USAMRMC STRATEGIC COMMUNICATION PLAN

U.S. ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY (USAMMDA)

MISSION

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

BACKGROUND

USAMMDA is the DoD's advanced medical materiel development activity for products designed to protect and preserve the lives of service members. USAMMDA develops new drugs, vaccines, and medical devices that enhance readiness, ensures the provision of the highest quality medical care to the DoD, and maximizes survival of medical casualties on the battlefield. As the designated Program Manager, Combat Medical Systems, USAMMDA develops and fields medical products for the U.S. armed forces in conjunction with the Army Medical Department (AMEDD) Center and School (the combat developer), U.S. Army Medical Materiel Agency (USAMMA) (the logistician), and other service input. USAMMDA product managers take promising new concepts and technologies developed in USAMRMC laboratories, guide them through the regulatory process to obtain U.S. Food and Drug Administration (FDA) certification, and develop plans for fielding medical materiel in conjunction with USAMMA.

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; for example, the Salk Institute (Swiftwater, Pennsylvania), FDA, supporting USAMRMC laboratories, U.S. Navy, and others.

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USAMMDA is a subordinate activity under USAMRMC supporting the Command as the primary advanced development medical research, development, and acquisition organization within DoD and is responsible for meeting medical developmental requirements from both the Army and other military services.

QUESTIONS & ANSWERS

Q ***What process does USAMMDA employ to prioritize funding for advanced product development?***

A USAMMDA developed and employs a Decision Gate model to apply proven business techniques to USAMRMC programs to conserve resources and speed medical products to all U.S. armed forces. This effort was designed to more effectively bridge the gap from research and development to advanced product development. Decision Gate provides a structured process to evaluate the relative maturity of mission-oriented products in development. The process provides a rational approach to prioritize the advancement of products through development stages.

Q ***How does USAMMDA work with other USAMRMC activities?***

A Products being developed by USAMRMC laboratories are evaluated by USAMMDA for advanced development. Product managers at USAMMDA work with the laboratories to guide the advanced development. Regulatory affairs scientists and specialists at USAMMDA provide regulatory guidance to the laboratories for product development and testing requirements needed for FDA approval. Regulatory submissions are prepared by USAMMDA subject matter experts working with the laboratories, and clinical studies are monitored at least three times for regulatory compliance. USAMMDA also works with USAMMA and the AMEDD Center & School to acquire and field products.

KEY THEMES AND MESSAGES

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

USAMMDA provides the required support to complete regulatory testing, evaluation, and compliance requirements for medical products.

USAMMDA professionals work as a team with scientists at USAMRMC laboratories, commercial and other government partners, and logistical acquisition managers at the USAMMA and AMEDD Center & School to bring promising medical materiel from concept to the battlefield.

USAMMDA is composed of advanced development project management offices, support divisions for regulatory affairs, force health protection divisions, and supporting quality control, technology transfer, and administrative services divisions.

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U.S. ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY (USAMMDA) CONTINUED

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

A 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.

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

A USAMMDA develops and fields medical products for the U.S. armed forces in conjunction with the AMEDD Center & School, 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.

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