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February 20, 2024

BARDA BioMaP-Consortium Up and Running



In a [previous Update](#), we reported on the Biomedical Advanced Research and Development Authority's (BARDA)[\[1\]](#) plans to implement the new Biopharmaceutical Manufacturing Preparedness-Consortium (BioMaP-Consortium or Consortium), which was created to ensure the nation's preparedness in the face of a future pandemic or other biomedical threat.

These plans are now underway, with the first BioMaP-Consortium General Membership Meeting scheduled to take place in Washington, D.C., on February 21, 2024.

The Consortium was established in September 2023 when BARDA awarded Advanced Technology International (ATI) an Other Transaction Authority (OTA) agreement allowing ATI to act as the Consortium management firm. Under the OTA, Consortium members will be eligible to compete for awards of individual Project Agreements under specified Key Domain Areas.

The [website for the Consortium](#) lists 90 current members and counting. Members include industry partners, academia, and nonprofit organizations. The website also contains an application for membership, which requires prospective BioMaP-Consortium members to agree to the Articles of Collaboration and make a "good faith effort" to execute the BioMaP Base Agreement upon acceptance into the Consortium. A copy of the Base Agreement is available to prospective members upon request.

The application and Articles of Collaboration also require representations that the prospective member will maintain a commitment to domestic U.S. investment in work under the Consortium, such as infrastructure, manufacturing, and technology development. Although international sourcing may be acceptable in some cases (not explicitly identified in the application or Articles of Collaboration), "commitment to U.S. domestic supply sourcing to the maximum practical extent is desired." A prospective member must also represent that it is not "barred or suspended" from participating in government funding activities, that it will not be included in the U.S. Department of Treasury or Department of Commerce's prohibited source lists (nor utilize such sources under

work performed for the Consortium), and that it will comply with antitrust laws and export control laws (such as the Arms Export Control Act (AECA), the International Traffic in Arms Regulations (ITAR), and the Export Administration Regulations (EAR)).

Importantly, the application also requires the prospective member to demonstrate that it is "capable of making a contribution in BioMaP technologies and other relevant subject, technology, and capability domains" to support the U.S. government. The Base Agreement currently lists three "Technical Key Domain Areas": (1) Industrial Base Expansion of biomanufacturing supply chain, (2) biomanufacturing capacity expansion and reservation, and (3) advanced biomanufacturing technologies. The government may revise these Key Domain Areas, and updates will be posted on the BioMaP-Consortium website.

An early indication of BARDA's priorities can be seen in the form of two draft Statements of Objectives (SOOs) for upcoming solicitations, available for viewing on the Consortium's website. The first, issued on January 24, 2024, is titled, "Production of Drug Substances and Drug Product at Commercial Scale," with the objective of commercializing production of up to three drug substances at population scale within a two-year period. The second, issued on February 7, 2024, is titled, "Sterilization Capacity for Vaccines and Therapeutics." This SOO contemplates awards to up to three industry partners to establish or expand domestic sterilization capacity by investing in up to three sterilization lines using X-ray or dual E-beam/X-ray technologies. This SOO also includes a requirement for awardee(s) to provide priority access and preferred "lowest commercial" pricing to government customers for the use of the sterilization capability created under the award. Requests for Project Proposals (RPPs) will be issued once BARDA has had the opportunity to review comments and questions from industry.

OTAs and Consortia in general—and the BioMaP-Consortium in particular—are a continuously evolving area of government contracting. Perkins Coie's Government Contracts team advises on legal issues related to OTAs and Consortia participation, including the negotiation of—and compliance with—resulting Project Agreements.

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).

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