



Statement of Objectives (SOO)
BioMaP-Consortium OT Vehicle



Project Title: Repurposing Equipment for Drug Delivery (REDD)

1. SCOPE

Topic Area: BioMaP-Consortium Domain 2– Repurposing Equipment for Drug Delivery (REDD)

- 1.1.** BARDA's Chemical, Biological, Radiological, and Nuclear (CBRN) Division, Chemical Medical Countermeasures (Chem MCM) Program possesses specialized Government-Furnished Equipment (GFE) originally customized under a prior contract to manufacture an emergency autoinjector platform. This platform features a novel glass-free, collapsible primary drug container (PDC) made from high-barrier films. The prior contract ended prematurely, and the equipment has since been packed and placed in storage at a BARDA facility in Perry Point, MD.
- 1.2.** The equipment supports discrete process steps associated with PDC manufacture, including handling and cleaning of high-barrier polyvinyl chloride (PVC) film, forming of the film into specific conformations, insertion into a pre-assembly configuration, and fill/finish sealing of the PDC.
- 1.3.** This effort seeks a Recipient who can take possession of the equipment, transport it from Perry Point, MD to its own facility, and repurpose it to develop a drug closure system and delivery device (e.g., an autoinjector or other single-use delivery system), thereby maximizing the return on the Government's prior investment. Technologies applicable to chemical medical countermeasures are of primary interest, with preference for platforms broadly applicable across multiple CBRN indications. Commercial applications for the resulting device technology may also exist, and the Government encourages proposals that create a platform usable for other emergency-use drug products across the BARDA portfolio.

2. REQUIREMENTS

2.1. General Objectives

- 2.1.1.** This Request for Project Proposal (RPP) seeks an offeror who can take possession of BARDA's specialized GFE and repurpose it for a drug closure system and delivery device (e.g., autoinjector or other single-use delivery system), maximizing the value of the Government's prior investment.
- 2.1.2.** Equipment scope includes items supporting:

- Handling and cleaning of high-barrier PVC film
- Forming of PVC film into specific PDC conformations
- Insertion into a pre-assembly configuration
- Fill and finish sealing of the primary drug container (PDC)

2.1.3. The equipment was originally customized to support a previous autoinjector production line and, per information independently corroborated by multiple RFI respondents, reportedly includes: fill/seal stations and associated upgrades; a Watson-Marlow Flexicon PF7 peristaltic pump; a film-cleaning web handler and particle counter; MacTec drug-container forming cells; Wilco leak-detection systems, a laser seal profiler, and bubble/burst and aseptic-cover burst testers; checkweighers and force/torque gauges; Mikron mini-cells for device/needle-hub assembly; and laser marking equipment. BARDA has assembled a complete, authoritative equipment list and provide it to offerors as part of the RPP data package, consistent with the information needs identified during market research (see Market Research, below).

2.1.4. Because the equipment and underlying PDC design originated under a prior, differently sponsored program, offerors should expect to address background intellectual property considerations as part of their technical and legal diligence (see Intellectual Property Adherence, below). BARDA will provide SME experience and capability to assist and provide support with intellectual property considerations.

2.1.5. The anticipated scope of awardee activities includes:

2.1.5.1. Equipment Transfer and Logistics

2.1.5.1.1. Recipient shall propose and execute a logistical plan for transport of all identified equipment and consumables from Perry Point, MD, to the Recipient's facility, including any special handling, packaging, or transport requirements.

2.1.5.1.2. Transport shall be completed no later than April 1, 2027.

2.1.5.2. Equipment Set-Up and Assessment

2.1.5.2.1. Recipient shall set up the transferred equipment at its facility and determine which components are usable/serviceable. This includes the disposal or repurposing of unnecessary consumables or minor equipment

2.1.5.2.2. Recipient shall receive and review the Device Readiness Transfer Package (to be provided by BARDA, including equipment details and photographs) to inform set-up and requalification activities.

2.1.5.2.3. Recipient shall bring the equipment up and into operational running condition

2.1.5.3. Primary Drug Container and Process Optimization

2.1.5.3.1. Recipient shall determine the optimal PVC film characteristics for a collapsible PDC with no leachables, complete seal, long shelf-life, and sterilization method.

- #### 2.1.5.4. Process Verification and Characterization

4. DELIVERABLES

See Appendix 1.

5. PHYSICAL PROPERTY

Title to the Government-Furnished Equipment (GFE) transferred to the Recipient under this Agreement remains vested with the Government. The Recipient shall maintain, safeguard, and account for the GFE in accordance with the terms of the Project Agreement and applicable Government property management requirements. Treatment of any newly acquired equipment/tooling procured by the Recipient under this effort, consistent with BioMaP-Consortium Base Agreement physical property terms.

6. REQUIRED TERMS RELATED TO USG INVESTMENT

Consider whether the following four (4) regulatory flow downs are required for the proposed project. Each project may require All, None, or a Combination. Please work with your BioMaP-Consortium Sponsor Liaison to mark those that apply or provide additional regulatory requirements as necessary for final submission.

- ☐ Needle Exchange
- ☐ Product Licensure
- ☐ Final Distribution
- ☒ Manufacturing Standards
- ☐ All of these
- ☐ None of these
- ☐ Other, please provide additional information:

7. SCHEDULE OBJECTIVES

The complete period of performance for this effort shall not exceed 18 months from date of award. Equipment transport from the Perry Point, MD storage facility shall be completed no later than April 1, 2027. Interim milestones (e.g., equipment set-up/qualification complete, process optimization complete, media fill run completion) shall be proposed by the Recipient and finalized at award.

8. RISK MANAGEMENT OBJECTIVES

The Recipient will establish a Risk Management program including a Risk Management Plan, Risk Register, and risk mitigation strategies (see Deliverables Table). Given the nature of this effort — repurposing previously idle, specialized equipment of unconfirmed current condition — the Recipient's Risk Management Plan should specifically address:

- Risk that transported equipment is damaged, degraded, or non-functional upon receipt, and associated contingency/mitigation plans.
- Risk associated with identifying an appropriate sterilization method, including management of byproducts from radiation sterilization.
- Schedule risk associated with the 18-month period of performance given equipment set-up and requalification uncertainties.

The Recipient must manage all project risks and report changes to identified risks to the USG as they occur. The USG must be permitted to participate in risk management and mitigation processes associated with this project.

9. INTELLECTUAL PROPERTY

The Government requires not less than Government Purpose Rights to any intellectual property developed under this effort with USG funds. IP rights are further defined in, and subject to, the BioMaP-Consortium Base Agreement; the BioMaP- Consortium Consortium Management Firm (CMF) reserves the right to assist in negotiation of IP, royalties, licensing, and future development between the Government and the Recipient. [Note: Because this effort involves repurposing existing GFE and PDC technology developed under a prior contract, Recipient proposals should specifically address treatment of any pre-existing/background IP associated with the transferred equipment and PDC design and clearly delineate it from any new IP arising from the repurposing effort.] BARDA will provide SME experience and capability to assist and provide support with intellectual property considerations

APPENDIX 1. Project Agreement Deliverables

Deliverable Description	Content Requirements and Instructions ⁱ	Reporting Frequency ⁱⁱⁱⁱ
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 an agenda. Follows Agenda mutually agreed upon in advance of meeting. RECIPIENT to provide meeting minutes within 3 business days from date of meeting.	As needed for special topics, when specifically requested by the OTAO or OTTR.
Biweekly Project Team Meetings	Purpose is to review monthly progress report findings, any changes since last biweekly and any projected issues or challenges. Recipient to provide agenda and slides two (2) business days prior to the meeting.	Virtual. Biweekly, 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 15th of the month. Contractor 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, Construction, Validation, Regulatory. Projections against project expectations, including risks and mitigation plans. Go/No-Go decision gate Milestones and progress should be included using a mutually agreed upon template prior to the IPR.	Every 3 months from start of project. Recipient to send brief 3 working days in advance of meeting.
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.	Due within 60 days of contract award. 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	Updated monthly and submitted with Monthly Technical Progress Report and posted to

	contain information regarding identification date, severity of risk, mitigation plan(s) and dates for implementation, risk owner, etc.	USG identified document site.
Project Action Items List	Actions identified throughout the project, which are not tracked by some other project management tool, and which require follow-up and monitoring for completion, will be captured in an Action Items List. (Or similar list/tracking tool.) List should contain information regarding identification date, target completion, responsible individuals/groups, etc.	Submitted if/as required with monthly technical progress report.
Site Visits	Host visits from USG following agenda/schedule mutually agreed upon with USG in advance of visits. Provide visit notes within 3 business days from date of visit.	Typically, quarterly, commensurate with quarterly IPR, at the Agreements Officer's discretion.
Annual Project Progress Report	High level project progress review of overall objectives. Updated projections against project expectations, including risks and mitigation plans, should be reported with respect to the previous annual report. Summary of critical changes that took place over the year. Recommended to not exceed 20 pages.	Annually from award. To review progress over the previous 12 months. A Draft to be submitted 30 days after the completion of each year of performance. Within 15 days of receipt, the Government will provide review comments. The Respondent shall respond within 15 days of receipt of comments. Report format: Microsoft Word and PDF
Final Report	Final report summarizing stated objectives and the progress that was achieved in meeting those objectives; summary of risks incurred, impacts and mitigation; quantitative discussion of production improvements achieved; financial summary of project; schedule summary for project,	Initial submission to be submitted 30 days prior to the end of the period of performance. Within 15 days of receipt, the Government will provide review comments. The Respondent shall

	comparing original schedule to final schedule; recommendations for path forward as applicable.	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 submission 30 Days after Award, updated as necessary See BARDA Security Plan checklist
Quality Management Plan	The recipient shall develop and submit a Quality Management Plan that details the methods/processes they will use to demonstrate the ability to produce NBR and deliver a Quality Management Report.	Initial submission 30 Days after Award, updated as necessary Report format: Microsoft Word and PDF
Detailed Objective Project Plan	The recipient shall develop and submit a detailed objective project plan that at minimal include the following: a. Plan should describe in detail the proposed plan to the objective outlined above. b. Plan should include all analytical assumptions that will be employed in preparing and executing the sustainment effort. c. Plan should include a range of assumptions/variables that can be used to assess various market	Initial submission 30 Days after Award, updated as necessary Report format: Microsoft Word and PDF

	conditions. d. Plan should include metrics, variables, and milestones for gauging domestic and global market progress of required technologies and infrastructure that will be needed to sustain capacities beyond the period of US Government investment. e. Plan should include all metrics, variables and milestones that define the various gates and decision points (distinct from the bullet above). f. Plan should include a detailed description of the proposed sustainment effort. Details should include the basic steps for each phase of implementation, and which includes all dependencies between phases. g. Plan should include identification of risks associated with execution of the plan.	
Infrastructure and Management Structure Organizational Chart	The recipient shall complete description of the infrastructure and management structure (organizational chart) including but not limited to addressing all elements that will accomplish the program's goals and milestones. The recipient shall propose a workforce management plan, e.g., how workforce will train, maintain, etc., that reflects the ability to meet the requirements.	Initial submission 30 Days after Award, updated as necessary Report format: Microsoft Word and PDF
FDA Correspondence	The recipient shall memorialize and submit any original and unredacted correspondence between the recipient and FDA including formal, informal emails, correspondence, telephone calls, and official information requests. All documents shall be duly marked as either 'Draft' or 'Final'	All copies should be submitted within five (5) business days of correspondence

FDA Submissions	The recipient shall provide BARDA the opportunity to review and comment upon all draft submissions before submission the FDA. The recipient shall provide an electronic copy of the final FDA submission. All documents shall be duly marked as either 'Draft' or 'Final'	Draft FDA submissions should be provided at least 15 business days prior to FDA submission. BARDA will provide feedback to the recipient within ten (10) business days of receipt. Final FDA submissions shall be submitted no later than five (5) calendar days from its submission to FDA
FDA Inspections/Site Visits/Audits	In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the Government with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.	Recipient must notify the OTAO and Senior PAR within ten (10) business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice. • Recipient must provide copies of any FDA audit/inspection report received from subcontractors/partners that occur as a result of this contract or for this product within five (5) business days of receiving correspondence from the FDA or third party. • Within ten (10) business days of audit/inspection report, Contractor shall provide CO and COR with a plan for addressing areas of nonconformance, if any are identified.
Device Control Documentation	All required device control documentation to include, but limited to, User Requirements Specification; Product Requirements Specification; Use FMEA, design FMEA, & process	When specifically requested via e-mail by USG Project Manager (or designee), post latest version of requested

	FMEA; Fault Tree Analysis; Risk Assessment; Design and Development File; Design and Development Plan; Design Review documentation and reports; Reliability Report; Design Verification Plan, Protocol and Report; Design Validation Plan, Protocol, and Report (including sterilization and stability planning, protocols, and reports); Human Factors Plan, Protocols, and Reports; Design Transfer Plan and Report	documents to shared documents site
Design and Development Framework Documentation	All required device control documentation to include, but limited to, User Requirements Specification; Product Requirements Specification; Use FMEA, design FMEA, & process FMEA; Fault Tree Analysis; Risk Assessment; Systems Level Requirements Document; Documented list of system level functions that fulfill the system requirements; Documented list of candidate critical parameters – system level; Estimated System Cost Projection; Design and Development Plan; Documented Critical Parameter Database with Estimated Subsystem and Subassembly CFR (Critical Functional Response) Ideal Functions; Updated Reliability model (or Fault Tree Analysis); Documented Design Failure Modes and Effects Analysis for Subsystems, Subassemblies, Reliability Critical Components and Manufacturing Processes; Documented test methods and measurement systems analysis; Documented Stack Up Tolerance Analysis and Summary; Initial	When specifically requested via e-mail by USG Project Manager (or designee), post latest version of requested documents to shared documents site

	Cp/Cpk Assessment for candidate Critical-to-Function Specifications from manufacturing processes from supply chain; Subsystem and subassembly noise diagrams; Complete set of critical robustness parameters and their nominal set points; Subsystem and Subsystem Reliability Test Plans; System CFR Nominal Performance Capability Indices; Subsystem, subassembly and component reliability and life test performance; System CFR Nominal Performance Capability Indices; System CFR Stressed Performance Capability Indices; System Reliability Performance; System CFR Nominal Performance Capability Indices; System Reliability Performance; Subsystem, subassembly and component reliability and life test performance; Updated Critical Parameter database	
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¹ Unless otherwise specified, RECIPIENT's format is acceptable. Submissions may be in MS Office or PDF format. Funding and schedule information shall be MS Excel and MS Project, respectively

² Unless otherwise specified, ALL deliverables shall be emailed to the Other Transaction Agreements Officer (OTAO) and Other Transaction Technical Representative (OTTR) listed in the Agreement AND uploaded to USG-specified database/folder.

³ All Final Deliverable Submissions are subject to USG review and comment which may result in additional Deliverable submissions by the RECIPIENT.