



**U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE**



**CENTERS FOR INNOVATION IN ADVANCED DEVELOPMENT AND MANUFACTURING**  
Center established by Texas A&M University System, College Station, Texas

Centers for Innovation in Advanced Development and Manufacturing are part of a national strategy recommended in the August 2010 *Public Health Emergency Medical Countermeasures Enterprise Review*. The review found that the nation needed a nimble, flexible capacity to produce medical countermeasures rapidly for any threat, known or unknown, including a novel, naturally occurring emerging infectious disease. The Center established by Texas A&M University System (TAMUS) will meet this need in the following ways:

**CONSTRUCTING NEW AND/OR RETROFITTING EXISTING BIOPHARMACEUTICAL FACILITIES TO AUGMENT CURRENT U.S.-BASED CAPACITY**

TAMUS will design, construct, and commission a biologics development and manufacturing facility adjacent to the existing National Center for Therapeutics Manufacturing building located on the Texas A&M campus in College Station, Texas, with an expected operational opening by 2015. This facility will support core services for advanced development and manufacturing of medical countermeasures for chemical, biological, radiological, and nuclear (CBRN) threats with the added capability of developing and manufacturing live virus vaccine candidates.

Additionally, TAMUS will design, construct, and commission a commercial scale cGMP (current Good Manufacturing Practices) vaccine bulk manufacturing facility dedicated to pandemic influenza vaccine production (Pandemic Influenza Facility or PIF) located on the Texas A&M campus in College Station, Texas, with an expected operational opening by 2017. This facility will provide for large scale surge manufacturing of pandemic vaccines.

In addition, TAMUS will design, construct, and commission a fill/finish facility in collaboration with LONZA of Houston, Texas, with an expected operational opening by 2015. This facility will support the fill/finish requirements for medical countermeasures with the added capability of processing live virus vaccine candidates and can utilize lyophilization (freeze drying) technology.

TAMUS will also design, renovate, and commission an existing lab/office building located on the Texas A&M campus in College Station, Texas, with an expected operational opening by 2014. This facility will support process development and technology transfer of CBRN medical countermeasures into the Center.

**PROVIDING ADVANCED DEVELOPMENT AND MANUFACTURING CORE SERVICES**

At the request of the U.S. government, TAMUS will provide product development core services required to advance a biopharmaceutical product candidate to FDA licensure or approval using all of their experienced support resources within TAMUS and their industry partners, LONZA, GlaxoSmithKline of Marietta, Pa., and Kalon Biotherapeutics of College Station, Texas. On a day-to-day basis, the Center will support development and manufacturing of CBRN medical countermeasures.

To increase biopharmaceutical production surge capacity TAMUS, with its partner GlaxoSmithKline, is committed to manufacturing at least 50 million finished doses of pandemic influenza vaccines at the College Station facility within four months of pandemic onset with first doses available within 12 weeks.



### **DEVELOPING THE BIOTECH WORKFORCE**

TAMUS will develop an in-house comprehensive workforce development program to train personnel related to the operation of the Center.

### **ABOUT CONTRACT HHSO100201200002I**

The Center demonstrates a long-term public-private partnership committed to national health security. The contract builds on progress made by HHS to protect the public from acts of bioterrorism, pandemic influenza, and emerging infectious diseases.

This is a cost sharing contract. HHS is investing \$176,664,509 over a base period of five years. TAMUS will provide 38 percent of the overall construction costs. After that base period, HHS has the option to extend the contract up to a maximum of 25 years.

The options could be exercised with task orders for operational readiness reimbursement, development and manufacturing core services, warm base maintenance, surge manufacturing, and/or workforce development.