Countermeasure Consortium (MCMC)  
– US/UK/CAN/AUS



# Enhancing Industry Partnerships



- **We are developing products that we hope will never be used and for which the threat is totally unpredictable (don't know what, where, when or how much)**
- **Poor ROI makes it difficult to attract “right” partners, even when we pay all R&D costs**
- **We are trying to better understand the incentives/disincentives that affect industry decisions on working with us:**
  - MCM OTA Consortium
  - Working with Tuft's Center for the Study of Drug Development to bring together an expert panel to make recommendations on incentivizing industry (e.g., FDA priority voucher-like incentives)

# MCS Joint Product Managers



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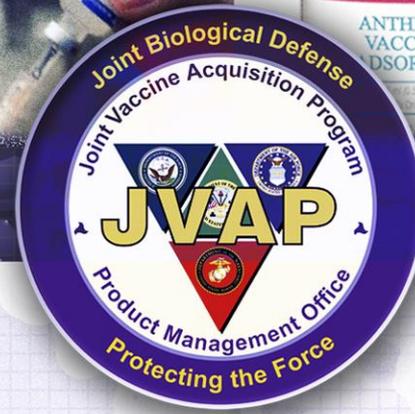
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# MCS-Joint Vaccine Acquisition Program (MCS-JVAP)

*Mission*



**Develop, produce & stockpile FDA-licensed vaccine systems to protect the Warfighter from biological agents**



**JVAP Opportunities (Next 12 months):**

**Engineering and manufacturing development of a Filovirus vaccine that will protect against Ebola, Sudan, and Marburg through FDA approval (licensure)**

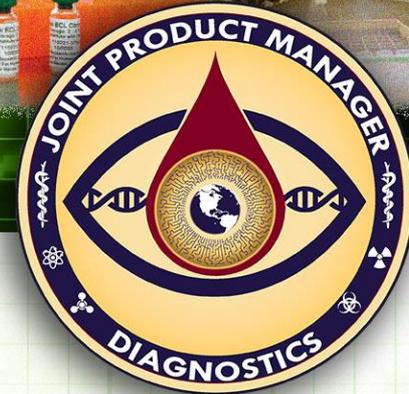


# MCS-Diagnostics

*Mission*



**Develop, acquire, integrate, and field identification technologies and FDA-cleared diagnostic devices intended for Service Members to aid in the early diagnosis, prevention, and treatment of the effects of exposure to chemical, biological, and radiological (CBR) agents**



**Diagnostics Opportunities (Next 12 months):  
Next Generation Diagnostics System Increment 2 platform component development**

# MCS-Chemical Defense Pharmaceuticals (MCS-CDP)

*Mission*



**Provide the Warfighter and the Nation robust & affordable  
FDA-approved lifesaving medical countermeasure drug capabilities  
against chemical, radiological and nuclear threats**



## **CDP Opportunities (Next 12 months):**

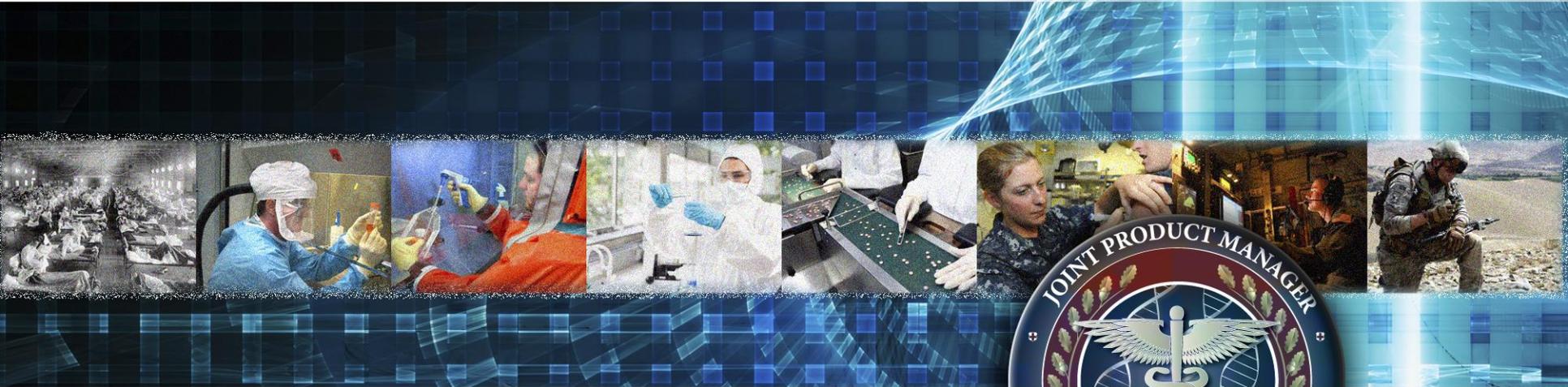
- Improved oxime treatment increment to replace 2-PAM in the currently fielded ATNAA, for a broad spectrum of traditional nerve agents and emerging threats
- Expansion of autoinjector manufacturing base

# MCS-Biological Defense Therapeutics (MCS-BDTX)

*Mission*



**Provide U.S. military forces and the nation safe, effective, innovative, and affordable therapeutic solutions to counter traditional, emerging and engineered biological threats**



## **BDTX Opportunities (Next 12 months):**

- Antiviral therapeutic
- Antibacterial therapeutic

# MCS-Advanced Development & Manufacturing Capabilities(MCS-ADMC)

*Mission*



**Develop a national capability and capacity to develop and produce MCMs rapidly to counter known or unknown CBRN threats, including novel and previously unrecognized, naturally-occurring emerging infectious diseases**

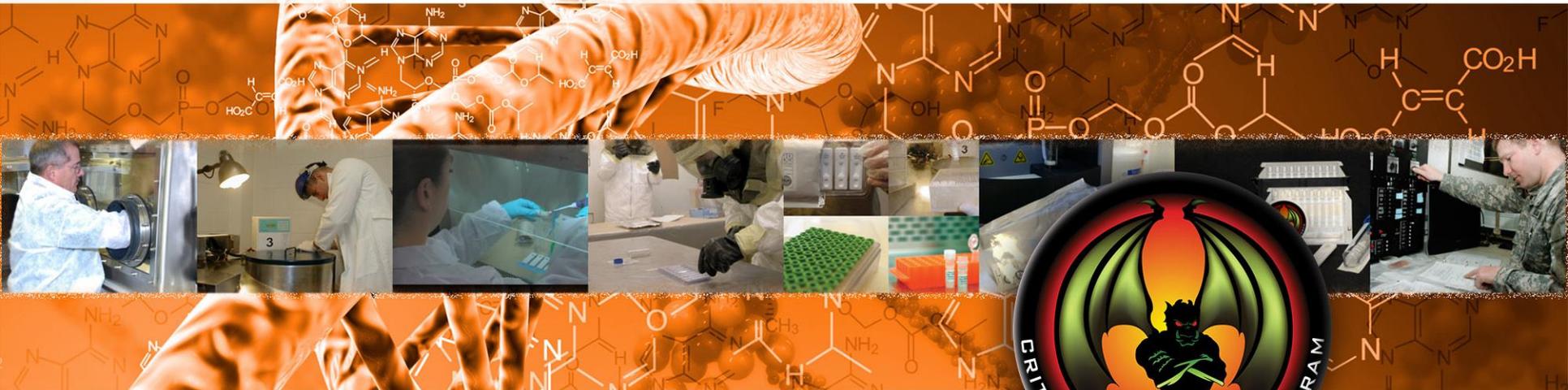


**ADMC Opportunities (Next 12 months):  
None**

# MCS-Critical Reagents Program (MCS-CRP) Mission



To serve as the principle resource of high quality, validated, and standardized biological reference materials, reagents, and assays that meet the technology-development and sustainment needs of the Department of Defense and its partners; support the biological defense community's mission by facilitating the transition of new technologies and coordinating their advanced development, efficient production and timely distribution



**CRP Opportunities (Next 12 months):  
None**



# Contact Us



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