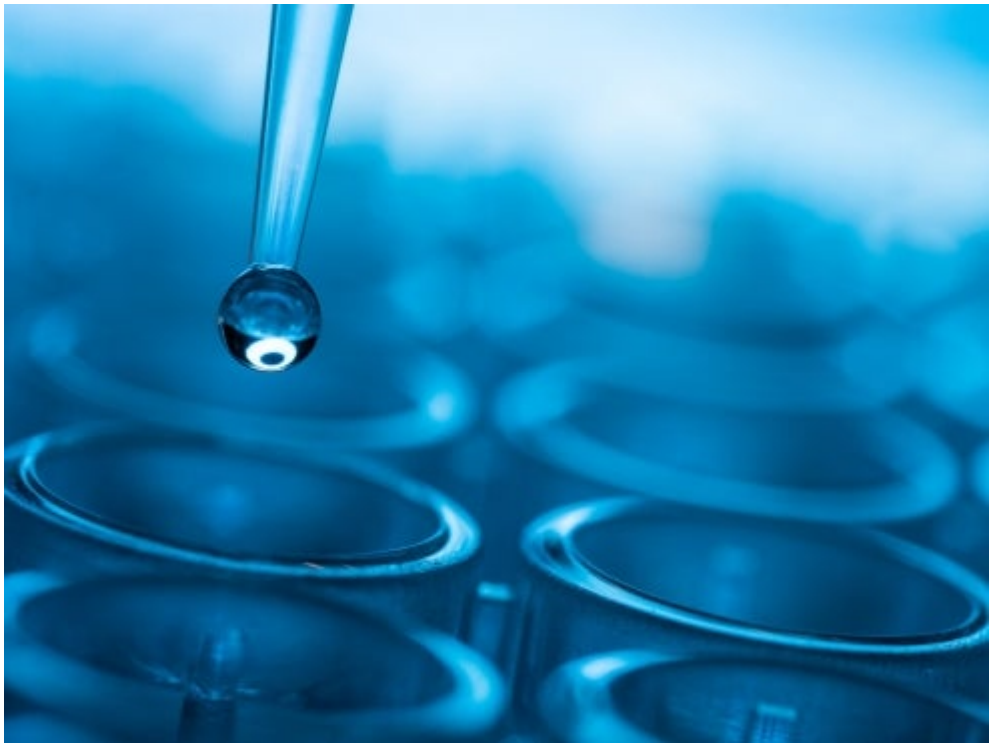
Updates
December 22, 2023
BARDA Shares Details About Innovative BioMaP Consortium at BARDA Industry Day 2023



The Biomedical Advanced Research and Development Authority (BARDA)[1] held its first in-person BARDA Industry Day (BID) since the beginning of the COVID-19 pandemic in Washington, D.C., on November 13-14, 2023.

BID is an annual event that brings together representatives of the life sciences and biodefense industry with BARDA and other agencies to discuss BARDA's processes for partnering with industry and its priorities for the research and development (R&D) of medical countermeasures (MCMs). BARDA supports R&D for MCMs to counter threats in areas such as Chemical, Biological, Radiological, and Nuclear (CBRN), Pandemic Influenza, Antimicrobial Resistance, and Emerging Infectious Diseases (EID). Since its 2006 inception, BARDA has spent billons of dollars on projects that have led to U.S. Food and Drug Administration (FDA) approval, licensure, or clearances of 84 MCMs, and its Fiscal Year (FY) 2024 budget is expected to exceed $1 billion. Life science and biodefense companies often look to BARDA for nondilutive funding options as an alternative to private investors who would obtain equity in return for their investment.

As would be expected, the lessons of the COVID-19 pandemic were at the forefront of discussions during the two-day event. BARDA covered the successes of government-industry partnerships in the rapid development, manufacture, and distribution of responsive vaccines to the public, as well as the COVID-19 pandemic's revelation of weaknesses throughout the MCM supply chain. BARDA specifically identified the continued need to have facilities prepared to engage in critical tasks such as vial manufacture, technology transfer, assay development, formulation, fill/finish, and vaccine lot release.

One tool BARDA is implementing to address these supply chain concerns is the rollout of a new consortium: the Biopharmaceutical Manufacturing Preparedness-Consortium (BioMaP-Consortium or BioMaP-C). The consortium will seek to build on the lessons of the Centers for Innovation in Advanced Development and Manufacturing (CIADM), the Fill-Finish Manufacturing Network (FFMN), and existing consortia, such as the U.S. Department of Defense's (DOD) Medical CBRN Consortium (MCDC). As with previous programs, the

BioMaP-Consortium is intended to enhance preparedness by funding certain readiness activities to reduce lead times in the event of another crisis. The BioMaP-Consortium model will allow it to function as a liaison between the U.S. government and its industry partners.

Key aspects of the BioMaP-Consortium include the following:

- **The Consortium Model.** Interested companies must join the BioMap-Consortium to be eligible to compete for awards under requests for proposals (RFPs) or requests for prototype projects (RPPs) issued by BARDA through the BioMap-Consortium. The consortium model also encourages members to communicate with each other to find areas where industries can partner.
- **The Consortium Manager.** Advanced Technologies International (ATI) has been designated the BioMap-Consortium's Consortium Manager (CM). ATI manages numerous other consortia, including MCDC. As the CM, ATI will issue RFPs or RPPs and manage awards made under the BioMaP-Consortium.
- **Other Transaction Authority (OTA) Agreements.** Awards to BioMap-Consortium members will be in the form of OTA Agreements, which are not subject to the Federal Acquisition Regulation (FAR) or grant regulations. The use of OTAs is intended to provide a more streamlined, faster approach to making awards, and OTAs typically provide more flexibility in the negotiation of key terms such as intellectual property (IP). The use of OTAs may also permit BARDA to award follow-on production awards to prototype project awardee on a noncompetitive basis in certain circumstances.
- **Regular Exercises.** BARDA also described plans to establish a program under BioMaP-C to engage industry to perform exercises, likely on an annual basis, to ensure supply chain readiness and a warm base. Under this "BioMaP-X" program, BARDA contemplates conducting national exercises with testable activities for industry to perform. Awardees of contracts under HHS's Industrial Base Expansion (IBx) program may also be eligible to participate in these exercises.
- **Workforce Development.** BARDA noted that workforce training impeded industry from ramping up production of COVID-19 vaccines and necessary supplies and materials. To respond to this gap, BARDA is establishing a program dubbed "BioMaP-W," under which it contemplates funding workforce development activities. These may entail engaging universities to develop curriculums and establishing standardized certification procedures to ensure, for example, that industry can rely on a degree or certificate issued in one part of the country to ensure that a person is the right fit for a job available in another part of the country.

BARDA added that plans for an inaugural "BioMaP Industry Day" to be held in February or March of 2024 are underway, with the first RFPs or RPPs expected to be issued sometime in FY 2024. To date, the BioMaP-Consortium website is a work in progress, but companies interested in becoming a member should monitor the site for updates. As noted above, companies interested in seeking nondilutive government funding must join the BioMaP-Consortium to be eligible for awards under this program.

For more information on BARDA's solicitation and award process, including under the BioMaP-C programs discussed above, please contact experienced counsel.

Endnotes

[1] BARDA is a component of the Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS).

Authors

Explore more in

Government Contracts Life Sciences & Healthcare

Related insights

Update

The FY 2025 National Defense Authorization Act: What's New for Defense Contractors

Update

January Tip of the Month: Trump Executive Orders Challenge DEI Programs