Overview of building sustainable public health manufacturing capabilities from BARDA Industry Day (BID) 2023



On November 13 and 14, BARDA (Biomedical Advanced Research and Development Authority <u>https://medicalcountermeasures.gov/</u>) held its annual conference highlighting successful industry partnerships and provided insight into future interagency priorities to support product development to address public health threats. BARDA and their interagency partners provide nondilutive funding to support advanced research and development of medical countermeasures (MCMs).



BDO's Biodefense & Life Science Product Development and Government Contracting team will be providing a series of detailed insights from the conference over the coming weeks filtered through our experience with BARDA.

Topics will include:

- New partnership opportunities and new mechanisms for engagement with BARDA and its interagency partners.
- Recent changes to the Broad Agency Announcements (BAA and EZ BAA), the primary mechanism whereby BARDA provides non-dilutive funding to its industry partners.
- A synopsis of the strategic priority of developing threat agnostic MCMs.

Here we will take a quick glimpse at ASPR (Administration for Strategic Preparedness and Response) and BARDA's programs to enhance the nation's biomedical industrial base and supply chain capacity. The COVID-19 pandemic brought to light the inadequate availability of essential medical needs. In response to these deficiencies, the USG/ HHS (Health and Human Services) (Health and Human Services) is expanding the public health industrial base through innovative solutions.

The new office of Industrial Based Management and Supply Chain (IBMSC) was instituted to build a diverse, agile public health supply chain and sustain long-term U.S. manufacturing capabilities by investing in medical product Industrial Base Expansion (IBx) capacities that can enable USG/ASPR to respond to public health emergencies. Prior to the COVID-19 pandemic, there was a limited public health industrial base to address pandemic needs and was dependent on a just-in-time manufacturing paradigm.

The IBMSC Office, a permanent capability within ASPR and a sister office to BARDA, will be focused on the following key areas: Defense Production Act & Emergency Response Authorization; advanced manufacturing technologies, supply chain optimization, personal protective equipment (PPE) and durable medical equipment and testing & diagnostics.

IBMSC coordinates the activities related to medical product industrial base expansion and sustainment by:

- 1. Promoting multi-functional capabilities.
- 2. Establishing innovative domestic industrial base programs and enduring sustainable partnerships across the MCM ecosystem.
- 3. Sustaining critical medical countermeasures and public health supply advancement and capacity.

The IBMSC along with BARDA's Pharmaceutical Countermeasures Infrastructure (PCI) and Detection, Diagnostics, and Devices Infrastructure (DDDI) divisions will work to address shortages of medical supplies, including personal protective equipment (PPE), durable medical equipment and other ancillary devices & equipment. While the IBMSC focuses on the entire public health and medical industrial base, the BARDA PCI division will focus on expanding the U.S. capacity in medical countermeasure manufacturing (i.e., vaccines, and therapeutics) and DDDI on expanding the U.S. capacity for developing diagnostic tests and increasing the rapid transfer to manufacturing capabilities for high-priority biothreats.

In addition, BARDA's BioMAP consortium was established to create and maintain cooperative partnerships with members to expand the industrial and manufacturing base for MCMs to include the required capabilities, flexibility, and strategies to secure needed medical supplies to meet the nation's public health preparedness and response requirements.

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