



CENTERS FOR INNOVATION IN ADVANCED DEVELOPMENT AND MANUFACTURING

The U.S. Department of Health and Human Services is creating a new capability to protect Americans' health during an emergency. On June 15, 2012, HHS awarded contracts to three Centers for Innovation in Advanced Development and Manufacturing based in Maryland, North Carolina and Texas. Together the Centers will expand the nation's domestic ability to respond to bioterrorism threats, pandemic influenza, and other epidemics.

These Centers offer a new model for public-private partnerships, bringing together small biotech companies, academic institutions and large experienced pharmaceutical companies to develop and deliver medical countermeasures quickly and cost effectively to the American public.

MEETING A NATIONAL NEED

The Centers 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 the nimble, flexible capacity to produce medical countermeasures rapidly in the face of any threat, known or unknown, including a novel, previously unrecognized, naturally occurring emerging infectious disease.

These Centers incorporate innovative platform technologies that will provide a more efficient model for medical countermeasure product development relative to cost and time.

The development of safe and effective medical countermeasures against bioterrorism threats, pandemic influenza, and emerging infectious diseases has been hindered by the lack of a viable

market for such products, and the significant challenges faced by drug discovery companies that have limited late stage product development experience.

The U.S. biopharmaceutical industry as a whole has been shifting production capabilities overseas, jeopardizing the national manufacturing and development infrastructure and raising concern over where the U.S. biopharmaceutical workforce of the future will acquire the requisite skills and experience.

These Centers assist the United States in overcoming these challenges.

ABOUT THE CENTERS

The Centers will increase the nation's preparedness for bioterrorism and influenza pandemic by using modern technologies for accelerating production, improving quality, and expanding vaccine manufacturing capacity. On a day-to-day basis, the Centers will support development and manufacturing of chemical, biological, radiological and nuclear (CBRN) medical countermeasures. In an emergency, each Center is committed to producing at least 50 million finished doses of pandemic influenza vaccine within four months with the first doses available to the U.S. government for distribution to the public within 12 weeks.

These Centers will also provide the biopharmaceutical manufacturing workforce with programs that promote the development of the next generation of biopharmaceutical scientists and engineers.



ABOUT THE CENTER CONTRACTS

Through the Biomedical Advanced Research and Development Authority within the HHS Office of the Assistant Secretary for Preparedness and Response, HHS will invest in establishing the Centers through cost-sharing contracts with the Center leads. The contract awards total \$399,727,252 (U.S. government share), and all facilities and activities funded under these contracts will be in the United States. The Centers are providing 35 percent of the construction costs for the new or retrofitted facilities.

Emergent Manufacturing Operations Baltimore LLC, Baltimore, Md.

Emergent is constructing a cGMP (current Good Manufacturing Practices) manufacturing suite at its Baltimore facility and renovating a development and manufacturing pilot plant at its Gaithersburg, Md., facility.

Emergent will work with a network of partners, including Michigan State University, Kettering University in Flint, Mich., and the University of Maryland, Baltimore.

This contract is for \$163,221,997 (U.S. government share) over an eight-year base period of performance.

Novartis Vaccines and Diagnostics, Inc., of Cambridge, Mass.

Novartis is renovating a clinical trials material filling suite in their pilot plant and constructing a technical services building, at its Holly Spring, N.C., site. Novartis will partner with North Carolina State University and Duke University.

This contract is for \$59,840,746 (U.S. government share) over a four-year base period of performance.

Texas A&M University System (TAMUS) of College Station, Texas

TAMUS is constructing a biologics development and manufacturing facility adjacent to its existing NCTM facility; constructing a commercial scale vaccine manufacturing facility; constructing a fill/finish facility with its subcontractor, LONZA of Houston, Texas; renovating the NCTM facility, and renovating a development lab/office facility, all on the Texas A&M campus.

In addition, TAMUS will collaborate with GlaxoSmithKline of Marietta, Pa., and Kalon Biotherapeutics of College Station, Texas.

The contract is for \$176,664,509 (U.S. government cost share) over a five -year base period of performance.

These contract awards were made under Solicitation HHS 11-100-SOL-00011 "Centers for Innovation in Advanced Development and Manufacturing" released in March 2011.