

FOR MORE INFORMATION ABOUT USAMMDA

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PROJECT MANAGEMENT OFFICES

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DIVISIONS

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Last updated: March 2016

USAMMDA

U.S. ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY



WORLD CLASS MILITARY MEDICAL SOLUTIONS



U.S. ARMY MEDICAL
RESEARCH AND MATERIEL COMMAND

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
- Serves as The Surgeon General's Lead Component for IND treatment, prophylaxis and diagnostic capabilities

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

DIVISION OF REGULATED ACTIVITIES AND COMPLIANCE

The Division of Regulated Activities and Compliance (DRAC) is a multidisciplinary team of regulatory affairs and regulatory 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 to support The Surgeon General (TSG) Sponsor's 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. DRAC also has the only electronic Common Technical Document capability for submissions to the FDA in electronic format within the DOD.

Branches of DRAC:

- Regulatory Science Branch
- Regulatory Operations Branch
- Medical Devices and Diagnostics Branch



CLINICAL SERVICE SUPPORT DIVISION

Clinical Service Support Division 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.

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 include:

MEDICAL SUPPORT SYSTEMS (MSS)

MSS develops, tests, procures and sustains the best medical evacuation, combat casualty care support and operational and preventive medicine solutions for the Warfighter. MSS collaborates with other Army Program Executive Offices for integration of medical products on ground, air and Soldier platforms. As an enabler of solutions for transition, the Medical Prototype Development Laboratory within the MSS rapidly designs and builds prototype medical devices and hardens commercial off-the-shelf products for use in a field environment.

PHARMACEUTICAL SYSTEMS

Pharmaceutical Systems 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.

TISSUE INJURY AND REGENERATIVE MEDICINE (TIRM)

TIRM oversees the development of innovative therapeutic solutions to address catastrophic injuries incurred by our Warfighters. The TIRM receives funding from USAMRMC; the U.S. Navy, Office of Naval Research; the U.S. Air Force, OTSG; the National Institutes of Health; the Office of the Assistant Secretary of Defense for Health Affairs; and the Veterans Administration. This enables the TIRM to support dynamic, interdisciplinary collaborations between academic, government and industry partners who are recognized leaders in the fields of regenerative medicine and tissue repair research who work toward the goal of making Warfighters whole by restoring form and function.

HYPERBARIC OXYGEN (HBO₂) TREATMENT FOR MILD TRAUMATIC BRAIN INJURY (MTBI)

HBO₂ 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 determining whether HBO₂ should be used as a treatment for TBI.

NEUROTRAUMA AND PSYCHOLOGICAL HEALTH (NPH)

NPH was formed to support advanced development of materiel and select nonmateriel (Medical Knowledge) products to protect, sustain and care for Warfighters with TBI and psychological health issues including Post Traumatic Stress Disorder. Additionally, NPH provides advanced development assistance to USAMRMC Military Operational Medicine and Combat Casualty Care Research Programs and associated Joint Program Committees.

FORCE HEALTH PROTECTION

Force Health Protection (FHP) is the Lead Component under the Army OTSG. FHP provides services to all DOD forces for use of investigational medical products under Emergency Use Authorizations or IND applications in response to chemical, biological, radiological, or nuclear warfare or terrorism and other health threats. FHP 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 U.S. Forces using IND countermeasures
- Provide logistical support for the unique requirements for acquisition, storage, shipping and testing of investigational countermeasures
- Deploy investigational countermeasures in support of civilian authorities or military commanders