

U.S. Army Contracting Command – Joint COVID Response Division (ACC-JCRD)
Joint Program Executive Office - Chemical Biological Radiological Nuclear Defense (JPEO-CBRND)
Health and Human Services (HHS)
Biomedical Advanced Research and Development Authority (BARDA)
Medical Countermeasures (MCM) Commercial Solutions Opening (CSO)
Solicitation Number: W911QY-20-S-C001
Area of Interest (AOI) Number A004: SARS-CoV-2 Industrial Base Expansion (IBX)
Amendment 0001, Date: 17 December 2021

1. AoI Background:

In December 2019, a novel (new) coronavirus known as SARS-CoV-2 (“the virus”) was first detected in Wuhan, Hubei Province, People’s Republic of China, causing outbreaks of the coronavirus disease COVID-19 that has now spread globally. The Secretary of Health and Human Services (HHS) declared a public health emergency on January 31, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19. On March 1, 2020, the President of the United States, pursuant to sections 01 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.) and consistent with section 1135 of the Social Security Act (SSA), as amended (42 U.S.C. 1320b-5), proclaimed that the COVID-19 outbreak in the United States constitutes a national emergency.

Under the US Government’s COVID-19 Response Mission, HHS is leading a whole of nation effort with the primary goal to execute on a well-defined portfolio of COVID-19 medical countermeasure (MCM) candidates to maximize availability of safe and effective vaccines, therapeutics, and diagnostics as fast as possible for mass distribution.

The current COVID-19 pandemic response exposed the limited availability of the consumables (and the raw materials to make them) that are required to manufacture COVID-19 MCMs and the fragility of the global supply chain. In many cases, the majority of key consumables are manufactured overseas and are subject to greater global demand pressure, which limits access to the consumables for US manufacturers and threatens domestic supply of COVID-19 MCMs. Increasing the availability of these consumables, including the raw materials required to make them, within the continental US is critical to national security and ongoing domestic manufacturing of COVID-19 vaccines, therapeutics, and diagnostics. Because the enhanced consumable supply targeted by this Area of Interest facilitates manufacturing of MCMs against *other* potential pathogens, enhancing domestic production of these MCM “precursors” has the added benefit of positioning the US for a more effective public health response to future pandemics. Accordingly, BARDA has an Area of Interest (AoI) for innovative commercial products, technologies, or services that establish, expand, and/or accelerate domestic supply of consumables and domestic manufacturing capabilities related to MCMs.

2. AoI Objective:

To decrease US reliance on the fragile global supply chain for MCMs and increase US preparedness for COVID-19 and future pandemics, the government requires innovative¹ commercial products, technologies, or services that establish, expand, and/or accelerate domestic supply of consumables and domestic manufacturing capabilities related to MCMs, using novel technologies, processes, methods, or applications of commercial technologies for defense purposes, agile development

¹ “Innovative” means any technology, process, or method, including research and development that is new as of the date of submission of a proposal, or any application that is new as of the date of submission of a proposal of a technology, process, or method existing as of such date.

activity, creation, design, development, demonstration of technical or operational utility, or combinations of the foregoing as follows:

- Bioprocess consumable products, including but not limited to:
 - Single Use Assemblies
 - Bioreactor Bags
 - Braided hose
 - Buffers
 - Cell culture media
 - Filtration media, dry and liquid
 - Ion exchangers
 - Reagents
- Filtration devices
- Delivery devices for vaccines, therapeutics, and other medications
- Vials suitable for vaccine products, including but not limited to borosilicate glass/hybrids
- Fill/finish production
- Raw materials to support enablers and consumable products, including but not limited to:
 - Lipids including, but not limited to LNP lipids and high purity excipients
 - Cholesterol
 - Ribonucleotide triphosphates (NTPs)
 - Polypropylene
 - Chromatography Resins
- Domestic capacity of cold storage suitable for pharmaceutical products
- Technologies to monitor, expedite, improve, and sustain the supply chain from raw material to finished pharmaceutical product.
- Other domestic consumables or domestic manufacturing capabilities related to MCMs for COVID-19 and future pandemics. This list is intended to be illustrative, not exhaustive.

Submitted responses to establish, expand, and/or accelerate domestic supply of consumables and domestic manufacturing capabilities related to the aforementioned products should address:

1. A description of the requirement, capability gap, or potential technological advancement with respect to which the innovative commercial item, technology, or service acquired provides a solution or a potential new capability.
2. The location of the capacity expansion within the continental United States and its Territories, and whether the company is based domestically or overseas.
3. An innovative capacity expansion plan to enable execution or acceleration of operations within approximately 36 months or less from date of award.

3. AoI Constraints:

- a. Offeror(s) selected to receive an award will be required to be registered in the System for Award Maintenance (SAM.gov, <https://www.sam.gov/>). Companies will be ineligible for an award if not registered in SAM at the time your proposal is submitted. Additionally, verify that you are registered to receive contracts (not just grants) and that your address matches your proposal and SAM.
- b. When registering in SAM.gov, be sure to select ‘YES’ to the question ‘Do you wish to bid on contracts?’ in order to be able to compete for CSO. If you are only registered to compete for grants, you may be ineligible for award.

- c. The government is working to move expeditiously to execute contract(s), therefore it is extremely important that all companies double check your CAGE codes and Unique Entity Identifier (currently DUNS) numbers to ensure they are accurate. If they are not accurate at the time of submission, you may be ineligible for award.
- d. The government reserves the right to request clarifying information or not to request clarifying information after receipt and evaluation of proposals.
- e. The government reserves the right to enter into discussions or not to enter into discussions.
- f. The government intends to issue Fixed Price FAR Part 12 type contract(s) and/or Other Transaction Authority agreement(s) under 10 USC 2371b. However, the government may elect to negotiate any type of instrument permitted by the CSO solicitation.

4. AoI Solution Brief Submission Requirements:

Solution Briefs must not exceed five (5) single-sided written pages using 12-point font or, alternatively, Solution Briefs may take the form of briefing slides which should not exceed fifteen (15) slides. Solution Briefs must be submitted no later than 0600 AM Eastern on 17 January, 2022. The government reserves the right to evaluate or not to evaluate Solution Briefs received after the submission deadline. All submissions must be sent to the points of contact (POC) listed in the POC section of this AoI. Due to the urgent nature surrounding the Federal COVID-19 Response (FCR) Mission CSO, the government does not intend to enter into CSO Phase 2 procedures but reserves the right to do so based on the evaluation results.

Solution Briefs must include the following:

- a. Company Name, Title, Date, Point of Contact Name, E-Mail Address, Phone, Address, CAGE code, and DUNS number. Specifically identify the AoI for which the Solution Brief is submitted.
- b. Executive Summary: Provide an executive summary of the technology. (This is included in the 5 written pages limit).
- c. Technology Innovations: Show and/or describe how your proposed solution or potential new capabilities fulfill innovative, commercial products, commercial technologies and services or adaptations/modifications of existing commercial product technologies and services to manufacture products used to combat the current COVID-19 pandemic, as well as address future pandemics or medical emergencies. CSO can be used to obtain solutions or potential new capabilities to close capability gaps or provide potential technological advancements. Describe the unique aspects of your technology and the proposed work as it relates to the AoI. Identify whether the effort includes the pilot or demonstration of existing commercial technology (identified as commercially ready and viable technology), or the development of technology for potential defense application. If development or adaptation is proposed, identify a suggested path to mature the technology. Identify aspects of your proposal, to include date and software, which may be considered proprietary.
- d. Rough Order of Magnitude (ROM) pricing.

5. AoI Request for Commercial Solutions Proposal (CSP) Submission Requirements:

Proposals must include separate technical and price volumes. All submission are limited to 10 pages (12-

point font) per volume not including the cover page and table of contents. Based on the government's market research and previous efforts, the government anticipates selecting multiple offerors to submit proposals as a result of Solution Brief evaluations. The government reserves the right to request proposals from "all, some, or none" of the offerors who submitted Solution Briefs based on the evaluation and individual merits.

If an offeror(s) receives a request to submit a proposal from the government, proposals must be submitted no later than the date and time identified in the request for proposal. The government reserves the right to or not to evaluate proposals received after the submission deadline. All proposal submissions must be sent via e-mail, with subject line stating "(Insert Company Name) W911QY-20-S-C001 AoI #A004" to the POCs listed in the POC section of this AoI. Due the urgent nature surrounding the FCR Mission, the government may execute awards against this AoI at any time after the receipt of proposals.

Proposals must include the following:

- a. A technical volume that includes a detailed statement of work indicating how each aspect of the objectives are to be accomplished. CSP's technical volumes must be in as much detail as considered necessary to fully explain the proposed technical approach or method including all assumptions utilized to develop the reservation plan and associated costs. The technical volume must reflect a clear understanding of the nature of the work being undertaken. The technical volume must include information on how the project will be organized, staffed, and managed, including a monthly breakdown of capacity available. Information must be provided that demonstrates an understanding and management of important events or tasks. The technical volume must include a list of suggested deliverables and deliverable dates.
- b. A price volume that includes sufficient information to allow the government to determine the reasonableness of the proposed cost or price of the work. If a price proposal includes a time and materials contract line item, the proposal must include labor categories and corresponding number of direct labor hours; fixed hourly rates that include wages, overhead, general and administrative expenses, and profit; and actual costs for materials.

6. Points of contact:

Contracting Officer: Julia Wertley-Rotenberry; Julia.b.wertleyrotenberry.civ@mail.mil
Procurement Analyst: George Hunt; george.r.hunt6.civ@mail.mil

7. General Note:

This AoI does not commit the government to pay the costs associated with your proposal preparation or transmission. The Contracting Officer is the only individual who can legally commit the government to the expenditure of public funds on any resultant contract.