Biomedical Advanced Research and Development Authority (BARDA)

Rapid Response Partnership Vehicle (RRPV)

Request for Project Proposals (RPP)

Solicitation Number: RRPV 24-02-ODM

"On-Demand Manufacturing"

Request Issue Date: 13 August 2024
Closed 25 September 2024 by 1pm Eastern

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

1 Executive Summary

1.1 Rapid Response Partnership Vehicle Consortium

The Rapid Response Partnership Vehicle (RRPV) Consortium is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the Biomedical Advanced Research and Development Authority (BARDA), Administration for Strategic Preparedness and Response, U.S. Department of Health and Human Services (HHS).

The RRPV will help fortify national health security by developing medical countermeasures products prior to and during a pandemic or public health emergency. The RRPV will focus on the acceleration of products and technology development, regulatory approval, commercialization, and sustainment to address pandemic influenza, emerging infectious diseases, and other biological threats.

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

RRPV is openly recruiting members to join a broad and diverse biomedical consortium that includes representatives from all organizations who work within stated technical focus areas; for more information on the RRPV mission, refer to the RRPV website at RRPV.org. For entities interested in joining the RRPV Consortium and responding to this solicitation, please visit http://www.rrpv.org/how-to-join.

1.2 Purpose

Although major advances in science and technology have accelerated the development of medical countermeasures (MCMs) for pandemics and other public health emergencies, there remain considerable gaps and inefficiencies in the current processes of centralized, large-scale MCM manufacturing and deployment. Vulnerabilities in MCM manufacturing, storage, and delivery compromise readiness, impede rapid response, and expose major inequities in access to life-saving products. These vulnerabilities include:

(1) **Delays in product availability** due to disruptions to supply chain, and bottlenecks in manufacturing and delivery;
(2) **Complex storage and transportation requirements** from point(s) of production to areas of need;
(3) **Inability to rapidly pivot** to new targets (e.g., an emerging infectious disease) and/or to increase productivity to meet surges in demand;
(4) **Operations in a resource constrained environment** where manufacturing may occur in rooms/facilities not designed or environmentally controlled according to regulatory standards.

Under Project NextGen, and in coordination with the BARDA Division of Research, Innovation, and Ventures (DRIVe), the On-Demand Manufacturing Program will support the overall vision and goals of advancing manufacturing technologies that will improve access and enable faster, cheaper, more rapid, and more flexible production of vaccines and other biologics. To that end, the development of decentralized, on-demand manufacturing strategies will ultimately enable timely and equitable distribution of lifesaving MCM when and where they are needed most. Distributed on-demand manufacturing capabilities are expected not to replace, but rather, to supplement the capabilities of existing centralized, large-scale manufacturing facilities. Together, both approaches support the collective goal of accelerating the deployment and maximizing the impact of MCMs, especially during periods of critical need.

The design and development of a portable, continuous, and end-to-end system for on-demand manufacturing has faced many technical and logistical hurdles. Successful development and adoption of on-demand manufacturing capabilities requires solutions for a number of key areas, including:

- **Systems, equipment, and processes** must be designed and specified to meet the increased product risks associated with operating in a resource-constrained environment.
- **Standardization of inputs and starting materials** (e.g., DNA templates, *in vitro* transcription (IVT) reagents) to reduce process complexity and to enable system transferability.
- **Optimization of processes** (e.g., increase fidelity and efficiency of IVT, develop biomass expansion, intensification, clarification, and purification methods) to increase speed, efficiency, and yield.
- **Incorporation of process controls** (e.g., sensors to detect impurities and contaminants, methods to accelerate product release) to ensure product quality.
- **Development of capabilities for in-line formulation** to produce a dosage-ready product that can be readily administered to patients.
- **Training and retention of a highly specialized workforce** in product development, systems engineering, clinical evaluation, and regulatory oversight

2 Administrative Overview

2.1 RPP Approach

A multi-stage approach will be employed to streamline the process for preparation, submission, evaluation, and notification to reduce the burden on industry partners. A series of down selections will occur between Stages 1, 2, and 3. Participation in Stage 2 does not guarantee the opportunity to submit a Full Technical and Cost Proposal in Stage 3, and submission of a Full Technical and Cost Proposal in Stage 3 does not guarantee an award. Each stage of this solicitation process is competitive.

Submission review may include a panel of subject matter experts (SMEs), to include the use of contractor consultants or subject matter experts (SMEs), who will make recommendations to a Source Selection Authority. Where appropriate, the Government will employ non-disclosure agreements to protect information. An offeror's submission at any stage under this RPP indicates concurrence with the aforementioned use of contractors and SMEs.

The solicitation stages are as follows:

Optional Teaming Profile

Optional collaboration initiative to promote teaming. See Section 2.3 of this RPP for details and instructions for this optional activity.

Stage 1 - Abstract

In Stage 1, Offerors will submit a 5-page Abstract. Abstracts submitted under this RPP shall follow the mandatory template provided in Attachment 1 and contain the following minimum:

- Cover Page (excluded from page count)
- Executive Summary
- Offeror TPP Table
- Technical approach overview

- Teaming/subcontractors
- Facilities and personnel qualification
- Budget estimation
- Period of Performance/Schedule
- Data Rights Assertions (excluded from page count)

BARDA will evaluate the Stage 1 Abstracts to determine which proposed solutions best meet the evaluation criteria as well as BARDA's current technology priorities and program objectives. Those Offerors will be provided feedback and invited to proceed to Stage 2. Offerors who are not invited to proceed into Stage 2 will be notified.

Stage 2 - (By Invitation Only) Presentation

The successful Stage 1 Offeror(s) will receive an invitation letter from the CMF to participate in a virtual presentation of the proposed project during a meeting with the Government sponsors. Offerors invited to Stage 2 will be invited to present (virtual format) their on-demand manufacturing concept to BARDA in a slide presentation that will be immediately followed by a Question-and-Answer session. The Presentations will allow BARDA to efficiently evaluate Stage 2 concepts, determine their respective alignment with the ODM program goals, and engage directly with the Offeror to address technical questions or concerns. While the Government reserves the right to request that additional information related to specific areas of interest be included in the presentation, at a minimum, Offerors should be prepared to include the following information and present on the following topics:

Executive summary (up to approximately 10 to 15 slides):

· Technical approach overview

· Facilities and personnel qualification

Technical presentation (up to approximately 25 to 30 slides):

· Detailed technical approach

· Detailed risks and mitigation plan

· Budget estimation

· Teaming/subcontractors

Instructions, including content due date, presentation time and date, and technical questions, will be provided to the Offerors in advance. Offerors will be requested to provide advanced copies of their Presentation materials 3 business days prior to the meeting date.

The information discussed during the Presentation provides a means for the Government to engage in a discussion with the Offeror to gain a greater understanding of the proposed solution and the Offeror's capabilities. The Presentation should be restricted to a maximum of 60 minutes with an additional 30 minutes to address any questions from the Government and discussion (total of 90 minutes).

BARDA will evaluate the Stage 2 Presentations to determine which proposed solutions best meet the evaluation criteria as well as BARDA's current technology priorities and program objectives.

Stage 3 - (By Invitation Only) Full Technical Proposal & Cost Proposal

The successful Stage 2 Offeror(s) will receive an invitation letter from the CMF to submit a full technical proposal and cost proposal. Stage 3 is anticipated to require Technical Proposal, Cost Proposal Narrative, Cost Proposal Format, and Statement of Work. Further instructions will be provided to successful Stage 2 Offerors in the invitation letter.

2.2 Project Tasks

The technical activities for this program are structured into three sequential phases listed below. Each Phase is specific to the development and readiness of the proposed solution.

Offerors may propose under either Phase 1 or Phase 2. It is anticipated that BARDA will make initial awards for one (1) Phase only (either Phase 1 or Phase 2), with the potential to include the next Phase as an optional task. In other words, Offerors proposing Phase 1 work are requested to describe in brief detail their plans for Phase 2 (inclusive of an estimated budget), and Offerors proposing Phase 2 work are requested to describe in brief detail their plans for Phase 3 (inclusive of an estimated budget). BARDA reserves the right to award any proposed phases as determined to be in the best interest of the Government.

Phase 1: Engineering & Prototyping: The goal of Phase 1 is to support the development of early technologies/processes (i.e., *individual component technologies or manufacturing processes* that have yet to be integrated into a functional, dedicated system). Offerors should propose new technologies that will achieve some or all of the goals listed under the Target Platform Profile (TPP) in Table 1**.**

BARDA will consider promising early-stage approaches and more technologically mature solutions. To that end, example technologies that are eligible for funding under this phase may include but are not limited to: interconnected upstream fed-batch processes with downstream continuous processes, intensification and purification processes, development of in-line sensors or analytics for in-line product quality monitoring, methods of product modification (e.g., capping, encapsulation, surface assembly, functionalization etc.) and buffer exchange for final drug product formulation.

Phase 2: Integration & Proof-of-Concept (POC) Run in non-GMP conditions: The goal of Phase 2 is to support the early development of an end-to-end, on-demand manufacturing system that meets some or all of the goals outlined in the TPP. At the end of this phase, performers will demonstrate a proof-of-concept manufacturing run under non-GMP conditions and then provide a plan to further optimize their system and approach.

Tasks to be completed under this phase may include (but are not limited to):

- Assess necessary quality measures and controls at appropriate steps to achieve "Goal State"
- Process development & establishing Critical Quality Attributes (CQAs)

- Demonstration that the prototype development or POC run meets a predefined degree of improvement and quality over baseline
- Production of R&D grade material (non-GMP, non-clinical grade material)
- Establish plan for optimization or integration to improve manufacturing process for Phase 2

Phase 3: Optimization & Initial Small Quantity Production Run: The goal of Phase 3 is to optimize the previous system from Phase 2 based on the optimization plans and to conduct an initial small quantity production run to demonstrate feasibility. In addition, the performer will be required to provide a plan for Chemistry, Manufacturing and Controls (CMC) and regulatory engagement to support scale out activities.

Tasks under this phase include (but may not be limited to):

- Provide updated schematics and CQAs that are aligned with Optimization Plan
- If a component technology, integrate process into an end-to-end system
- Optimization run: Conduct an initial production run (X scale) of the new system and produce material that meets CMC objectives
- Meets predefined degree of improvement CQAs
- Confirmation run: Demonstrate scalability and CMC suitability based on initial production run (2X or 3X scale)
- Submit plan for CMC and regulatory engagement

Each proposal selected for award under this RPP will be executed as a Project Award under the RRPV by the RRPV CMF and be funded under the OTA Number 75A50123D00005. The same provisions will govern this Base Agreement as the OTA between the USG and ATI, unless otherwise noted in the Project Award.

2.3 Teaming

The ideal Abstract would consist of a multi-partner, multi-component effort that: (i) leverages existing capabilities and strengths of the respective partners; and (ii) articulates a detailed project plan with achievable goals. **Partnerships are highly encouraged.**

Offerors are invited to submit a one-page teaming profile describing their technical competencies, relevancy to project categories (as listed below), and other capabilities as they relate to the program and desired attributes/capabilities sought from a potential team partner. Offerors should not include proprietary information. At a minimum, the one-page profile should include:

- Contact information (e.g., name, organization, email, phone number, mailing address, website)
- Brief description of the Offeror's technical competencies in one or more of the following technology areas All technology areas are of equal importance.
  - Unit operations for DS
  - Unit operation modules for DP
  - Unit operation modules fill/finish
  - Technologies applied across production continuum
- Desired technical competencies from other potential team members, if applicable

Under this program, offerors may function individually, or as a team with one legal entity identified as the prime Offeror. It is anticipated that offerors may provide capabilities in one or more of the categories listed above. Offerors may support more than one technology area (as indicated above) to support the development of a full end-to-end, continuous manufacturing solution.

Teaming profiles must be emailed to RRPV@ati.org no later than August 30th, 2024. Profiles that exceed the one-page limit will not be accepted. Information contained in the profiles should be publicly releasable and profile submitters consent to distribution among other interested RRPV members. An Industry Day will be held in conjunction with this release. More information will be posted on the RRPV website with information and registration details. After the Industry Day, teaming profiles will be made available via the RRPV members only website. Specific content, communications, networking, negotiations, and team formation are the sole responsibility of the Offeror and participants. BARDA or ATI do not endorse any participating organization or take responsibility for improper dissemination of teaming profiles.

2.4 Period of Performance and Type of Funding Instrument Issued

The anticipated period of performance for each Phase is 18-24 months.

It is anticipated that BARDA will make initial awards for one (1) Phase only (either Phase 1 or Phase 2), with the potential to include the next Phase as an optional task. BARDA reserves the right to award any proposed phases as determined to be in the best interest of the Government.

Multiple Phase 1 and Phase 2 Project NextGen-funded awards are expected to total approximately $22M. Project NextGen awards prioritize vaccine-based manufacturing technologies. If proposing a solution for a therapeutics-based manufacturing technology, the Offeror should provide a strong technical rationale for how advancing the therapeutic solution would benefit and could be translated to on-demand manufacturing of vaccines. A focus on SARS-CoV-2 is encouraged.

BARDA DRIVe-funded Phase 1 and 2 awards are expected to be approximately $7M and may be distributed across up to two awards. BARDA DRIVe awards will focus on other BARDA-relevant threats and will consider a vaccines- or therapeutics-based manufacturing technology(ies). Topics that are eligible to receive DRIVe funding would include other MCM candidates for biological threats that are within the BARDA mission space as indicated by a Material Threat Determination.

Funding of proposals received in response to this RPP is contingent upon the availability of federal funds for this program.

2.5 Expected Award Date

Offeror should plan on the period of performance beginning sometime in the second quarters of fiscal year 2025. Government reserves the right to change the proposed period of performance start date through negotiations via the RRPV CMF and prior to issuing a Project Award.

2.6 Anticipated Stage Advancement Notification

A series of down selections will occur between Stages 1, 2, and 3. Participation in Stage 2 does not guarantee the opportunity to submit a Full Technical and Cost Proposal in Stage 3, and submission of a

Full Technical and Cost Proposal in Stage 3 does not guarantee an award. Each stage of this solicitation process is competitive. Offerors will be invited to participate in the next stage of the process via email from the RRPV CMF following the results of the evaluation. All Offerors will receive feedback on eligible submissions.

2.7 Proprietary Information

The RRPV CMF will oversee submission of abstracts, presentations, and proposals submitted in response to this RPP. The RRPV 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. Please mark all Confidential or Proprietary Information as such. An Offeror's submission of a response under this RPP indicates concurrence with the aforementioned CMF responsibilities.

2.8 Mandatory Eligibility Criteria and Scope

In order to be eligible for consideration, Offerors must be RRPV members when their Abstract is submitted. As mentioned above, prospective Offerors may join the consortium at www.rrpv.org/how-to-join.

Abstracts on the following topics will be considered out of scope:

- Development and optimization of novel devices or formulations for therapeutic/vaccine delivery
- Preclinical development or clinical evaluation of therapeutic/vaccine candidates
- Development of manufacturing technologies or systems targeted toward disease indications that are not within the BARDA mission space https://aspr.hhs.gov/AboutASPR/ProgramOffices/BARDA/Pages/default.aspx
- Applications of Artificial Intelligence / Machine Learning that do not include efforts in the development and evaluation of actual products or processes.

Abstracts found to not meet minimum eligibility criteria(s) or determined to be out of scope as detailed above may be removed from consideration, no further evaluation will be performed, and feedback will not be provided to these Offerors.

2.11 Special Considerations

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

1. Multi-partner, multi-component efforts are encouraged
2. Cost share is encouraged
3. If proposing a solution for a therapeutics-based manufacturing approach, a focus on SARS-CoV-2 is encouraged.
4. Preference will be given to Abstracts focusing on the on-demand manufacturing of vaccines but BARDA will consider other classes of biologics.

2.10 Cost Sharing

Cost sharing is defined as the resources expended by the Project Awardee on the proposed Statement of Work (SOW). Cost sharing is encouraged, if possible, as it leads to stronger leveraging of Government-Performer collaboration.

2.11 Intellectual Property and Data Rights

Intellectual Property (IP) rights for RRPV Project Awards will be defined in the terms of a Project Awardee's Base Agreement. The RRPV 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 Offeror shall comply with the terms and conditions defined in the RRPV Base Agreement regarding Data Rights**. It is anticipated that anything delivered under this proposed effort would be delivered to the Government with unlimited data rights as defined in the RRPV Base Agreement unless otherwise specified in the submission and agreed to by the Government.** All proposed data rights are subject to Government review and approval. Rights in technical data agreed to by the Government will be incorporated into the Project Award.

3 Abstracts

3.1 Question and Answer Period

Key dates related to this RPP are provided below. Please submit questions to Ms. Rebecca Harmon (rrpv-contracts@ati.org). Answers will be posted publicly to the RRPV website.

Date	Event	Method
13 Aug 2024	RPP Released	RRPV Website
30 Aug 2024 Noon Eastern	Teaming Profiles Due	Email to RRPV@ati.org
30 Aug 2024	Questions & Answers Due	Email to rrpv-contracts@ati.org
25 Sep 2024 1PM Eastern	Abstracts Due	BARDA BDR Portal

3.2 General Instructions

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

The format provided in this RRPV RPP is mandatory and shall reference this RPP number. ***At the time of the submission, Offerors must certify on the cover page of their Abstract that, if selected for award, they will abide by the terms and conditions of the latest version of the RRPV Base Agreement.*** Offerors may request a current copy of the RRPV Base Agreement terms and conditions by emailing RRPV-contracts@ati.org. Base Agreements are typically not executed until Offeror is selected for award.

Offerors are encouraged to contact the Point of Contact (POC) identified herein up until the Abstract submission date/time to clarify requirements.

All eligible Offerors shall submit Abstracts for evaluation according to the criteria set forth in this RPP. Offerors are advised that only ATI, as the RRPV's CMF, with the approval of the Other Transaction Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected Project Awards as result of this RPP.

3.3 Abstract Submission

Abstracts shall be submitted by the date and time specified on the cover page to the BARDA Digital Resource (BDR) portal website at RRPV.HHS.GOV

Offerors will be required to register for a BDR portal account before a response can be submitted. A BDR account can be requested by contacting ATI at RRPV@ati.org. The account request process is simple but may take several days for approval and access. Upon confirmation of a BDR portal account, the Offeror will login using the prescribed two-factor authentication method.

Failure to submit on time for any reason (e.g., due to late registration in BDR portal) will result in the submission not being considered for award. Offerors will be provided an automated confirmation of successful submission.

Do not submit any classified information in the Abstract submission.

3.4 Preparation Cost

The cost of preparing Abstracts, Presentations, and/or Proposals in response to this RPP is not considered a direct charge to any resulting award or any other contract.

3.5 Submission Format

Abstracts shall reference this RPP number. The Abstract is mandatory and shall remain valid for 180 days unless otherwise specified by the Offeror in the submission. Offerors are encouraged to contact the RRPV CMF with any questions so that all aspects are clearly understood by both parties.

Abstract submission (5-page limit, unless noted*) – See Attachment 1

- Cover Page*
- Executive Summary
- Offeror TPP Table

- Technical approach overview
- Teaming/subcontractors
- Facilities and personnel qualification
- Budget estimation
- Period of Performance/Schedule
- Data Rights Assertions*

The following formatting requirements apply:

- 12-point font (or larger), single-spaced, single-sided, 8.5 by 11 inches
- Smaller type may be used in figures and tables, but must be 8-point font (or larger)
- Margins on all sides (top, bottom, left, and right) should be at least 1-inch
- Submit files in Microsoft Word, Adobe Acrobat (PDF – portable and searchable document format) formats. ZIP files and other application formats are not acceptable. All files must be print-capable and without a password required. Filenames shall contain the appropriate filename extension (.docx.pdf). Filenames should not contain special characters. IOS users must ensure the entire filename and path are free of spaces and special characters. Movie and sound file attachments or other additional files, will not be accepted.

4 Technical Requirements

4.1 Introduction

The Offeror shall clearly state how it intends to meet and, if possible, exceed the technical requirements. Mere acknowledgement or restatement of the requirements is not acceptable, unless specifically stated otherwise.

4.2 Scope

The goal of this program is to accelerate the development of an on-demand manufacturing [1]capability that can support the emergency preparedness and response mission of the Biomedical Advanced

[1] In this program, "On Demand Manufacturing" ("ODM)" broadly describes the platform capability of locally producing MCMs on an as-needed basis at the point-of-service depending on the requirements of the community. The ideal platform would possess many key characteristics outlined in the Target Platform Profile (Table 1)

[2] A "Portable" ODM system is generally defined as a self-contained, independently functioning unit with a moveable physical footprint that can be deployed, installed, and maintained at local healthcare sites or resource-limited geographic locations with minimal to no need for modification.

[3] The term "Continuous Manufacturing" describes the goal state in which the conversion of raw materials to active pharmaceutical ingredients to formulated, dosage-ready drug products occurs without interruption to the overall MCM manufacturing process and is automated to minimize or remove operator intervention.

Research and Development Authority (BARDA) within the Administration for Strategic Preparedness and Response (ASPR). The program challenges offerors and innovators to aspire towards the ultimate goal:

"Develop a portable[2], continuous[3], end-to-end manufacturing system that can produce medical countermeasures (MCM) on-demand in compliance with Good Manufacturing Practice (GMP)"

Specifically, this program aims to identify, develop, and implement novel manufacturing technologies that will improve the speed, scale, and flexibility of MCM production and delivery at reduced cost while maintaining high levels of product integrity and quality. For this particular effort, targeted toward capabilities for on-demand manufacturing, it is important to note that development and optimization of the *process,* as opposed to generation of a particular product, is the primary interest for the program.

The objectives of the program are as follows:

1) To advance the development of portable, continuous/automated manufacturing systems.
2) To develop and optimize component technologies and/or processes that can be scaled up/scaled out as a platform.
3) Develop fully closed system(s) or a single manufacturing unit using disposable technologies and continuous flow process and monitoring capabilities. The single manufacturing unit should demonstrate smaller production footprint and showcase automated production capability for drug substance (DS) and/or drug product (DP).
4) The manufacturing system should demonstrate production of either nucleic acid, microbial vectored, or protein-based MCM.
5) Product integrity and critical quality attributes should be maintained through the continuous production process.

The long-term vision for the program is the establishment and sustainment of a network of deployable, rapid response, automated manufacturing systems that can produce MCM closer to the point of need during pandemics, localized outbreaks, and other public health emergencies with a small, physical footprint. The ideal on-demand manufacturing system would have *platform* design, to pivot from production of one drug substance (DS)/drug product (DP) to another DS/DP without major modifications to the existing system and unit operations. Additional characteristics of the optimal on-demand manufacturing platform are described in the Target Platform Profile (TPP) in Table 1. Specific characteristics of the DS/DP, components, or system are anticipated to be highly variable depending on the product and approach and therefore are purposefully not defined to allow for the consideration of innovative approaches.

Table 1. *Target Platform Profile: Characteristics of the Optimal On-Demand Manufacturing Platform*

Characteristic	**Description**
Continuous Manufacturing	Automated processes that require minimal operator involvement and generate finished DS/DP from readily accessible starting materials
Yield / Purity	DS and/or DP yield and purity consistently meets acceptance criteria and is comparable to that of reference product(s)
Production Time	DS and/or DP production, purification, and release is expedited in relation to current state and aligned with public health response requirements

Scalability	Processes and modules can be scaled down to minimize product waste or scaled out to address surges in demand
Product and Process Control	Demonstrate real-time, in-line, analytical monitoring, including control over critical process parameters (CPPs), critical quality attributes (CQAs) and/or product- and process-related impurities
Portability	Has a physical footprint that enables rapid deployment in resource-limited environments and is adaptable to local conditions (i.e., changing or challenging environmental conditions, supply chain disruptions, etc.)
In-line Formulation	Incorporates processes of in-line product modification to produce dosage-ready forms of DP
Tech Transfer Potential	Utilizes technologies and components that are transferable to partner(s) for scale-up/out

Example technologies that are eligible for funding under Phases 1 and 2 may include but are not limited to: interconnected upstream fed-batch processes with downstream continuous processes, intensification and purification processes, development of in-line sensors or analytics for in-line product quality monitoring, methods of product modification (e.g., capping, encapsulation, surface assembly, functionalization, dilution, pH control, filtration, etc.) and/or buffer exchange for final drug product formulation.

4.3 Technical Requirements

- Clearly define the problem(s) that will be addressed by the adoption and utilization of the proposed technology and process.
- If the proposed effort involves prototyping and proof-of-concept manufacturing, the offeror must demonstrate production of a MCM (i.e., vaccine or therapeutic) against SARS-CoV-2 or other threats in the BARDA mission.
- The proposed effort must contain either a plan for development and integration of a component technology and/or process, or a plan for prototyping and proof-of-concept manufacturing for full end-to-end systems.
- Specify (1) the "Current State" of the technology/process; and (2) how the proposed technology/process will (a) result in significant improvements to existing methods for upstream, downstream, or fill-finish processes; (b) advance the field toward the "Goal State" (Table 2). The offeror must provide technical justification for the degree of process/system improvement over the current state. The offeror should specify how the current process or technology integrates prototype quality measures to ensure reliable performance to achieve the desired "Goal State". Prior to award, the parties will negotiate the metrics of success.
- Aim to demonstrate consistent production of DS/DP at a small-scale and/or low volume production setting. Automated processes with control over critical process parameters is a key requirement. For example, a process or a system that can produce and release >1000 vaccine doses per batch in thirty days would be highly desirable but not required. The prototype technology should demonstrate suitability and readiness for CMC-related activities for the MCM candidate.
- If proposing a component technology, the offeror will (1) describe the plan for integrating this technology into an end-to-end on-demand manufacturing process, either as part of the project

(i.e., future capability demonstration stages) or as an independent effort; and (2) identify a suitable industry partner(s), if needed, that will provide knowledge and expertise of the respective domain.

- Abstracts will illustrate a clear and well-described plan to continue optimization into the next Phase of the program. In addition, Offerors should describe the commercial viability aspects of their approach for sustainment beyond the program.
- Provide a plan on how systems, equipment and processes will be designed and, if relevant, specified to meet the increased product risks associated with operating in a resource-constrained environment.
- Systems or component technologies with non-GMP capabilities may be considered if the approach will significantly advance the field.
- Include a regulatory and commercial development plan that will eventually enable the manufacturing of product. If the system is ultimately envisioned to manufacture drugs for human use, the system and equipment must be qualifiable for its intended purpose, according to GMP and ICH Q8 and ICH Q9. Offerors must justify the system design and equipment specifications in terms of product/process understanding, using Quality by Design and Quality Risk Management standards.

5 Selection/Evaluation

5.1 Compliance Screening

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

5.2 Evaluation Process

This process may involve the use of contractors as SME consultants or reviewers. Where appropriate, the USG will employ non-disclosure agreements to protect information contained in the RPP. An Offeror's submission of an Abstract, Presentation, and/or Proposal under this RPP indicates concurrence with the aforementioned use of contractors and SMEs.

Stage 1:

Following the preliminary screening by the Consortium Management Firm (CMF) for compliance with the RPP requirements, BARDA will perform an evaluation of all eligible Stage 1 Abstracts.

Evaluation of Stage 1 Abstracts will be based on an independent, comprehensive review and assessment of the work proposed. The Government will evaluate each Abstract against the evaluation factors detailed below and assign one of the following adjectival ratings in order to determine the best value to the Government.

· Outstanding
· Good
· Acceptable

· Marginal
· Unacceptable

Stage 1 Abstract evaluation factors are as follows:

• **Factor 1: Technical Approach:** This factor evaluates the relevancy, thoroughness, completeness, and feasibility of the proposed approach. Preference will be given to Abstracts focusing on the on-demand manufacturing of vaccines but BARDA will consider other classes of biologics.

• **Factor 2: Project Management:** This factor evaluates the following:

a) Whether the background and expertise of the organization/team are appropriate to accomplish the proposed work.
b) Feasibility of proposed schedule.
c) Whether the proposed costs are within the available funding limits and sufficient to execute the proposed work. Offerors are encouraged to consider cost share.

Stage 2 and Stage 3:

To the maximum extent practicable the evaluation factors found below are anticipated for subsequent submissions beyond Stage 1 but may be subject to change.

• **Factor 1: Technical Approach:** This factor evaluates the relevancy, thoroughness, completeness, and feasibility of the proposed approach.

• **Factor 2: Relevant Experience**: This factor evaluates the Offeror's demonstrated organizational experience, as well as the technical and management experience of the proposed team to perform the proposed work. The Government may also consider information in Contractor Performance Assessment Reporting System (CPARS), and the Federal Awardee Performance and Integrity Information System (FAPIIS) or similar systems. The Government reserves the right to contact customer references to verify performance and assess quality of that performance, and to perform independent relevant experience analysis.

5.3 Cost/Price Evaluation

Successful Stage Offerors will be invited to submit full proposals. If a proposal is selected for award, the RRPV CMF will evaluate the estimated cost proposed by the Offeror for performing all requirements outlined in this RPP. Evaluation will include analysis of the proposed cost together with all supporting information. The RRPV CMF will request additional information or clarification as necessary. The RRPV CMF will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government will review this assessment and make the final determination that the project value is fair and reasonable, subject to final Government negotiations.
Proposals will be evaluated using the understanding of cost realism, reasonableness and completeness as outlined below:

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

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

The RRPV CMF will make a determination 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) 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 in the Cost Proposal Format. An optional template is located on the Members-Only RRPV website.

c) Completeness. The RRPV CMF will evaluate whether the proposal clearly and thoroughly documents the rationale supporting the proposed cost and is compliant with the requirements of the solicitation.

The proposal should clearly and thoroughly document the cost/price information supporting the proposed cost in sufficient detail and depth. The RRPV CMF will evaluate whether the Offeror's cost proposal is complete with respect to the work proposed. The RRPV 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 selected for award.

5.4 Best Value

The Government will conduct the source selection based on the evaluation criteria and ratings listed above. The overall award decision will be based upon a Best Value determination by considering and comparing factors in addition to cost or price. Funding recommendations depend on various factors and programmatic relevance. Based on the evaluation of the Technical Approach, Relevant Experience, and Cost/Price, the Government reserves the right to negotiate and request changes to any or all parts of the

SOW. Offerors will have the opportunity to concur with the requested changes, propose further changes and revise cost proposals, as necessary.

5.5 Evaluation Results

Following the evaluation, the Source Selection Authority may:

1. Select the proposal (or some portion of the proposal) for award;
2. Place the proposal in the Basket if funding currently is unavailable; or
3. Reject the proposal (will not be considered for award and will not be placed in the Basket)

The Government does not guarantee a minimum or maximum number of awards resulting from this solicitation.

5.6 Basket Provision

The electronic "Basket" is an innovative acquisition tool. Stage 2 Presentation and Stage 3 Full Technical and Cost Proposals rated as Acceptable through Outstanding, but not immediately selected for award, will be placed in the Basket for 2 years and eligible for award during that time. Proposals rated as below Acceptable 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.

6 Points of Contact

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

All technical questions must be submitted by **August 30, 2024** to allow for Government response. The Government will respond to questions at its discretion. All questions and responses will be posted to the RRPV Solicitation webpage https://www.rrpv.org/opportunities/. Questions received after the stated deadline are not guaranteed a response.

Once an Offeror has submitted a submission under this RPP, the Government and the RRPV CMF will not discuss evaluation/status until the evaluation results have been provided to the Offerors.

ATTACHMENT 1 – ABSTRACT TEMPLATE

General Instructions

The Abstract 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. Offerors are strongly encouraged to use pictures and graphics to succinctly represent proposed ideas, organization, etc.

The Abstract shall be limited to 5 pages; however, the Cover Page and the Data Rights Assertions are not included in the page count. Pages in excess of this limitation may not be considered**.** Offerors are advised that the number of pages should be commensurate with the degree of complexity of the proposed effort.

To ensure Abstracts receive proper consideration, **the format shown below is mandatory**. If there are any items which are not applicable to a specific Abstract, include the section topic in the Abstract with a short explanation as to why it is not applicable.

- Cover page (not included in page count)
- Executive Summary
- Offeror TPP Table
- Technical approach overview
- Teaming/subcontractors
- Facilities and personnel qualification
- Budget estimation
- Period of Performance/Schedule
- Data Rights Assertions (not included in page count)

[Name of Offeror]
[Address of Offeror]
[Phone Number and Email Address of Offeror]

Unique Entity Identifier (UEI) #: [UEI #]
CAGE code: [CAGE code]

RRPV 24-02-ODM

[Title of Abstract]

[Offeror] certifies that, if selected for selected for an Award, the Offeror will abide by the terms and conditions of the RRPV Base Agreement.

[A proprietary data disclosure statement if proprietary data is included. Sample: This Abstract includes data that shall not be disclosed outside the RRPV Consortium Management Firm and the Government and shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than to evaluate this Abstract and negotiate any subsequent award. If, however, an award agreement is a result of, or in connection with, the submission of this data, the RRPV Consortium Management Firm and the Government shall have the right to duplicate, use, or disclose these data to the extent provided in the resulting agreement. This restriction does not limit the RRPV Consortium Management Firm and the Government's right to use the information contained in these data if they are obtained from another source without restriction. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).]

[Title of Abstract]

1. **Executive Summary**
   - Identify if you are proposing to PHASE 1 or PHASE 2.
   - Provide the background and the Offeror's understanding of the problem.
   - Provide a description of the technology/process.
   - Emphasize how the proposed technology/process meets the overall objective specified in this RPP.

2. **Offeror TPP Table**
   - Complete the table to indicate the current and goal states.

	Current State	**Goal State**
Continuous Manufacturing		
Yield/Purity		
Production Time		
Scalability		
Product and Process Control		
Portability		
In-line Formulation		
Tech Transfer Potential		

3. **Technical Approach Overview**
   - Demonstrate how your proposed solution currently meets the Technical Requirements described in **Section 4.3**.
   - Offerors proposing Phase 1 work are requested to describe in brief detail their plans for Phase 2, and Offerors proposing Phase 2 work are requested to describe in brief detail their plans for Phase 3.
   - Include any previous studies or preliminary data [non-clinical and/or clinical] that support the feasibility of the proposed technology solution.

4. **Teaming/Subcontractors**
   - Describe any current or potential partnerships or collaborations that may be of use when developing this process/technology.

5. **Facilities and Personnel Qualification**
   - Describe the qualifications and expertise of the key personnel and organizations associated with the proposed solution.
   - Detail any past performance(s) that demonstrate relevance to the program objective and solution requirements.
   - Identify any key facilities, equipment, and other resources relevant for the solution

being proposed.

6. **Budget Estimation**
   - Provide rough order of magnitude (ROM) and any pertinent assumptions for the current Phase of work.
   - Provide estimated budget for the next Phase of work.

7. **Period of Performance/Schedule**
   - For the current Phase, identify the proposed Period of Performance (PoP) in months and describe the overall schedule.
   - For the next Phase, identify the PoP for the next Phase of Work.

8. **Data Rights Assertions**
   - It is anticipated that anything delivered under this proposed effort would be delivered to the Government with unlimited data rights. If this is not the intent, then you should discuss any restricted data rights associated with any proposed deliverables. If applicable, complete the below table for any items to be furnished to the Government with restrictions. An example is provided. This section is not part of the page count.

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