Question #	Question	Response
1	In attachment B (ASPR security requirements) there is a "manufacturing data requirements" section that states that data on all materials, sources, and manufacturing sites must be shared within 30 days of contract award. This implies that any applicant already has a fully functional / compliant facility in existence before getting the award. Our proposal would be to develop a manufacturing plan within Objective A (the first phase of the program). Can you help clarify this item?	The Mfg. Data Requirements section refers to the supply chain for ancillary materials and other inputs required to produce the identified target medicine(s). Site identification can be provided to clarify where the construction of the new facility will take place as this satisfies the requirement for "location and nature of work performed".
2	Are oral antimicrobials within scope?	Oral antibiotics and other oral antimicrobial drug products are within scope of this RPP, as the solicitation broadly targets antimicrobial drug substances and finished product forms without imposing any restriction on route of administration. Please refer to the Essential Medicines List reference for the list of medicines considered within scope.
3	Section 2.7 of the RPP states that there is an Attachment C to the RPP regarding cost-sharing between the federal U.S. Government and Mission Pharmacal Company, but there is no Attachment C to the RPP. Can you please let me know how to obtain a copy of Attachment C to the RPP?	Attachment C should not have been mentioned in section 2.7 as there is no Attachment C to this RPP.
4	For this RPP, do anti-virals fall in the preferred "anti-microbial" category? If not, would anti-viral tablets still be duly considered, or will they fall outside the range of interest?	Please refer to the Essential Medicines List referenced in section 7 for acceptable targets. Medicines not identified within this list are considered out of scope.
5	We have produced this anti-viral tablet at our non-GMP facility and have met all of the required specifications (e.g., purity, dissolution); however, none of the work has been done at a manufacturing facility. Furthermore, we have not yet secured a commercial manufacturing facility yet, though we are planning to do so in the near future. Are we at a stage that would be duly considered?	The plan to establish the commercial manufacturing facility falls within scope of what would be provided via deliverables in Objective A to then be executed within Objective B.
6	How do you define 'population scale'? Is this equivalent to the consumption needs of the U.S. population through all government and commercial trade channels?	"Population scale" in this RPP refers to manufacturing capacity sufficient to support national-level demand, typically on the order of hundreds of millions of doses, particularly in preparedness or surge scenarios. It is a capacity and throughput concept rather than an estimate of routine

		commercial consumption across government and trade channels.
7	How do you characterize ‘distributed manufacturing’? Are there particular ‘distributed’ objectives toward which this RPP aims?	“Distributed” is one approach to addressing the population scale ability to produce KSMs, APIs, and/or FDFs that is defined as “deployable, decentralized production model to produce goods closer to the end-user”.
8	Will the evaluation focus mainly on single product success versus a repeatable manufacturing platform?	The evaluation is expected to focus primarily on the robustness, scalability, and repeatability of the proposed manufacturing platform rather than the success of any single drug substance. The required molecule demonstration serves principally as a validation of the broader distributed manufacturing infrastructure and analytical/production model.
9	On teaming is existing contractual relationships expected, or is intent-to-team sufficient at this stage?	Provided the period of performance can be achieved, intent-to-team is acceptable.
10	What level of granularity is expected in ROM pricing at the white paper stage?	At the white paper stage, provide a high-level ROM pricing estimate using the ROM pricing estimate table identified in Attachment A, Enhanced White Paper template (Section 11).
11	Are there preferred positions on data rights assertions for platform technologies and product-specific data?	There are not.
12	What if the drug product selected is already contracted to another company, will you provide the opportunity to either select drug products that are still needed?	Yes – we can be flexible in our target selection provided the selection is within scope.
13	The Rough Order of Magnitude (ROM) Pricing Estimate table has a note that the “Fee” is “not applicable if cost share proposed.” Would you please confirm that this applies to the RPP and if so, please share the rationale for why we cannot propose a profit/fee?	USG is requiring a cost-share and is therefore unable to consider a fee at this time.
14	Is the performer required to conduct stability testing of DS substance and if so, for how long?	Stability testing of the drug substance is functionally required to support advancement to MRL 10, compliance with USP standards, adherence to ICH guidelines, and execution of registration batches/ANDA activities. Performers are expected to implement stability studies consistent with standard regulatory frameworks (e.g., accelerated and long-term

		stability), with study length justified by the development stage and intended regulatory objectives.
15	Is a domestic partnership agreement required in order to meet the DPA definition of a “domestic source” for the purposes of responding to the RPP?	“Domestic source” is defined as the U.S., Canada, the U.K., and Australia.
16	The RPP indicates a period of performance of 24 months. Could you please clarify what outcomes or milestones are expected to be achieved within this 24 month period? Specifically, would it be acceptable if, for example, within the 24 months, the project has progressed through detailed project planning and engineering design, the project team is fully established on the ground, and construction activities have already commenced?	All required technical milestones have been reached by the end of the period of performance, including the final milestone of submitting the necessary regulatory documentation to the FDA (e.g., DMF, ANDA, BLA).
17	What documentation or evidence is considered sufficient to demonstrate experience at or beyond Manufacturing Readiness Level (MRL) 6?	MRL 6 is defined as a process or technology proven to be successful at the laboratory scale.
18	Must the demonstrated MRL6+ experience be for the same molecule class proposed, or is comparable manufacturing experience acceptable?	Comparable manufacturing experience is acceptable.
19	With respect to the Small Business Utilization clause, if an offeror intends to pursue partnerships, must all teaming partners be members of the BioMaP Consortium, or may the offeror partner with non consortium entities that can provide relevant expertise or capabilities?	Teaming partners or subcontractors are not required to be a BioMaP-Consortium for this RPP.
20	Is there a minimum cost share threshold or target range the Government considers competitive, given that cost share is required for eligibility?	Cost-share can be negotiated, but cannot be more than 80:20 with 80% funded by USG. Preference is close to 50:50.
21	Could you please clarify what types of in kind contributions are considered acceptable for cost sharing, and which specific cost items may be counted as in kind contributions and are there restrictions on what qualifies as in kind cost share?	Existing goods, materials, and/or equipment that would otherwise be purchased to support the project. Example is existing assets being repurposed for the project.
22	Does “all work and/or capacity expansion shall be focused on US soil” apply to all activities, or only to physical manufacturing and capacity expansion?	The location of work to be performed must adhere to the definition of “domestic source” as defined by the DPA. Desired that as much work as possible be performed inside the United States.

23	Alternatively, what activities may be performed outside the U.S., provided manufacturing and capacity expansion occur domestically?	See answer above.
24	Can you please confirm whether having a UEI is sufficient to have prior to award of Project Agreement or must companies be fully registered in SAM.gov?	Companies must fully be registered in Sam.gov.
25	How will compliance with the DPA "domestic source" definition (50) U.S.C. 4552(7)) be assessed in practice (e.g., by manufacturing location, inputs, etc.)?	“Domestic source” is evaluated as where the location(s) where the work is performed. Non-compliance with performing work within location(s) that adhere to this formal definition will lead to disqualification of the submission.
26	Are there any recommended or expected duration ranges for Objective A to ensure sufficient execution time for Objective B?	This will vary depending on the submission and technology being utilized. Objective A and B can be performed in parallel (in part or in whole) to meet the 24-month requirement.
27	Can you please confirm where we can locate MRL 6-MRL 10 (Manufacturing Proof of Concept Developed, see MRL definitions in Section 8, Reference #2) guidelines?	Link provided for MRL definition. MRL 6 is generally viewed as a proven process or technology at laboratory scale.
28	Are there defined go/no go criteria or decision gates the Government will apply when approving progression from Objective A to Objective B?	A Stage Gate Review is planned for closure of Objective A and initiation of Objective B. SGR timing to be evaluated if A and B performed in parallel.
29	How will advancement from MRL 6/7 to MRL 10 be assessed and validated (self assertion vs. third party or Government review)?	Solicitation requirement of population scale manufacturing requires achieving MRL 10 to be able to supply hundreds of millions of doses of medicine(s).
30	If a proposed molecule already exceeds MRL 6/7 at project start, is full documentation of MRL progression still expected?	No – capturing the progression and development of the molecule(s) in the MRL scale past MRL 6 can be highlighted in the Drug Substance Selection Report.
31	Are there specific ICH guidelines the Government considers most relevant for evaluation or will compliance be assessed holistically?	Standard ICH guidelines for quality, safety, and efficacy will be used to evaluate molecule(s).
32	Can you please clarify if additional details need to be provided to support responses for Objective A and Objective B apart from expected timelines?	Provide high-level details as to how each aspect of both Objectives will be executed. In-depth details (where available) are helpful and provide clarity upon USG review.

33	Within Factor 1 (Technical Approach) evaluation factor, are there priority elements (e.g., domestic impact, scalability, vertical integration) that carry greater weight?	No – Factors are evaluated as a whole and do not have separate weighted elements.
34	Within Factor 2 (Relevant Experience), for non federal or commercial projects, what information should be provided to enable experience verification equivalent to CPARS/FAPIIS?	Relevant Experience executing projects similar to what is being proposed to demonstrate a foundational understanding of what is required, what issues can arise, and how to effectively troubleshoot to deliver on-time, within budget, and within scope.
35	Please provide an expected timeframe as to when evaluation results will be provided to the Offerors.	This is dependent on the number of submissions received.
36	Is cost share evaluated relative to total project value or total cost to Government?	Total project value.
37	For offerors that qualify as U.S.-based small businesses, please clarify whether there are any stipulations or considerations under the Small Business Utilization section when the proposed approach includes the use of services from larger, experienced U.S.-based firms that do not meet SBA small business size standards.	The adherence to the “domestic source” definition is a requirement, but use of larger firms to allow for small businesses to participate is acceptable.
38	Please share size standards of SBAs as the link below does not currently work (see https://www.sba.gov/document/support-table-size-standards) for more details)	Please refer to the SBA website for formal definitions.
39	Please clarify whether the “current and/or relevant experience examples” are expected to be limited to performance executed within the United States and U.S. territories, or whether relevant experience performed outside the United States may also be included.	Relevant experience can be OUS.
40	What are the expectations for completing the ASPR Deliverables and Security Requirements Appendix? Is it sufficient enough to provide a high-level overview of the key milestones and expected timelines for the Final Security Plan in the RPP?	This isn’t required upon submission with the EWP, but is required for completion if award is received.
41	Can the government please confirm that under DoD guidelines, a non-profit research institution qualifies as a non-traditional defense contractor and therefore is exempt from cost-sharing requirements.	This OTA is not issued under the Department of War (formerly the Department of Defense). Therefore, any guidelines regarding non-traditional defense contractors and cost-sharing exemptions do not apply.

42	Can the government specify the contract type that will be awarded? (ex. FFP, Cost Reimbursable)	Offerors may propose the contract type they consider most appropriate for their approach, subject to Government review and negotiation at the time of award.
43	In Item (i), offerors are instructed to select at least one proposed target drug substance. Can the government clarify whether proposing more than one drug substance is permissible and, if so, whether there is any added value or consideration associated with doing so?	More than one is preferred, but the minimum is one target.
44	Can the government advise if the manufacturer must match the final drug form to what is listed in #1 under References to what the manufacture does under this program? For example, if Drug is listed as IV, does the drug form manufactured have to be IV?	It does not – the medicine must be captured on the list, but the route of administration can be adjusted.
45	Please clarify whether offerors may propose multiple FDFs for a given drug substance, or whether the intent is to focus only on the final dosage form identified in Reference #1. How should offerors address drugs that have more than one dosage form listed?	Proposers are welcome to submit multiple FDFs from one drug substance.
46	In the ROM Pricing Estimate Chart, the instructions state Fee is "Not applicable if cost share is proposed." We have a subcontractor providing cost share. Please confirm that profit/fee should be excluded only from the cost-shared portion of the subcontractor's costs, and that it is not the intent to remove profit/fee from the Prime's proposal in its entirety.	As stated in section 2.7 of the RPP, the USG is requiring a cost-share type agreement and is therefore unable to consider fee at this time. The lead offeror proposal should reflect a cost-share type. This is not applicable to proposed subcontractors.
47	The RPP requires a "minimum entry requirement of MRL 6." For offerors proposing to manufacture well-established generic products (e.g., standard hospital IV solutions) using commercially available, FDA-proven process equipment and FDA-approved container materials, does the demonstrated manufacturing history of these technologies across the industry satisfy the MRL 6 requirement, even if the offeror has not yet produced product at its own facility?	The underlying technology being used by the proposer to reach MRL 10 must be MRL 6+. Equipment is not a consideration for the underlying technology.
48	Section 2.5 requires "demonstrated experience in the scalable manufacturing of KSMs/APIs and finished product form drugs." For a newly formed entity whose leadership team has extensive individual experience at major manufacturers (e.g., Baxter,	The team's prior experience would be considered satisfactory.

	Sanofi, Eli Lilly), does the team members' prior technical and commercial leadership experience satisfy this requirement?	
49	The RPP references both "drug substance" and "drug product" manufacturing. For Large Volume Parenterals (e.g., 0.9% NaCl injection), the drug substance (sodium chloride) is a widely available commodity, while the drug product (the filled, sterilized IV container) is where the manufacturing challenge lies. Is the government's primary interest in drug product manufacturing capability for LVPs, or is there an expectation of drug substance (API) synthesis as well, even for widely available APIs?	For LVPs, the primary interest lies in the drug product manufacturing.
50	The RPP requires manufacturing at "population scale" defined as "hundreds of millions of doses." For some programs, like LVPs, meaningful production for market impact is far less than "hundreds of millions of doses". Will the evaluation of proposals consider the definition of "population scale" relative to the impact a proposed program would have and its scalability to further increase capacity beyond the initial project?	The definition of population scale is dependent on the underlying patient population and will be considered on a medicine-by-medicine basis.
51	The RPP mentions "distributed manufacturing systems" and "distributed scalable manufacturing." Does the government envision a single-site initial demonstration with plans for future distributed regional plants, or is a multi-site approach required from the outset within the 24-month period of performance?	Single site would be considered acceptable.
52	For Objective B analytical modeling, is BARDA expecting a digital twin-style computational model, or scenario-based economic modeling using industrial assumptions?	Scenario-based economic modeling is preferred.
53	The total estimated funding is "approximately $200 million" across multiple awards. Is there a maximum or typical individual award ceiling the government expects for LVP-focused proposals? Note that a single plant investment could utilize substantially all monies available to demonstrate at "population scale".	Multiple awards are desired with the allotted funding.
54	Is there a minimum or preferred cost-share ratio (e.g., 1:1, 2:1)? Will proposals with higher cost-share ratios receive significantly higher evaluation scores?	Desired cost share is 50:50, but will consider alternatives on a case-by-case basis.
55	Given the OTA framework, is the government open to structuring the award as an equity investment or convertible instrument alongside private investors, rather than a traditional cost-	For the purposes of this solicitation, a traditional cost-reimbursement arrangement is desired.

	reimbursement arrangement? Would the government consider accepting an equity stake and/or Most Favored Nation pricing as return mechanisms?	
56	Assuming successful demonstration of an LVP project, would BARDA anticipate long-term procurement agreements or stockpile purchasing to support commercial sustainability?	Long-term procurement agreements cannot be promised and are not a part of this solicitation, but are an ongoing consideration for ASPR with respect to the SAPIR.
57	Can the offeror propose overlapping durations for Objective A and Objective B within the 24-month total? For example, 12 months for Objective A and 18 months for Objective B? To accelerate the critical path of the program, some impactful critical path actions can be taken during Objective A that would accelerate Objective B. Conversely, there are Objective A design activities that can be done in parallel with Objective B enabling Objective B to start in parallel rather than sequentially.	Yes.
58	Objective B deliverables include “ANDAs for each drug product filed with the FDA.” For LVPs requiring 9+ months of stability data from registration batches and Pre-Approval Inspection, is the government expecting ANDA filing within the 24-month PoP, or is some flexibility available if the manufacturing demonstration (production validation runs with product on stability) is substantially complete and the filing is imminent?	Filing submission by 24mo is required per the PoP, but alternative regulatory approaches including use of an amendment to provide FDA with additional data is acceptable.
59	Does the government expect facility construction costs (estimated at up to $200M for a small sterile facility and product platform build-out) to be within the scope and budget of this award, or is the award primarily intended to fund the engineering design, process development, regulatory, and demonstration activities described in Objectives A and B? Note: For LVPs, demonstration at any reasonable definition of “population scale” requires a full-scale production facility to be built and validated. Given the well-established and proven nature of these technologies, demonstration at pilot scale would not likely yield definitive technical insights or risk mitigation that would change a go/no-go decision for Objective B.	Yes – construction costs can be included under DPA Title III authorities.