



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



CENTERS FOR INNOVATION IN ADVANCED DEVELOPMENT AND MANUFACTURING
Center established by Emergent Manufacturing Operations Baltimore LLC, Baltimore, Maryland

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 Emergent will meet this need in the following ways:

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

Emergent will design, construct, and commission a biologics development and manufacturing suite as an addition to its existing manufacturing facility in Baltimore, with an expected operational opening by 2015. This suite will support core services for advanced development of chemical, biological, radiological and nuclear (CBRN) medical countermeasures on a routine basis and support manufacturing of vaccines for an influenza pandemic or other threat in an emergency.

Additionally Emergent will design, renovate, and commission a pilot plant at its existing facility in Gaithersburg, Md., with an expected operational opening by 2014. This facility, along with its existing process development labs, will support core services for advanced development of CBRN medical countermeasures.

PROVIDING ADVANCED DEVELOPMENT AND MANUFACTURING CORE SERVICES

Upon HHS request, Emergent will provide product development core services required to advance a biopharmaceutical product candidate to FDA licensure or approval using the Baltimore, Gaithersburg,

Md., and Lansing, Mich., sites, and all of the experienced support resources within the organization.

INCREASING BIOPHARMACEUTICAL PRODUCTION SURGE CAPACITY

Emergent is committed to manufacture at least 50 million finished doses of pandemic influenza vaccine at the Baltimore facility within four months of pandemic onset, with the first doses available within 12 weeks.

DEVELOPING THE BIOTECH WORKFORCE

Emergent will augment its existing workforce development program to accommodate personnel related to Center operations. Emergent will work with Michigan State University, East Lansing, Mich., Kettering University, Flint, Mich., and University of Maryland, Baltimore, to train new workers in biopharmaceutical product development and manufacturing.

ABOUT THIS CONTRACT, HHSO100201200004I

The Center demonstrates a long-term commitment to national health security by partnering with the biopharmaceutical industry and academia. 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. Under the contract, HHS will invest \$163,221,997 over a base period of eight years. Emergent will provide 31 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 of CBRN products, warm base maintenance, surge manufacturing, and/or workforce development.

