



## Mission

Develop and deliver quality medical solutions to protect, treat, and sustain the health of Our Service Members.

## Vision

USAMMDA is the premier developer of world class military medical solutions.



## For more information about USAMMDA

### Or contact us at:

USAMMDA  
1430 Veterans Drive  
Fort Detrick, MD 21702  
301.619.7056

### Visit our web site:

[www.usammda.army.mil](http://www.usammda.army.mil)

 [www.facebook.com/usammda](http://www.facebook.com/usammda)

 [www.twitter.com/usammda](http://www.twitter.com/usammda)

### Project Management Offices

Pharmaceutical Systems  
Project Management Office  
301.619.2051

Medical Support Systems  
Project Management Office  
301.619.7582

Armed Forces Institute of Regenerative Medicine  
Project Management Office  
301-619- 8053

Hyperbaric Oxygen Treatment  
Project Management Office  
301-619-3647

Neurotrauma and Psychological Health  
Project Management Office  
301-619-2973

### Divisions

Division of Regulated Activities and Compliance  
301.619.1087

Clinical Support Services Division  
301.619.1106

Force Health Protection - IND  
301.619.1104

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# USAMMDA

U.S. Army Medical Materiel Development Activity

## Developing Quality Medical Products for U.S. Forces



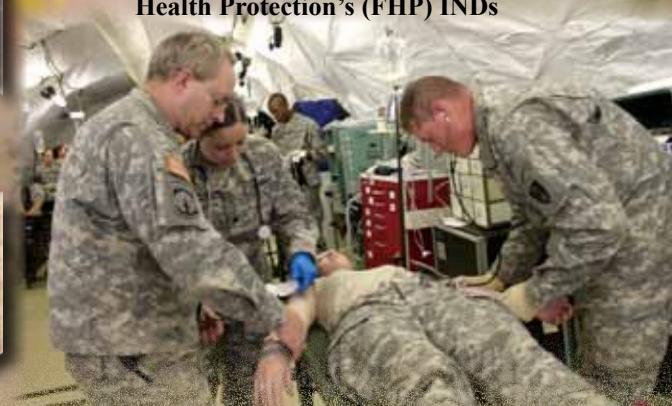
## U.S. Army Medical Materiel Development Activity

USAMMDA is the Department of Defense's (DoD) advanced development activity for products designed to protect and preserve the lives of Warfighters. USAMMDA develops new drugs, vaccines, and medical support equipment that enhance readiness, ensures the provision of the highest quality medical care to the DoD, and maximizes survival of medical casualties on the battlefield.

USAMMDA project managers guide the advanced development of medical products for the U.S. Army Medical Department, other U.S. Services, the Joint Staff, the Office of the Secretary of Defense and U.S. Special Forces community. The process takes promising technology from DoD and academia to U.S. Forces, from the testing required for FDA approval or licensing to fielding of the finished product.

USAMMDA Accomplishes its mission by exercising three core capabilities:

- Program management for USAMRMC advanced development projects
- Regulated activities of all protocols conducted using Investigational New Drugs (IND) applications or Investigational Device Exemptions (IDE)
- Coordinate The Surgeon General's Executive Agent management of Force Health Protection's (FHP) INDs



U.S. Army Medical Research and Materiel Command  
(USAMRMC)

## Division of Regulated Activities and Compliance

The Division of Regulated Activities and Compliance (DRAC) is a multidisciplinary team of regulatory affairs and compliance professionals dedicated to support the USAMMDA mission of developing medical products for the Warfighter on point for the Nation. DRAC provides full-service regulatory support for products through the DoD acquisition spectrum, from individual investigator-initiated clinical studies to products in the advanced development pipeline. DRAC carries out its delegated responsibilities as the Office of The Surgeon General Sponsor's (OTSG) representative for the Army regarding medical materiel development, and its operations are mandated in FDA, DoD, and Army regulatory requirements. DRAC supports investigators at medical centers and laboratories, institutional review boards, and product development teams in laboratories and advanced development organizations throughout the Army and the DoD.

### Four Branches of DRAC:

- Pharmaceuticals Branch
- Vaccines and Blood Products Branch
- Medical Devices Branch
- Regulatory Submissions Branch

## Clinical Service Support Division

Clinical Service Support Division (CSSD) supports the development of medical products by providing expert assistance in the areas of IND product manufacturing, testing and accountability; clinical study monitoring; clinical data management; biostatistics, including study design and data analysis; and adverse event monitoring and reporting.

## Force Health Protection - Investigational New Drug

Force Health Protection-Investigational New Drugs (FHP-IND) is an Executive Agency under the Army OTSG. FHP-IND provides services to all DoD Components as the lead organization for using medical products under Emergency Use Authorizations (EUA) or IND applications in response to chemical, biological, radiological, or nuclear warfare or terrorism and other health threats. FHP-IND provides an urgent treatment capability using novel investigational countermeasures to protect U.S. Forces against man-made or natural threats in accordance with federal regulations and DoD instructions.



### Critical Tasks:

- Provide a safe and compliant program to protect the force using IND countermeasures.
- Provide logistical support for the unique requirements for acquisition, storage, shipping, and testing of investigational countermeasures.
- Deploy personnel and investigational countermeasures in support of civilian authorities or military commanders.

## Project Management



USAMMDA project managers address critical readiness issues identified in user requirement documents to meet cost, schedule and performance objectives. Tailored procurement, rapid prototyping and a variety of cooperative and contractual arrangements with academia and industry are among the most current acquisition procedures used. Project Management Offices (PMO) include:

**Medical Support Systems (MSS) PMO** advances development of medical products used to sustain and support the Warfighter. Product managers analyze functional requirements, conduct market investigations, and plan for all acquisition program phases. MSSPMO designs, develops, and tests field medical equipment and specializes in developing innovative technology as well as adapting commercial-off-the-shelf (COTS) systems. The Medical Prototype Development Laboratory is a small team of engineering technicians who rapidly design and build prototype medical devices, and harden COTS products for use in a field environment.

**Pharmaceutical Systems PMO** centrally manages the development and acquisition of pharmaceutical and biological products (drugs, vaccines, diagnostics, protective and therapeutic modalities for use against infectious diseases and similar products for combat casualty care). Product Managers work with USAMRMC laboratories, academia, and industry partners (both domestic and foreign) to identify, develop, license, and field products to remedy deficiencies identified by the Army Medical Department Combat Developer.

**Armed Forces Institute of Regenerative Medicine (AFIRM) PMO** is a multi-Institutional, interdisciplinary network working to develop advanced treatment options for our severely wounded Warfighters. AFIRM is managed and funded through the USAMRMC; with additional funding from the U.S. Navy, Office of Naval Research; the U.S. Air Force, OTSG; the National Institutes of Health; the Veterans Administration; and local public and private matching funding.

**Hyperbaric Oxygen (HBO2) Treatment For Mild Traumatic Brain Injury (mTBI)** is the administration of oxygen in a chamber at greater than sea-level atmospheric pressure in which oxygen becomes increasingly dissolved in the blood, resulting in greater than normal every day oxygen tension in cells and tissues in the body. There is some compelling anecdotal evidence to suggest this may be beneficial in the treatment of acute and chronic symptoms linked to traumatic brain injury. Stronger evidence must be obtained prior to determine if HBO2 should be used as a treatment for TBI.

**Neurotrauma and Psychological Health (NPH) PMO** was formed in May 2011 to support advanced development of materiel and select nonmateriel (Medical Knowledge) products to protect, sustain and care for Warriors with TBI and psychological health issues including Posttraumatic Stress Disorder. Additionally NPH provides advanced development assistance to USAMRMC Military Operational Medicine and Combat Casualty Care Research Programs and associated Joint Program Committees.