Biomedical Advanced Research and Development Authority (BARDA)

Request for Project Proposals (RPP)

RPP Name: Production of Drug Substances and Drug Products at Commercial Scale: Anti-Microbials and Large Volume Parenterals

RPP Identifier: 26-2-AM-LVP

RPP Issue Date: February 6, 2026

Enhanced White Paper Due: March 9, 2026, 1 PM ET

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

Platform Technologies for Efficient Distributed Scalable Manufacturing of Active Pharmaceutical Ingredients (APIs) Drugs, includes key regulatory/chemical starting material(s) (KSMs), precursor(s), intermediate, enzymes or catalyst necessary, up to and including the synthesis of essential APIs (See Section 8, Reference #1), with a preferred application to multiple medicines, with a programmatic focus on Anti-Microbials and Large-Volume Parenterals. Examples of platforms include but are not limited to those that incorporate distributed manufacturing systems with a special focus on vertical integration of the systems with fill and finish lines.

An important strategic goal of the Administration for Strategic Preparedness and Response (ASPR) Industrial Base Management and Supply Chain (IBMSC) Office Advanced Manufacturing Domain is to support and facilitate development of the technological infrastructure within the Domestic pharmaceutical manufacturing industry to provide new materials, products, capabilities, and manufacturing paradigms for the Nation. Specifically,

ASPR IBMSC is seeking to develop a drug substance and drug product manufacturing design-build-test cycle at a scale that demonstrates the ability to produce hundreds of millions of doses of drug substances to support the American public (population scale), with a focus of sustaining domestic production capacities. This objective will support ASPR IBMSC's broader long-term goal of commercializing infrastructure that will be accessible to a broad community of users for the purpose of producing drug substances and drug products, creating a new manufacturing paradigm that can be competitive in the domestic and global market, with the added benefit of onshoring drug production.

The Department of Health and Human Services (HHS) Defense Production Act (DPA) Title III Program is interested in submissions that strengthen the Nation's security of supply for at least one (1) key starting material (KSM), drug substance, and/or drug product identified within the FDA's List of Essential Medicines, with a preference for submissions that focus on Anti-Microbials and Large Volume Parenterals.

The objective of this supplement is to commercialize production for at least one (1) key starting material, drug substance, and/or drug product at population scale.

- Compliant with the DPA definition of a "domestic source" (i.e., 50 U.S.C. 4552(7))

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)

This RPP will be conducted using the Enhanced White Paper approach. Offerors are invited to submit Enhanced White Papers using the mandatory format contained in this RPP (see Attachment A). The Government will evaluate Enhanced White Papers submitted and will recommend those that best meet their current technology priorities using the criteria in Section 5 of this RPP. Offerors whose proposed solution is recommended for further consideration based on the Enhanced White Paper evaluation will be invited to submit a Statement of Work (SOW) and Full Cost Proposal (and may be required to submit additional documentation or supplemental information).

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.

It is expected that there will be a total of one or more qualified respondents to accomplish the statement of objectives. 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 Enhanced White Paper that, if selected for award, they will abide by the terms and conditions of the latest version of the BioMaP-Consortium Base Agreement.

Offerors are advised to check the BioMaP-Consortium website periodically during the proposal preparation period for any changes to the BioMaP-Consortium Base Agreement terms and conditions.

2.2 Period of Performance

The anticipated period of performance shall not exceed 24 months. Offerors should plan for the period of performance to begin in Quarter 3 of Government Fiscal Year 2026. 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.

2.3 Estimated Funding

The total estimated funding for all projects is approximately $200 million. This amount is approximate and subject to adjustment based on program requirements and the availability of funds. Funding of proposals submitted in response to this RPP is contingent upon the availability of federal funds for this program. The Government anticipates making multiple awards under this RPP.

2.4 Proprietary Information

The BioMaP-Consortium CMF will oversee submission of Enhanced White Papers 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 Enhanced White Papers under this RPP indicates concurrence with the aforementioned CMF responsibilities.

2.5 Minimum Eligibility Criteria

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

- Offerors submitting Enhanced White Papers must be members of the BioMaP-Consortium prior to award of a Project Agreement. Click here to learn how to join the consortium.
- Demonstrated experience in the scalable manufacturing of KSMs/APIs and finished product form (FPF) drugs, specifically at or beyond Manufacturing Readiness Level (MRL) 6

Enhanced White Papers 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.

2.6 Special Considerations

The following are special considerations in the evaluation and/or negotiation process; however, neither are 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.

2.7 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 Enhanced White Papers.

Cost share is required in order to be eligible to receive an award under this RPP. 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 leads to stronger leveraging of Government-contractor collaboration. For more information regarding cost share, please see Attachment C.

2.8 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 the RPP's Attachment A, Data Rights Appendix, identifying any Intellectual Property or Data Rights to be furnished to the Government with restrictions.

2.9 Regulatory Terms

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

While additional regulatory terms have not been identified at this time for this project, information on potential regulatory terms is provided in the BioMaP-Consortium Base Agreement.

2.10 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.
- **SAM.gov Registration**. Offerors are required to obtain a Unique Entity Identifier (UEI) from SAM.gov prior to award of a Project Agreement.

2.11 Security Requirements

See Attachment B of this RPP 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.

2.12 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 Enhanced White Papers

3.1 Timelines

All questions regarding this RPP must be submitted via email to biomap-contracts@ati.org no later than 1:00 PM ET on February 18, 2026.

Key Dates for this RPP

Date	Event
2/6/2026	RPP Released
2/12/2026	Virtual Teaming Speed Networking Event
2/18/2026	Deadline for submitting questions to biomap-contracts@ati.org (by 1:00 PM ET)
Notification sent via email	Questions & Answers posted on the BioMaP-Consortium website
3/9/2026	Enhanced White Papers Due (by 1:00 PM ET)

3.2 General Instructions

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

The Enhanced White Papers 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 submission date/time to clarify requirements (Section 4 of this RPP).

The Government will evaluate Enhanced White Papers submitted and will select the offer(s) that best meets their current technology priorities using the criteria in Section 5 of this RPP.

All eligible Offerors shall submit Enhanced White Papers 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 Enhanced White Paper Submission

Enhanced White Papers must be submitted online via BIDS at

https://submissions2.ati.org/ATI2/Portal.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 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 the CMF 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 Enhanced White Papers 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

The Enhanced White Paper must be submitted in Word format (docx or .doc) or as a PDF, and must follow the mandatory template in Attachment A of this RPP. The Enhanced White Paper is limited to a maximum of 15 pages. The following items are excluded from the page count:

- Cover Page
- Data Rights Appendix
- Relevant Experience Appendix
- Teaming Partners Identified through BioMaP-Consortium Resources Appendix

The section headers in Attachment A are mandatory.

The following formatting requirements apply:

- 12-point font (or larger), single-spaced, single-sided, 8.5 by 11 inches
- Smaller type may be used in figures and tables, but must be 8-point font (or larger)
- Margins on all sides (top, bottom, left, and right) should be at least 1-inch

ZIP files and other application formats are not acceptable. All files must be print-capable and without a password required. Filenames shall contain the appropriate filename extension(.docx,.doc, or pdf). Filenames should not contain special characters. IOS users must ensure the entire filename and path are free of spaces and special characters.

4 Technical Requirements

4.1 Overview

ASPR IBMSC is seeking to develop a drug substance and drug product manufacturing design-build-test cycle at a scale that demonstrates the ability to produce hundreds of millions of

doses of drug substances to support the American public (population scale), with a focus of sustaining domestic production capacities. This objective will support ASPR IBMSC's broader long-term goal of commercializing infrastructure that will be accessible to a broad community of users for the purpose of producing drug substances and drug products, creating a new manufacturing paradigm that can be competitive in the domestic and global market, with the added benefit of onshoring drug production.

The HHS DPA Title III Program is interested in submissions that strengthen the Nation's security of supply for at least one (1) key starting material, drug substance, and/or drug product identified within the FDA's List of Essential Medicines, with a preference for submissions that focus on Anti-Microbials and Large Volume Parenterals.

4.2 Technical Objectives

The objective of this supplement is to commercialize production for at least one (1) key starting material, drug substance, and/or drug product at population scale. This will be achieved by employing a multi-step approach as described below, with a total period of performance of no more than 24 months. The offeror must be compliant with the DPA definition of a "domestic source" (i.e., 50 U.S.C. 4552(7))

4.2.1 Objective A:

Objective A is an engineering design and study phase to allow the performer to explore, develop and refine an infrastructure design and technical approach, including management, logistics, pricing/costing and other non-technical elements necessary to achieve the primary goal of distributed scalable manufacturing of drug substances at population scale. The following incremental objectives are required:

i. Jointly with the Government, select at least 1 proposed target drug substance(s), with a minimum entry requirement of MRL 6 (Manufacturing Proof of Concept Developed, see MRL definitions in Section 8, Reference #2). Must include rationale and basis for selection.

ii. Develop a detailed list of molecules and/or molecule classes, as well as other materials and systems and equipment required for each phase of manufacture, for each drug substance.

iii. Develop a proposed analytical/characterization and manufacturing plan for the manufacture of the selected drug substance(s) at population scale that includes automated and integrated processes across all stages of design, manufacturing, testing, and analysis. Plan must increase MRL to 10 and meet U.S. Pharmacopeia standards and ICH guidelines for purity, potency, safety, validation, quality, etc. Concepts to be considered in the analytical/characterization and manufacturing plan development may include, but are not limited to:

    a. Design tool innovations to enable forward engineering of novel synthetic pathways and population scale manufacturing.

b. Methods for automated, scalable, high-throughput and distributed drug substance and drug product manufacturing.

c. Design evaluation tools to enable massively parallel testing, analysis, validation, and verification of engineered systems, including analysis of intermediates.

d. Fully integrated computational and physical infrastructure to optimize design, manufacturing, validation/quality control, and analysis.

e. Include in the plan an infrastructure governance framework required to achieve population scale manufacturing of the selected drug substances, including considerations of academic and industrial partnerships, schedule requirements for each phase of drug substance development.

iv. Evaluate the maturity of necessary technology and infrastructure in the domestic market.

v. Conduct a risk assessment based on the maturity of domestic capabilities.

vi. Refine and finalize the analytical/characterization and manufacturing plan.

vii. Present final results of Objective A and the Plan for Objective B to the Government for approval to execute Objective B

4.2.2 Objective B:

Upon approval from the government to proceed with Objective B at the conclusion of Objective A, develop and execute an analytical model and demonstrate the manufacturing of a KSM/API including the development from MRL 6/7 to MRL 10, in compliance with U.S. Pharmacopeia standards and ICH guidelines for purity, potency, safety, validation, quality, etc.

i. Execute an analytical model and demonstrate manufacturing of the drug substance under various conditions and assumptions that:

a. Demonstrates the ability to produce a minimum of 1 drug substance(s) at population scale.

b. Assesses, through multiple production runs, various scenarios using various assumptions that exercises the limits the model and the assumptions, with a goal of identifying a set of input market conditions that can positively influence best results for drug substance manufacturing at population scale, and those which negatively influence results for drug substance manufacturing at population scale. Outcomes to be considered include, but are not limited to:

1. Shortest time to market
2. Lowest development and deployment costs
3. Optimal time to market with cost considerations

4. Major influencers in time to market
5. Major factors and influencers in development and deployment costs
6. Recommendations for future investment that can improve real-market ability to enable manufacturing of drug substances at population scale

4.3 Project Agreement Deliverables

The following deliverables are mandatory. Any additional technical deliverables proposed by the Offeror must be clearly identified.

Unless otherwise specified, the Offeror, hereafter referred to as Recipient in the table below, may submit deliverables in its own format. Acceptable submission formats include MS Office or PDF. Funding information shall be submitted in MS Excel, and schedule information may be submitted in either MS Excel or MS Project.

All deliverables are subject to U.S. Government review and comment. This review may require the Offeror to provide additional revisions or submissions.

4.3.1 Objective A Deliverables

i. Monthly technical progress report
ii. Objective A Project Plan (1 month after award):
   a. Plan should describe in detail the proposed plan to achieve each numbered step in sub-paragraph a above.
   b. Plan should include all analytical assumptions that will be employed in preparing and executing the model.
   c. Plan should include a range of assumptions/variables that can be used to assess various market conditions in Objective B.
   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 validate the model in real world scenarios.
   e. Plan should include all metrics, variables and milestones that define the various gates and decision points in the model (distinct from the bullet above).
   f. Plan should include a detailed analytical and manufacturing (Production) information that will be developed. Details should include the basic steps for each phase of analysis (anticipated to follow the various MRLs from 6-10), and which includes all dependencies and data interfaces between phases.
   g. Plan should include identification of risks associated with execution of the plan.
iii. Drug Substance Selection Report
   a. Basis for selection for each drug substance
   b. List of required materials for each molecule/molecule class
iv. Analytical/Characterization and Manufacturing Plan (at conclusion of Objective A)

a. Final analytical and manufacturing plan that describes all analytical and manufacturing steps, data interfaces between phases, and other pertinent data and facts that will allow the reader to fully understand the methodology of the proposed plan.
b. Complete description of the infrastructure and management structure, including but not limited to addressing all elements that will accomplish the program's goals and milestones (at conclusion of Objective A)

v. Objective A Review (at conclusion of Objective A)
   a. Written briefing and oral presentation to the government team summarizing Objective A results and description of the technical approach and a plan for Objective B.

4.3.2 Objective B Deliverables

i. Monthly technical progress reports
ii. Technical Batch Reports describing the analytical/characterization and manufacturing data of each manufacturing batch
iii. Final Technical Report:
   a. Thorough discussion of the analytical/characterization and manufacturing (Production) model and its inherent limitations.
   b. Full list of variables
   c. Full list of assumptions
   d. A discussion of each model "run" that includes:
      i. Market scenarios tested
      ii. List of assumptions and variable values used in each scenario
      iii. Discussion of observations and trends based on changes in assumptions and variables
      iv. Detailed discussion of each bulleted item from Objective B requirements i.b above
      v. Summary of fundings regarding major influencers identified through the production process
      vi. Recommendations for further study
iv. Established Registration Batches for each drug product
v. Completion of environmental, engineering and registration batch runs for each drug product.
vi. Abbreviated New Drug Applications (ANDAs) for each drug product filed with the Food and Drug Administration (FDA)

4.4 Program Management

The Awardee will be responsible for overall management and oversight of the work necessary to achieve the objectives of this effort. The Awardee will provide the overall management, integration, and coordination of all objective activities, including a technical and

administrative organization that ensures the efficient planning, initiation, implementation, and direction of all activities.

The Awardee will establish and maintain a project milestone schedule for the entire effort that includes all critical steps, critical path, and phases to include go/no-go and success criteria.

Any changes or deviations planned or incurred by the Awardee in pursuing the objectives of this effort shall be reported to USG. While primary responsibility for management and execution of the effort resides with the Awardee, USG shall have input to the milestone review process and any changes to the objectives.

4.5 Risk Management Objectives

The Awardee shall identify all anticipated project risks and track them via a Risk Register in accordance with deliverables requirements. The Awardee shall manage all project risks using its in-house risk management capabilities, and report to the USG changes to all identified risks as they occur/arise. USG shall be permitted to participate in the risk management and mitigation processes associated with this project.

4.6 Schedule Objectives

The Government's schedule objective for this effort is a period of performance of no more than 24 months. High-level milestones are outlined below, however responders should include durations for Objective A and Objective B in their response, with anticipated dates of the high-level milestones.

Milestone	***Due Date***
Objective A	
Kickoff meeting	Within 30 days of award
Objective A Project Plan	1 month from the award
Drug Substance Selection	TBD
Draft Analytical/Characterization and Manufacturing Plan	TBD
Objective A Review	TBD
Objective B	
Demonstration of population-scale production of at least one (1) drug substance(s) that meet U.S. Pharmacopeia standards for purity, potency, safety, and quality	21 months from the award
a. Demonstrate the overarching analytical and manufacturing infrastructure to enable end-to-end process.	

b. Demonstrate the analytical and manufacturing (production) Design tool innovations to enable the commercial production of at least (1) small molecule drug substance(s).	
c. Establish validated Methods for automated, scalable, high-throughput distributed manufacturing.	
d. Design evaluation tools to enable massively parallel testing, analysis, validation, and verification of engineered systems, including analysis of intermediates.	
e. Demonstrate a Fully integrated analytical and production infrastructure supporting design, fabrication, validation/quality control, and analysis, the totality of which should be tightly for design, process, manufacturing, and quality control optimization.	
f. Completion of environmental, engineering and registration batch runs for each drug product, including acceptable analytical/characterization data	
g. Technical Batch Report for each Environmental Batch	
h. Technical Batch Report for each Engineering Batch	
i. Technical Batch Reports for each Registration Batch	
j. Filing of an ANDA for each drug product	
Final Report	30 days from completion

4.7 Teaming and Partnerships

It is anticipated that multi-disciplinary teams will approach this program, and that successful implementation will result from collaborations between academia and industry. Teams may be led by industrial, academic, or non-profit entities, and along with other organizations. Teams can incorporate members with experience in fields such as computer science, engineering, automation, regulatory, supply chain, industrial process development, chemistry/chemical engineering, and pharmaceutical sciences, among others. It is expected that the proposed leadership team will include individuals with significant experience and expertise in directing operations and technology development. These teams will lead large and diverse teams with both academic and industrial partners and have significant experience in industrial process design, identify industrial and commercial partners to aid in focusing technology development and identifying target drug substances. This expectation allows the rapid design and prototyping infrastructure to benefit from industrial partner knowledge and allows industrial

partners to impact design processes based on experience. Team efforts should be fully integrated and demonstrate that all components are necessary and inseparable.

5 Evaluation and Selection

5.1 Compliance Screening

The BioMaP-Consortium CMF will conduct a preliminary screening of submitted Enhanced White Papers to ensure compliance with the RPP requirements. As part of the preliminary screening process, Enhanced White Papers 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 Enhanced White Papers 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 Enhanced White Papers. 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 an Enhanced White Paper under this RPP indicates concurrence with the aforementioned use of contractors and SMEs.

Evaluation of Enhanced White Papers 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 Enhanced White Paper against the evaluation factors detailed below.

5.3 Evaluation Factors Overview

The Government will evaluate the information provided in each Offeror's Enhanced White Paper to determine which Enhanced White Paper(s) provide(s) the most advantageous solution to the Government. Such a determination will be based on the following criteria:

- Factor 1: Technical Approach/Solution
- Factor 2: Cost/Price
- Factor 3: Relevant Experience

5.4 Adjectival Merit Rating

Adjectival merit ratings that will be used for the non-cost/price factors.

- Technical Approach/Solution
- Relevant Experience

GENERAL MERIT RATING ASSESSMENTS	
RATING	DESCRIPTION
Excellent	Meets all requirements and presents substantial benefits identified by a combination of significant strengths and/or strengths that significantly outweigh risk presented by the evaluated weaknesses, if any. Generally, there are no significant weaknesses identified. If there are any, they are very limited. No deficiencies are found.
Very Good	Meets all requirements and presents benefits identified by a combination of significant strengths and/or strengths. If any weaknesses or significant weaknesses are present, the associated risks are outweighed by the evaluation benefits. No deficiencies are found.
Acceptable	Meets all requirements with essentially offsetting benefits and risks presented by significant strengths, strengths, weaknesses, and/or significant weaknesses, if any are present. No deficiencies are found.
Unacceptable	May have significant strengths and/or strengths; however, the benefits presented are irrelevant because the proposal does not meet all requirements and/or has a combination of weaknesses, significant weaknesses, and/or deficiencies that present an unacceptable level of risk.

5.5 Evaluation Factors

- **Factor 1 – Technical Approach/Solution (Adjectival Rating):** This factor evaluates the relevancy, thoroughness, completeness, and feasibility of the proposed approach.
- **Factor 2 – Relevant Experience (Adjectival Rating)**: This factor evaluates the Offeror's 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. The Government reserves the right to contact customer references to verify performance and assess quality of that performance, and to perform independent relevant experience analysis.
- **Factor 3 – Cost/Price Rough Order of Magnitude (ROM) Estimate:** The Enhanced White Paper shall include as thorough a cost/price estimate as is possible. The primary objectives of the Government's evaluation is to assess (1) if the proposed estimate is based on realistic assumptions, (2) if the estimate reflects a sufficient understanding of the technical goals and the objectives, and (3) if the estimate is consistent with the Offeror's technical approach.

5.6 Evaluation Outcome

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

- Recommend proposal(s) (or some portion of the proposal) for negotiations towards the 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 the recommendations is completed, the Government will forward its recommendations to the BioMaP-Consortium CMF to notify the Offerors. Offerors will be notified of their results via email from the BioMaP-Consortium CMF. All Offerors will receive feedback on eligible submissions. Recommended Offeror(s) will receive a request letter detailing the next steps in the award process.

5.7 Basket Provision

The electronic "Basket" is an innovative acquisition tool. Proposals rated as Acceptable through Excellent, 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 after it has received and reviewed a Full Cost Proposal and Statement of Work.

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..

6 Points of Contact

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

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

7 References

1. Reference for essential medicines to be considered in this solicitation:
https://www.fda.gov/media/143406/download?attachment

2. Manufacturing Readiness Level (MRL) definitions:
https://acqnotes.com/acqnote/careerfields/manufacturing-readiness-levelmanufact

8 Attachments

Attachment A: Enhanced White Paper Template

Attachment B: ASPR Security Requirements

Attachment A: Enhanced White Paper Template

Directions: The following pages are the mandatory Enhanced Whitepaper template. The template includes mandatory aspects including a cover page, section headers, charts, and appendixes. Guidance indicated in [brackets] is provided to assist the Offeror. Delete the guidance and replace with content.

[Name of Offeror]

[Address of Offeror]

RPP Identifier: 26-2-AM-LVP

[Proposal Title]

[Offeror] certifies that, if selected for award, the Offeror will abide by the terms and conditions of the BioMaP-Consortium 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 Enhanced White Paper 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).]

[Title of Enhanced White Paper]

1. **Minimum Eligibility Requirement**: [Address how the Offeror currently satisfies the following minimum eligibility requirements.]

2. **Background**: [Briefly provide background understanding of the problem.]

3. **General Approach:** [Briefly summarize the general approach and how it will solve the problem.]

4. **Technical Strategy**: [Thoroughly describe the proposed technical strategy in detail, with a clear course of action to address the entirety of objectives as described in Section 4 of this RPP.]

5. **Principal Investigator:** [Identify the Principal Investigator and provide his/her relevant experience and expertise to be leveraged to meet the program's objectives.]

6. **Teaming and Project Management:** [Team Management - If the proposal involves more than one organization, identify the team that will perform the proposed work along with respective qualities or contributions (e.g., qualifications, technical experience, management experience, etc.) Indicate if the team has worked together before.

   Project Management - If the proposal involves more than one organization, clearly identify roles and responsibilities Describe plans for managing communication and conflict resolution.]

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

8. **Organizational Conflict of Interest:** [An Organizational Conflict of Interest can occur, but is not limited to, 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.]

9. **Period of Performance:** [Identify the proposed Period of Performance (PoP) in months from award.]

10. **Timeline**: [Provide a schedule (e.g., Gantt chart) that clearly shows program tasks in an orderly manner. Provide each major task as a separate line. At a minimum, must address the RPP's Schedule Objectives in Section 4]

11. **Rough Order of Magnitude (ROM) Pricing Estimate:** [Complete the following chart to provide sufficient pricing estimation information to substantiate that the estimate reflects a sufficient understanding of the technical goals/objectives and is consistent with the Offeror's technical approach. If subcontractors or consultants are proposed, the estimates for their labor, travel, material, other directs, indirects, and fee should all be included on their respective Subcontractor or Consultant row. As a result, the Labor, Material, Other Direct Costs, Indirect Cost, and Fee rows should only reflect the Offeror's costs.]

Rough Order of Magnitude (ROM) Pricing Estimate	
Cost Element	**Total Estimate**
Labor	*$XXX*
Labor Hours	*XX*
Subcontractors	*$XXX*
Subcontractor Hours	*XX*
Consultants	*$XXX*
Consultant Hours	*XX*
Material/Equipment	*$XXX*
Other Direct Costs (ODCs)	*$XXX*
Travel	*$XXX*
Indirect Costs	*$XXX*
Fee *(Not applicable if cost share proposed)*	*$XXX*

Total Cost to Government	*$XXX*
Additional Offeror-Provided Cost Share	*$XXX*
Total Project Value	**$XXXXXX**

12. **Estimate Rationale:** [Provide brief rationale describing how the estimate was calculated and is appropriate for the proposed work. Include list of important pricing assumptions.]

13. **Offeror Resources**: [Identify any key facilities, equipment, cost share, and other resources proposed for the effort. Identified facilities, equipment, and resources should be available and relevant for the technical solution being proposed. If none, state as such.]

14. **Government Resources**: [Identify any key Government facilities, Government equipment, Government property, etc. that requested to use for the effort. If none, state as such.]

15. **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).]

15.1. 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

15.2. 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

15.3. Potential Small Business Utilization: [Identify any additional potential and realistic opportunities with the technical approach/scope to meaningfully involve small businesses, which have not otherwise been addressed in the previous subsections. If none, state as such.]

Relevant Experience Appendix

[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 enhanced white paper, each relevant experience is limited to three pages.]

<table>
<tr><th colspan="4">Respondent's Name and Contract/Example Name</th></tr>
<tr><td>Contract Number</td><td></td><td>Contract Type</td><td></td></tr>
<tr><td rowspan="2">Period of Performance</td><td rowspan="2"></td><td>Contract Value</td><td rowspan="2"></td></tr>
<tr><td>(Base and Sub-awards)</td></tr>
<tr><td>Agency</td><td></td><td colspan="2">Customer Points of Contact</td></tr>
<tr><td rowspan="6">Name & Address of Contracting Organization</td><td rowspan="6"></td><td>Project Officer</td><td></td></tr>
<tr><td>Phone</td><td></td></tr>
<tr><td>E-mail</td><td></td></tr>
<tr><td>Contracting Officer</td><td></td></tr>
<tr><td>Phone</td><td></td></tr>
<tr><td>E-mail</td><td></td></tr>
<tr><td colspan="4">Similarities to this Solicitation</td></tr>
<tr><td colspan="4"></td></tr>
<tr><td colspan="4">Brief Description of Project Scope and Customer Expectations</td></tr>
<tr><td colspan="4"></td></tr>
<tr><td colspan="4">Brief Description of Approach and Performance</td></tr>
<tr><td colspan="4"></td></tr>
</table>

Data Rights Appendix

[Note that this assertion is subject to negotiation prior to award. Failure to complete this appendix in its entirety may result in removal from the competition and the proposal determined to be ineligible for award. This appendix does not count towards the overall page limit of the enhanced white paper.]

Directions: Review and check the appropriate box. Only complete the table if asserting data rights. Add additional rows as needed.

☐ 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 as detailed in the table below.

Technical Data or Computer Software to be Furnished with Restrictions	**Basis of Assertion**	**Asserted Rights Category**	**Name of Organization Asserting Restrictions**	**Affected Deliverable(s)**

☐ Offeror will NOT be asserting data rights for the proposed effort.

Teaming Partners Identified through BioMaP-Consortium Resources Appendix

Identify any teaming partners/subcontractors for this proposal that were identified through the BioMaP-Consortium's **Collaboration Database on the Members-Only Website** or the **RPP Speed Networking Event**. This information is collected for informational purposes only and has no impact on the evaluation. If no teaming partners/ subcontractors were identified through either BioMaP-Consortium resource, state "None."

Teaming Partner Name	**Was this teaming partner identified via the BioMaP-Consortium's Collaboration Database?** ***(Yes/No)***	**Was this teaming partner identified via the BioMaP-Consortium's RPP Speed Networking Event?** ***(Yes/No)***

Attachment B: ASPR Security Requirements

Mandatory* ASPR Deliverables and 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.

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 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.
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.	