Biomedical Advanced Research and Development Authority (BARDA)

Biopharmaceutical Manufacturing Preparedness – Consortium (BioMaP-Consortium)

Request for Project Proposals (RPP)

Advanced Research and Development of Medical Countermeasures Through Agile and Distributed End-to-End (KSM, API and FDF) Drug Manufacturing

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Amendment No. 03 updates Section 3 and Attachment A of the RPP. Changes are indicated in red font. All other terms and conditions remain unchanged.

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Contents

1 Executive Summary 4
1.1 Biopharmaceutical Manufacturing Preparedness Consortium 4
1.2 Purpose 4
2 Administrative Overview 5
2.1 RPP Approach 5
2.2 Period of Performance 6
2.3 Estimated Funding 6
2.4 Proprietary Information 6
2.5 Minimum Eligibility Criteria 6
2.6 Special Considerations 8
2.7 Cost Sharing 8
2.8 Intellectual Property and Data Rights 8
2.9 Regulatory Terms 10
2.10 Special Requirements 10
2.11 Security Requirements 10
2.12 Preparation Cost 10
3 Proposals 11
3.1 Questions 11
3.2 Key Dates for this RPP 11
3.3 General Instructions 11
3.4 Submission 11
3.5 Submission Format 12
3.6 Teaming Partners Identified through BioMaP-Consortium Resources 12
4 Evaluation and Selection 13
4.1 Compliance Screening 13
4.2 Evaluation Process 13
4.3 Evaluation Factors Overview 13
4.4 Adjectival Merit Rating 13
4.5 Evaluation Factors 14
4.6 Evaluation Outcome 16
4.7 Basket Provision 16
4.8 Cost/Price Estimate and Evaluation 16
4.9 Award Determination 17
5 Points of Contact 17

6 Attachments 18
Attachment A: Technical Requirements 19
Attachment B: ASPR Security Requirements 63
Attachment C: Full Proposal Template (Technical and Cost) 75
Technical Proposal 76
Organization Information Sheet 78
Executive Summary 79
Technical Approach 79
Supporting Project Information Appendix 83
Cost Proposal Template 86
Cost Proposal Section I: Cost Proposal Narrative 86
Cost Proposal Section II: Cost Proposal Format 91
Attachment D: Additional Required Documentation 93

1 Executive Summary

1.1 Biopharmaceutical Manufacturing Preparedness Consortium

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

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

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

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

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

1.2 Purpose

The Administration for Strategic Preparedness and Response, Industrial Base Management and Supply Chain (APSR IBMSC) is seeking to establish advanced research and development of medical countermeasures through agile and distributed drug substance and drug product manufacturing capacities. This includes establishing end-to-end manufacturing capacities under current good manufacturing practices (cGMP) and all associated regulatory filings to include drug master files (DMFs), New Drug Applications, (NDAs) and Abbreviated New Drug Applications (ANDAs). This scope also includes the use of qualified laboratories for product verification, environmental and shelf-life testing, and adherence to industry-recognized consensus standards applicable to performance and its goals (e.g., ISO, ASTM).

Agile manufacturing is defined as manufacturing that is able to move quickly and adapt easily to change. Distributed manufacturing is defined as manufacturing spread across multiple locations rather than centralized in one place.

Required capabilities include the development and commercialization of agile and distributed manufacturing technologies and platforms that can rapidly scale production, conversion, finishing and availing of drug substances and drug products. The specific focus of this effort is the establishment of agile and distributed manufacturing capabilities for small molecule drug products used as medical countermeasures in multiple finished drug dosage forms. The approach must be built on flexibility, innovation, and augmentation. Data-driven production, inventory management and conversion that aligns supply with demand is required. Development and commercialization of repurposable equipment, parallel component production, increased efficiency, reduced waste, automation, digital monitoring for real-time quality assurance, responsive local and regional manufacturing capacities, and innovative inventorying, manufacturing, packaging and fill-finish methods are preferred.

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

2 Administrative Overview

2.1 RPP Approach

Each response submitted to this RPP shall contain a full Technical Proposal and full Cost Proposal using the mandatory format contained in this RPP (see Attachment C), as well as additional documents detailed in Section 2.5 and Attachment D of this RPP. White Papers are not required for this RPP.

The Government will evaluate proposals submitted and will recommend those that best meet their current technology priorities using the criteria in Section 4 of 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.

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 ASPR 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. A copy of the Base Agreement can be requested from biomap-contracts@ati.org. 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 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 1 of Calendar Year 2027. 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

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. The preferred cost type is Firm Fixed Price, however, alternative cost types may be considered.

2.4 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.

2.5 Minimum Eligibility Criteria

Offerors must be members of the BioMaP-Consortium prior to award of a Project Agreement. Click here to learn how to join the consortium.

To be eligible for a potential award, Offerors must include the following in their proposal, if applicable. If not applicable, the Offeror must indicate as such.

- Submit an attestation that all work on the Project must be performed within the continental United States and its territories; the Performer is U.S. owned, U.S. operated, and has their global headquarters located within the U.S. If circumstances change after Project Agreement award, the Performer must obtain an Agreement Officer's Authorization (AOA) approval for any proposed arrangement where the Performer will not meet the U.S.-owned and operated requirement.
- Submit a maximum two-page explanation letter that identifies all of the following since March 2020: contract/order/agreement terminations or settlement

agreements with the U.S. Government, bankruptcy filings, receivership and eviction history, postponements or defaults on financial obligations, default judgments from a court, adverse decisions as part of binding arbitration, and any other information that informs the risk the government is taking if the Performer and Sub-Performer(s) is/are selected for an award.

- Submit a letter of bondability for construction-related bonding by a surety that is capable of executing the project. The letter of bondability must identify the bonding company and specify the Performer's bonding capacity. Bonding capacity is defined as the maximum dollar amount of contracts the surety will allow the Performer to take on at once. The letter must also address how much of the bonding capacity is available for the proposed project.
- Submit a statement identifying all of the following for the Performer and any Sub-Performer(s): Contacts with the Department of Justice (DOJ) and/or any Office of Inspector General (OIG) for any reason in the last five years, to include the names and contact information.
- Submit an attestation stating that the Performer's corporate bylaws will be amended within 90 days of a Project Agreement award to require all of the following:
    - The Performer, any successor interest to the Performer, will remain a U.S. owned U.S. operated, with global headquarters located within the U.S., domestically controlled company with corporate governance in place to prohibit foreign influence for at least ten years after a Project Agreement award.
    - In the event of a public health emergency, the Performer, any successor in interest to the Performer, and any other entity that owns, operates, leases, occupies, or uses the Government-funded capacity for any reason, must provide priority access, in terms at least as favorable to the Government as those the Government could require under the Defense Production Act of 1950, ch. 932, 64 Stat. 798, as amended and extended (codified as amended at 50 U.S.C. § 4501 et seq.)", to the Government if there is a public health emergency, or other triggering emergency declaration for a period of ten (10) years after the period of performance ends.
    - The Performer, any successor in interest to the Performer, and any other entity that owns, operates, leases, occupies, or uses the Government-funded capacity for any reason, must not use the real property, equipment, or other assets funded by the Government as collateral or for a purpose that is not related to production of drug substances and drug products, for a period of ten (10) years after the period of performance ends.
    - The Performer, any successor in interest to the Performer, and any other entity that owns, operates, leases, occupies, or uses the Government-funded capacity for any reason, must prioritize utilizing USG-funded capacity to meet U.S. market demand for drug substances and drug products for a period of ten (10) years before meeting global market demands. Prioritizing USG-funded capacity to meet U.S. market demands

is defined as fulfilling domestic need before meeting any global market need.

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.

2.6 Special Considerations

The following are special considerations for this RPP.

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) from sources other than ASPR. Cost sharing leads to stronger leveraging of Government-contractor collaboration. The extent of cost sharing is a consideration in the evaluation of proposals.

Cost sharing is preferred, however, not required under this RPP. Proposals must include a detailed and accurate cost estimate and the source of funds necessary to complete the proposed project. The proposal must also include a detailed and accurate cost estimate and source of funds to maintain the facilities and infrastructure necessary to carry out the proposed manufacturing effort for a period of at least ten (10) years after the project period of performance end date. Proposals must include cost share information to demonstrate the percentage of funds to complete the proposed project are available from an outside source. **Offerors must provide a full Capitalization Plan that identifies all proposed cost share contributions, including the total amount, the specific sources of funding (e.g., corporate funds, third-party contributions, or nonfederal governmental support), and the timing and availability of funds over the period of performance.** Offerors must provide supporting documentation (e.g., letters of commitment or financial statements), as appropriate. The cost sharing plan must also describe how the Performer will track, manage, and report cost share expenditures throughout project execution. Offerors must propose a project milestone schedule with associated invoicing that takes the cost share into account. Work, construction, tasks, etc. completed before award will not be considered as a portion of the Offerors's cost share for the proposed project. Offeror's proposed cost share must only apply to new efforts completed under this agreement. 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, as part of its proposal, each Performer must demonstrate that it holds sufficient rights in the technology it proposes to use to perform this Agreement and to convey the rights described in this Section. Each Performer must submit at proposal:

a. An inventory of background intellectual property on which the proposed platform or any proposed drug product depends, identifying for each item the owner, the patent or application number, and the nature and scope of the Performer's rights in that item.

b. A freedom to operate assessment covering the manufacturing platform and each proposed drug product, including any component licensed from, or developed jointly with, a third party.

c. Copies or executive summaries of every in-license, option, joint development, or technology transfer agreement on which performance depends, identifying field of use, territory, sublicensing rights, termination triggers, and any third-party consent required before the Government's license rights can attach.

d. Identification of any third party right that would limit the Government license, the escrow obligation, or successor performer rights described in this Section, together with the Performer's plan to clear that limitation prior to award.

Performers must propose Intellectual Property (IP) rights arrangements that protect the interests and investments of the United States Government to the maximum extent possible. The Government expects a presumption for nonexclusive, irrevocable, paid-up, worldwide license to use, reproduce, modify, prepare derivative works of, distribute, and disclose all IP first developed, generated, or delivered under this order, and to authorize others to do so on the Government's behalf.

Additionally, the Government expects a presumption that in the event of default, termination, nonperformance, or the Performer's inability or unwillingness to continue performance, the Government must have the irrevocable right to use, transfer, assign, or license to a successor performer all IP, technical data, software (including source code), and associated documentation necessary to continue, complete, or sustain the project. The Performer must, upon request, deliver or place in escrow all such materials, including source code, build instructions, and design documentation, sufficient to enable a third party to assume performance without the Performer's further involvement.

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 are expected to comply with the relevant FDA, DEA, USP and cGMP regulatory practices.

For this project, cGMP refers to the regulatory standards enforced by the U.S. Food and Drug Administration (FDA) under 21 CFR Parts 210–211.

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 of the BioMaP-Consortium Base Agreement:

- **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.
- **GXP (GMP, GDP, GLP) Compliance.** All facilities must be GXP (GMP, GDP, GLP) compliant and comply with all Federal, Local, and State laws and regulations, in addition to all FDA requirements.

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 Proposals

3.1 Questions

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

3.2 Key Dates for this RPP

Date	Event
9/21/2026	RPP Released
9/25/2026	Virtual Teaming Speed Networking Event
10/1/2026	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
11/09/2026	Full Technical and Cost Proposals Due (by 5:00 PM ET)

3.3 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 template 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.

All eligible Offerors shall submit proposals for evaluation according to the criteria set forth in this RPP. The Government will evaluate proposals submitted and will select the offer(s) that best meets their current technology priorities using the criteria in Section 4 of 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.

3.4 Submission

Proposals must be submitted online through ATI's Acquisition Management Platform (AMP) at https://identity.ati.org. Offerors will use AMP to submit proposals and review associated feedback.

Submissions will not be accepted by any other means. **Offerors are strongly encouraged to review the AMP Submitter Training, confirm access to AMP, and submit a proposal well in advance of the submission deadline. Please reach out to the POC identified in Section 3.1 of the RPP in advance of the deadline if experiencing issues.**

Neither the Government nor CMF will make allowances or exceptions for submission problems encountered by offerors using system-to-system interfaces with AMP. If an

offeror encounters errors and fails to upload the complete submission before the submission deadline, the submission will not be accepted.

A receipt confirmation will be emailed upon submission of a proposal. Submissions can be made in advance of the deadline and updated up until the submission deadline.

3.5 Submission Format

Each document listed below is mandatory and must be submitted as separate files. These documents will 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 to ensure that all aspects are clearly understood by both parties. The proposal should include the following items:

- **Technical Proposal:** A Technical Proposal is required in Word (docx or .doc) or PDF using the mandatory template in Attachment C.
- **Cost Proposal:**
    - Section I: Cost Proposal Narrative is required in Word (docx or .doc) or PDF using the mandatory template in Attachment C.
    - Section II: Cost Proposal Format is required in Excel (xlsx) format, with working formulas to the maximum extent practicable.
- **Additional Required Files** (see Section 2.5 and Attachment D for full requirements):
    - **Performance Location Attestation:** One Word (.docx or .doc) or PDF file.
    - **Legal and Financial History:** One Word (docx or .doc) or PDF file, 2-page maximum. If not applicable, the Offeror must submit a letter indicating as such.
    - **Letter of Bondability:** One Word (docx or .doc) or PDF file
    - **DOJ and OIG Contacts:** One Word (docx or .doc) or PDF file. If not applicable, the Offeror must submit a statement indicating as such.
    - **Bylaw Amendment Attestation:** One Word (.docx or .doc) or PDF file
    - **Draft Security Plan:** One Word (docx or .doc) or PDF file
    - **Capitalization Plan:** One Word (docx or .doc) or PDF file

ZIP files and other application formats are not acceptable. All files must be print-capable and not password protected. 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.

3.6 Teaming Partners Identified through BioMaP-Consortium Resources

When submitting your proposal in AMP, you will be asked to 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."

4 Evaluation and Selection

4.1 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.

4.2 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 criteria and evaluation factors. The Government will evaluate each proposal against the evaluation factors detailed below.

4.3 Evaluation Factors Overview

The Government will evaluate the information provided in each Offeror's proposal to determine which proposal(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: Relevant Experience
- Factor 3: Cost/Price

Evaluation factors will be weighted as follows: Factor 1 Technical Approach/Solution is significantly more important than Factor 2 Relevant Experience, and Factor 2 Relevant Experience is more important than Factor 3 Cost/Price.

4.4 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
Outstanding	Proposal meets requirements and indicates an exceptional approach and understanding of the requirements. Strengths far outweigh any weaknesses. Risk of unsuccessful performance is very low.
Good	Proposal meets requirements and indicates a thorough approach and understanding of the requirements. Proposal contains strengths which outweigh any weaknesses. Risk of unsuccessful performance is low.
Acceptable	Proposal meets requirements and indicates an adequate approach and understanding of the requirements. Strengths and weaknesses are offsetting or will have little or no impact on contract performance. Risk of unsuccessful performance is no worse than moderate.
Marginal	Proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements. The proposal has one or more weaknesses which are not offset by strengths. Risk of unsuccessful performance is high.
Unacceptable	Proposal does not meet requirements and contains one or more deficiencies. Proposal is not awardable.

4.5 Evaluation Factors

- **Factor 1 – Technical Approach/Solution (Adjectival Rating):** This factor evaluates the relevancy, thoroughness, completeness, and feasibility of the proposed approach.

  All proposals must meet the Minimum Eligibility Requirements and will be assigned a merit rating based on the consensus-established strengths, weaknesses and/or deficiencies described below.

  Technical Approach/Solution will be evaluated as follows: Each proposal will be evaluated on the strengths, weaknesses and/or deficiencies addressing evaluation elements described below.

  Technical Approach evaluation elements for consideration are as follows:
    - How the proposal demonstrates a thorough understanding of the program objectives described in the Statement of Objectives.
    - How the proposal demonstrates the respondent's ability to produce drug products in an agile way.
    - How the proposal demonstrates the respondent's ability to perform active pharmaceutical ingredient (API) and Finished Dose Form (FDF)production in an agile and distributed fashion under cGMP.
    - How the proposal demonstrates the respondent's ability to develop and commercialize agile and distributed manufacturing technologies and

platforms that can rapidly scale production, conversion, finishing and availing of drug substances and drug products.
    - How the proposal demonstrates the respondent's ability to establish agile and distributed manufacturing capabilities for small molecule drug products used as medical countermeasures in multiple finished drug dosage forms.
    - How the proposal describes the respondent's understanding of relevant FDA, DEA, USP and cGMP regulatory practices.

- **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 for information related to relevant experience.

    - The respondent shall provide at least one (1) and no more than five (5) current and/or relevant experience examples. Each relevant experience example shall be for performance within the past 5 years.
    - Whether the Respondent provides an adequate description of the company's experience on manufacturing drug substances and drug products and the extent to which that description and experience is sufficient to meet current objectives.
    - The extent to which the Respondent provides evidence of a stable customer base to whom product has been supplied over an extended period of time.
    - The extent to which the Respondent describes the company's experience in product development, innovation, and project management.
    - Relevant experience must be captured in accordance with Attachment C.

- **Factor 3 – Cost/Price:** The proposed cost/price will be reviewed for fairness and reasonableness, and a fair and reasonable determination will be developed by the BioMaP CMF. Proposals will be reviewed to ascertain if the costs proposed are based on realistic assumptions, reflect a sufficient understanding of the technical goals and the objectives of the proposed work, and are consistent with the Respondent's technical approach. Quotes from proposed sub-performers and suppliers to help substantiate the project expenses must be included. Similarly, a breakdown of significant costs in order to show reasonableness will be included.

4.6 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 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.

4.7 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 and Marginal 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.

4.8 Cost/Price Estimate and Evaluation

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

If a proposal is recommended for Project Agreement award, the BioMaP-Consortium CMF will review the cost proposal submitted in response to the RPP. If necessary, the BioMaP-Consortium CMF may request an updated cost proposal. 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 provide concurrence to the BioMaP-Consortium CMF fair and reasonableness determination.

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

a) 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.

b) 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 Offeror's 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.

4.9 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. The Government will forward their recommendation, 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.

5 Points of Contact

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

Once the RPP submission window closes, the Government and the BioMaP-Consortium CMF will not discuss evaluation/status until the evaluation results have been provided to the Offerors.

6 Attachments

Attachment A: Technical Requirements

Attachment B: ASPR Security Requirements

Attachment C: Full Proposal Template

Attachment D: Additional Required Documentation

Attachment A: Technical Requirements

Statement of Objectives (SOO)

Project Title: Advanced Research and Development of Medical Countermeasures Through Agile and Distributed End-to-End Drug Manufacturing

1. SCOPE

1.1. Background:

The Administration for Strategic Preparedness and Response, Industrial Base Management and Supply Chain (APSR IBMSC) is seeking to establish advanced research and development of medical countermeasures through agile and distributed drug substance and drug product manufacturing capacities. This includes establishing end-to-end manufacturing capacities under current good manufacturing practices (cGMP) and all associated regulatory filings to include drug master files (DMFs), New Drug Applications, (NDAs) and Abbreviated New Drug Applications (ANDAs). This scope also includes the use of qualified laboratories for product verification, environmental and shelf-life testing, and adherence to industry-recognized consensus standards applicable to performance and its goals (e.g., ISO, ASTM).

Agile manufacturing is defined as manufacturing that is able to move quickly and adapt easily to change. Distributed manufacturing is defined as manufacturing spread across multiple locations rather than centralized in one place. Multiple qualified U.S. sites operated by the same corporate entity satisfy this definition if the proposal shows how the sites operate as one agile, integrated system; independently operated regional nodes are not required, and a single co-located site is not required.

Required capabilities include the development and commercialization of agile and distributed manufacturing technologies and platforms that can rapidly scale production, conversion, finishing and availing of drug substances and drug products. The specific focus of this effort is the establishment of agile and distributed manufacturing capabilities for small molecule drug products used as medical countermeasures in multiple finished drug dosage forms. For purposes of this RPP, a small molecule drug product is a product regulated by the FDA Center for Drug Evaluation and Research (CDER) as a drug, for which generic versions are approved through ANDAs, regardless of molecular weight (for example, heparin sodium is in scope). Products licensed as biologics under a Biologics License Application (BLA), including monoclonal antibodies, are out of scope. Biologically derived routes to small molecule APIs, including fermentation, cell-free, and plant-based production, are in scope. The approach must be built on flexibility, innovation, and augmentation. Data-driven production, inventory management and conversion that aligns supply with demand is required. Development and commercialization of repurposable

equipment, parallel component production, increased efficiency, reduced waste, automation, digital monitoring for real-time quality assurance, responsive local and regional manufacturing capacities, and innovative inventorying, manufacturing, packaging and fill-finish methods are preferred. Any small molecule drug product selected and approved by the USG under this RPP may be considered as, or may become, a qualified medical countermeasure; a specific countermeasure indication is not required.

The USG's requirement is for a base and option-type contract subaward structure to establish and fund agile and distributed end-to-end manufacturing capacities. This effort can be done through multiple sub-awards, if determined to be in the best interests of the USG. Objective A is the base period, and Objective B is an option, exercised based on Objective A results and the availability of funds; the option is not expected to be funded at award. Other priced options may be exercised independently at the Government's discretion. No option may extend the total period of performance beyond twenty-four (24) months. Any additional funds added to this requirement will be used to add additional funds on one or more existing subawards, award new subawards to new performers, or add additional option years.

Additional options may be used to add additional funds on an existing awards or sub-awards and new subawards to new partners to expand agile and distributed end-to end manufacturing capacities.

1.2. Introduction:

A key strategic goal of ASPR IBMSC is to support, strengthen, and modernize the Nation's medical countermeasure industrial base. This includes development of new materials, products, technologies, and manufacturing paradigms across pharmaceuticals, medical devices, PPE, and testing and diagnostic product categories. This requirement is for:

- Development and commercialization of agile and distributed manufacturing capabilities for drug substances and drug products used in medical countermeasures;

- End-to-end Key starting materials, drug substance and drug product manufacturing while operating within current good manufacturing practices (cGMP). cGMP refers to the regulatory standards enforced by the U.S. Food and Drug Administration (FDA) under 21 CFR Parts 210–211.

- Completion of all regulatory filings that would allow for commercial sale of drug product(s), including Drug Master File(s) (DMFs), New Drug Applications (NDAs), and/or Abbreviated New Drug Applications (ANDAs).

This effort supports ASPR IBMSC's broader long-term goal of establishing and commercializing infrastructure accessible to a wide community of users for production and distribution of medical countermeasures critical to national health security and preparedness.

At least one drug product must be produced end-to-end in an agile and distributed fashion, from Key Starting Material to API to finished dosage form, with the regulatory filings that allow commercial sale. The requirement for multiple finished drug dosage forms applies across the proposed portfolio as a whole, not to each product. No minimum or preferred number of products or sites is set. A drug substance only end point does not satisfy Objective B. The finished dosage form step may be performed by a teamed U.S. sub-performer; the Performer remains accountable for the full end-to-end scope and must furnish teaming evidence as described in Section 8.

2. REQUIREMENTS

2.1. General Objectives

The primary objective of this project is to develop and commercialize manufacturing capabilities that allow for end-to-end production of drug substances and drug products under cGMP and subsequent regulatory filing that enables broad commercial adoption and sale of domestically produced drug substances and drug products to meet US demands for medical countermeasures. Performers must include activities that enable the commercialization and sustainment of agile and distributed manufacturing capacities, including those that improve cost competitiveness and establish capacities that can rapidly scale up manufacturing of drug substances and drug products during high-demand periods and national emergencies. Approaches must be built on flexibility, innovation, augmentation and commercial sustainability. Data-driven production that aligns in-process metrology with rich data collection to bolster cGMP production and regulatory review is preferred, while traditional batch manufacturing and reliance on global just-in-time supply chains will not be considered.

For purposes of this RPP, a process that combines continuous unit operations, in-line monitoring, and real-time release with steps that are inherently batch (for example, lyophilization, aseptic filling, or final crystallization and isolation), consistent with ICH Q13, is not traditional batch manufacturing. Continuous operation is not required at every stage of Key Starting Material, drug substance, and drug product manufacturing, provided the overall process is not traditional batch manufacturing; fully continuous processing is preferred. A conventional batch finished dosage form step is not preferred unless the line itself demonstrates agile attributes such as modular design, rapid changeover, and digital monitoring for real-time quality assurance. For modular lines, the Performer must propose how changeover time will be measured (for example, from the end of the last batch of one product to the release-ready start of the next, including cleaning, line clearance, and validation). Process Analytical Technology (PAT) and Real-Time Release Testing (RTRT) are expected for wet-to-dry platforms and preferred for all other platforms; a staged feasibility, development, validation, and regulatory acceptance plan within the period of performance is acceptable if milestones are defined.

Performers must commercialize one or more of the following:

- Continuous and fully integrated end-to-end manufacturing of biologically derived or synthetic APIs with high volume, modular and rapidly interchangeable production and finished drug formulation capacities. This includes integrated domestic production of Key Starting Materials, APIs and Finished Dose Form Drugs.
- Production platforms with integrated downstream “wet-to-dry” processing from cell-based or cell-free systems to API and finished dose form drugs. These should include Process Analytical Technology (PAT) and Real-Time Release Testing (RTRT) to enable "release-by-exception" and streamlined regulatory validation.
- Modular lines (including, but not limited to Continuous Direct Compression, sterile fill/finish, or other FDF manufacturing lines) capable of rapid changeover (<24 hours) between distinct drug substances and drug products.
- Micro-scale, artificial intelligence (AI)-governed molecular printers at the point of care that use standardized, stable precursors to manufacture, purify and finish small-molecule drugs from standard digital recipes.
- Large-scale living foundries, including, but not limited to plant crops that produce complex precursors or APIs at low-cost.
- Self-contained units that leverage AI-driven manufacturing and quality by design to operate with limited to no human interaction.
- Miniature manufacturing platforms, including deployable, desktop size units that integrate microfluidics, synthesis and finished drug formulation to achieve hyper-localized production of medicines at the point of need.

Focus on repurposable equipment, parallel component production, increased efficiency, reduced waste, automation, digital monitoring for real-time quality assurance, responsive and scalable localized manufacturing capabilities, and innovative manufacturing, packaging and fill-finish methods for medical countermeasures are preferred. Focus on final FDA approval and bringing Finished Dose Form drugs to the commercial market while implementing a realistic and feasible commercialization plan that leverages regulatory approval and focuses on long-term private sustainment are also preferred. These objectives will be achieved by employing a two-step approach as described below. Performers must be able to complete both steps.

Domestic sourcing. Foreign-sourced API or Key Starting Material may be used for development activities only, such as formulation and process development, including parallel drug substance and drug product development with a bridging plan to the fully domestic end-to-end manufacturing process. Exhibit, registration, and validation batches supporting the regulatory filing, and all commercial production of funded products, must use domestic Key Starting Materials and API. Pairing an existing qualified domestic API source with new agile finished dosage form capacity may be acceptable if the domestic API supply is secured and documented; foreign-sourced API as the commercial end state is not acceptable. Upstream raw materials, reagents, and catalysts used to produce a

domestic Key Starting Material may be sourced internationally if supplier diversification and risk are addressed in the Supply Chain Resiliency Plan, except that Schedule II controlled substances must be sourced domestically at every stage. Where a Key Starting Material has no commercial U.S. source at award, a phased plan using qualified Trade Agreements Act (19 U.S.C. § 2501 et seq.) compliant supply and strategic inventory is acceptable only if it includes a defined, milestone-based path that achieves domestic production within the period of performance. Proposals that include domestic end-to-end manufacturing of Key Starting Materials, APIs, and finished dosage forms are preferred.

2.2. Specific Objectives and Requirements

A. Objective A – 6 Months

1. Objective A is a design and study phase to allow the performer to develop and refine a manufacturing design and technical approach, including management, logistics, pricing/costing and other non-technical elements necessary to achieve the primary goal of enabling commercial end-to-end production of small molecule drug substances used in medical countermeasures. Objective A must result in the development of metrics and milestones to gauge progress for intended technologies and capabilities. Also required is a method to quantify the risks and maturity of each technology and capability. The following incremental objectives are required:

    a. Select proposed target small molecule drug products that are at least at Manufacturing Readiness Level (MRL) 3 (Manufacturing Proof of Concept Demonstrated), as defined in the Department of Defense Manufacturing Readiness Level Deskbook, including justification of rationale and basis for selection, from the ASPR list of essential medicines published in May 2022 (ASPR 86, the same list published in the September 25, 2026 Federal Register Request for Information) or from the FDA Essential Medicines List. The example table of drug products in BioMaP Task Order 12 identifies additional products of interest to ASPR and may be used as a reference. No automatic preference is given to either list; selection is evaluated on the rationale and supply chain mapping required below, and all products require USG approval.

        1. Perform supply chain mapping and develop reports that clearly define current manufacturing challenges and dependencies as they relate to meeting US needs as part of the rationale for drug product selection.

        2. USG must approve all drug products developed under the Project Agreement.

        3. The selected medicine must appear on one of the lists identified above. A dosage form or route of administration different from the one shown on the

list may be proposed with justification, subject to USG approval. Branded or generic status is not a selection criterion. Schedule II controlled substances remain eligible and must be sourced domestically at every stage.

4. MRL is assessed on the Performer's proposed manufacturing process for each product, not on the product's current commercial manufacturing state. Products already manufactured commercially at MRL 9 or MRL 10 are eligible if the effort establishes new agile or distributed domestic capacity for the product, and a starting point above MRL 3 may be proposed. The Performer proposes the evidence supporting the starting MRL and advancement through MRL 10 (for example, engineering runs, commercial batch history, validated methods, equipment qualification, PPQ results, inspection history, and commercial achievements mapped to the MRL criteria) and the method for quantifying the maturity and risk of each technology and capability.

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

c. Develop a manufacturing and commercial expansion plan that includes automated and integrated processes across all stages of design, manufacturing, testing, analysis, and subsequent regulatory filing(s) for the selected small molecule drug products that meet U.S. Pharmacopeia (USP) standards for purity, potency, safety, and quality. Establish a cGMP-compliant pilot, engineering and scale-up production capacity. Concepts to be considered in the development and commercialization phases should include:

    1. Design tool innovations to enable forward engineering of novel biosynthetic pathways.

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

    3. Integrated feedback tools exploiting high-volume data generation to inform future designs and processes, including analysis of failure modes, implementation of learning and data mining algorithms, and generation of design rules for assembling biological systems with predictable behavior; and

    4. Fully integrated computational and physical infrastructure supporting design, fabrication, process validation, quality control, analysis, and manufacturing optimization.

d. Performers must establish a relationship with a business development management company that has an established track record of establishing and implementing startup pharmaceutical companies and develop a comprehensive marketing and market development plan. This plan must also demonstrate a path to parity with global competitive benchmarks. Performers must establish a relationship with a business development management company that has an established track record of establishing and implementing for startup pharmaceutical companies, a comprehensive marketing and market development plan. The Performer will take the lead on identifying the appropriate firm and the USG, if requested by the Performer, shall provide input and advice. The ultimate goal of such a program will be for the Performer to work with said company in order to both develop and implement a comprehensive market development and marketing plan, aimed at establishing and ensuring, both in the short-term, as well as in the long-term, their launch as a new entity in the area of pharmaceutical manufacturing, as well as set up and ensure the Performer's ability to reach and grow to financial self-sufficiency in the long term. An established manufacturer may propose an in-house commercial organization in place of an external business development management company if the proposal demonstrates a proven commercialization track record, existing customers, and a comprehensive marketing and market development plan with a path to financial self-sufficiency.

e. Performers must take the lead on identifying the appropriate firm and the USG, if requested by the Performer, shall provide input and advice. The ultimate goal of such a program will be for Performers to work with said company in order to both develop and implement a comprehensive market development and marketing plan, aimed at establishing and ensuring, both in the short-term, as well as in the long-term, the launch of any commercialization effort, as well as to set up and ensure the Performer’s ability to reach and grow to financial self-sufficiency in the long term. Performers must meet all milestones established with the business development management company and the USG.

f. Performers must establish a relationship with a proven regulatory affairs expert or firm to ensure proper regulatory strategies are defined prior to FDA engagement and submission. The regulatory affairs expertise may be proposed as internal to the Performer or a sub-performer if the individual or team is identified as Key Personnel and has a demonstrated ANDA, NDA, or DMF track record; an external firm is not required. Acceptable evidence of the relationship includes a letter of commitment, teaming agreement, memorandum of understanding, subcontract, or named Key Personnel. The relationship must be in place during Objective A and may be finalized during Objective A.

g. Performers must provide a Supply Chain Resiliency plan demonstrating at a minimum raw materials and components supplier diversification, supply visibility and risk monitoring, and inventory strategy. All Schedule II controlled substances must be sourced domestically.

h. Performers agree not to sell, convey, donate, trade, repurpose, materially alter, recycle, or otherwise dispose of Performer-acquired property without government consent within the period of performance of the Project Agreement and for ten (10) years after the agreement period of performance end date. Specifically excluded property includes immaterial, low-value items and trash. Government-funded equipment may be relocated to another facility owned or operated by the Performer if it continues to produce the same drug substances or drug products, only with prior Government consent. Notice must be given to the Government 60 days prior to any contemplated relocation.

i. Staffing, Training & Infrastructure: Performers must ensure adequate personnel and training programs are in place. Performers must ensure the appropriate staff including, but not limited to, chemists, engineers, facility managers, inventory managers, operations, logistics and business/management personnel are in place. Performers must also ensure that analytical chemists are in place and experienced and are proficient in various instrumental techniques such as, but not limited to, High-Performance Liquid Chromatography (HPLC), Gas Chromatography – Mass Spectrometry (GC-MS), and Spectroscopy. Performers must ensure that the appropriate microbiologists (if applicable) are hired for APIs requiring microbial limit or sterility testing. Performers must also have access to and provide comprehensive training to relevant personnel on United States Pharmacopeia (USP) monographs, specific analytical methods, instrument operation, data interpretation, current Good Manufacturing Practices (cGMP) and Good Laboratory Practice (GLP) regulations, and safety procedures.

    1. All facilities must be Good Practice Quality Guidelines (GXP) (Current Good Manufacturing Practice (cGMP), Good Distribution Practice (GDP), Good Laboratory Practice (GLP)) compliant and comply with all Federal, Local, and State laws and regulations, in addition to all FDA requirements. GxP compliance applies to the extent relevant to the activities performed at each facility: cGMP for manufacturing and release testing, GLP for nonclinical laboratory studies under 21 CFR Part 58, and GDP for distribution. Consistent with ICH Q7 and ICH Q11, cGMP applies from the introduction of the API starting material; Key Starting Material manufacture need not be performed under full cGMP, but appropriate quality controls and supplier qualification are expected. Development laboratories that produce no material for human use are not subject to cGMP; quality control laboratories supporting release testing are.

2. Performer must ensure end-to-end supply chain control and visibility, including establishing an inspectable dashboard infrastructure that must display, at a minimum, a status of all materials, equipment, consumables, reagents, testing, inspection and release. A segregated, validated reporting environment or dashboard is acceptable if it covers all project materials, equipment, consumables, reagents, testing, inspection, and release status and provides the USG unrestricted access to project data; unrelated commercial or patient data need not be exposed.

j. Security Requirements: See Attachment B of the RPP

k. Additional Requirements:

The facility requirements in items 1 through 11 below apply to the facilities, systems, equipment, and areas that support work under the Project Agreement, including areas modified under the award, and not to unrelated portions of a shared facility. Objective B work may be performed in a sub-performer's existing FDA-registered cGMP facility with novel processes or equipment. Early facility modifications and long-lead equipment purchases may be proposed in Objective A with justification, subject to the approval requirements in Section 5. All Performers and sub-performers must comply with all applicable Federal, State, and local regulations.

1. OSHA & Worker Safety Requirements
   a. Personnel Facilities
   b. Locker room with PPE storage and changing area
   c. Safety showers and emergency eyewash stations
   d. Caged ladder access per OSHA 29 CFR 1910.23
   e. Fire suppression system: wet pipe or gas-based per NFPA 13
   f. Gas bottle restraints and dedicated hazardous storage

2. Utilities & Facility Services Requirements.
Infrastructure
   a. Electrical grid with redundant emergency backup
   b. Pharmaceutical-grade plumbing systems (minimum 304 SS (stainless steel) piping for fluid contact surfaces). Exception upon design if required.
   c. Integrated pest control program per FDA 21 CFR 211.56

3. Information Systems & Connectivity Requirements
Regulatory and Compliance
   a. Must comply with GxP (cGMP, GDP, GLP) requirements
   b. System must be 21 CFR Part 210, Part 211, Part 11 compliant with electronic records and signatures

c. Full CSV validation package which includes validation protocol, URS, UAT, risk management assessments (GAMP 5), disaster recovery (RTO/RPO)
d. Must provide a validated audit trail (who/what/when/why) on all stages of process
e. Must enable role-based access control with segregation of duties
f. Must support data retention, archival, and retrieval per regulatory guidelines
g. Must include full ANDA filings and Pre-Approval Inspection (PAI) readiness

4. Environmental Monitoring and Compliance Requirements
a. Environmental monitoring system (EMS) to control, track and collect data (temperature, humidity, and other critical parameters).
b. Alerting and escalation for excursions
c. Integration with Building Management System (BMS) and Environmental Monitoring System (EMS)

5. Reporting and Analytics Requirements
a. Standard cGMP-compliant reports (stock on hand, expiry, batch traceability)
b. Real-time dashboards for manufacturing and quality KPIs, at a minimum: batch cycle time, right first-time rate, deviation and out of specification rate, on time in full release, and equipment utilization
c. Audit-ready reports for regulatory agencies
d. Configurable reporting and data export functionality

6. Facility Design and Layout Requirements
a. Segregation: Dedicated areas for receipt/quarantine, sampling, testing laboratories (wet chemistry, instrumental, microbiology), sample retention, and approved material storage.
b. Environmental Control: Ensure HVAC systems can maintain appropriate temperature and humidity, especially in analytical areas and storage.
c. Safety: Incorporate fume hoods, emergency showers, eye wash stations, fire suppression systems, and appropriate chemical storage.
d. Provision for simplified permitting zones (e.g., pre-approved layouts for FDA/EPA reviews) to accelerate domestic facility upgrades, reducing build times.

7. Equipment Procurement and Qualification Requirements
a. Prioritization: Based on the API list, identify the most frequently used instruments (e.g., HPLC, UV-Vis, FTIR)
b. Supplier Selection: Choose reputable suppliers for all instruments
c. Qualification (IQ/OQ/PQ): All new equipment must undergo Installation Qualification, Operational Qualification, and Performance Qualification to ensure it is installed correctly, operates as intended, and consistently produces accurate results

d. Require annual reviews of suppliers for single-source risks, prioritizing those with domestic supply chains to avoid foreign dependencies.

8. Reference Standards Management Requirements
   a. Procurement: Obtain USP Reference Standards for all APIs and their related compounds.
   b. Storage and Tracking: Implement a robust system for storing, tracking inventory, and managing the expiration/retest of reference standards.

9. Reagent and Consumables Management Requirements
   a. Inventory Control: Maintain adequate stock of all necessary reagents, solvents, columns, and other consumables
   b. Quality Control: Ensure all reagents are of appropriate grade for the intended purpose (e.g., HPLC grade solvents, USP grade chemicals)

10. Method Validation Requirements
Verification/Validation: While USP methods are generally considered validated, their suitability for a specific laboratory's equipment and conditions must be verified. For non-compendial methods or significant modifications, full method validation (specificity, linearity, accuracy, precision, detection/quantitation limits, robustness) is required as per ICH guidelines.

11. Quality Management System (QMS) Requirements
   a. SOPs: Develop and implement Standard Operating Procedures for all aspects of acceptance testing, retesting, stability testing, equipment operation, calibration, maintenance, sample management, data handling, and out-of-specification (OOS) investigations
   b. Documentation System: Establish a robust document control system for all quality records
   c. Change Control: Implement a change control system for any modifications to procedures, equipment, or specifications. Establish expedited change control processes for the strategic active pharmaceutical ingredients reserve -impacted modifications, such as shifts in API suppliers to prioritize U.S.-based production or updates to the critical drug list. Require impact assessments on supply chain resilience, with mandatory notifications to HHS/ASPR for federally funded stockpiles.
   d. Audit Readiness: Be prepared for internal and external audits to ensure compliance with regulatory requirements (e.g., FDA)

l. Development should begin with the identification of the proposed drug products and incorporate all steps necessary to take each drug substance from MRL 3 to MRL 10 (Full Rate Production demonstrated and lean production practices in place), and which will meet U.S. Pharmacopeia standards for purity, potency, safety, and quality.

m. Establish a governance structure required to achieve commercial scale manufacturing of the selected drug substances, including considerations for each phase of drug substance development.

n. Develop the metrics necessary to gauge and measure domestic market progress of the required technologies and infrastructure needed to achieve commercial scale production.

o. Develop metrics to assess progress towards development and commercial scale production.

p. Refine and finalize development and commercialization plans to achieve commercial scale production.

B. Objective B – 18 Months

1. Establish end-to-end cGMP drug substance (API) and Finished Dose Form drug product manufacturing capacity(ies).

2. Demonstrate production of drug substances and drug products and progress from current MRL to MRL-10 while ensuring compliance with US Pharmacopeia standards for purity, potency, safety and quality.
   a. Process Validation Protocol: Following FDA Guidance on Process Validation (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/process-validation-general-principles-and-practices), develop a written Process Performance Qualification (PPQ) protocol. The protocol combines the actual facility, utilities, equipment (each now qualified), and the trained personnel with the commercial manufacturing process, control procedures, and components to produce commercial batches. This milestone will provide that protocol.
   b. Conduct pilot, engineering and validation production runs, as applicable compliant with cGMP standards.

3. Assess, through multiple product runs the viable pathway towards production at commercial scale that minimizes Cost of Goods and Services (COGS) while maximizing commercial viability as a medical countermeasure. Considered outcomes to be presented to the USG include:
   a. Time to market
   b. Development and deployment costs
   c. Optimal time to market with cost consideration
   d. Major influencers
   e. Whether private investments are necessary to enable commercial scaling, and where those investments will come from

4. Complete FDA Inspection Readiness and Site Training Plan: In preparation for FDA inspection, formalize an FDA inspection readiness plan. This plan will include SOPs for how an FDA inspection is conducted and orchestrated when the FDA arrives on site, inclusive of the data room, documentation review, and planned facility tour approach. In addition, companywide training tailored to individual roles and responsibilities will be defined and executed to prepare the organization for inspection.

5. Develop final cGMP Drug Product Business Plans. Develop business models and plans that identify the best commercial path forward to enable sustainability.

6. Conduct qualification and validation batch runs and place product on stability to enable regulatory submissions.

7. Conduct formal pre-submission engagement with FDA appropriate to the designated pathway for each product, which may include a pre-ANDA meeting, a Type B or Type C meeting, or controlled correspondence. Deliverables are the meeting request, the briefing package as submitted, and the FDA meeting minutes or written response. Pre-submission engagement must be completed before the corresponding marketing application is submitted

8. Conduct appropriate regulatory submission and post-submission activities towards final approval of product(s) for sale in the US.
    a. This includes completion of all regulatory filings that would allow for commercial sale of drug product(s), including Drug Master File(s) (DMFs), New Drug Applications (NDAs), and/or Abbreviated New Drug Applications (ANDAs). Acceptable filings also include NDAs submitted under section 505(b)(2) and post-approval supplements and amendments to an existing application when the filing brings product made by the funded domestic process to commercial sale. The regulatory pathway for each product requires prior USG approval, normally as part of product selection in Objective A. The application may be held by a teamed sub-performer or by another company that references the Performer's DMF, with prior USG approval, provided the application holder is part of the proposed team and the approved product uses API from the Performer's funded domestic process. For an application already under FDA review, review interactions with FDA count toward the pre-submission engagement objective in item 7, and formal pre-submission engagement still applies to each new filing. Approval that falls after the period of performance because of FDA review time outside the Performer's control will not be treated as nonperformance, provided the Performer responds to FDA requests on time. Milestone payments may be tied to submission and to FDA acceptance for review.

3. PROGRAM MANAGEMENT:

A. The Consortium Management Firm (CMF) is responsible for administrative oversight of executed Project Agreements. The Performer is responsible for execution of the technical work and both the CMF and Performer are accountable for achievement of the stated objectives.

B. The CMF is responsible for coordinating project administration and monitoring status against approved milestones. The CMF is responsible for ensuring that any changes or deviations planned or incurred by the Performer are reported to the Agreements Officer as the earliest possible date. The CMF must obtain Agreement Officer approval for changes to the approved project milestones.

C. Performer must 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.

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

E. Program Reviews

The Performer must conduct monthly and quarterly reviews to provide details to the USG for development, manufacturing and commercialization activities, progress against performance objectives, incurred and forecasted expenditures and detailed progress towards meeting milestones and deliverables.

F. Requirements for Performers and Sub-Performers

1. All Performers, including sub-performers, must be U.S. owned and operated unless AOA has been obtained. For purposes of this RPP, U.S. owned means more than fifty (50) percent owned by U.S. persons, including lawful permanent residents, or corporations/organizations incorporated or organized under the laws of any U.S. state, the District of Columbia, or U.S. territories and not subject to foreign control or influence. The ownership structure must be disclosed in the Performance Location Attestation. Sub-performers must also meet the U.S. owned and operated requirement unless an Agreement Officer's Authorization (AOA) is approved. The Performer must submit an AOA request for a sub-performer with its proposal, supported by the documentation listed in Attachment A, Section 3.F; the request is considered during evaluation and negotiations, and AOA approval is required before award.

2. No exceptions to the requirements of 2.1 will be made for Performers. An Agreement Officer's Authorization (AOA) approval request is required for any proposed sub-Performer that does not meet the U.S.-owned and operated requirements specified in paragraph 2.1. The Performer submits the AOA request on behalf of the sub-Performer with its proposal; the request is considered during evaluation and negotiations, and approval is required before award. The Performer certifies and enforces sub-Performer compliance with these requirements through flow-down provisions. The supporting documents shall include the following, and additional information may be required at the discretion of the USG:

    a. Competition activities, as well as technical and cost/price evaluation activities performed, in the selection of the sub-Performer(s);
    b. The sub-Performer's qualifications/capabilities statement and past performance as they pertain to the activities included in the proposed subcontract;
    c. The sub-Performer's willingness/commitment to perform under the Performer (i.e. commitment letters/preliminary agreements), with a list of specific duties included in the proposed subcontract;
    d. The priority that the work will be given, how it will relate to other work, how it will be monitored and enforced;
    e. The amount of time and facilities available for the subject requirement; and
    f. A complete sub-Performer cost proposal or quote, in similar format as the Performer's cost proposal.
    g. A detailed risk analysis of engaging a non-U.S.-owned or non-U.S.-operated sub-Performer, focusing on risks to national security, intellectual property protection, supply chain resilience, and remedies for non-performance.
    h. Documentation confirming that the non-U.S. sub-Performer complies with relevant U.S. regulations, including, but not limited to, FDA regulations, and how compliance will be monitored and maintained;
    i. Certifications or third-party audits verifying the sub-Performer's adherence to quality, safety, and environmental standards, and how compliance will be monitored and maintained.

3. Staffing, Training & Infrastructure: Performer must ensure adequate personnel and training programs are in place. Performer must ensure the appropriate chemists, engineers, facility managers, inventory managers, operations, logistics and business/management personnel are in place. Performer must also ensure that analytical chemists are in place and experienced and proficient in various instrumental techniques such as but not limited to HPLC, GC-MS, and Spectroscopy. Performer must ensure that the appropriate microbiologists (if applicable) are hired for APIs requiring microbial limit or sterility testing. Performer must also have access to and provide comprehensive training on United States Pharmacopeia (USP) monographs, specific analytical methods, instrument

operation, data interpretation, current Good Manufacturing Practices (cGMP) and Good Laboratory Practice (GLP) regulations, and safety procedures.

4. All Performer facilities must be licensed, comply with all Federal, Local, and State laws and regulations, in addition to all FDA and related regulations.

5. Performer must ensure end-to-end supply chain control and visibility, including establishing an dashboard infrastructure that allows for unrestricted USG access and inspection.

4. DELIVERABLES

A. A preliminary milestone schedule and high-level tasks (deliverables) are expected to be as follows:

Milestones and Deliverables	***Due Date***
Objective A	
Kickoff meeting	Within 5 days of award
Detailed project plan and a complete description of the infrastructure and management structure, including addressing all elements that will accomplish the program's goals and milestones. Detailed Project Plan will include: a. Describe in detail the proposed plan to achieve all objectives and requirements. b. Plan should include all assumptions that will be employed in preparing and executing the program. c. Plan should include a range of assumptions/variables that can be used to assess various market conditions. d. Plan should include metrics, variables, and milestones for gauging domestic market progress of required technologies and infrastructure that will be needed for market entry. e. Plan should include all metrics, variables and milestones that define the various gates and decision points (distinct from the bullet above).	Within 30 days of award

Milestones and Deliverables	***Due Date***
Objective A	
f. Plan should include details for each phase of program execution (anticipated to follow the various MRLs from 3-10). g. Plan should include identification of risks associated with execution of the plan.	
Draft Security Agreement	Within 30 days of award
Monthly Progress Reports. These reports must include a detailed technical progress report and report on all problems, technical issues, major developments and the status of external collaborations during the reporting period.	10th of every Month
Special technical reports - will include special reports on significant events such as significant target accomplishments or deviations by the Performer or sub-Performer, significant tests, experiments or symposia.	As needed and when requested by the USG
1. Select proposed target small molecule drug substances that are at least at Manufacturing Readiness Level (MRL) 3 (Manufacturing Proof of Concept Demonstrated), from the ASPR list of essential medicines published in May 2022 (ASPR 86) or from the FDA Essential Medicines List. USG must approve all drug products developed under this agreement. 2. 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 product. 3. Develop a manufacturing and commercial expansion plan. 4. Identify the proposed drug products and incorporate all steps necessary to take each drug substance from MRL 3 to MRL 10. 5. Establish a governance structure required to achieve commercial scale manufacturing of the selected drug substances. 6. Develop the metrics necessary to gauge and measure domestic market progress of the required technologies and infrastructure needed to achieve commercial scale production. 7. Develop metrics to assess progress towards development and commercial scale production. 8. Performers must provide a Supply Chain Resiliency plan demonstrating at a minimum raw materials and components supplier diversification, supply visibility and risk monitoring, and inventory strategy. All Schedule II controlled substances must be sourced domestically. 9. Performers must provide a Work Locations Report. 10. Performers must provide a OPSEC Standard Operating Procedure (SOP)/Plan.	Within 6 months of award

Milestones and Deliverables	***Due Date***
Objective A	
11. Performers must develop a comprehensive security program and plan that provides overall protection of personnel, information, data, and facilities associated with fulfilling the Government requirement. This plan must establish security practices and procedures that demonstrate how the Performer will meet and adhere to the security requirements outlined in Attachment B prior to the commencement of product manufacturing, and must be delivered to the Government (draft within 30 calendar days after award; final within 60 days post award) 12. Final commercialization plan and business strategy to achieve commercial scale production and domestic market sustainment. 13. Evidence of site control for each proposed manufacturing site, no later than the end of Objective A. Site addresses must be reported in the Work Locations Report within 5 business days of award; where a site will be selected after award, the proposal must include a time-bound site selection plan.	
Objective B	
1. Demonstrated production of drug substances and drug products with progress from current MRL to MRL-10. Performers must follow FDA's published Guidance for Industry Process Validation: General Principles and Practices. a. Submit a process performance qualification (PPQ) validation protocol. 2. Complete all building modifications and infrastructure upgrades identified in the infrastructure design plan and perform EMPQ activities to demonstrate the required environmental controls following the building modifications and infrastructure completion. Building modifications, infrastructure upgrades, and EMPQ are Objective B deliverables due within 24 months of award and are not required within the 6-month Objective A period. Existing cGMP facilities may be used; the timing of any modifications must be proposed in the project schedule. a. Submit report on the completion of environmental monitoring performance qualification (EMPQ). EMPQ is required for classified and controlled environments, including all sterile operations. For non-sterile facilities, the Performer must demonstrate that environmental controls meet the Environmental Monitoring and Compliance Requirements and the Facility Design and Layout Requirements in Section 2.2, with the scope of qualification matched to the room classification.	Within 24 months of award

Milestones and Deliverables	***Due Date***
Objective A	
3. Assess, through multiple product runs the viable pathway towards production at commercial scale that minimizes Cost of Goods and Services (COGS) while maximizing commercial viability. 4. Complete and implement a comprehensive marketing and market development plan. Performers must establish a relationship with a business development management company that has an established track record of establishing and implementing for startup pharmaceutical companies, a comprehensive marketing and market development plan. The Performer will take the lead on identifying the appropriate firm and the USG, if requested by the Performer, shall provide input and advice. The ultimate goal of such a program will be for the Performer to work with said company in order to both develop and implement a comprehensive market development and marketing plan, aimed at establishing and ensuring, both in the short-term, as well as in the long-term, their launch as a new entity in the area of pharmaceutical manufacturing, as well as set up and ensure the Performer's ability to reach and grow to financial self-sufficiency in the long term. An in-house commercial organization meeting the conditions in Section 2.2.A.1.d may be considered. 5. Complete an FDA inspection readiness plan which shall include establishing a data room, documentation review, and planned facility tour approach. a. Complete remediations to address observations from FDA pre-approval inspection and any FDA response documentation. 6. Draft final validation and stability batch reports. 7. Complete FDA pre-submission engagement for each product. Submit the meeting request, briefing package, and FDA minutes or written response. 8. Conduct formal regulatory submission, summarize all FDA correspondences and establish and implement corrective action plans based on regulatory feedback from the FDA. a. Complete any required process validations batches of drug products as required by the corrective action plan. b. Submit process validation reports summarizing release data for drug products. 9. Gain approval to market FDF products. Submission of the marketing application(s) and/or DMF and FDA acceptance for review, with no Refuse to Receive or Refuse to Review issued by FDA, within the period of performance satisfies this regulatory milestone. Final FDA approval within the period of performance remains the preferred outcome. 10. Final report. The Performer shall submit a final report making full disclosure of all major developments by the Performer upon completion of	

Milestones and Deliverables	***Due Date***
Objective A	
this Agreement or within sixty (60) calendar days of termination of this agreement.	

5. PHYSICAL PROPERTY

5.1. Physical property is broken into three categories:

a. Mission-Essential Property. Property that is indispensable to the primary objectives of this Agreement, including active pharmaceutical ingredients (APIs), drug substances, and their precursors and subcomponents; manufacturing equipment, tooling, and instrumentation used in production; and manufacturing facilities and installed infrastructure. Mission-Essential Property is that property, tangible or intangible, without which the Performer could not meet the core performance requirements of this Agreement. Performer retains title to all Mission-Essential Property acquired under the Project Agreement, upon successful completion of all milestones in the Task Order.
b. Performance-Supporting Property. Property that materially supports performance under this Agreement but is not itself indispensable to the primary manufacturing function, including ancillary laboratory and quality-control equipment, environmental and monitoring systems, materials-handling and storage equipment, spare parts inventories, and similar property that facilitates or enhances performance without being directly tied to the core production function. The Government has the right to control the disposition of all Performance-Supporting property acquired under the Project Agreement at the Government's sole discretion.
c. Consumable and Expendable Property. Property that is consumed, expended, or rendered valueless in the ordinary course of performance, or in which the Government has no continuing interest, including office supplies and consumables; packaging and shipping materials; waste, scrap, and residue; and equipment or materials that are broken, spent, or otherwise beyond economical repair or reuse. The Government asserts no accountability or disposition interest in Consumable and Expendable Property, and the Performer may dispose of such property in the ordinary course without further approval, except as required by applicable law (including handling of hazardous or controlled materials).

5.2. The Performer must provide the USG a security interest in all property acquired under the Project Agreement. The Performer must propose a Security Agreement for the Government to approve within the first 30 days. The Government reserves the right to unilaterally direct the transfer of property to the Government or to a third party named by the Government at the Government's sole discretion.

In the event of non-performance, or Project Agreement termination for any reason, the Government will control the disposition of the Government funded property and inventories through a Disposition Order, which the Performer must carry out based on a timeline established by the Government. Failure to comply with this timeline shall result in the Government gaining title to the Government funded property and inventories for transfer or disposition in accordance with the terms of the Security Agreement. If inventories are lost, damaged or compromised in any way, the Performer must replace to levels previously established using USG funding, at their own expense, within 90 days or another timeline agreed to by the Government. The Performer must present evidence of insurance or other financial resources to cover such an event.

5.3. Purchase of Property: Expenditure Based (and other) Project Agreements
For items greater than $10,000, the Performer must obtain approval from the OTAO, through the CMF, prior to purchasing property using Government funds. Property listed in the approved cost proposal is considered as having received OTAO approval. The Security Agreement must protect the Government from the point of approval through disposition. Title to property acquired by a sub-performer follows the terms of the BioMaP Base Agreement; such property must be reported through the Performer and is covered by the Performer's Security Agreement.

Performer must replace to levels previously established by USG funding, at their own expense, within 90 days or another timeline agreed to by the Government.

6. TERMS RELATED TO CONSIDERATION FOR USG INVESTMENT

6.1. Purpose and Consideration

6.1.1 As consideration for the U.S. Government's investment under this Agreement, the Performer, on behalf of itself and each sub-Performer, agrees to be legally bound by the priority access and related covenants in this Article. The Performer acknowledges that these covenants are a material inducement to the Government's award and funding and are intended to secure a continuing public benefit from the Government-Funded Capacity.

6.1.2 The Performer shall flow down the obligations of this Article to each sub-Performer and to any person or entity described in the definition of Covered Party, and shall take all steps necessary to make those obligations binding and enforceable by against each such party.

6.2. Definitions

(a) "Government-Funded Capacity" means the manufacturing and related capacity funded, established, expanded, or supported in whole or in part under this Agreement, as identified in Sections 2.2, 3 and 4 of Attachment A, together with any replacement or relocation of such capacity.

(b) "Covered Party" means the Performer, any sub-Performer, any successor in interest to any of them, and any other person or entity that owns, operates, controls, leases, subleases, occupies, uses, or acquires (whether by purchase, assignment, novation,

merger, consolidation, foreclosure, deed in lieu of foreclosure, receivership, bankruptcy sale, or otherwise) all or any part of the Government-Funded Capacity.
(c) "Priority Access" means that the Government has priority access to the Government-Funded Capacity over performance under any other unrated contract, agreement, or order, and that each Covered Party shall accept and perform the Government's contracts, agreements, and orders in preference to any other contracts, agreements, or orders, on terms no less favorable to the Government than those a rated order would receive under the standard in § 3.
(d) "DPA" means the Defense Production Act of 1950, ch. 932, 64 Stat. 798, as amended (codified as amended at 50 U.S.C. § 4501 et seq.); "HRPAS" means the Health Resources Priorities and Allocations System, 45 C.F.R. part 101; and "Public Health Emergency" means a determination by the Secretary of Health and Human Services under Section 319(a) of the Public Health Service Act, 42 U.S.C. § 247d(a).
(e) "Protection Period" meaning the period of ten (10) years beginning on the effective date of this Task Order’s conclusion, notwithstanding the earlier conclusion of the period of performance or of any other contractual commitment under this Agreement.

6.3. Priority Access Covenant

6.3.1 Throughout the Protection Period, each Covered Party shall, upon request by or on behalf of the Government, accept and perform the Government's contracts and orders relating to the Government-Funded Capacity on terms no less favorable to the Government than those a rated order under the DPA and the HRPAS would receive, including by giving such contracts and orders precedence over the Covered Party's other contracts and orders to the maximum extent permitted by law. Each Covered Party shall accept and give priority to any order made under this covenant.
6.3.2 This covenant applies whether or not a specific DPA rated order has been issued; it establishes, by contract, a standing priority at least equal to that of a rated order for the duration of the Protection Period.

6.4. Emergency Activation

6.4.1 The covenant in § 3 is continuously operative throughout the Protection Period. In addition, during any period in which a Public Health Emergency has been determined to exist, or any other applicable national emergency, major disaster, or emergency has been declared, the Government may exercise its rights under this Article on an expedited basis, and each Covered Party shall give the Government's orders immediate precedence to the maximum extent permitted by law.

6.5. Domestic-Demand-First

6.5.1 Throughout the Protection Period, each Covered Party shall use the Government-Funded Capacity in a manner that prioritizes meeting domestic demand within the United States before meeting demand outside the United States.

6.6. Permitted Use of Capacity

6.6.1 Throughout the Protection Period, each Covered Party shall use the Government-Funded Capacity exclusively for the manufacture of drug substances and drug products or for such other uses as the Contracting Officer approves in writing.

6.7. Corporate Governance; Domestic Control; Anti-Circumvention

6.7.1 The Performer and any successor in interest shall remain a majority United States owned and majority domestically controlled company and shall adopt and maintain corporate governance (including bylaw amendments or equivalent depending on the legal form and structure of the organization) sufficient to prohibit foreign influence over the Government-Funded Capacity during the Protection Period.

6.7.2 Each Covered Party shall maintain in full force and effect the governance commitments required by this Article and shall not take, permit, or suffer any action, whether through amendment of bylaws, articles or certificate of incorporation, shareholder, operating, voting, or sale agreement, or any other governing or contractual instrument, or through any course of conduct, that would repeal, modify, override, circumvent, or render ineffective any required governance provision. If any conflict exists between the required governance provisions and any other governing instrument, the required provisions shall control, and the Covered Party shall conform the conflicting instrument accordingly.

6.8. Covenants Run with the Capacity; Successors and Transfers

6.8.1 The covenants in this Article run with the Government-Funded Capacity and bind every Covered Party. If any Covered Party novates, assigns, sells, leases, or otherwise transfers responsibility for, or any interest in, the Government-Funded Capacity, the covenants of this Article shall follow the transfer and bind the transferee for the full remaining Protection Period, and the transferring party shall make these covenants an enforceable condition of the transfer.

6.8.2 Anti-illusory deliverables. To ensure Priority Access is not illusory, the Performer shall furnish approved ANDAs to the Agreements Officer upon successful acceptance, review and approval by the FDA.

6.9. Notice and Change in Circumstances

6.9.1 Notice of Triggering Events. Each Covered Party shall give the OTA Officer written notice of any of the following (each, a "Triggering Event") and, where the event is within the Covered Party's control, at least 60 days' advance written notice:

(a) any proposed sale, assignment, novation, lease, sublease, transfer, or other disposition of, or any grant of a lien or encumbrance on, all or any part of the Government-Funded Capacity;

(b) any proposed change of control, merger, consolidation, reorganization, recapitalization, or change in ownership of the Performer or any Covered Party, including any transaction that may be subject to review by the Committee on Foreign Investment in the United States (CFIUS);

(c) any default under, or any notice of termination, modification, or non-renewal of, any lease or other instrument underlying the Government-Funded Capacity;

(d) any material reduction, idling, relocation, or cessation of operations at the Government-Funded Capacity, or any material adverse change in a Covered Party's ability to perform the covenants of this Article;

(e) any insolvency, inability to pay debts as they become due, assignment for the benefit of creditors, or appointment of (or application for) a receiver, trustee, or custodian; and

(f) any filing, or good-faith contemplation of filing, of a voluntary petition under the Bankruptcy Code, or receipt of notice of an involuntary petition.

For any involuntary or external event under (c), (e), or (f), the Covered Party shall give notice within 5 business days after it knows or reasonably should have known of the event.

6.9.2 Consultation and Good-Faith Negotiation. Promptly after a Triggering Event, the parties shall confer in good faith for a period of 30 days to identify and implement measures to preserve the Government's Priority Access and the continuity of the Government-Funded Capacity, which may include the transferee's binding assumption of this Article, assignment of the covenants, additional or replacement security under § 10, or other mutually acceptable protections. The Covered Party shall provide the information the Government reasonably requests to evaluate the effect of the Triggering Event.

6.9.3 Government Rights. No Triggering Event relieves any Covered Party of its obligations under this Article. The Government may condition any consent it gives on terms that preserve its rights, including requiring a transferee's written assumption of this Article as a condition of any transfer, and may exercise any right or remedy under § 10, § 13, or otherwise.

6.9.4 No Waiver. The Government's receipt of notice, participation in consultation, or grant of any consent does not waive, release, or modify any covenant of this Article except in a writing signed by the OTA Officer.

6.10. Security for Performance; Bankruptcy

6.10.1 Purpose. The parties acknowledge that the covenants in this Article are intended to bind the Government-Funded Capacity and every Covered Party, including upon a Covered Party's insolvency or bankruptcy. To ensure these covenants are not defeated by financial distress, the Performer shall provide and maintain the security specified below for the full Protection Period.

6.10.2 Security Interest/Lien

6.10.2.1 Grant. The Performer grants to the Government a first-priority security interest in, and lien on, the Government-Funded Capacity and its proceeds, including the equipment, fixtures, and leasehold interest / real property constituting or used in the Government-Funded Capacity, to secure the full and timely performance of all obligations under this Article and repayment of the Government's investment as provided in § 13. For real property or leasehold interests, the Performer shall execute and record a mortgage or deed of trust in recordable form.

6.10.2.2 Perfection and Priority. The Performer authorizes the Government to file UCC-1 financing statements and any other filings, and shall execute such further documents (including landlord consents, estoppels, leasehold-mortgagee protections, and control agreements) as the Government reasonably requests to perfect and maintain its interest. The Performer shall not grant any lien or encumbrance senior to the Government's without the OTA Officer's prior written consent and shall keep the Government-Funded Capacity free of other liens except Permitted Liens.

6.10.2.3 Remedies; Release. On a material breach of this Article, the Government may exercise all rights of a secured party at law and in equity, and its interest shall attach to the proceeds of any disposition of the Government-Funded Capacity. The Government shall release its security interest upon expiration of the Protection Period and satisfaction of all obligations under this Article.

6.10.3 Performance Bond / Alternative Security

6.10.3.1 Bond. The Performer shall furnish, and maintain in effect for the Protection Period, a performance bond naming the United States as obligee in a penal sum of the funded amount on the Task Order, from a surety holding a certificate of authority from the U.S. Department of the Treasury as an acceptable surety on federal bonds (31 U.S.C. §§ 9304–9308; Treasury Department Circular 570), securing performance of the covenants in this Article.

6.10.3.2 Alternative Security. In lieu of or in addition to the bond, the OTA Officer may accept an irrevocable standby letter of credit from a financial institution acceptable to the Government, a funded escrow, or cash collateral, in the amount and on the terms the OTA Officer approves.

6.10.3.3 Maintenance. The security shall be evergreen or renewed not less than 90 days before expiration. The Government may draw the full amount upon notice of non-renewal, or upon the surety or issuer ceasing to meet the applicable standards, and the Performer shall promptly provide replacement security if the surety or issuer is downgraded or removed from the Treasury list.

6.11 Common Bankruptcy Provisions

Intent; Covenants Run with the Capacity. The parties intend that the covenants in this Article run with the Government-Funded Capacity as covenants and equitable servitudes binding all successors, assignees, and purchasers — including a purchaser in a sale under 11 U.S.C. § 363 — to the maximum extent permitted by law, and that any security granted under this Article be a perfected, enforceable interest.

6.12 No Ipso Facto Forfeiture.

Nothing in this Article terminates or modifies any obligation solely because of a Covered Party's insolvency or bankruptcy filing. Rather, upon any such event the Government may (a) draw upon or enforce the security under this Article; (b) exercise its lien and secured-party remedies, subject to the automatic stay; (c) seek relief from the automatic stay, adequate protection, and other appropriate relief; and (d) require that any sale, assumption, assignment, or plan treatment of the Government-Funded Capacity be conditioned on the acquirer's binding assumption of this Article.

6.13 Cooperation.

Each Covered Party shall support, and shall not oppose, the Government's efforts to have the covenants of this Article bind any purchaser or assignee of the Government-Funded Capacity, including by seeking entry of any sale or confirmation order that expressly preserves these covenants. If this Article is determined to be an executory contract, the parties agree it is a material and integrated part of the Government's bargain.

6.14 No Priming.

No Covered Party shall seek or consent to any debtor-in-possession financing or other lien that primes the Government's interest under this Article without the OTA Officer's prior written consent or without providing the Government adequate protection.

6.15 Survival

6.15.1 The obligations of this Article survive the end of the period of performance and the conclusion of any other contractual commitment, and continue without interruption for the full Protection Period notwithstanding any of the following illustrative and non-limiting events: any change in ownership, control, or shareholder interest; any assignment, sale, lease, or other transfer of the Government-Funded Capacity; any merger, consolidation, conversion, division, reorganization, recapitalization, or restructuring; any transfer of assets; or any dissolution, receivership, insolvency, or bankruptcy proceeding.

6.16. Objective and Construction

6.16.1 These covenants are intended to support ASPR emergency response and the public-health purpose of this Agreement, to secure essential medicines, including generic medicines, and the active pharmaceutical ingredients necessary to reduce the long-term risk of domestic shortages and to help address future pandemic threats, and the objectives of Executive Order 14336 and Section 319 of the Public Health Service Act.

6.17. Enforcement and Remedies

6.17.1 The Performer agrees that the Government would be irreparably harmed by a breach of this Article and that the Government shall be entitled to seek specific performance and injunctive relief, in addition to any other remedy available at law or in contract, without the necessity of posting bond. The remedies in this Article are cumulative.

7. RISK MANAGEMENT OBJECTIVES

The performer shall identify all anticipated project risks and track them via a Risk Register in accordance with deliverables requirements. The performer 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.

8. TEAMING AND PARTNERSHIPS

Multi-disciplinary teams of performers and sub-performers are encouraged, and successful implementation is expected to require industrial collaborations. Teams of performers and sub-performers may be led by industrial, academic, or non-profit entities, and along with other organizations. It is expected that the proposed leadership team will include individuals with significant experience and expertise in pharmaceutical manufacturing and cGMP operations. These teams of performers and sub-performers will lead large and diverse cohorts with industrial partners and have significant experience in industrial process design and identify industrial and commercial partners to aid in

achieving the milestones and implementing the deliverables outlined within this SOO. Efforts should be fully integrated and demonstrate that all components are necessary and inseparable. Teams will incorporate members with experience in diverse fields such as computer science, engineering, automation, regulatory, supply chain, industrial process development, chemistry/chemical engineering, cGMP manufacturing, and drug substance and drug product manufacturing, among others. Evidence of teaming agreements must be furnished and include letters of intent, MOUs, teaming agreements, subcontracts, and/or reservation contracts. The Performer may perform a defined portion of the end-to-end scope with identified sub-performers covering the remainder; the Performer remains accountable for the full scope. Letters of intent or memoranda of understanding are sufficient at proposal for partners whose final scope and pricing remain subject to USG product approval; sub-performer quotes are still required to support cost reasonableness. Prequalified Key Starting Material suppliers under teaming agreements are acceptable at proposal, with final supplier selection following route development in Objective A. The business development management company and the regulatory affairs expert or firm may be selected during Objective A.

9. PRIORITY RATING

OTA Task Order and Project Agreements under this Statement of Objectives may include a priority rating pursuant to HHS' delegated Defense Production Act (DPA) Title I authorities, including the Health Resource Priorities and Allocations System (45 CFR Part 101) and Defense Priorities and Allocations System regulation (15 C.F.R, Part 700). The Performer, through the CMF, may initiate a request for a DPA rating to the Agreements Officer.

10. ADMINISTRATIVE DELIVERABLES

Deliverable Description	Content Requirements and Instructions[i]	Reporting Frequency[ii],[iii]
Kick Off Meeting	Recipient to develop Agenda and host an in-person or virtual kick-off meeting to discuss overall project objectives, key personnel, deliverables, risks, schedule and funding/payment procedures. Provide meeting minutes.	Kickoff meeting conducted within 5 days of award. Minutes to be submitted within 3 business days of meeting.
Ad-hoc Project Team Meetings	Recipient to schedule and create and agenda. Follows Agenda mutually agreed upon in advance of meeting. RECIPIENT to provide meeting minutes within 3 business days from date of meeting.	As needed for special topics, when specifically requested by the OTAO or OTTR.

Deliverable Description	Content Requirements and Instructions[i]	Reporting Frequency[ii],[iii]
Inventory Reports	Report of all key starting materials, drug substances, intermediates, and finished dose form drug products held in inventory, including lot number, quantity, and release status. Available on cloud or remote access by ASPR.	Monthly, and upon each lot release
Monthly Project Team Meetings	Purpose is to review monthly progress report findings, any changes since last month and any projected issues or challenges.	Virtual. Monthly, 5 business days after the monthly report deliverable. 1 hour duration, hosted by the recipient. Minutes to be submitted within 3 business days of meeting.
Monthly Project Progress Report	Monthly report of overall status including cost, performance and schedule progress and variance from plan. Include discussion of important design considerations and milestones, such as Process Flow Diagrams complete, P&IDs Issued for Design, Process Description complete, etc. Include status of other engineering disciplines, project delays, risk management, funding issues, Construction, Startup, Commissioning/Validation, and Regulatory progress. Level of detail for various aspects of project may decrease or increase in detail as the project moves through the various phases of execution.	Monthly. Due 10th of the month. Performer format acceptable, in PDF.
Quarterly In-Process Review (IPR)	Organized, scheduled and hosted by Recipient. May be virtual or physical at the Recipient's facilities based on USG preference. High level project progress review of overall objectives including, but not limited to Schedule, Budget, Quality, Cost Control (i.e. changes), Design,	Every 3 months from start of project. Recipient to send brief 3 working days in advance of meeting.

Deliverable Description	Content Requirements and Instructions [i]	Reporting Frequency [ii],[iii]
	Construction, Validation, Regulatory. Projections against project expectations, including risks and mitigation plans.	
Integrated Master Project Schedule	MS Project Detailed Project Schedule, full detailed schedule for entire Project, including all major activities, critical path, and milestones. Status updated regularly.	Status updated monthly and when milestones and/or major events change.
Project Budget	Excel Detailed Project Budget, full detailed budget for entire Project	Notify USG via e-mail whenever Project Budget is revised/updated and post to shared documents site
Project Documents and List(s)	Full listing of project, documentation organized by engineering discipline or other category (e.g. drawings list, specifications list, procurement packages list, instrument index, URS/FRS, etc.)	Submitted, uploaded and updated as required to USG specified site.
Project Documentation	Project Design, Procurement, Construction, Validation, Regulatory, and other related project execution related documents	When specifically requested via e-mail by USG Project Manager (or designee), post latest version of requested documents to shared documents site
Project Risk Register	Project risks identified throughout the project shall be tracked via a Risk Register Log (or similar list/tracking vehicle). Log should contain information regarding identification date, severity of risk, mitigation plan(s) and dates for implementation, risk owner, etc.	Updated monthly and submitted with Monthly Technical Progress Report and posted to USG identified document site.

Deliverable Description	Content Requirements and Instructions[i]	Reporting Frequency[ii],[iii]
Project Action Items List	Actions identified throughout the project, which are not tracked by some other project management tool, and which require follow up and monitoring for completion, will be captured in an Action Items List. (Or similar list/tracking tool.) List should contain information regarding identification date, target completion, responsible individuals/groups, etc.	Submitted if/as required with monthly technical progress report.
Site Visits	Host visits from USG following agenda/schedule mutually agreed upon with USG in advance of visits. Provide visit notes within 3 business days from date of visit.	Typically, quarterly, commensurate with quarterly IPR, ad-hoc and no-notice inspections will occur at the Agreements Officer's discretion.
Annual Project Progress Report	High level project progress review of overall objectives. Updated projections against project expectations, including risks and mitigation plans, should be reported with respect to the previous annual report. Summary of critical changes that took place over the year. Recommended to not exceed 20 pages.	Annually from award. To review progress over the previous 12 months. A Draft to be submitted 30 days after the completion of each year of performance. Within 15 days of receipt, the USG will provide review comments. The Respondent shall respond within 15 days of receipt of comments. Report format: Microsoft Word and PDF

Deliverable Description	Content Requirements and Instructions [i]	Reporting Frequency [ii],[iii]
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 period of performance. Within 15 days of receipt, the USG will provide review comments. The Respondent shall respond within 15 days of receipt of comments.
Security Plan	The Security Plan must detail how the RECIPIENT will adhere to established ASPR Informational Technology (IT) and Operational Security (OPSEC) policies and requirements. The Security Plan must include but is not limited to; • Internal management security measures that meet the ASPR, IT, and OPSEC security requirements • Plan to ensure Project Agreement security compliance, to include roles and responsibilities • Plan to manage Consortium member physical, IT, and OPSEC security compliance as a contingency of Consortium membership	Initial draft is due upon proposal submission, revised draft is due 30 days after award and final within 60 days after award.
Supply Chain Resiliency Plan	In Accordance with Attachment B	Submit within 30 calendar days of project award
Manufacturing Data Requirements	In Accordance with Attachment B	Submit within 30 calendar days of project award

Deliverable Description	Content Requirements and Instructions[i]	Reporting Frequency[ii],[iii]
Performer Locations	In Accordance with Attachment B	Submit within 5 business days of project award Submit within 30 business days after a substantive location or capabilities change Submit 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) SOP/Plan	In Accordance with Attachment B	Initial submission 90 calendar days of project award.

APPENDIX I: HHS Policy for Information Technology Procurements - Security and Privacy

1. Baseline Security Requirements
   a. **Applicability.** The requirements herein apply whether the entire agreement or modification (hereafter "agreement"), or portion thereof, includes either or both of the following:
      i. **Access (Physical or Logical) to Government Information:** A Performer (and/or any sub-performer) will have or will be given the ability to have, routine physical (entry) or logical (electronic) access to government information.

      ii. **Operate a Federal System Containing Information:** A Performer (and/or any sub-performer) will operate a federal system and information technology containing data that supports the HHS mission. In addition to the Federal Acquisition Regulation (FAR) Subpart 2.1 definition of "information technology" (IT), the term as used in this section includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources.

   b. **Safeguarding Information and Information Systems.** All government information and information systems must be protected in accordance with HHS/*ASPR* policies and level of risk. At a minimum, the Performer (and/or any sub-performer) must:
      i. Protect the:
         - **Confidentiality**, which means preserving authorized restrictions on access and disclosure, based on the security terms found in this agreement, including means for protecting personal privacy and proprietary information;
         - **Integrity**, which means guarding against improper information modification or destruction, and ensuring information non-repudiation and authenticity; and
         - **Availability**, which means ensuring timely and reliable access to and use of information.

      ii. Categorize all information owned and/or collected/managed on behalf of HHS/ASPR and information systems that store, process, and/or transmit HHS information in accordance with FIPS 199 and National Institute of Standards and Technology (Based on information provided by the ISSO, CISO, OpDiv SOP, or other representative, the impact level for each Security Objective (Confidentiality, Integrity, and Availability) and the Overall Impact Level, which is the highest

watermark of the three factors of the information or information system are the following:

- **Confidentiality: [ ] Low [X] Moderate [ ] High**
- **Integrity: [ ] Low [ ] Moderate [X] High**
- **Availability: [ ] Low [X] Moderate [ ] High**
- **Overall Impact Level: [ ] Low [X] Moderate [] High**

iii. Based on the agreed-upon level of impact, implement the necessary safeguards to protect all information systems and information collected and/or managed on behalf of HHS/ASPR regardless of location or purpose.

iv. Report any discovered or unanticipated threats or hazards by either the agency or performer, or if existing safeguards have ceased to function immediately after discovery, within one (1) hour or less, to the government representative(s).

v. Adopt and implement all applicable policies, procedures, controls, and standards required by the HHS/ASPR Information Security Program to ensure the confidentiality, integrity, and availability of government information and government information systems for which the Performer is responsible under this agreement or to which the Performer may otherwise have access under this agreement. Obtain all applicable security and privacy policies by contacting the OTAO/PAR or HHS/ASPR security and/or privacy officials.

c. **Privacy Act.** Comply with the Privacy Act requirements (when applicable), and tailor FAR and HHSAR clauses as needed.

d. **Privacy Compliance.** Comply with the E-Government Act of 2002, NIST SP 800-53, and applicable HHS/ASPR privacy policies, and complete all the requirements below:

i. Per the Office of Management and Budget (OMB) Circular A-130, Personally Identifiable Information (PII), is "information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual." Examples of PII include, but are not limited to the following: Social Security number, date and place of birth, mother's maiden name, biometric records, etc.

ii. To ensure that the public's personal information is protected in a manner commensurate with the privacy risks, HHS uses a privacy analysis process to assess the risks associated with HHS's collection and maintenance of PII and to ensure information is handled in accordance with applicable legal, regulatory, and

policy requirements. PTAs analyze how information is handled in IT systems and electronic information collections and determines if the IT system or electronic information collection collects, disseminates, maintains, or disposes of PII. PIAs are used to assess the privacy risks of IT systems and electronic information collections that collect, disseminate, maintain, or dispose of PII about members of the public. PIAs also provide transparency into how HHS collects, disseminates, maintains, or disposes of the public's PII.

iii. The Performer must support the agency with conducting a Privacy Threshold Analysis (PTA) for the information system and/or information handled under this agreement to determine whether or not PII is collected, disseminated, maintained, or disposed as part of the agreement. The PTA will determine if a full Privacy Impact Assessment (PIA) needs to be completed.
   - If the results of the PTA show that a full PIA is needed, the Performer must support the agency with completing a PIA for the system or information within 1 month after completion of the PTA and in accordance with HHS policy and OMB M-03-22, Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002.
   - The Performer must support the agency in reviewing the PIA at least every three years throughout the system development lifecycle (SDLC)/information lifecycle, or when determined by the agency that a review is required based on a major change to the system, or when new types of PII are collected that introduces new or increased privacy risks, whichever comes first.

e. Controlled Unclassified Information (CUI). Executive Order 13556 defines CUI as "information that laws, regulations, or Government-wide policies require to have safeguarding or dissemination controls, excluding classified information." The Performer (and/or any sub-performer) must comply with Executive Order 13556, Controlled Unclassified Information, (implemented at 3 CFR, part 2002) when handling CUI. 32 C.F.R. 2002.4(aa) As implemented the term "handling" refers to "...any use of CUI, including but not limited to marking, safeguarding, transporting, disseminating, re-using, and disposing of the information." 81 Fed. Reg. 63323. The requirements below apply only to nonfederal systems that process, store, or transmit CUI, or that provide security protection for such components. All sensitive information that has been identified as CUI by a regulation or statute, handled by this solicitation/agreement, must be:
   i. Marked appropriately;

ii. Disclosed to authorized personnel on a Need-To-Know basis;

iii. Protected in accordance with NIST SP 800-53, Security and Privacy Controls for Information Systems and Organizations applicable baseline if handled by a Performer system operated on behalf of the agency, or NIST SP 800-171, Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations if handled by internal Performer system; and

iv. Returned to HHS control, destroyed when no longer needed, or held until otherwise directed. Information and/or data must be disposed of in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

f. Protection of Sensitive Information. For security purposes, information is or may be sensitive because it requires security to protect its confidentiality, integrity, and/or availability. The Performer (and/or any sub-performer) must protect all government information that is or may be sensitive by securing it with a solution that is validated with current FIPS 140 validation certificate from the NIST CMVP.

g. Confidentiality and Nondisclosure of Information. Any information provided to the Performer (and/or any sub-performer) by HHS or collected by the Performer on behalf of HHS must be used only for the purpose of carrying out the provisions of this agreement and must not be disclosed or made known in any manner to any persons except as may be necessary in the performance of the agreement. The Performer assumes responsibility for protection of the confidentiality of Government records and must ensure that all work performed by its employees and sub-performers must be under the supervision of the Performer. Each Performer employee or any of its sub-performers to whom any HHS records may be made available or disclosed must be notified in writing by the Performer that information disclosed to such employee or sub-performer can be used only for that purpose and to the extent authorized herein.

The confidentiality, integrity, and availability of such information must be protected in accordance with HHS and *ASPR* policies. Unauthorized disclosure of information will be subject to the HHS/*ASPR* sanction policies and/or governed by the following laws and regulations:

i. 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);

ii. 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and

iii. 44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act).

h. **Internet Protocol Version 6 (IPv6).** All procurements using Internet Protocol must comply with OMB Memorandum M-21-07, Completing the Transition to Internet Protocol Version 6 (1Pv6) available at https://www.whitehouse.gov/wp-content/uploads/2020/11/M-21-07.pdf, links to an external website, opens in a new tab [PDF, 5.87 MB]

i. **Information and Communications Technology (ICT).** ICT products and services from prohibited entities/sources must not be used/acquired in compliance with Public Law 115-232, Section 889 Parts A and B, FAR 4.21, FAR 52.204.23, FAR 52.204.24, and FAR 52.204.25. The Performer (and/or any sub-performer) must notify the government if they identify prohibited ICT products and/or services are used during the agreement performance. Manufacturing equipment purchased with award funds may be sourced globally; the Performer must prioritize suppliers with domestic supply chains and must comply with the Trade Agreements Act and the Section 889 prohibitions above.

j. **Government Websites.** All new and existing public-facing government websites must be securely configured with Hypertext Transfer Protocol Secure (HTTPS) using the most recent version of Transport Layer Security (TLS). In addition, HTTPS must enable HTTP Strict Transport Security (HSTS) to instruct compliant browsers to assume HTTPS at all times to reduce the number of insecure redirects and protect against attacks that attempt to downgrade connections to plain HTTP. For internal-facing websites, HTTPS is not required, but it is highly recommended. Consult the HHS Policy for Internet and Email Security for additional information.

k. **Project Agreement Documentation.** The Performer must use provided templates, policies, forms and other agency documents to comply with agreement deliverables as appropriate. The Government may approve deviations on a case-by-case basis when submitted to…"

l. **Standard for Encryption.** The Performer (and/or any sub-performer) must:
   i. Comply with the HHS Standard for Encryption of Computing Devices and Information to prevent unauthorized access to government information.

   ii. Encrypt all sensitive federal data and information (i.e., PII, protected health information [PHI], proprietary information, etc.) in transit (i.e., email, network connections, etc.) and at rest (i.e., servers, storage devices, mobile devices, backup media, etc.) with encryption solution that is validated with current FIPS 140 validation certificate from the NIST CMVP.

iii. Secure all devices (i.e.: desktops, laptops, mobile devices, etc.) that store and process government information and ensure devices meet HHS and OpDiv-specific encryption standard requirements. Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).

iv. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with current FIPS 140 validation certificate from the NIST CMVP. The Performer must provide a written copy of the validation documentation to the PAR.

v. Use the Key Management system on the HHS personal identification verification (PIV) card or establish and use a key recovery mechanism to ensure the ability for authorized personnel to encrypt/decrypt information and recover encryption keys http://csrc.nist.gov/publications/, links to an external website. Encryption keys must be provided to the PAR upon request and at the conclusion of the agreement.

m. **Performer Non-Disclosure Agreement (NDA).** Each Performer (and/or any sub-performer) employee having access to non-public government information under this agreement must complete the OpDiv non-disclosure agreement. . Performers (and/or sub-performers) must submit a copy of each signed and witnessed NDA to the Agreements Officer (AO) and/or Project Agreements Representative (PAR) prior to performing any work under this acquisition.

2. Training Requirements
   a. **Mandatory Training for All Performer Staff.** All Performer (and/or any sub-performer) employees assigned to work on this agreement must complete the applicable HHS/OpDiv Contractor Information Security Awareness, Privacy, and Records Management training (provided upon agreement award) before performing any work under this agreement. Thereafter, the employees must complete ASPR Information Security Awareness, Privacy, and Records Management training at least annually, during the life of this agreement. All provided training must be compliant with HHS training policies.

   b. **Role-based Training.** All Performer (and/or any sub-performer) employees with significant security responsibilities (as determined by the program manager) must

complete role-based training annually commensurate with their role and responsibilities in accordance with HHS policy and the HHS Role-Based Training (RBT) of Personnel with Significant Security Responsibilities Memorandum.

c. **Training Records.** The Performer (and/or any sub-performer) must maintain training records for all its employees working under this agreement in accordance with HHS policy. A copy of the training records must be provided to the OTAO and/or PAR within 30 days after agreement award and annually thereafter or upon request.

3. Rules of Behavior
   a. The Performer (and/or any sub-performer) must ensure that all employees performing on the agreement comply with the HHS Information Technology General Rules of Behavior and HHS Rules of Behavior for Privileged Users.

   b. All Performer employees performing on the agreement must read and adhere to the Rules of Behavior before accessing Department data or other information, systems, and/or networks that store/process government information, initially at the beginning of the agreement and at least annually thereafter, which may be done as part of annual OpDiv Information Security Awareness Training. If the training is provided by the Performer, the signed ROB must be provided as a separate deliverable to the OTAO and/or PAR per defined timelines above.

4. Incident Response
   a. The Performer (and/or any sub-performer) must respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/ASPR IRT teams within 24 hours, whether the response is positive or negative. In accordance with FISMA and OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information (PII), an incident is "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies" and a privacy breach is "the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose." For additional information on the HHS breach response process, please see the HHS Policy and Plan for Preparing for and Responding to a Breach of Personally Identifiable Information (PII)."

b. In the event of a suspected or confirmed incident or breach, the Performer (and/or any sub-performer) must:

i. Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this agreement, with encryption solution that is validated with current FIPS 140 validation certificate from the NIST CMVP.

ii. NOT notify affected individuals unless so instructed by the Agreements Officer or designated representative. If so instructed by the Agreements Officer or representative, the Performer must send ASPR approved notifications to affected individuals as directed by the OTAO.

iii. Report all suspected and confirmed information security and privacy incidents and breaches to the OpDiv Incident Response Team (IRT), PAR, OTAO, OpDiv SOP (or his or her designee), and other stakeholders, including breaches involving PII, in any medium or form, including paper, oral, or electronic, as soon as possible and without unreasonable delay, no later than one (1) hour, and consistent with the applicable OpDiv and HHS policy and procedures, NIST standards and guidelines, as well as US-CERT notification guidelines. The types of information required in an incident report must include at a minimum: company and point of contact information, contact information, impact classifications/threat vector, and the type of information compromised. In addition, the Performer must:

- Cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;
- Not include any sensitive information in the subject or body of any reporting e-mail; and
- Encrypt sensitive information in attachments to email, media, etc.

iv. Comply with OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information, and HHS/ASPR and ASPR privacy breach response policies when handling PII breaches.

v. Provide full access and cooperate on all activities as determined by the Government to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. This may involve disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls. This may also involve physical access to performer facilities during a breach/incident investigation.

5. Position Sensitivity Designations
   All Performer (and/or any sub-performer) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 of Title 5, Code of Federal Regulations (CFR). The following position sensitivity designation levels apply to this solicitation/agreement:

   Tier 1 – Public Trust
   Tier 2 – Public Trust

6. Homeland Security Presidential Directive (HSPD)-12
   The Performer (and/or any sub-performer) and its employees must comply with Homeland Security Presidential Directive (HSPD)-12, *Policy for a Common Identification Standard for Federal Employees and Contractors*; OMB M-05-24; OMB M-19-17; FIPS 201, *Personal Identity Verification (PIV) of Federal Employees and Contractors*; HHS HSPD-12 policy; and *Executive Order 13467, Part 1 §1.2*.

7. Roster
   The Performer (and/or any sub-performer) must submit a roster by name, position, e-mail address, phone number and responsibility, of all staff working under this acquisition where the Performer must develop, have the ability to access, or host and/or maintain a government information system(s). The roster must be submitted to the PAR and/or OTAO within 1 month of the effective date of this agreement. Any revisions to the roster as a result of staffing changes must be submitted within *5 days* of the change. The PAR will notify the Performer of the appropriate level of investigation required for each staff member.

   If the employee is filling a new position, the Performer must provide a position description and the Government will determine the appropriate suitability level.

8. Project Agreement Initiation and Expiration
   a. General Security Requirements. The Performer (and/or any sub-performer) must comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the agreement. All information systems development or enhancement tasks supported by the Performer must follow the HHS EPLC framework and methodology and in accordance with the HHS Contract Closeout Guide (2012).

b. System Documentation. Performers (and/or any sub-performers) must follow and adhere to HHS System Development Life Cycle requirements, at a minimum, for system development and provide system documentation at designated intervals (specifically, at the expiration of the agreement) within the EPLC that require artifact review and approval.

c. Sanitization of Government Files and Information. As part of agreement closeout and at expiration of the agreement, the Performer (and/or any sub-performer) must provide all required documentation to the OTAO and/or PAR to certify that, at the government's direction, all electronic and paper records are appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

d. Notification. The Performer (and/or any sub-performer) must notify the OTAO and/or PAR and system ISSO within 1 month before an employee stops working under this agreement.

e. Performer Responsibilities upon Physical Completion of the Project Agreement. The Performer (and/or any sub-performers) must return all government information and IT resources (i.e., government information in non-government-owned systems, media, and backup systems) acquired during the term of this agreement to the OTAO and/or PAR. Additionally, the Performer must provide a certification that all government information has been properly sanitized and purged from Performer-owned systems, including backup systems and media used during agreement performance, in accordance with HHS and/or ASPR policies.

f. The Performer (and/or any sub-performer) must perform and document the actions identified in the ASPR Performer Employee Separation Checklist when an employee terminates work under this agreement within 30 days of the employee's exit from the agreement. All documentation must be available to the OTAO and/or PAR upon request.

9. Records Management and Retention
   a. The Performer (and/or any sub-performer) must maintain all information in accordance with Executive Order 13556 -- Controlled Unclassified Information, National Archives and Records Administration (NARA) records retention policies and schedules and HHS Policy for Records Management and ASPR policies and must not dispose of any records unless authorized by HHS/ASPR.

b. In the event that a performer (and/or any sub-performer) accidentally disposes of or destroys a record without proper authorization, he/she must document and report the incident in accordance with HHS/ASPR policies.

10. High Value Asset (HVA)

If a system is identified as HVA, the Performer must comply with the HHS Policy for the High Value Asset (HVA) Program and the DHS HVA Control Overlay in addition to the above requirements.

11. Should any of these requirements change, the USG will notify the CMF and Performer(s) within 30 days and Performers may submit a Request for Equitable Adjustment if additional work and cost is required to maintain compliance with the new requirements.

Appendix II: Glossary

Agile: Able to move quickly and adapt easily to change.

Distributed: Spread across multiple locations rather than centralized in one place. Multiple qualified U.S. sites operated by the same corporate entity satisfy this definition if the proposal shows how the sites operate as one agile, integrated system; independently operated regional nodes are not required, and a single co-located site is not required.

End-to-end: Refers to the entire lifecycle or process of a product—from raw materials and manufacturing through quality control, distribution, and delivery to the patient—managed as one continuous, integrated system.

Performer: Means the BioMaP-Consortium member that is issued a Project Agreement by the CMF to complete the performance of the SOO

Sub-performer: Any entity that performs work under the performer through an agreement with the Performer or another sub-performer. A supplier or Key Starting Material vendor that sells materials on commercial terms to the broad market, performs no work under the Project Agreement and is not a sub-performer; such entities are not subject to the U.S.-owned requirement, the AOA process, or the facility and security requirements of this SOO, but foreign-sourced critical materials and equipment must be addressed in the Supply Chain Resiliency Plan.

Surge: A sudden and rapid increase in activity, demand, or capacity.

Qualified API: Under FDA guidelines is a substance manufactured by an establishment registered with the FDA, complying with Current Good Manufacturing Practices (cGMP), and accompanied by a valid Certificate of Analysis (COA)

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[i] Unless otherwise specified, PERFORMER's format is acceptable. Submissions may be in MS Office or PDF format. Funding and schedule information must be MS Excel and MS Project, respectively.

[ii] Unless otherwise specified, ALL deliverables must be emailed to the Other Transaction Agreements Officer (OTAO) and Other Transaction Technical Representative (OTTR) listed in the Agreement AND uploaded to USG-specified database/folder.

[iii] All Final Deliverable Submissions are subject to USG review and comment which may result in additional Deliverable submissions by the PERFORMER.

Attachment B: ASPR Security Requirements

1. Security Reporting Requirements
The performer facility must notify the Government Security Team within 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 the Agreement. The facts and circumstances associated with these incidents will be documented in writing for government review.

2. 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 sub-performers. Minimum length of notification is 10 business days prior to any on-site audit.

3. Supply Chain Resiliency Plan
The Performer must develop and submit within 30 calendar days of agreement award, a comprehensive Supply Chain Resiliency Plan 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 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 Performer must identify key equipment suppliers, their locations, local resources, and the associated control processes at the time of award. This document must 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 must be updated as part of an annual review, or as necessary, as part of regular Agreement communications.

b. For upstream and downstream processing, both single-use and re-usable in-place processing equipment, and manufacturing disposables also must be addressed. For

finished goods, the inspection, labeling, packaging, and associated machinery must be addressed taking into account capacity capabilities.

c. The focus on the aspects of resiliency must be on critical components and aspects of complying with the Agreement delivery schedule. Delivery methods must be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the agreed deliveries.

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

d. Production rates and lead times must be understood and communicated to the Other Transaction Agreements Officer (OTAO) or the Other Transaction Agreements Officer Project Agreement Representative (PAR) as necessary.

e. Production throughput critical constraints should be well understood by activity and by design, and communicated to performer personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

f. Reports for critical items should include the following information:
   1. Critical Material
   2. Vendor
   3. Supplier, Manufacturing / Distribution Location
   4. Supplier Lead Time
   5. Shelf Life
   6. Transportation / Shipping restrictions

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

4. Manufacturing Data Requirements

The Performer must submit within 30 calendar days of agreement 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 the Performer 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

5. Performer Locations

a. The Performer must submit detailed data regarding locations where work will be performed under this agreement, including addresses, points of contact, and work performed per location, to include sub-performers.

b. Performer must submit Work Locations Report:
   - Within 5 business days of agreement 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

6. Operational Security (OPSEC)

The performer must 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 PAR for coordination of approvals. This SOP/Plan will include identifying the critical information related to this agreement, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.

7. Security Plan

The Performer must develop a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the Government requirement. This plan must establish security practices and procedures that demonstrate how the Performer will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing, and must be delivered to the Government (draft within 30 calendar days after award; final within 60 days post award).

The Performer must also ensure all sub-performers, consultants, researchers, etc. performing work on behalf of this effort, comply with all Government security requirements and prime Performer security plans.

a. The Government will review in detail and submit comments within ten (10) business days to the Other Transaction Agreements Officer (OTAO) to be forwarded to the Performer. The Performer must review the Draft Security Plan comments, and, submit a Final Security Plan to the U.S. Government within thirty (30) calendar days after receipt of the comments.

b. The Security Plan must include a timeline for compliance of all the required security measures outlined by the Government.

c. Upon completion of initiating all security measures, the Performer must supply to the OTAO a letter certifying compliance to the elements outlined in the Final Security Plan.

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

1. Facility Security Plan As part of the partner facility's overall security program, the Performer must 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 agreement 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 The partner facility must 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 The partner facility must 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 must include recent data obtained from local law enforcement agencies. The assessment should be updated annually.	
4. Physical Security	
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 agreement. 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 agreement. 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 agreement 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 of 12 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. i) Access 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	
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 Law Enforcement (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 sub-performer compliance with all Government security requirements.
6. Personnel Security	
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	
Physical Document Control	a) Applicable documents must 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	
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	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	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	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 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 The partner facility must notify the Government Security Team as soon as possible and no later than 72 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 The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and sub-performer.	

Attachment C: Full Proposal Template (Technical and Cost)

Directions
The following pages are the mandatory Full Proposal template. The template includes required elements, including a cover page, section headings, charts, and appendices. Guidance provided in [brackets] is intended to assist the Offeror. Delete all bracketed guidance and replace it with the applicable proposal content.

Technical Proposal

Directions
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.

Format Requirements
The Technical Proposal shall:

- Be single-spaced and single-sided;
- Use 8.5 x 11-inch pages;
- Use a 12-point font; and
- Have margins of at least 1 inch on all sides.

Smaller font sizes may be used in figures and tables but must be clearly legible. Offerors are strongly encouraged to use pictures and graphics to succinctly represent proposed ideas, organization, and other relevant information.

Page Limitation
The Technical Proposal shall be limited to 30 pages. Sections excluded from this page count are marked with an asterisk (*) below. Pages in excess of this limitation may not be considered.

The number of pages should be commensurate with the 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.

Required Template
To ensure Technical Proposals receive proper consideration, the Technical Proposal format and all sections detailed within this template are mandatory. If an item is not applicable to a specific proposal, include the section topic with a short explanation of why it is not applicable.

The Technical Proposal shall consist of the following sections:

1. Cover Page*
2. Organization Information Sheet*
3. Executive Summary
4. Technical Approach
5. Supporting Project Information Appendix*

*Excluded from the page limitation.

Technical Proposal Cover Page

[Name of Offeror]

[Address of Offeror]

RPP Identifier: 26-13-EDM

[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.

[Offeror] certifies that, if selected for award, the Offeror will adhere to APPENDIX I: HHS Policy for Information Technology Procurements - Security and Privacy

[As detailed in Section 2.4 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).]

Organization 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 (Months)	
Preferred Payment Method (FFP, CPFF, Cost Reimbursable (CR), CR/Cost Share)	
Requested Use of Government Resources, Property, Labs, etc. (Yes/No; list if Yes)	
Proposed Use of Select Biological Agents or Toxins (Yes/No)	
Contract/Negotiation Contact (Name, Address, Phone, Email)	
Technical/Principal Investigator Contact (Name, Address, Phone, Email)	
Cognizant Rate Audit Agency Office (if known, include POC, Address, Phone, Email)	

Executive Summary

Please do not include the instructions in [brackets] in your proposal.

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

Technical Approach

[If recommended for award, this section will serve as the basis for the Statement of Work, which may be further refined and negotiated. Write this section accordingly and avoid generic proposal language. Provide sufficient technical detail and analysis to fully support the proposed solution and clearly define the core approach. Do not simply list or discuss multiple potential solutions; focus on the intended strategy. The following sections are required.]

1. **Background:** [Describe the problem that the solution is addressing.]
2. **Objectives:** [Describe the goal of the project and what you are going to do to achieve the goal, including the final product(s) and/or anticipated outcome(s). Be as concise as possible.]
3. **Key Personnel and Project Team:** [Identify Key Personnel considered essential to the work to be performed. Key Personnel are defined as employees of the contractor or of any subcontractor(s), affiliates, joint venture partners, or team members, as well as consultants engaged by any of those entities. *No changes to the awarded Key Personnel are authorized without express written approval from the Agreements Officer through the CMF.* Using the summary table below, identify the proposed Key Personnel and other management and technical personnel for the project. The Principal Investigator must be identified. If you are partnering with additional organizations to execute the proposed technical and programmatic work, provide details before the table that identify the partners and clearly describe the roles and responsibilities of each organization. If you are not partnering, state that no partners are proposed.]

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

4. **General Approach:** [Summarize your overarching approach/solution and framework for 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 or progress has been made.]

5. **Technical Approach**: [Provide a detailed approach, broken out by major phases/top-level tasks and gates/decision points, explaining how your organization intends to address the requirements set forth in the RPP and showing a clear course of action and the 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. The Gantt chart may be rolled up to the task level for space efficiency, if necessary.]

7. Deliverables and Milestone Payments:

Instructions:

- Submitted information may change during negotiations if the Government recommends the proposal for award.
- The deliverables listed in Sections 4 and 10 of Attachment A to the RPP are mandatory. Please populate the table below with all deliverables identified in Sections 4 and 10 of Attachment A to the RPP, as well as any additional technical deliverables you propose to support the technical effort. The results of the technical effort are contractually binding and must be clearly identified. Offerors should carefully read the Base Agreement. Additionally, any hardware or software to be provided to the Government as a result of this project must be specified.
- The proposed milestones and deliverables should be appropriate in number relative to the project's size and duration, and they should have sufficient monetary value to justify the generation of a deliverable and any related invoices. Please note that recurring programmatic reporting will not be funded. For cost-reimbursable agreements, the Offeror is still required to assign a monetary value to each milestone. However, the total invoice amounts will be based on actual costs incurred and do not have to match the specified amounts exactly.
- List the data rights assertions using the numbers assigned in the data rights assertion table. If an assertion is not applicable to a deliverable, write "N/A."

Deliverable #	**Task #** *[For technical deliverables in Section 5 (Technical Approach), the Offeror shall reference the applicable Task # or Paragraph #. For mandatory deliverables specified in the RPP, the Offeror may indicate "N/A"]*	**Deliverable Name** *[Include all technical and mandatory deliverables specified in the RPP.]*	**Deliverable Description** *[All technical deliverables proposed by the Offeror must include a description. For mandatory deliverables outlined in the RPP, the Offeror may instead state "**the full description is outlined in the RPP**" rather than copying the entire text into the table.]*	**Due Date (Month)/ Reporting Frequency**	**Total Cost** *[Provide a breakout distinguishing Government funding from cost-share contributions for each deliverable (if applicable).]*	**Assertion #**
1						
2						
3						
4						
Etc.						

Total Period of Performance: # Months

8. Intellectual Property, Data Rights, and Copy Rights

[If the Offeror intends to provide technical data that existed prior to, or was produced outside of, the proposed effort and for which the Offeror wishes to maintain additional rights, the Offeror should assert these rights by completing the table below. Note that each 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 table below 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 Appendix

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

Cost Summary EXAMPLE This form is to be completed by Offeror and evaluated by Technical Evaluators. Items in italics are provided as samples only. Offeror must complete table with the applicable information.		
Cost Element	**Total Proposed Cost**	**Description/Explanation**
Labor	*$XXX*	*xx hrs of senior scientist; xx hours of program management; include additional as required.*
Labor Hours	*XX*	
Subcontractors	*$XXX*	*Sub A - $xxx; xx legal advisor hours* *Sub B - $xxx; xx hours of Testing*
Subcontractor Hours	*XX*	
Consultants	*$XXX*	*Financial consultant supporting all phases*
Consultant Hours	*XX*	
Material/Equipment	*$XXX*	*pipettes, gloves, computer software*
Other Direct Costs	*$XXX*	*ship testing materials to lab*
Travel	*$XXX*	*x trips for x people for x days to xx (city), xx (state) from xx (city), xx (state) for program meetings*
Indirect Costs	*$XXX*	*approved by DHHS (provide date)*
Fee	*$XXX*	*Not applicable if cost share proposed*
Total Cost to Government	*$XXX*	
Total Project Value	*$XXX*	

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

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

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

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

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

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

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

5. Relevant Experience

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

<table>
<tr><td colspan="4">Respondent's Name and Contract/Example Name</td></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>

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 of cost or price can be conducted and reflect the best estimate of the costs for the project. The Cost Proposal must be consistent with information provided in the Statement of Work and general technical approach (i.e., costs, cost share, dates, etc.). Proposals that deviate substantially from these guidelines, omit substantial parts or sections, or deviate significantly from the original Proposal Rough Order of Magnitude (ROM) estimate may be eliminated from further review and funding consideration.

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

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

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

Cost Proposal Section I: Cost Proposal Narrative

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

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

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

Preferred Payment Method. Identify which of the payment methods is preferred. The methods are (1) Cost Reimbursable Milestones with Ceiling, (2) Cost Reimbursable/Cost

Share with Ceiling, (3) Cost Plus Fixed Fee Milestones with Ceiling and (4) Fixed Price Milestones with Ceiling.

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

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

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

   Provide an explanation for any proposed labor escalation.

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

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

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

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

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

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

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

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

Support is required for each subcontractor/consultant as follows:

- If a subcontractor/consultant is based on commercial pricing, provide an explanation of the commerciality determination and supporting documentation (e.g., website pricing, catalogue pricing, etc.)
- For a subcontractor/consultant less than $250,000, provide a brief explanation of the work to be performed.
- For a subcontractor/consultant greater than $250,000 and less than or equal to $2,000,000, provide a supporting quote and confirmation of compliance with the Salary Rate Limitation.
- If a subcontractor/consultant over $2,000,000 was competitively solicited, provide the price analysis showing how the price was determined reasonable, summary of competition, and copies of the competitive quotes.

- Absent any of the above, if relying on cost data for a subcontractor/consultant greater than $2,000,000, a cost-by-cost element breakout must be provided to the same level of detail as the Offeror.

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

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

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

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

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

the organization or the history base used); and (3) all factors, by year, applied to derive the proposed rates.

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

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

i. 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.).

j. **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 D: Additional Required Documentation

[Each of the below files must be submitted as its own individual file outside of the full Technical and Cost Proposal.]

File Name	Description
Performance Location Attestation	Submit an attestation that all work on the Project must be performed within the continental United States and its territories; the Performer is\ U.S. owned, U.S. operated, and has their global headquarters located within the U.S. If circumstances change after Project Agreement award, the Performer must obtain an Agreement Officer's Authorization (AOA) approval for any proposed arrangement where the Performer will not meet the U.S.-owned and operated requirement.
Legal and Financial History	Submit a maximum two-page explanation letter that identifies all of the following since March 2020: contract/order/agreement terminations or settlement agreements with the U.S. Government, bankruptcy filings, receivership and eviction history, postponements or defaults on financial obligations, default judgments from a court, adverse decisions as part of binding arbitration, and any other information that informs the risk the government is taking if the Performer and Sub-Performer(s) is/are selected for an award.
Letter of Bondability	Submit a letter of bondability for construction-related bonding by a surety that is capable of executing the project. The letter of bondability must identify the bonding company and specify the Performer's bonding capacity. Bonding capacity is defined as the maximum dollar amount of contracts the surety will allow the Performer to take on at once. The letter must also address how much of the bonding capacity is available for the proposed project.
DOJ and OIG Contacts	Submit a statement identifying all of the following for the Performer and any Sub-Performer(s): Contacts with the Department of Justice (DOJ) and/or any Office of Inspector General (OIG) for any reason in the last five years, to include the names and contact information.
Bylaw Amendment Attestation	Submit an attestation stating that the Performer's corporate bylaws will be amended within 90 days of a Project Agreement award to require all of the following: a. The Performer, any successor interest to the Performer, will remain a U.S. owned U.S. operated, with global headquarters located within the U.S., domestically controlled company with corporate governance in place to prohibit foreign influence for at least ten years after a Project Agreement award. b. In the event of a public health emergency, the Performer, any successor in interest to the Performer, and any other entity that owns, operates, leases, occupies, or uses the Government-funded capacity for any reason, must provide priority access, in terms at least as favorable to the Government as those the Government could require under the Defense Production Act of 1950, ch. 932, 64 Stat. 798, as amended and extended (codified as amended at 50 U.S.C. § 4501 et seq.)", to the Government if there is a public health emergency, or other triggering emergency declaration for a period of ten (10) years after the period of performance ends. c. The Performer, any successor in interest to the Performer, and any other entity that owns, operates, leases, occupies, or uses the Government-funded capacity for any reason, must not use the real property, equipment, or other assets funded by the Government as

	collateral or for a purpose that is not related to production of drug substances and drug products, for a period of ten (10) years after the period of performance ends. d. The Performer, any successor in interest to the Performer, and any other entity that owns, operates, leases, occupies, or uses the Government-funded capacity for any reason, must prioritize utilizing USG-funded capacity to meet U.S. market demand for drug substances and drug products for a period of ten (10) years before meeting global market demands. Prioritizing USG-funded capacity to meet U.S. market demands is defined as fulfilling domestic need before meeting any global market need.
Draft Security Plan	In accordance with Attachment B
Capitalization Plan	Offerors must provide a full Capitalization Plan that identifies all proposed cost share contributions, including the total amount, the specific sources of funding (e.g., corporate funds, third-party contributions, or nonfederal governmental support), and the timing and availability of funds over the period of performance. Offerors must provide supporting documentation (e.g., letters of commitment or financial statements), as appropriate. The cost sharing plan must also describe how the Performer will track, manage, and report cost share expenditures throughout project execution.