Biomedical Advanced Research and Development Authority (BARDA)
Request for Project Proposals (RPP) for

"Manufacturing Optimization for Filovirus Monoclonal Antibodies"

RPP #: 24-07-mAbs

Issued: June 24, 2024

Due: July 22, 2024 1PM Eastern

Biomedical Advanced Research Development Authority (BARDA) Contracts Management & Acquisition (CMA)
400 7th Street, SW, Washington, DC 20024

MedicalCountermeasures.gov

Contents

1 Executive Summary

1.1 Biopharmaceutical Manufacturing Preparedness Consortium

The Biopharmaceutical Manufacturing Preparedness Consortium (BioMaP-Consortium) is a multiple-purpose acquisition vehicle comprised of industry partners across the drug and vaccine manufacturing supply chain, including, but not limited to, drug substance manufacturers of required raw materials and consumables, suppliers of fill-finish services, and developers of innovative manufacturing technologies.

The BioMaP-Consortium brings together pharmaceutical, medical, academic, and scientific organizations working toward successful development and delivery of medical countermeasure materials and products. Cooperative partnerships are maintained to ensure that there are adequate manufacturing capabilities to provide and make available requisite products and materials, so that countermeasures and therapies can be delivered to civilian populations addressing threats to the nation's public health or other security interests.

The BioMaP-Consortium is also focused on expanding the United States' domestic industrial and manufacturing base for medical countermeasures.

Advanced Technology International (ATI) has been awarded an Other Transaction Agreement (OTA) by BARDA to serve as the Consortium Management Firm (CMF) for the BioMaP-Consortium.

BioMaP-Consortium openly recruits members to join a broad and diverse biomedical consortium that includes representatives from all organizations who work within stated key domain areas. For more information on the BioMaP-Consortium mission, refer to the BioMaP-Consortium website at BioMaP-Consortium.org. For entities interested in joining the BioMaP-Consortium and responding to this solicitation, please visit www.BioMaP-Consortium.org/how-to-join.

1.2 Purpose

The Biomedical Advanced Research and Development Authority (BARDA) works with its industry partners to develop vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies such as chemical, biological, radiological, and nuclear (CBRN) accidents, incidents, and attacks; pandemic influenza (PI), and emerging infectious diseases (EID). As a part of this mission, BARDA seeks to support cost-effective countermeasures that can fill the gaps in our national preparedness. In 2006, the Department of Homeland Security (DHS) determined that Ebola virus and Marburg virus are material threats to national health security. The threat of filovirus agents being used as biological/bioterror weapons led the DHS to issue a Material Threat Determination based on its Material Threat Assessment for Ebola virus and Marburg virus. Medical countermeasures (MCM) that can be deployed in the event of a filovirus outbreak are a crucial component to the United States Government's (USG's) outbreak response plan. BARDA is seeking to augment the USG's response capabilities with therapeutics targeting filovirus disease caused by Ebola virus (EBOV), Marburg virus (MARV), or Sudan virus (SUDV). There are currently two US Food and Drug Administration (FDA) approved therapeutics for treatment of Ebola Virus Disease (EVD), Inmazeb and Ebanga, both of which are monoclonal antibodies or antibody cocktails. There are no therapeutics approved for the treatment of patients infected with SUDV or MARV.

As a part of BARDA's commitment to develop therapeutic countermeasures against filovirus disease, BARDA is interested in advancing manufacturing development for a monoclonal antibody (mAb)

cocktail composed of two mAbs, 1C3 and 1C11, which was developed by Emory Vaccine Center and Department of Microbiology and Immunology (Emory), who holds the intellectual property (IP) for the product (Milligan et al., 2022). These mAbs were isolated from survivors of filovirus infection and target the glycoprotein (GP) trimer to potently neutralize diverse ebolaviruses; a 1C3/1C11 cocktail protected cynomolgus macaques from SUDV infection and rhesus monkeys from EBOV infection (Milligan et al., 2022). While the final product use and formulation will be dependent upon the outcomes of future efficacy studies, it is anticipated that the product will be administered intravenously at concentrations up to 100 mg/kg as a therapeutic. BARDA investment in the development of these mAbs is aimed at identifying a high yield manufacturing process that will subsequently enable development of a cost-effective therapeutic product.

Strategic oversight for the Project Agreement(s) supported by this RPP will be provided by BARDA.

2 Administrative Overview

2.1 Request for Project Proposals (RPP)

Each response submitted to this RPP shall contain a Technical Proposal and a Cost Proposal, as well as additional documents described in Section 3 of this request. White papers are not required for this RPP.

The Government reserves the right to modify this process if it is determined to be in its best interest at any time during the solicitation process. In such instance, the CMF would provide additional and/or revised requests for information, clarifications, presentations, etc. and include any modified evaluation criteria to be used for the remaining portion of the selection process, if applicable.

2.2 RPP Approach

It is expected that there will be a total of one or more qualified respondents to fulfill the technical requirements. If an optimal team is not identified, then BARDA may direct the BioMaP-Consortium CMF to make multiple, individual awards to Offeror(s) to accomplish subset(s) of the key tasks. The Government also reserves the right to make one, multiple, or no awards as a result of this RPP.

This RPP is issued under OTA Number 75A50123D00003 between the Government and the CMF. The same provisions are contained in the BioMaP-Consortium Base Agreement. BioMaP-Consortium members typically execute the BioMaP-Consortium Base Agreement with the CMF upon entering the consortium. Each proposal selected for award under this RPP will be executed as a Project Agreement funded under OTA Number 75A50123D00003 and governed by the Base Agreement terms and conditions, unless otherwise noted in the Project Agreement. In the event of conflict or inconsistency among the following documents, the order of precedence 1) Project Agreement 2) BioMaP Base Agreement.

At the time of the submission, Offerors must certify on the cover page of their Proposal that, if selected for award, they will abide by the terms and conditions of the latest version of the Base Agreement.

2.3 Period of Performance

Offeror should plan for the period of performance to begin during Quarter 4 of Government Fiscal Year 2024. Government reserves the right to change the proposed period of performance start date through negotiations via the CMF and prior to issuing a Project Agreement.

The anticipated period of performance is detailed in the table below. Specific dates are to be negotiated. It is anticipated that the primary place of performance will be the Offeror's facilities, however this aspect can be negotiated as part of each Offeror's submission.

Period	Description	Anticipated Period of Performance
Base	Cell Line Generation and Initial Process Development	09/01/2024 – 12/1/2025
Option 1	Expression and Manufacturing Optimization	10/1/2025 – 12/1/2027
Option 2	Technology Transfer	12/01/2026 – 09/30/2029

2.4 Estimated Funding

The funding estimated for this RPP is approximate and subject to realignment. Funding of proposals received in response to this RPP is contingent upon the availability of federal funds for this program. The Government anticipates awarding 3-5 agreements from this solicitation. However, the Government is under no obligation to make any awards and will not reimburse Offeror proposal preparation expenses.

2.5 Proprietary Information

The BioMaP-Consortium CMF will oversee submission of proposals submitted in response to this RPP. The BioMaP-Consortium CMF shall take the necessary steps to protect all proprietary information and shall not use such proprietary information for purposes other than proposal evaluation and agreement administration. Offerors should mark all Confidential or Proprietary Information as such. An Offeror's submission of a proposal under this RPP indicates concurrence with the aforementioned CMF responsibilities.

2.6 Minimum Criteria

In order to respond to this RPP, Offerors must show evidence they satisfy the following **minimum eligibility criteria**:

1. Offerors submitting proposals must be BioMaP-Consortium members when the proposal is submitted. As mentioned above, prospective Offerors may join the consortium at www.BioMaP-Consortium.org/how-to-join.
2. Strategy proposed to tech transfer the manufacturing process in an option period.

Proposals not meeting the minimum criteria as detailed above may be removed from consideration, no further evaluation will be performed, and feedback will not be provided to these Offerors.

2.7 Special Considerations

The following are special considerations in the evaluation and/or negotiation process; however, they are not required in order to be eligible to receive an award under this RPP.

- **United States Industrial Base.** Consistent with BioMaP-Consortium's focus to expand the United States' domestic industrial and manufacturing base for medical countermeasures, proposals are expected to be focused on United States investments, and all work and/or capacity expansion shall be focused on US soil (including United States territories) to satisfy domestic requirements. This does not preclude offers from non-US companies, provided they meet the minimum eligibility criteria and work supports US domestic purposes, nor does it preclude non-US companies from utilizing non-US employees to provide subject matter expertise.
- **Small Business Utilization.** Small Business utilization is encouraged to the maximum extent practicable as a means to build an agile and resilient industrial and manufacturing base, which ultimately supports economic growth and development in the United States.

2.8 Cost Sharing

Cost sharing is defined as the resources expended by the Project Awardee on the proposed Statement of Work (SOW). The extent of cost sharing is a consideration in the evaluation of proposals.

However, this is not required in order to be eligible to receive an award under this RPP. If cost sharing is proposed, then the Offeror shall state the amount that is being proposed and whether the cost sharing is a cash contribution or an in-kind contribution; provide a description of each cost share item proposed; the proposed dollar amount for each cost share item proposed; and the valuation technique used (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips). Cost sharing is encouraged, if possible, as it leads to stronger leveraging of Government-contractor collaboration. For more information regarding cost share, please see Attachment B.

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2.9 Joint Material Transfer Agreement

As a condition of award, awardee(s) will be required to successfully negotiate and execute a Joint Material Transfer Agreement (MTA) with BARDA and Emory University (the Intellectual Property (IP) holder) in order to obtain the mAb sequences and comparability material. Joint MTA must be executed within 120 days after award. This condition is non-negotiable. Under no circumstances will negotiations of the Joint MTA be permitted to delay contract performance. Awardee agrees to negotiate in good faith and make best efforts to execute the MTA in a timely manner. To expedite MTA negotiations, the draft Joint MTA, which has been agreed upon by USG and Emory, is attached as Attachment D.

Product-specific information to be made available upon establishment of Material Transfer Agreement with IP Holder:

- Up to 10 mg of each antibody, to serve as a process control
- Antibody sequence information and all available information on manufacturing process to date

Successful execution of a Joint Material Transfer Agreement with BARDA and Emory to obtain the mAb sequences and access to comparability material is required for the performance of the anticipated award. Failure to fully execute the Joint MTA within 120 days after award **may result in termination of the award.**

2.10 Intellectual Property and Data Rights

Intellectual Property (IP) rights for BioMaP-Consortium Project Agreements are defined in the terms of the BioMaP-Consortium Base Agreement. The BioMaP-Consortium CMF reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the Government and the Project Awardees during the entire award period.

The BioMaP-Consortium Base Agreement contains general provisions regarding Data Rights. For this specific RPP, it is anticipated that anything delivered under this proposed effort would be delivered to the Government with government purpose rights, unless otherwise specified in the proposal and agreed to by the Government. All proposed data rights are subject to Government review and approval. Rights in technical data agreed to by the Government will be incorporated into the Project Agreement. The Government does not anticipate requesting rights to the mAb sequences. However, the Government does require any and all technical rights needed to facilitate transfer of Awardee's manufacturing process including, but not limited to, all technical reports, data and resources required to ensure a successful transfer.

Neither BARDA nor the Offeror will obtain IP rights to the 1C3 or 1C11 monoclonal antibodies developed by Emory University under this agreement. The Offeror will be required to enter into a Material Transfer Agreement with Emory University to obtain the 1C3 or 1C11 data package required to complete the technical requirements detailed herein. A proposed draft Material Transfer Agreement is included as Attachment D for consideration; and may be amended upon mutual agreement of the parties.

The Offeror shall complete the table provided in Section 9 of the Technical Proposal for any items to be furnished to the Government with restrictions. An example is provided below.

Assertion #	Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights	Name of Organization Asserting Restrictions

2.11 Regulatory Terms

Project Awardees must be expected to comply with the relevant FDA, DEA, USP and cGMP regulatory practices.

Additional information on the applicable regulatory terms is provided in the BioMaP-Consortium Base Agreement. These restrictions include mandatory government review and reporting processes that may impact the Offeror's schedule.

2.12 Special Requirements

Offerors must be prepared to comply with the following special requirements:

- **Salary Rate Limitation**. Payment of the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II is an unallowable cost under the BioMaP-Consortium OTA. See the BioMaP-Consortium Base Agreement for further details.
- **Expansion.** In accordance with the BioMaP-Consortium Base Agreement, any work for capacity expansion shall be executed within the continental United States and its Territories, whether the company is based domestically or overseas.
- **Purchases**. Equipment purchases are not allowed under this agreement.
- **SAM.gov Registration.** Offerors are required to be fully registered in SAM.gov prior to award of a Project Agreement.

2.13 Security Requirements

See Attachment E for Administration for Strategic Preparedness and Response (ASPR) Deliverables and Security Requirements that will be required for any resulting projects. BioMaP-Consortium members should be prepared to include the applicable deliverables and security requirements identified in the attachment.

2.14 Preparation Cost

The cost of preparing submissions in response to this RPP is not considered a direct charge to any resulting award or any other contract.

3 Proposals

3.1 Question and Answer Period

Key dates related to this RPP.

Date	**Event**
24 Jun 2024	RPP released
8 Jul 2024 12 PM ET	Questions due from potential Offerors to be answered during live Q&A
12 Jul 2024	Live Q&A with Government responses to Q&A Submitted
22 Jul 2024 1PM ET	Proposals due

3.2 Proposal General Instructions

Offerors who submit proposals in response to this RPP must submit by the date on the cover page of this RPP. Proposals received after the time and date specified may not be evaluated.

The proposal format provided in this RPP is mandatory and shall reference this RPP number. Offerors are encouraged to contact the Point of Contact (POC) identified herein up until the Proposal submission date/time to clarify requirements.

The Government will evaluate proposals submitted and will select the proposal(s) that best meets their current technology priorities using the criteria in Section 5.

All eligible Offerors shall submit proposals for evaluation according to the criteria set forth in this RPP. Offerors are advised that only ATI is legally authorized to contractually bind or otherwise commit funding for selected Project Awards as result of this RPP.

3.3 Proposal Submission

Proposals must be submitted online via BIDS at https://ati2.acqcenter.com/BIOMAP/BIDS.NSF/Start?ReadForm. Submissions will not be accepted by any other means. Offerors are strongly encouraged to register as a new user well in advance of the Proposals submission deadline.

The Home Page will also contain contact information for assistance with any problems associated with the electronic submission process. Also, you may reach out to the BioMaP-Consortium CMF.

Neither the Government nor ATI can make allowances/exceptions for submission problems encountered by the offeror using system-to-system interfaces with BIDS. If the offeror receives errors and fails to upload the full submission prior to the submission deadline, the submission will not be accepted.

Files submitted in BIDS must be print-capable and without a password required. Filenames must contain the appropriate filename extension (.docx, .doc, .pptx, .ppt or .pdf). Filenames should not contain special characters. Apple users must ensure the entire filename and path are free of spaces and special characters.

Offerors will also be required to provide general submission information in BIDS such as point of contact information.

Receipt confirmations will be e-mailed upon submission of proposals and will include the unique reference number. Submissions can be made in advance of the deadline and updated (replace any of the files) up until the submission deadline.

3.4 Submission Format

Proposals shall reference this BioMap solicitation number. Each document below is mandatory and must each be submitted as separate files and shall remain valid for two years unless otherwise specified by the Offeror in the proposal. Offerors are encouraged to contact the BioMaP-Consortium CMF with any questions so that all aspects are clearly understood by both parties. The proposal should include the following:

- **Technical Proposal submission (30-page limit, unless noted) – See Attachment A**
  - A Technical Proposal is required in Word (.docx or .doc) or PDF using the mandatory template in Attachment A.
- **Cost Proposal submission (no page limit) – See Attachment B**
  - Section I: Cost Proposal Narrative is required in Word (.docx or .doc) or PDF using the mandatory template in Attachment A.

- Section II: Cost Proposal Format is required in Excel (.xlsx) format, with working formulas to the maximum extent practicable.

4 Technical Requirements

4.1 Overview

As a part of BARDA's commitment to develop therapeutic countermeasures against filovirus disease, BARDA is interested in advancing manufacturing development for a monoclonal antibody (mAb) cocktail composed of two mAbs, 1C3 and 1C11, which was developed by Emory Vaccine Center and Department of Microbiology and Immunology (Emory), who holds the intellectual property (IP) for the product (Milligan et al., 2022). These mAbs were isolated from survivors of filovirus infection and target the glycoprotein (GP) trimer to potently neutralize diverse ebolaviruses; a 1C3/1C11 cocktail protected cynomolgus macaques from SUDV infection and rhesus monkeys from EBOV infection (Milligan et al., 2022). While the final product use and formulation will be dependent upon the outcomes of future efficacy studies, it is anticipated that the product will be administered intravenously at concentrations up to 100 mg/kg as a therapeutic. BARDA investment in the development of these mAbs is aimed at identifying a high yield manufacturing process that will subsequently enable development of a cost-effective therapeutic product.

BARDA is seeking submissions from contract development and manufacturing organizations (CDMOs) to perform cell line development and initial manufacturing process development of the mAb cocktail 1C3/1C11 at a scale greater than or equal to 5 Liter (L) bioreactors.

Comparability material (up to 10 mg per antibody) will be provided by Emory University to selected offerors and may be used as an internal potency benchmark to measure against the mAbs generated at the CDMOs, if so desired. Comparable material from Emory will be utilized in an optimized version of the potency assay at a contract research organization (CRO) of the government's choosing. At the end of the Base period of performance, the CRO will evaluate the potency of the material generated at the CDMOs in comparison to the material from Emory; these data will be one factor contributing to activation of Option 1.

4.2 Technical Objectives

If selected, the CDMO will be awarded a Base period to execute cell line generation and initial process development as detailed below in Section 4.3.1. Multiple project award agreements are anticipated to be made for the Base period. Offerors may propose development of an internal potency assay; the potency assay protocol currently used by Emory University is provided as Attachment C for reference. As of the date of this RPP, Emory is under no legal or financial obligation to support in the tech transfer of this assay to the CDMO. Base period activities should focus on producing high yield cell lines that support a low-cost, scalable manufacturing process without negatively impacting product potency.

4.2.1 Base Period: Generation of Stable 1C3 and 1C11 – Expressing Cell Lines

BARDA anticipates awarding agreements to multiple CDMOs to complete Base Period activities with a period of performance of 15 months. At BARDA's instruction, upon completion of the Base period and deliverables, product manufactured in the Base Period will be shipped to an external partner and undergo external potency testing using the assay developed by Emory. Upon request, the results of

the potency assessment will be shared with the CDMO. These results will contribute to the decision to activate Option 1.

4.2.2 Option Periods: Expression and Manufacturing Optimization at Pilot Scale

At the Government's discretion, option periods may be unilaterally exercised, based on successful contract performance within the current Period and continued funding. No more than two candidates will be chosen for Option activation. Award of Option Periods will be based on quality and process attributes such as potency and titer; anticipated cost of goods based on the proposed manufacturing specifications will also be a critical factor. During Option Period 1, the CDMO will perform expression optimization to improve manufacturing yield and efficiencies at a pilot scale manufacturing level (non-GMP).

Cell lines and manufacturing processes may be tech transferred later to another CDMO, dependent upon agreements with the IP Holder. Option Period 2 will support the tech transfer activities, if exercised by USG.

4.3 Technical Tasks

Awards made under this Other Transaction Authority (OTA) will support all efforts required to perform cell line development and initial manufacturing process development of the mAb cocktail 1C3/1C11. Antibodies will be developed as individual mAbs for drug substance (DS) but the final drug product (DP) will be a combination of the two mAbs.

4.3.1 Base Period: Cell Line Generation and Initial Process Development

- **Establishment of an MTA with Emory University**: Successful execution of a Joint MTA with BARDA and Emory to obtain the mAb sequences and access to comparability material is required for the performance of the anticipated award. Failure to execute an MTA within 120 days after award ***may result in unilateral termination of the effort***.
- Establishment of a clonal cell line (Research Cell Bank) (Chinese Hamster Ovary (CHO) preferred; other lines will be considered with justification).
- Establishment of a Cell Culture process in a scalable bioreactor (greater than or equal to 5L)
- Purification of drug substance to a state suitable for potency testing and at a concentration goal of >80 g/L.
- Product Quality testing to include but not limited to: glycosylation profile, charge profile, aggregation, intact protein, and titer using the CDMO's platform assays.
- Projected cost of goods/gram DS for commercial scale manufacturing (Proposed Cost Model).
- *Optional: Development of a potency assay, for internal assessment of material.*
- *Optional: Optimization of the mAb sequence without negatively impacting potency, if determined to be of value to enhance manufacturability or potency.*

4.3.2 Option Period 1: Expression and Manufacturing Optimization

This Option Period may be awarded at the Government's discretion based on offeror performance in the Base Period.

- Establishment of Master Cell Bank (MCB)
- Pre-clinical, phase-appropriate MCB Cell bank testing per guidelines established by ICH Q5D: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products.
- Optimization of upstream and downstream processes for DS production, prioritizing cost of goods and manufacturability
- Formulation development to identify a DS formulation that supports combining the two mAb DS into one DP and supports DS stability for both mAbs, with a target shelf life of 10 years for both the DS and DP.
    - Composition of the formulation should not preclude development of a lyophilized drug product.
- Pilot scale manufacture (200-2000L, non-GMP) for preclinical studies.

4.3.3 Option Period 2: Technology Transfer (TT)

This Option Period may be awarded at the Government's discretion and will support all activities necessary to enable the technology transfer of the process developed in the Base period and/or Option Period 1.

4.3.4 Program Management

Offeror is expected to provide program management which allows timely completion of all Deliverables listed in Appendix 1, including, but not limited to:

- Delivery of a signed Joint MTA with BARDA and Emory University (the IP holder).
- Identification and management of distinct stages of the product development pathway that are gates for Go/No-Go decisions for advancing to the next stage of the Integrated Product Development Plan;
- Establishment and tracking of milestones and timelines for the initiation, conduct, and completion of product development activities for each stage, with a budget (in direct costs) linked to each stage;
- Maintaining and managing staff (in-house and contracted) to ensure the necessary expertise and dedicated effort to perform the work;
- Conducting performance measurement that shall include:
    - establishing an initial plan;
    - defining measurable parameters;
    - defining how these parameters relate to cost and schedule impacts;
    - approach in providing a detailed schedule that generates a critical path for the project; and
    - description of the cost-accounting system used or intended to be used based on budget estimates to monitor all costs related to the contract award for both prime- and sub- contractors on a real time basis;
- Directing and overseeing subcontractors and consultants to ensure successful performance of planned activities within the cost and schedule constraints of the contract; and
- Development of a risk evaluation and mitigation strategy for the overall project.
    - The Offeror must identify all anticipated project risks and track them via a Risk Register. The Offeror must manage all project risks, and report to BARDA changes to all identified risks as they occur/arise. BARDA must be permitted to participate in the risk management and mitigation processes associated with this project.

4.4 Project Agreement Deliverables

The below deliverables are the standard, mandatory deliverables. Any additional technical deliverables should be added by the offeror.

Unless otherwise specified, Recipients format for the deliverables is acceptable. Submissions may be in MS Office or PDF format; funding and schedule information shall be MS Excel and MS Project, respectively.

Unless otherwise specified, ALL deliverables shall be emailed to the Project Agreement Officer (PAO) and Project Agreement Representative (PAR) listed in the agreement AND uploaded to US Government specified database/folder.

All Final Deliverable submissions are subject to US Government review and comment, which may result in additional Deliverable submission by the Recipient.

Deliverable Description	Content Requirements and Instructions	Reporting Frequency
Kick Off Meeting	Recipient to develop Agenda and host an in-person or virtual kick-off meeting to discuss overall project objectives, key personnel, deliverables, risks, schedule and funding/payment procedures. Provide meeting minutes.	Kickoff meeting conducted within 10 business days of award. Minutes to be submitted within 3 business days of meeting.
Ad-hoc Project Team Meetings	Recipient to schedule and create an agenda. Follows Agenda mutually agreed upon in advance of meeting. RECIPIENT to provide meeting minutes within 3 business days from date of meeting.	As needed for special topics, when specifically requested by the PAO and PAR
Monthly Project Team Meetings	Purpose is to review monthly progress, any changes since last month and any projected issues or challenges.	Virtual. Monthly, within 10 business days after the monthly report deliverable. 1 hour duration, hosted by the recipient. Minutes to be submitted within 3 business days of meeting.
Monthly Project Progress Report	Monthly report of overall status including cost, performance and schedule progress and variance from plan. Include discussion of important design considerations and milestones, such as Experiments completed, Process Description complete, etc. Include status of other disciplines, project delays, risk management, funding issues, etc. Level of detail for various aspects of project may decrease or increase in detail as the project moves through the various phases of execution.	Monthly. Due 15th of the month. Contractor format acceptable, in PDF.

Deliverable Description	Content Requirements and Instructions	Reporting Frequency
Integrated Master Project Schedule	MS Project Detailed Project Schedule, full detailed schedule for entire Project, including all major activities, critical path, and milestones. Status updated regularly.	Status updated monthly and when milestones and/or major events change.
Project Budget	Excel Detailed Project Budget, full detailed budget for entire Project	Notify USG via e-mail whenever Project Budget is revised/updated and post to shared documents site
Project Documents and List(s)	Full listing of project documentation organized by discipline or other category (e.g., Bill Of Materials, specifications list, process descriptions, reports, instrument index, etc.)	Submitted, uploaded and updated as required to USG specified site.
Project Documentation and Deliverables	Process development reports and other project execution related documents and materials: Base Period: • Cell Line Development Report, including all restrictions and requirements relevant for licensing the cell line by other CDMOs or development partners • Product Quality Assay Results • All antibody material generated under this effort, with protein concentration and assay parameters for assay used to generate protein concentration • Cell line vials generated under this effort • Proposed Cost Model Option Period 1: • Cell Line Testing Results • Cell Line Stability Report • Process Development Report • Upstream Process Description • Downstream Process Description • Stable Formulation Development Report • Bill of Materials • Batch Records for Pilot Scale Manufacturing • Final Manufacturing Report for DS at Pilot Scale • Refined Cost Model • Any available potency data generated by CDMO • Tech transfer package from final manufacturing process to include cell	When specifically requested via e-mail by USG Project Manager (or designee), post latest version of requested documents to shared documents site

Deliverable Description	Content Requirements and Instructions	Reporting Frequency
	line, manufacturing process, and any developed assays Option Period 2: • Tech Transfer report	
Project Risk Register	Project risks identified throughout the project shall be tracked via a Risk Register Log (or similar list/tracking vehicle). Log should contain information regarding identification date, severity of risk, mitigation plan(s) and dates for implementation, risk owner, etc.	Updated monthly and submitted with Monthly Technical Progress Report and posted to USG identified document site.
Project Action Items List	Actions identified throughout the project, which are not tracked by some other project management tool, and which require follow up and monitoring for completion, will be captured in an Action Items List. (Or similar list/tracking tool.) List should contain information regarding identification date, target completion, responsible individuals/groups, etc.	Submitted if/as required with monthly technical progress report.
Site Visits	Host visits from USG following agenda/schedule mutually agreed upon with USG in advance of visits. Provide visit notes within 3 business days from date of visit.	No more than quarterly at the Agreements Officer's discretion.
Annual Project Progress Report	High level project progress review of overall objectives. Updated projections against project expectations, including risks and mitigation plans, should be reported with respect to the previous annual report. Summary of critical changes that took place over the year. Recommended to not exceed 20 pages.	Annually from award. To review progress over the previous 12 months. A Draft to be submitted 30 days after the completion of each year of performance. Within 15 days of receipt, the Government will provide review comments. The Respondent shall respond within 15 days of receipt of comments. Report format: Microsoft Word and PDF
Final Report	Final report summarizing stated objectives and the progress that was achieved in meeting those objectives; summary of risks, objectives; summary of risks, incurred, impacts and mitigation; quantitative discussion of production improvements achieved; production improvements achieved; financial summary of project; schedule summary for project, comparing original schedule to final comparing original schedule to final schedule; recommendations for path forward as applicable.	Initial submission to be submitted 30 days prior to the end of the period of performance. Within 15 days of receipt, the Government will provide review comments. The Respondent shall respond within 15 days of receipt of comments.

Deliverable Description	Content Requirements and Instructions	Reporting Frequency
Security Plan	The Security Plan must detail how the Contractor will adhere to established ASPR Informational Technology (IT) and Operational Security (OPSEC) policies and requirements. The Security Plan must include but is not limited to; • Internal management security measures that meet the ASPR, IT, and OPSEC security requirements • Plan to ensure Project Agreement security compliance, to include roles and responsibilities • Plan to manage Consortium member physical, IT, and OPSEC security compliance as a contingency of Consortium membership	Initial submission 30 Days after Award, updated as necessary See BARDA Security Plan checklist
Quality Management Plan	The recipient shall develop and submit a Quality Management Plan that details the methods/processes they will use to demonstrate the ability to produce cell banks and deliver a Quality Management Report.	Initial submission 30 business days after Award, updated as necessary Report format: Microsoft Word and PDF

Deliverable Description	Content Requirements and Instructions	Reporting Frequency
Detailed Objective Project Plan	The recipient shall develop and submit a detailed objective project plan that at minimal include the following: a. Plan should describe in detail the proposed plan to the objective outlined above. b. Plan should include all analytical assumptions that will be employed in preparing and executing the sustainment effort. c. Plan should include a range of assumptions/variables that can be used to assess various market conditions. d. Plan should include metrics, variables, and milestones for gauging domestic and global market progress of required technologies and infrastructure that will be needed to sustain capacities beyond the period of US Government investment. e. Plan should include all metrics, variables and milestones that define the various gates and decision points (distinct from the bullet above). f. Plan should include a detailed description of the proposed sustainment effort. Details should include the basic steps for each phase of implementation, and which includes all dependencies between phases. g. Plan should include identification of risks associated with execution of the plan.	Initial submission 30 business days after Award, updated as necessary Report format: Microsoft Word and PDF
Infrastructure and Management Structure Organizational Chart	The recipient shall complete description of the infrastructure and management structure (organizational chart) including but not limited to addressing all elements that will accomplish the program's goals and milestones. The recipient shall propose a workforce management plan, e.g., how workforce will train, maintain, etc., that reflects the ability to meet the requirements.	Initial submission 30 business days after Award, updated as necessary Report format: Microsoft Word and PDF
Signed MTA with Emory and BARDA	Successful execution of an MTA with Emory to obtain the mAb sequences and access to comparability material is required for the performance of the anticipated awards	Failure to execute an MTA within 120 calendar days of award will result in termination unless BARDA agrees to an extension.

4.5 Preferred Criteria

- Proposals clearly stating costs associated with use of proprietary cell lines. If Offeror proposes to use proprietary cell lines in the development work, the Offeror should disclose within the proposal submission any cost or fees associated with use of the cell lines 1) in the development work scoped within this project's Base and Option periods; 2) if tech transfer of the cell line and manufacturing process from the Offeror to an external party occurs, and any restrictions associated with tech transfer; and 3) at various stages of development, including prior to IND, prior to BLA approval, for licensed products and/or prior to commercialization.
- Expertise in generating Research Cell Banks and Master Cell Banks of clonal cell lines.
- Proposed titer of no less than 4g/L for each mAb in fed batch process or comparable in perfusion approach.
- Proposed formulation to support high concentration (> 80 g/L) drug substance.
- Proposed formulation for the two mAbs that enables coformulation of the mAbs at the drug product stage. Formulations able to support product lyophilization are preferred.
- Manufacturing strategy that prioritizes product quality and lower cost of goods.
    - Criteria for Option Activation: Among selected Performers, no more than two will be selected to perform work under the Option periods. Activation of Option periods will be dependent on assessment of the following parameters from the Base period work and is contingent upon funding availability:
        - Investigational product produced by the awardees in the Base period will be evaluated by an external CRO using a potency assay that was developed by Emory and transferred to the CRO. The results of testing at that CRO will be one factor used in determining whether the option periods will be awarded. Upon request, awardees will be provided with a report that reflects the performance of their product in comparison to comparability material provided by Emory.
        - Product Quality attributes from Base period work (to include, but not limited to: potency, glycosylation profile, charge profile, aggregation, and intact protein)
        - Titer of each antibody generated from the cell line.
        - Anticipated cost of goods based on the titer and projected manufacturing strategy.

5 Evaluation and Selection

5.1 Compliance Screening

The BioMaP-Consortium CMF will conduct a preliminary screening of submitted proposals to ensure compliance with the RPP requirements. As part of the preliminary screening process, proposals that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the BioMaP-Consortium CMF. The Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration.

5.2 Evaluation Process

Following the preliminary screening, the Government sponsor will perform an evaluation of all qualified proposals. The Government sponsor team may include a panel of subject matter experts (SMEs), to include the use of contractor consultants, who will make recommendations to the Government during the evaluation. Where appropriate, the Government will employ non-disclosure agreements to protect information. An Offeror's submission of a proposal under this RPP indicates concurrence with the aforementioned use of contractors and SMEs.

Evaluation of proposals will be based on a comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors. The Government will evaluate each proposal against the evaluation factors detailed below.

5.3 Evaluation Factors

- Factor 1: Technical Approach - This factor evaluates the relevancy, thoroughness, completeness, and feasibility of the proposed approach in relation to the following subfactors:
    - General Technical Approach including ability of proposal to meet all requirements of this RPP.
    - Development and Manufacturing Approach
- Factor 2: Relevant Corporate Experience and Capabilities - This factor evaluates the offeror's demonstrated corporate experience and capabilities as well as the technical and program management experience of the proposed team to perform the proposed work. The Government may also consider information in past or present BARDA contracts with vendor, in Contractor Performance Assessment Reporting System (CPARS), and the Federal Awardee Performance and Integrity Information System (FAPIIS) or similar systems.
- Factor 3: Program Management Approach - This factor evaluates the quality, thoroughness, completeness and feasibility of the proposed Program Management approach in relation to the following subfactors:
    - Key Personnel & Personnel Management
    - Contract/Subcontract Management
- Factor 4: Cost/Price - Proposals will be evaluated to determine if the proposed costs are realistic, reasonable, and complete for the work to be performed, reflect a clear understanding of the requirements, and are consistent with the various elements of the Offeror's schedule proposal.

5.4 Evaluation Ratings

The Government will assign one of the following adjectival merit ratings to Factors 1 - 3:

- Outstanding
- Good
- Acceptable
- Marginal
- Unacceptable

The Cost/Price will receive a narrative rating to determine whether costs are realistic and complete.

5.5 Evaluation Outcome

The Government will recommend project(s) based on an evaluation of the information provided in the applicable proposal. Following the evaluation, the Project Agreement Evaluation Team (PAET) Chairperson may:

- Recommend proposal(s) (or some portion of the proposal) for negotiations towards award;
- Recommend placement of proposal(s) in the Basket if funding currently is unavailable; or
- Recommend rejection of proposal(s) (will not be considered for award and will not be placed in the Basket)

As the basis of recommendations are completed, the Government will forward their recommendations to the BioMaP-Consortium CMF to notify Offerors. Offerors will be notified of the decision via email from the BioMaP-Consortium CMF of the results of the evaluation. All Offerors will receive feedback on eligible submissions.

5.6 Basket Provision

The electronic "Basket" is an innovative acquisition tool. Proposals rated as Acceptable through Outstanding, but not immediately recommended for award, may be placed in the Basket for 2 years and are eligible for award during that time. Proposals rated as Unacceptable will not be placed in the Basket and will not be eligible for future award. If awarding from the Basket, the Government reserves the right to award whichever proposal best meets its needs.

5.7 Cost/Price Estimate and Evaluation

The Cost Proposal will receive a narrative rating to determine whether costs are realistic, reasonable, and complete.

If a proposal is recommended for Project Agreement award, the BioMaP-Consortium CMF will review the original cost proposal and the Offeror's response to a Proposal Update Letter, if applicable. The BioMaP-Consortium CMF will request additional information or clarification as necessary. The BioMaP-Consortium CMF will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government will review this assessment and make the final determination that the negotiated project value is fair and reasonable.

Full Cost Proposals will be evaluated by CMA using the understanding of cost reasonableness and completeness as outlined below:

a) Realism. Proposals will be evaluated to determine if Costs are realistic for the work to be performed, reflect a clear understanding of the requirements, and are consistent with the various elements of the Offeror's schedule proposal.

Estimates are "realistic" when they are neither excessive nor insufficient for the effort to be accomplished. Estimates must also be realistic for each task of the proposed project when compared to the total proposed cost.

The PAR will review the Technical Verification Form (TVF), which includes the proposed costs, to deem the proposed costs are appropriate for the technical effort.

b) Reasonableness. The Offeror's cost proposal will be evaluated to determine if it is reasonable. For a price to be reasonable, it must represent a price to the Government that a prudent person would pay in the conduct of competitive business. Normally, price reasonableness is established through cost and price analysis.

To be considered reasonable, the Offeror's cost estimate should be developed from applicable historic cost data. The Offeror should show that sound, rational judgment was used in deriving and applying cost methodologies. Appropriate narrative explanation and justification should be provided for critical cost elements. The overall estimate should be presented in a coherent, organized and systematic manner.

Costs provided shall be clearly attributable to activities or materials as described by the Offeror. Costs should be broken down to the level of detail outlined in the RPP.

The BioMaP-Consortium CMF will analyze and assess by directly comparing proposed costs with comparable current and historical data, evaluator experience, available estimates, etc. Proposed estimates will be compared with the corresponding technical proposals for consistency.

c) Completeness. The BioMaP-Consortium CMF will make an assessment on whether the proposal clearly and thoroughly documents the rationale supporting the proposed cost and is compliant with the requirements of the solicitation, as well as reflect a clear understanding of the requirements, and are consistent with the various elements of the offerors proposal.

The proposal should clearly and thoroughly document the cost/price information supporting the proposed cost in sufficient detail and depth. The BioMaP-Consortium CMF will evaluate whether the Offeror's cost proposal is complete with respect to the work proposed. The BioMaP-Consortium CMF will consider substantiation of proposed cost (i.e., supporting data and estimating rationale) for all elements.

Rate and pricing information is required to properly perform the cost analysis of the proposal. If the Offeror is unwilling to provide this information in a timely manner, its proposal will be lacking information that is required to properly evaluate the proposal and the proposal may not be eligible for further award.

5.8 Award Determination

Following final negotiations, the Government may determine award(s) based on an evaluation of the information provided in the proposal that provides the best value to the Government. After approval from the Source Selection Authority (SSA), the Government will forward their selection, if any, to the BioMaP-Consortium CMF to notify the applicable Offeror(s). The Offeror(s) will be notified of the decision and/or change in recommendation status via email from the BioMaP-Consortium CMF of the results of the selection.

6 Points of Contact

Questions related to this RPP should be directed to Ms. Rebecca Harmon (biomap-contracts@ati.org)

Once an Offeror has submitted a proposal, the Government and the BioMaP-Consortium CMF will not discuss evaluation/status until the evaluation results have been provided to the Offerors.

7 References

Milligan et al. Cell. Asymmetric and non-stoichiometric glycoprotein recognition by two distinct antibodies results in broad protection against ebolaviruses. 2022 March 17; 185(6): 995–1007.e18. doi:10.1016/j.cell.2022.02.023.

8 Attachments

Attachment A: Technical Proposal Template

Attachment B: Cost Proposal Template

Attachment C: Potency assay protocol (research grade assay)

Attachment D: DRAFT Joint Material Transfer Agreement

Attachment E: ASPR Security Requirements

Attachment A: Technical Proposal Template

General Instructions

The Technical Proposal must address the technical requirements described in the RPP in sufficient detail to permit evaluation from a technical perspective in accordance with the evaluation factors set forth in the RPP. The Technical Proposal shall be single-spaced, single-sided, and 8.5 x 11 inches, and 12-point font. Smaller type may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 1 inch. Offerors are strongly encouraged to use pictures and graphics to succinctly represent proposed ideas, organization, etc.

The Technical Proposal shall be limited to 30 pages (unless otherwise noted below). Pages in excess of this limitation may not be considered**.** Offerors are advised that the number of pages should be commensurate with the degree of complexity of the proposed effort. It is expected, and encouraged, that less complex, less expensive proposals will be significantly less than 30 pages in length.

To ensure Technical Proposals receive proper consideration, **the Technical Proposal format shown below and all sections detailed within the template are mandatory**. If there are any items which are not applicable to a specific proposal, include the section topic in the proposal with a short explanation as to why it is not applicable.

1. Cover Page*
2. BioMap Member Organization Information Sheet*
3. Executive Summary & Minimum Eligibility Criteria
4. Technical Approach
5. Supporting Project Information*

***Excluded from page limitation**

Technical Proposal Cover Page

[Name of Offeror]
[Address of Offeror]

RPP Number XXXXXX

[Proposal Title]

[Offeror] certifies that, if selected for award, the Offeror will abide by the terms and conditions of the BioMap Base Agreement, unless otherwise stated in the Project Agreement.

[Offeror] certifies that this Proposal is valid for two years from the close of the applicable RPP, unless otherwise stated.

[As detailed in Section 2.6 of the Request for Project Proposals, Offerors are to include a proprietary data disclosure statement/legend if proprietary data is included. Sample: *This Proposal includes data that shall not be disclosed outside the BioMap Consortium Management Firm and the Government. It shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than proposal evaluation and agreement administration. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).*]

Member Information Sheet

If an item is not applicable, then that section should be listed as “not applicable.”

OFFEROR NAME:	
ALL PLACES OF PERFORMANCE:	
TITLE OF PROPOSED EFFORT:	
UEI # (if applicable):	
CAGE CODE (if applicable):	
SMALL BUSINESS (YES/NO):	
SMALL/DISADVANTAGED BUSINESS (YES/NO): SOCIOECONOMIC CATEGORY?	
CONFLICT OF INTEREST (YES/NO):	
GOVERNMENT FUNDS:	
INDUSTRY COST SHARE:	
TOTAL COST OF PROPOSAL:	
PROPOSED PERIOD OF PERFORMANCE IN MONTHS:	
PREFERRED PAYMENT METHOD (FFP, CPFF, Cost Reimbursable (CR), CR/COST SHARE):	
REQUESTED USE OF GOVERNMENT RESOURCES, PROPERTY, LABS, ETC. (YES/NO, LIST IF YES):	
PROPOSED USE OF SELECT BIOLOGICAL AGENTS OR TOXINS (YES/NO):	
CONTRACT/NEGOTIATION CONTACT (NAME, ADDRESS, PHONE, EMAIL):	
TECHNICAL/PRINCIPAL INVESTIGATOR CONTACT (NAME, ADDRESS, PHONE, EMAIL):	
COGNIZANT RATE AUDIT AGENCY OFFICE (IF KNOWN, INCLUDE POC, ADDRESS, PHONE #, E-MAIL):	

Executive Summary & Minimum Eligibility Requirements

1. **Executive Summary:** [The Executive Summary allows Offerors to concisely present the important aspects of their proposals to evaluators. The summary should present an organized progression of the work to be accomplished, without the technical details, such that the reader can grasp the core concepts of the proposed project.]

2. **Minimum Eligibility:** [Additionally, this section must address how the Offeror currently satisfies the minimum eligibility requirement(s) as detailed in the RPP.]

Technical Approach

[**If recommended for award, this section will be used to create the Statement of Work, which is subject to refinement and negotiation. Please write as such in lieu of typical proposal language.** Provide sufficient technical detail and analysis to support the technical solution being proposed for the project. Clearly identify the core of the intended approach. It is not effective simply to address a variety of possible solutions to the technology problems. The following sections are required.]

1. **Background:** [Describe the problem that the solution is addressing.]
2. **Objectives:** [Describe the goal of the project and what you are going to do to achieve the goal, including the final product(s) and/or anticipated outcome(s). Be as concise as possible.]
3. **Project Team:** [Identify the proposed management and technical personnel for the project using a summary table in the below format. Principal Investigator must be identified. If you are partnering with additional organizations to execute the proposed technical and programmatic work, provide details prior to the table below identifying those partners with clear roles and responsibilities of each organization. If you are not partnering, state as such.]

Key Personnel	**Organization**	**Role and Key Contribution**	**Level of Effort**
Name (Principal Investigator)			%
Name			%
Name			%
Name			%
Name			%

4. **General Approach:** [Summarize your overarching approach/solution and framework addressing the requirements set forth in the RPP. Include relevant background data and information on your platform/facilities or solution and the current state of the solution if previous development/progress has been made.]

5. **Technical Approach**: [Provide a detailed approach, broken out by major phases/top level tasks and gates/decision points, on how your organization intends to address the requirements set forth in the RPP, showing a clear course of action and roles of organizations (if applicable).]
6. **Schedule:** [Include a Gantt chart of the project, developed to include the same level of detail as the work breakdown provided in the Technical Approach section. Gantt can be rolled up to the task level for space efficiency if necessary.]

7. **Deliverables and Milestone Payments:** [Submitted information is subject to change through negotiation if the Government recommends the proposal for award. The deliverables in section 4.4 of the RPP are required; populate the table below to include all deliverables from section 4.4 of the RPP and any additional technical deliverables proposed to support the technical effort. Results of the technical effort are contractually binding and shall be identified herein. Offerors are advised to read the Base Agreement carefully. Any and all hardware/software to be provided to the government as a result of this project shall be identified.]

   [The milestones and associated deliverables proposed should, in general, be commensurate in number to the size and duration of the project and be of sufficient monetary value to warrant generation of a deliverable and any associated invoices. Recurring programmatic reporting shall have no funding associated with them. For cost reimbursable agreements, the BioMaP-Consortium member is still required to assign a monetary value to each milestone, however invoice totals are based on cost incurred and will not have to match exactly to the amounts listed.]

   [List the data rights assertion as numbered in the data rights assertion table. If not applicable for that deliverable, "N/A".]

#	Task	Deliverable Description	Content Requirements and Instructions Unless otherwise specified, Awardee format is acceptable. Submissions may be in MS Office or PDF format. Funding and schedule information must be MS Excel and MS Project, respectively.	Reporting Frequency Unless otherwise specified, ALL deliverables will be emailed to the OTAO and Project Officer listed in the Agreement, AND uploaded to USG specified database/folder	Gov't Funds	Cost Share	Total Funding	Assertion #

8. Intellectual Property, Data Rights, and Copy Rights

[If the Offeror intends to provide technical data which existed prior to, or was produced outside of the proposed effort, to which the Offeror wishes to maintain additional rights, these rights should be asserted through the completion of the table below. Note that this assertion is subject to negotiation prior to award.]

Rights in such Data shall be as established under the terms of the Base Agreement, unless otherwise asserted in the proposal and agreed to by the Government. The below table lists the Awardee's assertions.

Assertion #	Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights	Name of Organization Asserting Restrictions

Supporting Project Information:

1. **Cost Summary:** [This section provides technical evaluators with high-level cost data in order for the evaluators to determine if the costs proposed are realistic as compared to the scope of work proposed. This information must be consistent with the Cost Proposal. The information must be provided in this section of the Technical Proposal. Include the following table as a summary of the costs by cost element.]

Cost Summary EXAMPLE This form is to be completed by Offeror and evaluated by Technical Evaluators. Items in italics are provided as samples only. Offeror must complete table with the applicable information.		
Cost Element	**Total Proposed Cost**	**Description/Explanation**
Labor	*$XXX*	*xx hrs of senior scientist; xx hours of program management; include additional as required.*
Labor Hours	*XX*	
Subcontractors	*$XXX*	*Sub A - $xxx; xx legal advisor hours* *Sub B - $xxx; xx hours of Testing*
Subcontractor Hours	*XX*	
Consultants	*$XXX*	*Financial consultant supporting all phases*
Consultant Hours	*XX*	
Material/Equipment	*$XXX*	*pipettes, gloves, computer software*
Other Direct Costs	*$XXX*	*ship testing materials to lab*

Travel	*$XXX*	*x trips for x people for x days to xx (city), xx (state) from xx (city), xx (state) for program meetings*
Indirect Costs	*$XXX*	*approved by DHHS (provide date)*
Fee	*$XXX*	*Not applicable if cost share proposed*
Total Cost to Government	*$XXX*	
Total Project Value	*$XXX*	

2. **Risks & Mitigation:** [Identify potential problem areas (e.g., technical, schedule, cost) in the proposed approach. Describe risk mitigation methods.]

3. **Organizational Conflict of Interest:** [An Organizational Conflict of Interest can occur when an individual or an entity is unable, or potentially unable, to provide impartial advice or service to the Government or separate entity because of other business activities or relationships. Disclose any potential conflict of interest pertaining to this opportunity. If none, state as such.]

4. **Small Business Utilization:** [Complete the following subsections with as much information as currently known. In accordance with the RPP, this information is not part of the Government's technical evaluation; however, small businesses utilization is encouraged to the maximum extent practicable under the BioMaP-Consortium. To be a small business, an organization must first be a for-profit legal structure. Next, it must qualify with the Small Business Association's (SBA) size standards, which are structured by NAICS Code (see https://www.sba.gov/document/support-table-size-standards) for more details). Lastly, some small businesses participate in one or more additional programs with the Small Business Administration (see https://www.hhs.gov/grants-contracts/small-business-support/programs-supporting-small-businesses/index.html for more details).]

   4.1. Offeror's Business Status: [Select and complete the appropriate option. Delete the other two options which do not apply.]

   - Offeror qualifies a small business under NAICS code(s) _____
   - Offeror qualifies a small business under NAICS code(s) _____ and further participates in the SBA's *[select from following list as appropriate: 8(a) Business Development; HUBZone; Service-disabled-veteran-owned; small-disadvantaged-business; Women-owned-small-business]* program.
   - Offeror does not qualify as small business

   4.2. Teaming with Small Businesses: [Select and complete the appropriate option based on currently proposed teaming plan. Teaming can include subcontractors, consultants, and significant material or service providers. Delete any options with do not apply.]

- Offeror plans to team with _____, who qualifies a small business under NAICS code(s) _____
- Offeror plans to team with _____, who qualifies a small business under NAICS code(s) _____ and further participates in the SBA's *[select from following list as appropriate: 8(a) Business Development; HUBZone; Service-disabled-veteran-owned; small-disadvantaged-business; Women-owned-small-business]* program.
- Offeror does not plan to partner with any small business
- At this time, it is unknown if Offeror will be able to team with any small businesses

5. Relevant Experience

[Provide at least one (1) and no more than five (5) current and/or relevant experience examples of performance within the past 5 years. Copy and paste the below template as needed. While this appendix does not count towards the overall page limit of the technical proposal, each relevant experience is limited to three pages.]

Relevant Experience Example #1			
Contract Number:		Contract Type:	
Period of Performance:		Contract Value: (Base and Sub-awards)	
Agency:		Customer Points of Contact	
Name & Address of Contracting Organization:		Project Officer	
		Phone	
		E-mail	
		Agreements Officer	
		Phone	
		E-mail	
Similarities to this Solicitation			
Brief Description of Project Scope and Customer Expectations			
Brief Description of Approach and Performance			

Attachment B: Cost Proposal Template

The objective of the Cost Proposal is to provide sufficient cost information to substantiate that the proposed cost is realistic, reasonable, and complete for the proposed work. The Cost Proposal should provide enough information to ensure that a complete and fair evaluation of the reasonableness and realism of cost or price can be conducted and reflect the best estimate of the costs for the project. The Cost Proposal must be consistent with information provided in the Statement of Work and general technical approach (i.e., costs, cost share, dates, etc.). Proposals that deviate substantially from these guidelines, omit substantial parts or sections, or deviate significantly from the original Enhanced White Paper Rough Order of Magnitude (ROM) estimate may be eliminated from further review and funding consideration.

To ensure Cost Proposals receive proper consideration, it is mandatory that the Cost Proposal include both Section I: Cost Proposal Narrative and Section II: Cost Proposal Format.

The Cost Proposal Narrative is used to assess various criteria. This section will be used to determine reasonableness, allowability, and allocability of costs. The Cost Proposal Narrative section should provide a more detailed breakdown of the figures that are contained in the Cost Proposal Format. The Cost Proposal Narrative section also should give substantiation and written explanation of proposed costs. Breakdowns should be as accurate and specific as possible. Ensure that any figures presented in this part are consistent with the figures in the Cost Proposal Format.

Separately, the Cost Proposal Format must be provided in Excel, with working formulas to the maximum extent practicable. Optional formats are available on the Members Only website. However, Offerors are encouraged to use their own formats so long as the required level of detail is provided.

Cost Proposal Narrative

The Cost Proposal Narrative must include sufficient information to evaluate the proposed value through cost information. This information is required to properly perform the cost and/or price analysis of a proposal. All Proposals must provide the following overview information as part of the Cost Proposal Narrative:

Overall Approach. Provide an overall and succinct explanation of how this Proposal is structured.

Assumptions. Provide any assumptions. Note that assumptions should be limited to cost or pricing. Technical assumptions are better captured in the Statement of Work.

Preferred Payment Method. Identify which of the payment methods is preferred. The methods are (1) Cost Reimbursable Milestones with Ceiling, (2) Cost Reimbursable/Cost Share with Ceiling, (3) Cost Plus Fixed Fee Milestones with Ceiling and (4) Fixed Price Milestones with Ceiling).

Detailed Cost Element Explanation: The Cost Proposal Narrative must include the following cost categories and details, at a minimum:

a. **Labor Rates**. Portions of labor information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Identify the position title of all personnel, the labor category description, the hourly rate for each individual, and show estimated hours for each labor category proposed. If an approved organizational estimating procedure use average labor rates for specific labor categories, this would be acceptable.

   It is recognized that an organization may not be able to identify all of the personnel to be assigned to the project several years in advance. Where this cannot be done, use generic position titles such as "scientist." If direct labor costs include allocated direct costs or other direct costs in accordance with established accounting and estimating practices and systems, identify these costs separately and provide an explanation and basis for proposed costs.

   Provide an explanation for any proposed labor escalation.

   Offerors are expected to avoid overtime as much as practicable, except when lower overall costs to the Government will result or when it is necessary to meet urgent program needs. If overtime is proposed, provide an explanation as to why.

b. **Salary Rate Limitation.** Payment of the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II is an unallowable cost under the BioMaP-Consortium OTA and shall be addressed in accordance the BioMaP-Consortium Base Agreement.

   For purposes of the salary rate limitation, the terms "direct salary," "salary," and "institutional base salary" have the same meaning and are collectively referred to as "direct salary." An individual's direct salary is the annual compensation that the entity pays for an individual's direct effort (costs). Direct salary excludes any income that an individual may be permitted to earn outside of duties to the entity. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

   The salary rate limitation does not restrict the salary that an entity may pay an individual, it merely limits the portion of that salary that may be paid with Federal funds.

   See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current period. See the BioMaP-Consortium Base Agreement for further details.

c. **Fringe Benefits.** Identify whether or not the proposed labor rates include fringe costs. If so, then identify the percentage rate. If not, then provide a statement to that effect and include the fringe costs in the indirect section instead.

d. **Travel.** Portions of travel information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Identify the total travel amount proposed. Provide an estimate of the cost per trip; number of trips; number of days; number of persons; departure city, destination city; approximate travel time frames; and the purpose of the travel. The key is to apply best estimating techniques that are auditable. Include a brief explanation of the methodology used to estimate travel costs. If exact destination is unknown at time of proposal, for pricing purposes use a potential location using best known information. Note that BioMaP-Consortium Project Awardees are expected to be cost-conscious regarding travel (e.g., using coach rather than first class accommodations and, whenever possible, using Government per diem, or similar regulations, as a guideline for lodging and subsistence costs). If travel is estimated based on an approved methodology, then state as such.

e. **Subcontractors/Consultants.** Portions of subcontractor/consultant information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Provide a list of all subcontractor/consultant and a total cost for each. If a cost and/or price analysis has been performed, provide a copy or summary of results.

   Support is required for each subcontractor/consultant as follows:

   - If a subcontractor/consultant is based on commercial pricing, provide an explanation of the commerciality determination and supporting documentation (e.g., website pricing, catalogue pricing, etc.)
   - For a subcontractor/consultant less than $250,000, provide a brief explanation of the work to be performed.
   - For a subcontractor/consultant greater than $250,000 and less than or equal to $2,000,000, provide a supporting quote and confirmation of compliance with the Salary Rate Limitation.
   - If a subcontractor/consultant over $2,000,000 was competitively solicited, provide the price analysis showing how the price was determined reasonable, summary of competition, and copies of the competitive quotes.
   - Absent any of the above, if relying on cost data for a subcontractor/consultant greater than $2,000,000, a cost-by-cost element breakout must be provided to the same level of detail as the Offeror.]

f. **Material/Equipment/Other Direct Costs.** Portions of the material/equipment/other direct cost information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Provide an itemized list of the material/equipment/other direct costs, including the itemized unit cost and quantity. Identify the supplier/manufacturer and basis of cost (i.e., vendor quote, catalog pricing data, past purchase orders, etc.) for each item, if known. Additionally, a copy of the basis of cost documentation for each piece of proposed material/equipment/other direct cost with a unit cost greater than or equal to $25,000; or total cost greater than or equal to $150,000; must be provided. If material/equipment/other direct cost is estimated based on an approved methodology, then state as such.

If any sort of usage cost is determined by a rate, identify the basis and rational used to derive the rate.

Only in extraordinary circumstances will government funds be used to purchase equipment. Examples of acceptable equipment might include special test equipment, special tooling, or other specialized equipment specific to the research effort. This award is not an assistance agreement/instrument and Offerors should normally have the required equipment to perform. The value of equipment should be prorated according to the share of total use dedicated to carrying out the proposed work. Include a brief explanation of the prorating methodology used.

g. Indirect Costs. Portions of the indirect cost information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Provide an estimate of the total indirect costs, identify each rate used in the proposal, and provide documentation to support the indirect cost rates by one of the below methods.

i. Provide a copy of certification from a Federal agency indicating these indirect rates are approved by the Federal agency; or
ii. Provide a letter from the Offeror's Administrative Agreements Officer, in lieu of a rate certificate, stating these indirect rates are approved by a Federal agency;
iii. Copy of current forward pricing rate proposal with date proposal was submitted to the Administrative Agreements Officer; or
iv. Absent Government approved rates, provide detailed supporting data to include (1) indirect rates and all pricing factors that were used; (2) methodology used for determining the rates (e.g., current experience in the organization or the history base used); and (3) all factors, by year, applied to derive the proposed rates.

Alternately, in lieu of providing indirect rates, if the Offeror can obtain appropriate Government assistance, it may provide a letter from the cognizant Federal audit agency stating that, based upon their review of the Offeror's proposal, the indirect rates used in the proposal are approved by a Federal agency and were applied correctly in this specific proposal. If the Offeror elects to rely on these Government inputs, it is responsible for ensuring any Government agency cooperation is obtained so that the proposal is complete when submitted.

h. Cost of Money. If applicable, Cost of Money should be proposed separately from indirect costs.

i. Fee/Profit. State the fee/profit percentage, if proposed. Fee/Profit is allowable for the effort being conducted. The fees shall be specific to the individual BioMaP-Consortium project and negotiated on a project-by-project basis.

j. Cost Share. Identify if any Cost Share is proposed. Cost Share includes any costs a reasonable person would incur to carry out (necessary to) proposed project's Statement of Work not directly paid for by the Government. If a proposal includes cost share, then it cannot include fee. Cost Share may be proposed only on cost type agreements. There are two types of cost sharing, Cash Contribution and In-Kind Contribution:

<u>Cash Contribution</u>:

Cash Contribution means the Project Awardee (or Awardees' lower tier subawards) financial resources expended to perform a Project Award. The cash contribution may be derived from the Project Awardee (or Awardees' subawards) funds or outside sources or from nonfederal contract or grant revenues or from profit or fee on a federal procurement contract.

An Offeror's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any other indirect cost pool allocation. New or concurrent IR&D funds may be utilized as a cash contribution provided those funds identified by the Offeror will be spent on performance of the Statement of Work (SOW) of a Project Award or specific tasks identified within the SOW of a Project Award. Prior IR&D funds will not be considered as part of the Offeror's Cost Share.

Cash contributions include the funds the Offeror will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), awardees' subaward efforts expended on the SOW of a Project Award, and restocking the parts and material consumed.

In-Kind Contribution:
In Kind Contribution means the Offeror's non-financial resources expended to perform a Project Award such as wear-and-tear on in-place capital assets like machinery or the prorated value of space used for performance of the Project Award, and the reasonable fair market value (appropriately prorated) of equipment, materials, IP, and other property used in the performance of the SOW of the Project Award.

Prior IR&D funds will not be considered as part of the Consortium Member's cash or In-Kind contributions, except when using the same procedures as those that authorize Pre-Award Costs, nor will fees be considered on cost share.

If cost share is proposed, the following must be provided:

- A description of each cost share item proposed;
- Proposed dollar value of each cost share item proposed; and
- The valuation technique used to derive the cost share amounts (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips, etc.).

k. Small Business Utilization. Small businesses utilization is encouraged to the maximum extent practicable under the BioMaP-Consortium. To be a small business, an organization must first be a for-profit legal structure. Next, it must qualify with the Small Business Association's (SBA) size standards, which are structured by NAICS Code (see https://www.sba.gov/document/support-table-size-standards for more details). Lastly, some small businesses participate in one or more additional programs with the Small Business Administration (see https://www.hhs.gov/grants-contracts/small-business-support/programs-supporting-small-businesses/index.html for more details).

As part of the Cost Narrative, provide details on any significant small business utilization proposed, similar to the below chart. Participation can include the Offeror, subcontractors, consultants, material providers, service providers, etc.

Small Business Name	NAICS Code	Proposed $ Value	Task Involvement	SBA Program*

**Can include: 8(a) Business Development; HUBZone; Service-disabled-veteran-owned; small-disadvantaged-business; and/or Women-owned-small-business. Otherwise, list N/A.*

Cost Proposal Section II: Cost Proposal Format

The Cost Proposal Format must be provided as a separate Excel document. Offerors are encouraged to use their own Excel cost formats so long as the necessary cost detail is provided. Working formulas should be included to the maximum extent possible. The Cost Proposal Formats provided on the BioMaP-Consortium Members Only Site are ***NOT*** mandatory.

The Cost Proposal Format section must include cost-by-element detail broken out by the Offeror's fiscal year. If required by the RPP, costs must also be broken out by phase to match the technical requirements and objectives. The sum of the phases must equal the total.

Supporting data and justification for labor, equipment/material, team member/subcontractor, consultants, travel, other direct costs, indirect costs, and profit used in developing the cost breakdown also must be included. The Offeror must provide sufficient details to allow a full understanding of and justification for the proposed costs. Offerors may refer to the RPP for a start date for cost estimating purposes.

Attachment C: Potency Assay Protocols (research grade assay)

Posted as a separate attachment.

Attachment D: DRAFT Joint Material Transfer Agreement

Posted as a separate attachment.

Attachment E: ASPR Security Requirements

* This list of deliverables and security requirements ASPR-mandated requirements that may be required for any contract or agreement awarded by or on behalf of ASPR. ASPR shall be the sole determiner of the necessity of inclusion of these requirements, or subset thereof, on a case-by-case basis, as identified in the Deliverables Section of each BioMaP-Consortium Project Solicitation. BioMaP-Consortium members should be prepared to include these deliverables and security requirements as part of their Project Proposal submissions. These ASPR deliverables and security requirements are included in the Base Agreement to enable awareness and early planning by Consortium members for their inclusion as performance requirements under Project Awards.

Security Reporting Requirements

The partner facility shall notify the Government Security Team within 24-72 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products associated with this Agreement. The facts and circumstances associated with these incidents will be documented in writing for government review.

Supply Chain Resiliency Plan

The contractor shall develop and submit within 30 calendar days of contract award, a comprehensive Supply Chain Resiliency Program that provides identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods.

a) A critical component is defined as any material that is essential to the product or the manufacturing process associated with that product. Included in the definition are consumables and disposables associated with manufacturing. NOT included in the definition are facility and capital equipment.

Consideration of critical components includes the evaluation and potential impact of raw materials, excipients, active ingredients, substances, pieces, parts, software, firmware, labeling, assembly, testing, analytical and environmental componentry, reagents, or utility materials which are used in the manufacturing of a drug, cell banks, seed stocks, devices and key processing components and equipment. A clear example of a critical component is one where a sole supplier is utilized.

The contractor shall identify key equipment suppliers, their locations, local resources, and the associated control processes at the time of award. This document shall address planning and scheduling for active pharmaceutical ingredients, upstream, downstream, component assembly, finished drug product and delivery events as necessary for the delivery of product.

a) Communication for these requirements shall be updated as part of an annual review, or as necessary, as part of regular contractual communications.
b) For upstream and downstream processing, both single-use and re-usable in-place processing equipment, and manufacturing disposables also shall be addressed. For finished goods, the inspection, labeling, packaging, and associated machinery shall be addressed taking into account capacity capabilities.
c) The focus on the aspects of resiliency shall be on critical components and aspects of complying with the contractual delivery schedule. Delivery methods shall be addressed,

inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries.

The contractor shall articulate in the plan, the methodology for inventory control, production planning, scheduling processes and ordering mechanisms, as part of those agreed deliveries.

a) Production rates and lead times shall be understood and communicated to the Contracting Officer or the Contracting Officer's Representative as necessary.
b) Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

Reports for critical items should include the following information:

a) Critical Material
b) Vendor
c) Supplier, Manufacturing / Distribution Location
d) Supplier Lead Time
e) Shelf Life
f) Transportation / Shipping restrictions

The CO and COR reserve the right to request un-redacted copies of technical documents, during the period of performance, for distribution within the Government. Documents shall be provided within ten (10) days after CO issues the request. The Contractor may arrange for additional time if deemed necessary, and agreed to by the CO.

Manufacturing Data Requirements

The Contractor shall submit within 30 calendar days of contract award detailed data regarding project materials, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing, processing, and fill/finish sites; and location and nature of non-clinical and clinical studies sites. The Government may provide a table in tabular format for Contractor to be used to submit such data which would include but not be limited to the following:

- Storage/inventory of ancillary materials (vials, needles, syringes, etc.)
- Shipment of ancillary materials (vials, needles, syringes, etc.)
- Disposal of ancillary materials (vials, needles, syringes, etc.)
- Seed development or other starting material manufacturing
- Bulk drug substance and/or adjuvant production
- Fill, finish, and release of product or adjuvant
- Storage/inventory of starting materials, bulk substance, or filled/final product or adjuvant
- Stability information of bulk substance and/or finished product
- Shipment of bulk substance of final product
- Disposal of bulk substance or final product

Contractor Locations

The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors.
Contractor will submit Work Locations Report:

- Within 5 business days of contract award
- Within 30 business days after a substantive location or capabilities change
- Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO

Operational Security (OPSEC)

The performer shall develop an OPSEC Standard Operating Procedure (SOP)/Plan within ninety (90)-calendar-days of project award to be reviewed and approved by the responsible Government OPSEC officer. This plan will be submitted to the COR for coordination of approvals. This SOP/Plan will include identifying the critical information related to this contract, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.

Security Plan

The contractor shall develop a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the Government requirement. This plan shall establish security practices and procedures that demonstrate how the contractor will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing, and shall be delivered to the Government within 30 calendar days of award. The contractor shall also ensure all subcontractors, consultants, researchers, etc. performing work on behalf of this effort, comply with all Government security requirements and prime contractor security plans.

a) The Government will review in detail and submit comments within ten (10) business days to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Draft Security Plan comments, and, submit a Final Security Plan to the U.S. Government within thirty (10) calendar days after receipt of the comments.
b) The Security Plan shall include a timeline for compliance of all the required security measures outlined by the Government.
c) Upon completion of initiating all security measures, the Contractor shall supply to the Contracting Officer a letter certifying compliance to the elements outlined in the Final Security Plan.

At a minimum, the Final Security Plan shall address the following items:

Security Requirements:

1. Facility Security Plan

Description: As part of the partner facility's overall security program, the contractor shall submit a written security plan with their proposal to the Government for review and approval by Government security subject matter experts. The performance of work under the contract will be

in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:	
Security Administration	• organization chart and responsibilities • written security risk assessment for site • threat levels with identification matrix (High, Medium, or Low) • enhanced security procedures during elevated threats • liaison procedures with law enforcement • annual employee security education and training program
Physical Security Policies and Procedures	• internal/external access control • protective services • identification/badging • employee and visitor access controls • parking areas and access control • perimeter fencing/barriers • product shipping, receiving and transport security procedures • facility security lighting • restricted areas • signage • intrusion detection systems • alarm monitoring/response • closed circuit television • product storage security • other control measures as identified
Information Security	• identification and marking of sensitive information • access control • storage of information • document control procedures • retention/ destruction requirements
Information Technology/Cyber Security Policies and Procedures	• intrusion detection and prevention systems • threat identification • employee training (initial and annual) • encryption systems • identification of sensitive information/media • password policy (max days 90) • lock screen time out policy (minimum time 20 minutes) • removable media policy • laptop policy • removal of IT assets for domestic/foreign travel • access control and determination • VPN procedures • WiFi and Bluetooth disabled when not in use • system document control • system backup • system disaster recovery • incident response

	• system audit procedures • property accountability
2. Site Security Master Plan Description: The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; IT Server Room; Product Storage Freezer/Room; and bio-containment laboratories.	
3. Site Threat / Vulnerability / Risk Assessment Description: The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually.	
4. Physical Security Description:	
Closed Circuit Television (CCTV) Monitoring	a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored. b) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. c) Video recordings must be maintained for a minimum of 30 days. d) CCTV surveillance system must be on emergency power backup. e) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. f) Video recordings must be maintained for a minimum of 30 days. g) CCTV surveillance system must be on emergency power backup.
Facility Lighting	a) Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. b) Lighting must have emergency power backup. c) Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	a) Must have CCTV coverage and an electronic access control system. b) Must have procedures in place to control access and movement of drivers picking up or delivering shipments. c) Must identify drivers picking up Government products by government issued photo identification.
Access Control	a) Must have an electronic intrusion detection system with centralized monitoring.

	b) Responses to alarms must be immediate and documented in writing. c) Employ an electronic system (i.e., card key) to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.). d) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. e) Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of12 months. f) Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company. g) Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months. h) Should have written procedures to prevent employee piggybacking access i) to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. j) Must have a written manual key accountability and inventory process. k) Physical access controls should present a layered approach to critical assets within the facility.
Employee/Visitor Identification	a) Should issue company photo identification to all employees. b) Photo identification should be displayed above the waist anytime the employee is on company property. c) Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. d) Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises at all times.
Security Fencing	Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
5. Security Operations Description:	
Security Management	a) Designate a knowledgeable security professional to manage the security of the facility. b) Ensure subcontractor compliance with all Government security requirements.
6. Information Security Description:	

Physical Document Control	a) Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate government markings. b) Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended. c) Access to sensitive information should be restricted to those with a need to know.
Document Destruction	Documents must be destroyed using approved destruction measures (i.e, shredders/approved third party vendors / pulverizing / incinerating).
7. Information Technology & Cybersecurity Description:	
Identity Management	a) Physical devices and systems within the organization are inventoried and accounted for annually. b) Organizational cybersecurity policy is established and communicated. c) Asset vulnerabilities are identified and documented. d) Cyber threat intelligence is received from information sharing forums and sources. e) Threats, vulnerabilities, likelihoods, and impacts are used to determine risk. f) Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes. g) Users, devices, and other assets are authenticated (e.g., single-factor, multifactor) commensurate with the risk of the transaction (e.g., individuals' security and privacy risks and other organizational risks)
Access Control	a) Limit information system access to authorized users. b) Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access. c) Limit physical access to information systems, equipment, and server rooms with electronic access controls. d) Limit access to/ verify access to use of external information systems.
Training	a) Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.
Audit and Accountability	a) Create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate system activity. Records must be kept for minimum must be kept for 12 months.

	b) Ensure the actions of individual information system users can be uniquely traced to those users. c) Update malicious code mechanisms when new releases are available. d) Perform periodic scans of the information system and real time scans of files from external sources as files are downloaded, opened, or executed.
Configuration Management	a) Establish and enforce security configuration settings. b) Implement sub networks for publically accessible system components that are physically or logically separated from internal networks.
Contingency Planning	a) Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.
Incident Response	a) Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents. Exercise this capability annually.
Media and Information Protection	a) Protect information system media, both paper and digital. b) Limit access to information on information systems media to authorized users. c) Sanitize and destroy media no longer in use. d) Control the use of removable media through technology or policy.
Physical and Environmental Protection	a) Limit access to information systems, equipment, and the respective operating environments to authorized individuals. b) Intrusion detection and prevention system employed on IT networks. c) Protect the physical and support infrastructure for all information systems. d) Protect information systems against environmental hazards. e) Escort visitors and monitor visitor activity.
Network Protection	Employ intrusion prevention and detection technology with immediate analysis capabilities.
8. **Transportation Security** Description: Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.	
Drivers	a) Drivers must be vetted in accordance with Government Personnel Security Requirements. b) Drivers must be trained on specific security and emergency procedures. c) Drivers must be equipped with backup communications. d) Driver identity must be 100 percent confirmed before the pick-up of any Government product.

	e) Drivers must never leave Government products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency. f) Truck pickup and deliveries must be logged and kept on record for a minimum of 12 months.
Transport Routes	a) Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency. b) Transport routes should be continuously evaluated based upon new threats, significant planned events, weather, and other situations that may delay or disrupt transport.
Product Security	a) Government products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed. • Tamper resistant seals must be verified as "secure" after the product is placed in the transport vehicle. b) Government products should be continually monitored by GPS technology while in transport, and any deviations from planned routes should be investigated and documented. c) Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.
9. Security Reporting Requirements Description: The partner facility shall notify the Government Security Team within 24 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review.	