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

"Sustainment of N95 Respirator Manufacturing Capacity"

RPP #: 24-05-N95

Issued: August 2, 2024

Amendment No. 2 Issue Date: August 19, 2024

Due: August 22, 2024 1PM Eastern

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

MedicalCountermeasures.gov

Amendment No. 02 does the following:
Revises language in Section 2.11 and Section 4.2 regarding requirements.
All other terms and conditions remain unchanged.

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

N95 respirators are critical for frontline workers involved in biomanufacturing, pharmaceutical production, as well as delivery of healthcare, providing a crucial barrier against airborne pathogens and reducing the risk of infection and preventing contamination during manufacturing. The COVID-19 pandemic revealed vulnerabilities in the global supply chain of these items and specifically highlighted the lack of domestic manufacturing capacity necessary to support pandemic surge demands. This effort seeks to sustain N95 Respirator manufacturing capacity through reserving capacity for a period of 36 months to maintain a minimum viable production capacity (determined to be no more than 10 percent of full capacity). Additionally, through this effort, the awardee(s) will develop and implement a long-term sustainment strategy for N95 respirator domestic manufacturing to maintain operational status of the domestic manufacturing capacity to be prepared for a future Public Health Emergency (PHE).

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.

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.

A 36-month funded effort for sustainment is planned, followed by a non-USG-funded sustainment effort that will commence immediately after the funded effort and run for 5 ½ years, or until Sep 30, 2029, whichever comes first.

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 at least one agreement 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. Offerors must ~~*confirm possession of an approved FDA 510K (pre-market notification) and*~~ detail their current annual capacity as a current manufacturer of N95 respirators.

3. Offerors must confirm their compliance and adherence to regulations set by the Food and Drug Administration (FDA), and possession of National Institute for Occupational Safety and Health (NIOSH) 510 compliance.

Proposals found to not meet 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, 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 Businesses 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 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 Offeror shall complete the table provided in Section 8 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

2.10 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.

2.11 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.
- **Physical Property**. Title or interest in any equipment acquired by Awardee under this Agreement will vest with the Recipient. As this is an effort to sustain existing capacity, purchase of equipment is expected to be minimal.
- **SAM.gov Registration.** The BioMaP Consortium Member will be required to obtain a Unique Entity Identifier (UEI) from SAM.gov prior to award of a Project Agreement. A full SAM.gov registration is not required. See www.sam.gov for more information.
- **Made in America Act and Make PPE In America Act.** The Made in America Act and Make PPE in America Act are applicable to any resulting award from this solicitation.

2.12 Terms Related to the Awardee's Consideration for USG Investment Subject to Negotiation

In consideration for the Government's investment and subject to negotiation, the Awardee will guarantee long term sustainment of the capability for not less than 5 ½ years after completion of the effort, or

through September 30, 2029, whichever comes first. During this period, the Awardee is permitted and encouraged to utilize the capability for commercial purposes to support long term sustainable manufacturing of N95 respirators. However, the Awardee will be prohibited from selling, shutting down, mothballing or dismantling any part of the manufacturing capability supported through this effort, without prior Government approval.

2.13 Security Requirements

See Attachment C 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

Technical questions must be submitted by August 8, 2024 to be answered by the Government. After August 8, 2024, technical questions will not be able to be answered.

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://submissions2.ati.org/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

Submissions 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.
- **Draft Sustainment Plan (4 page limit) – See Section 4.2.2**
  - A draft Sustainment Plan is required in Word (.docx or .doc) or PDF addressing the requirements in Section 4.2.2.

4 Technical Requirements

4.1 General Objectives

The objective of this effort is to sustain manufacturing capabilities of N95 respirators through warm basing capacity for a period of 3 years at the minimum rate necessary to keep the manufacturing lines operational (established at not more than 10% of annual manufacturing capacity), and to develop and implement a commercially viable long-term warm-base sustainment strategy to keep the manufacturing lines operational for at least 5 ½ years after expiration of the 3 year effort.

4.2 Specific Objectives

4.2.1 N95 Respirator Manufacturing Capacity Sustainment and Maintenance in a Warm-Base status:

4.2.1.1 For a period of 3 years after award, the Awardee will sustain and warm base its N95 Respirator manufacturing capacity for use as directed by ASPR to support a Government response to a Presidentially declared PHE. During this period, the Awardee may utilize its manufacturing capacity for its own commercial use. However, in the event of a Presidentially declared PHE, the Awardee agrees that, if issued a Government sponsored contract or agreement for N95 Respirators, the Awardee agrees to use all unused manufacturing capacity to meet that requirement and, if necessary immediately divert ongoing commercial manufacturing activity as needed to meet that requirement.

4.2.1.2 In order to sustain the Awardee's manufacturing capacity, the Awardee will manufacture N95 respirators at a rate sufficient to maintain warm-base sustainment, not more than 10% of its annual total manufacturing capacity, for the Agreement duration.

4.2.1.3 The Awardee will manufacture and package the N95 respirators manufactured per 4.2.1.2 above in accordance with all applicable regulations and standards**, including the Made in America Act and the Make PPE In America Act, which prescribe specific preferences and requirements for domestic sourcing of manufactured products and components.**

4.2.1.4 The Awardee will deliver the N95 respirators manufactured per 4.2.1.2 above to Government in accordance with a regular schedule, as negotiated, to locations as directed by the Government. Delivery schedule and locations are TBD but within the Continental United States.

4.2.2 10 year warm-base manufacturing capacity sustainment plan

4.2.2.1 The Awardee will develop and implement a 10-year (including the 3 year sustainment and warm base period) N95 Respirator manufacturing and warm-base sustainment plan that will enable long term sustainment of the Awardee's manufacturing capability beyond completion of the funded effort.

4.2.2.2 Long Term Warm-Base Manufacturing Capacity Sustainment Plan. Starting with the Government's review comments from the draft plan submitted with the offeror's proposal, the awardee will update and add fidelity to the plan in accordance with Deliverable Instructions contained in Appendix I. The plan will be regularly updated and submitted, with continued Government participation, and will include:

- Discussion of what the awardee requires to sustain the manufacturing capability in a warm-base state of readiness and the steps required to move from this state to a state of full rate production, including, but not limited to staff retention, hiring timelines, manufacturing equipment readiness, long lead items, and the inter-dependencies of these elements in transitioning from warm-base to full rate production.
- A 10-year sustainment strategy to enable continued sustainment of the capability at the minimum necessary manufacturing rate to keep the capability in a "warm base" status and that enables ramp up to full rate production to support a declared PHE, within 120 days of USG notice to proceed. Note that demonstration of this ramp up capability is not required.
- A list of long lead items necessary to achieve full rate production and the quantity-based lead time.
- A description of how the Awardee will maintain NIOSH certification and meet all Federal, State and Local guidelines for the 10-year strategy period.
- A description of assumptions, risks and mitigation plans that impact the strategy and its implementation.

- Discussion and plan of action necessary to achieve and maintain Manufacturing Readiness Level 10 (MRL 10) (Full Rate Production demonstrated and lean production practices in place).
- Up-to-date market assessment of items that impact long-term sustainability.
- Discussion of alternative sustainment strategies, including but not limited to a Vendor Managed Inventory (VMI) arrangement where the company would manufacture N95 Respirators at not less than the minimum sustainable level and store the manufactured products at its own expense and sell the products commercially at its own discretion (including through Government contracts during times of pandemic demand). Discussion should also include alternative approaches to manufacturing and sustainment, such as automation and other approaches that reduce warm-basing sustainment costs while enabling rapid ramp-up to full rate production, or other methods that enable cost-effective sustainment of the manufacturing capacity.
- Discussion of how the awardee plans to maintain warm-based manufacturing while adapting to demand fluctuations, raw-materials sourcing, and other factors that adversely impact the manufacturing landscape while preserving the ability to meet pandemic demand requirements.
- Description of a Risk Management Plan and Risk Register that will track, manage, and mitigate long term sustainment risk regarding N95 respirator manufacturing capacity.

4.3 Program Management

The Awardee is responsible for overall management and execution of the work to achieve the objectives of the agreement. The Awardee must provide the overall management, integration, and coordination of all agreement activities to ensure the efficient planning, initiation, implementation, and direction of all agreement activities.

The Awardee will be responsible for establishing and managing to project milestones for the effort. The Awardee will ensure that any changes or deviations planned or incurred by the Awardee in pursuing the objectives of any resulting agreement are reported to BARDA. While primary responsibility for management and execution of the effort resides with the Awardee, BARDA must have input to the milestone review process and any changes to the objectives of any resulting agreement.

4.4 Risk Management Objectives

The Awardee will establish a Risk Management program that includes development of a Risk Management Plan, Risk Register, and risk mitigation strategies to manage all project risks, and report changes to all identified risks to the Government as they occur/arise. The Government must be permitted to participate in the risk management and mitigation processes associated with this project.

4.5 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 Other Transaction Agreements Officer (OTAO) and Other Transaction Technical Representative (OTTR) 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
10 year N95 Respirator warm-base manufacturing capacity sustainment plan	See Section 4.2.2.	4-page draft: due with Proposal, which discusses critical elements regarding how the offeror plans to address Section 4.2.2 of the RPP. Post Award: Submitted and updated every 6 months as described below: 90 days after award, plan will be updated and submitted by awardee to address USG comments from draft plan submitted with proposal. USG will have 90 days to review and comment. Awardee will have 90 days to update plan to address USG comments. Thereafter, USG will have 90 days to review/comment, awardee will submit subsequent revisions within 90 days of receipt of USG comments until the end of the Government-funded effort.
Kick Off Meeting	Awardee to develop Agenda and host an in-person or virtual kick-off meeting to discuss overall project objectives, key personnel, deliverables, risks, schedule and invoicing procedures. Provide meeting minutes.	Kickoff meeting conducted within 2 weeks of award. Minutes to be submitted by Awardee to USG within 3 business days of meeting.

Deliverable Description	Content Requirements and Instructions	Reporting Frequency
Monthly and Ad-hoc Project Team Meetings	Awardee to schedule meetings and create agenda. Purpose is to review monthly and interim progress report findings, changes, and anticipated issues or challenges.	Monthly and as needed or when specifically requested by the Project Officer. May be virtual or in-person. If monthly, schedule approximately 5 business days after the monthly report deliverable. 1 hour duration, hosted by the Awardee. Minutes to be submitted by Awardee to USG within 3 business days of meeting.
Monthly Project Progress Report	Monthly report of overall status including budget, project performance (capacity available or milestones reached) and schedule progress noting variance from previous month's report. Include discussion of important design considerations and milestones. Level of detail for various aspects of project may decrease or increase as the project moves through execution. Feedback or revisions are to be incorporated in reports.	Monthly. Due date TBD aligning with monthly meetings. Awardee report format acceptable with USG content requirements at a minimum. Initial report delivered in Microsoft Word or equivalent for ease of edits and final in PDF for USG record keeping.
Quarterly In-Process Review (IPR)	Organized, scheduled, and hosted by Awardee. May be virtual or physical at Awardee's facilities based on USG preference. IPR will include but not be limited to schedule, budget, performance, risk, design, construction, validation, and regulatory/quality.	Occurs every 3 months from start of project. Awardee to provide review materials to USG 3 working days in advance of meeting. Awardee minutes to be submitted to USG within 3 business days of meeting.

Deliverable Description	Content Requirements and Instructions	Reporting Frequency
Integrated Master Schedule (IMS)	Detailed project schedule including all manufacturing and management activities, critical path, and Agreement milestones. Format and contents to be provided by USG. Updated monthly or as needed. Monthly report schedule summary must include details of at least the upcoming 6 months, with no subtask more than 2 weeks in duration. Include all contract and other milestones through completion of the effort.	Updated monthly or as needed. Summary to be included with monthly report.
Project Budget	Full detailed budget by month and year for entire Project, incorporating original proposal, changes, current projections and any escalation in cost, with all budget categories included as provided in proposal to USG.	Updates submitted with monthly project progress report with summary provided during monthly meetings.
Risk Management Plan	Awardee to provide a plan for categorizing risks.	Draft submission with proposal. Initial submission 14 days after Agreement award. Thereafter monthly, to be submitted with every other technical and programmatic progress report. Updated as required, with any changes clearly identified/ highlighted for easy identification.
Project Risk Register	All project risks identified throughout the project must be tracked via a Risk Register.	Updated monthly and submitted with Monthly Project Report.
Facility Security Plan	See BARDA Security Requirements, Attachment C	Initial submission 30 Days after Award, updated as necessary
Supply Chain Resiliency Plan	Provide information required in ASPR/BARDA Supply Chain Resiliency Plan Attachment C	Initial submission 30 Days after award, updated annually with annual report. Awardee format acceptable.
OPSEC Plan	See Attachment C	Initial submission 30 Days after award, updated annually with annual report. Awardee format acceptable.

Deliverable Description	Content Requirements and Instructions	Reporting Frequency
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 project progress report.
Site Visits	Host visits from USG following agenda/schedule mutually agreed upon with USG in advance of visits.	Typically, quarterly with IPR, at the Project Officer's discretion. Minutes to be submitted within 3 business days of meeting.
Annual Project Progress Report	High level project progress review of overall objectives including, but not limited to schedule, budget, quality, cost control (i.e., changes), design, construction, validation, and regulatory/quality. 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; not to exceed 20 pages.	Annually from start of project through completion of the funded effort. Draft to be submitted 30 days after the completion of each year of contract performance. Within 15 days of receipt, the Government review; Awardee must respond within 15 days of receipt of comments.
Final Report	Final report summarizing stated objectives and the progress that was achieved in meeting those objectives; summary of risks incurred, impacts and mitigation; quantitative discussion of production improvements achieved; financial summary of project; schedule summary for project, 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 funded effort. Within 15 days of receipt, the Government will review; Awardee must respond within 15 days of receipt of comments.

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
- Factor 2: Relevant Experience - demonstrated organizational experience, as well as the technical and management experience of the proposed team to perform the proposed work. The Government may also consider information in Contractor Performance Assessment Reporting System (CPARS), and the Federal Awardee Performance and Integrity Information System (FAPIIS) or similar systems.
- Factor 3: 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:

- Excellent
- Very Good
- Acceptable
- 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' schedule 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 Attachments

Attachment A: Technical Proposal Template

Attachment B: Cost Proposal Template

Attachment C: 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. 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.

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

[As detailed in Section 2.5 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 (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):	

Minimum Eligibility Requirements

1. **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.]

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 4.5 of the RPP are required; **populate the table below to include all deliverables from section 4.5 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 Cost	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. **Risks & Mitigation:** [Identify potential problem areas (e.g., technical, schedule, cost) in the proposed approach. Describe risk mitigation methods.]

2. **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, or omit substantial parts or sections 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. For this solicitation, the methods are (1) Cost Reimbursable Milestones with Ceiling or (2) Cost Reimbursable/Cost Share with Ceiling,

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

a. **If the Offeror is proposing a Cost-Type Agreement:**
   - Direct Labor: Identify all labor categories proposed, hours associated with each, and total amount proposed for each category. Labor proposed should be provided without burdens (indirects) applied.
   - Team Members/Subcontractors: Identify all team members/subcontractors and a total amount proposed for each team member.

- Consultants: Identify all proposed consultants and a total cost for each consultant.
- Material/Equipment: Provide a list of proposed material/equipment (i.e. a bill of materials) and identify the total amount proposed for material/equipment.
- Travel: Identify all proposed trips to include departure and destination, number of travelers per trip, number of days per trip, purpose of each trip, and total amount proposed for all travel.
- Other Direct Costs: Provide a list of the proposed other direct costs that do not fit into the cost elements above and identify the total amount proposed for other direct costs.
- Indirect Costs: Identify all indirect rates utilized in the proposal (e.g., fringe benefits, overhead, G&A, etc.) and the total amount proposed for each indirect.

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. 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:

Cash Contribution:
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.).

d. 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: ASPR Security Requirements

*** This list of deliverables and security requirements ASPR-mandated requirements that will be required for any agreement awarded by or on behalf of ASPR as a result of this solicitation.**

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.

Security Audits

Description: The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and subcontractors. Minimum length of notification is 10 business days.

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

Personnel Security	• policies and procedures • candidate recruitment process • background investigations process • employment suitability policy • employee access determination • rules of behavior/ conduct • termination procedures • non-disclosure agreements
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.
Protective Security Forces	Requirements for security officers will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces Operations	a) Must have in-service training program. b) Must have Use of Force Continuum. c) Must have communication systems available (i.e., landline on post, cell phones, handheld radio, and desktop computer). d) Must have Standing Post Orders. e) Must wear distinct uniform identifying them as security officers.
5. Security Operations Description:	
Information Sharing	a) Establish formal liaison with law enforcement. b) Meet in person at a minimum annually. Document meeting notes and keep them on file for a, minimum of 12 months. POC information for LE Officer that attended the meeting must be documented. c) Implement procedures for receiving and disseminating threat information.
Training	a) Conduct new employee security awareness training. b) Conduct and maintain records of annual security awareness training.
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. Personnel Security Description:	
Records Checks	Verification of social security number, date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, sex offender registry, credit check based

	upon position within the company; motor vehicle records check as appropriate; and local/national criminal history search.
Hiring and Retention Standards	a) Detailed policies and procedures concerning hiring and retention of employees, employee conduct, and off boarding procedures. b) Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network access.
7. 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).
8. 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 publicly 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.
9. **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.
10. 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.	
11. Security Audits Description: The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and subcontractor.	