



USAMRDC USAMMDA

U.S. ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY

MISSION

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

BACKGROUND

The U.S. Army Medical Materiel Development Activity is the primary medical product development, systems management and acquisition organization within the Department of Defense and is responsible for meeting medical developmental requirements, as well as sustaining deployable medical capabilities for the Warfighter throughout the Army and other military services. As the Army's medical product development activity, USAMMDA's products are designed to protect and preserve the lives of Warfighters. USAMMDA develops new drugs, vaccines, devices, and medical support equipment that enhance readiness, ensure provision of the highest quality medical care to the DOD, and maximize survival of medical casualties on the battlefield. USAMMDA is responsible for the Life Cycle Management of medical products is accountable for the implementation, management and oversight of all activities associated with the development, production, sustainment and disposal of medical systems across the lifecycle.

USAMMDA develops and fields medical products for the U.S. armed forces in conjunction with the Health Readiness Center of Excellence (HRCoE) (the combat developer), U.S. Army Medical Materiel Agency (the logistician), and other service input.

USAMMDA project managers guide the development of medical products for the U.S. Army Medical Department, other U.S. Services, the Joint Staff, the Defense Health Agency, and U.S. Special Forces community. The process takes promising technology from DOD, industry, and academia to U.S. Forces, from the testing required for U.S. Food and Drug Administration approval or licensing, to fielding and sustainment of the finished product.

USAMMDA is a subordinate activity of the U.S. Army Medical Research and Development Command under the Army Futures Command.



USAMMDA accomplishes its mission by exercising two core capabilities:

Providing program management for USAMRDC medical product development, systems management and acquisition through project management, medical devices assemblage management and the modernization of medical equipment

Serving as the Health Affairs Lead Service for Investigational New Drug (IND) treatment, prophylaxis and diagnostic capabilities (Force Health Protection Division)

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PROJECT MANAGEMENT

The USAMMDA Project Management Offices provide coaching and mentorship to companies or investigators in order to mitigate risks during development, to optimize regulatory and business strategies, and to advance the product to the clinic, and our Warfighters, as quickly as possible. This is accomplished by cultivating relationships with military, academia and industry, and by leveraging Service laboratories to ensure that wounded Warfighters have the right medical solutions at the right places in the field, and ultimately through all Roles of Care. The five USAMMDA PMOs are:

Warfighter Brain Health PMO

(Formerly Neurotrauma & Psychological Health)

The WBH PMO leads the development and acquisition of materiel products to Warfighters suffering from brain injuries and psychological health issues. The mission of the WBH PMO is to develop and field FDA-approved medical solutions across the continuum of care that aid in the detection, protection, sustainment, prevention and treatment of neurotrauma and psychological health conditions, such as Traumatic Brain Injury, post-traumatic stress disorder and suicide.

Warfighter Deployed Medical Systems PMO

Formed in April 2019, the mission of the WDMS PMO is to develop, deliver and sustain deployed medical capabilities for the Warfighter. The WDMS PMO is comprised of a team of experts in DOD acquisition and project management, clinicians, scientists and technical support personnel. The WDMS PMO accomplishes its mission through two product management offices:

Medical Devices Assemblage Management: The MDAM product management office oversees all Army medical unit assemblages by providing acquisition lifecycle management of Class VIII medical equipment, unit assemblages, devices and ancillary medical items to support human and animal patient care.

Modernization: The Modernization product management

office develops, procures and manages the modernization of medical devices to enhance the readiness and lethality of the Warfighter.

Warfighter Expeditionary Medicine and Treatment PMO

(Formerly Combat Trauma and Acute Rehabilitation)

The WEMT PMO leads the development and fielding of FDA-cleared or -approved medical devices, drugs, and biologics that fulfill the unmet requirements identified by the Service end-user. Focus areas include hemorrhage detection and control, extremity injury repair, combat burns and wounds, multi-organ support, extremity injury repair, sensory systems acute treatment and imaging devices. These solutions can be a new capability development effort or an improvement upon existing capabilities.

Our team of experts includes DOD acquisition and project management professionals, clinicians, engineers, scientists and entrepreneurs who work together to search for innovative diagnostic and therapeutic solutions to address unique, and sometimes catastrophic injuries sustained by our Warfighters. The WEMT PMO addresses challenges to medical product innovation through two lines of effort: 1) Product Development and 2) Biomanufacturing Innovation.

Warfighter Health, Performance and Evacuation PMO

(Formerly Medical Support Systems & Evacuation)

The WHPE PMO develops, tests and fields medical evacuation, field hospital infrastructure, combat casualty care support, Soldier optimization, and operational and preventive medicine solutions for the Service Member. The office collaborates with the Army Medical Department, Army Program Executive Offices, the Defense Health Agency, Joint PEO Chemical & Biological Defense, Training and Doctrine Command, and the Armed Forces Pest Management Board for integration of medical support products on ground, air, and Soldier platforms. As an enabler of solutions for transition, the Medical Prototype Development Laboratory within the WHPE PMO

CONTACT USAMMDA

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KEY THEMES AND MESSAGES

UNITED in SERVICE to our Nation's Warfighters

USAMMDA is the Army's medical product development activity for products designed to protect and preserve the lives of Warfighters.

USAMMDA provides the integrating function needed to translate proven medical research concepts into approved medical products for the Warfighter.

USAMMDA professionals work as a team with scientists at USAMRDC laboratories, commercial and other government partners to bring promising medical materiel from concept to the battlefield.

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rapidly designs and builds prototype medical systems, and hardens commercial off-the-shelf products for use in the field environment. In an effort to provide U.S. Forces with innovative, useful and relevant field medical equipment, the MPDL collaborates with various organizations within the medical community. This unique USAMRDC resource is instrumental in providing prototype design, fabrication, and evaluation/testing, as well as fixes for products, components and systems.

Warfighter Protection and Acute Care PMO

(Formerly Pharmaceutical Systems)

The WPAC PMO leads the development and fielding of pharmaceutical and biological products – drugs, vaccines, diagnostics, protective and therapeutic modalities – for use against infectious diseases and similar products for combat casualty care. The office works to move these products to U.S. licensure and fielding within the framework of DOD Acquisition Regulations and Policies, and the Consumer Protection Laws of the FDA and the U.S. Environmental Protection Agency. The WPAC PMO accomplishes its mission through the establishment of partnerships with industry (foreign and domestic), other governmental agencies (within and outside of the United States) and academia.

FORCE HEALTH PROTECTION DIVISION

The FHP is a Lead Service under Health Affairs. FHP develops and manages protocols for biological threats that are naturally occurring, accidental or intentionally released. The office provides an urgent treatment capability using novel investigational countermeasures to protect U.S. Forces against manmade or natural threats in accordance with federal regulations and DOD instructions. Another capability of FHP is interim fielding of DOD's promising IND products as treatment protocols for our Warfighters until the products have been licensed by the FDA. The mission of the FHP is to 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; and deploy investigational countermeasures in support of military commanders or civilian authorities.

QUESTIONS & ANSWERS

How does USAMMDA work with other USAMRDC activities?

Products being developed by USAMRDC laboratories are evaluated by USAMMDA for advanced development. Product managers at USAMMDA work with the laboratories to guide the advanced development process.

What role, if any, do other government agencies (FDA, U.S. Environmental Protection Agency, etc.) play in USAMMDA's development and acquisition?

For medical products, the FDA regulations (21 Code of Federal Regulations [CFR] – Food and Drug) must be followed. This regulation defines the quality and type of testing that are required for the FDA to approve or clear medical products for human and animal use. The processes are similar when the product is an insecticide with a medical indication, except the agency is the EPA, and the regulation that must be followed is 40 CFR – Protection of Environment.

Does USAMMDA partner with other government and civilian organizations to complete its mission?

USAMMDA develops and fields medical products for the U.S. armed forces in conjunction with the Health Readiness Center of Excellence (HRCoE), the combat developer; USAMMA, the logistician; and other service inputs. In addition to leveraging proven civilian technologies into military applications, USAMMDA has been able to achieve its success through partnerships with industry, academia, and other government agencies. Have a new Military Medical-Relevant Product or idea? Submit your idea at: <https://mrdc-npi.amedd.army.mil/>