We Are Pleased to Announce a Seminar Presented by:

Jonathan Phillips, Ph.D. PMP  
Chief Technical Advisor, U.S. Department of Defense  
Joint Program Executive office for Chemical and Biological Defense

“Pounding a Square Peg into a Round Hole: The Trials and Tribulations of Getting Biological Warfare Agent Medical Countermeasures Approved by the FDA”

Thursday, Sept. 7, 2017 at 9:00 AM  
Astellas Conference Room, SLSRC 3410/3430  
Refreshments will be served at 8:45 AM

The defense acquisition process designs, produces, operates, and sustains the most capable military systems in the world through the efforts of private sector companies, the Department of Defense (DOD), the Congress, the acquisition workforce, and the military and civilian personnel who test, train, use, and support these systems in war and peace. The core of acquisition success lies in aligning requirements, programs, and resources, including funding, technology, and an experienced, professional workforce. That alignment necessitates tradeoffs among needs, results, cost, timeliness, and risk. Although frustrating at times, the acquisition process allows for the design of a system and its requirements to change as tradeoffs are made, analysis is performed, and feedback is provided by potential users of the system. As part of a rigorous test and evaluation process, operational tests are conducted with warfighters to ensure that fielded products are operationally effective, operationally suitable, and operationally survivable. As a result, successful DoD acquisition programs involve extensive coordination between the program office and operational test agencies.

To achieve success in the development and fielding of Medical Countermeasures (MCMs) for the DoD, the acquisition workforce must identify promising candidates and coordinate test plans and reviews of test results with the US Food and Drug Administration (FDA) to ultimately achieve licensure. The FDA is chartered to protect and promote public health through the control and supervision of the food supply, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods and feed and veterinary products. For medicines and vaccines to maintain human health and cure diseases, the FDA is concerned, foremost, with human safety and secondarily with efficacy.

There are many dangerous pathogens recorded on the Select Agent list that are public health, Department of Homeland Security (DHS) and DoD concerns. There is a general lack of medical countermeasures for these pathogens. With few exceptions, these MCMs require FDA approval. Due to the threat of an attack with an aerosolized Biological Warfare Agent, a key feature of the DoD requirement is that the MCM must
be effective against an aerosol route of pathogen exposure. For other diseases, the FDA has not shown particular interest with the route of exposure, but instead has focused on the treatment of the disease itself. Conducting tests with specific routes of exposure is unfamiliar territory for the FDA. The DoD has performance attributes termed Key Performance Parameters (KPPs) and Key System Attributes (KSAs) that a product or system must meet in order to provide a measurable warfighting capability to defeat specific threats. The FDA has their own requirements, which can be described as ADMET, which stands for Absorption, Distribution, Metabolism, Excretion, and Toxicity.

The DoD acquisition structure consists of phases of development, decision points and Milestone reviews to measure progress towards meeting requirements and the associated risks, e.g. Milestone A, Milestone B, and Milestone C. The FDA has clinical trials described as Phase 1, Phase 2, Phase 3, and Phase 4. The acquisition phases and the FDA phases do not correspond to one another in any logical manner.

Some of the challenges to achieving FDA licensure for MCMs in the DoD include: the ‘Animal Rule’ to assess efficacy against diseases for which there are no naturally occurring cases and intentionally infecting subjects would be unethical; lack of natural history studies; lack of statistically powered studies; and the DoD not fully understanding what the FDA requires for MCM approval/licensure. For example, the DoD has assumed that the FDA will require information from non-human primate models when in actuality, the FDA has no such requirement. This document/presentation will attempt to elucidate the FDA and DoD processes that may be at odds and the trials and tribulations experienced during the FDA approval process of DoD lead medical countermeasures.

Bio: Dr. Phillips has B.S. and M.S. degrees in Animal Sciences and his doctorate degree in Cellular and Molecular Pathology. He is also a Certified Project Management Professional (PMP). He has more than 30 years of cumulative experience working for the Department of Defense, the Department of Homeland Security, and the Department of Health & Human Services in the areas of medical countermeasures development, biological decontamination, and reagent design and development. At the Centers for Disease Control and Prevention (CDC), Dr. Phillips developed cutting edge technologies for novel virus discovery and rapid identification of drug resistance in viruses. While at the CDC, Dr. Phillips caught the attention of United States Government Classified (USGC) clients and was recruited to run a research team focused on Biological Defense. Dr. Phillips has developed numerous pathogen detection and identification assays, including many for organisms that are listed in the National Select Agent Registry. He has spent much of his career in and around dangerous pathogens and has a unique perspective on the challenges of developing FDA approved medical countermeasures.

Dr. Phillips currently serves at Fort Belvoir as a Senior Scientist in support of the Medical Countermeasure Systems Program, Biodefense Therapeutics Division to assist in the development of medical countermeasures, specifically therapeutics and post exposure prophylaxis, leading to FDA approval/licensure. Dr. Phillips is the Co-chair for an interagency national committee on filovirus animal model development. Finally, he is the Co-chair for Task Group 4, an international consortium comprised of member countries Australia, Canada, the United Kingdom, and the United States, whose concern is the development of medical countermeasures for viral biological warfare agents.