Attachment A: Statement of Objectives (SOO)

BioMaP-Consortium OT Vehicle

Project Title: Ensuring American Pharmaceutical Supply Chain Resilience through Vendor Managed Inventory (VMI) Capabilities for Active Pharmaceutical Ingredients (APIs) Used in Medical Countermeasure Finished Dose Form (FDF) Drug Products

1. SCOPE

1.1. Background:

ASPR IBMSC is seeking to establish vendor managed inventory (VMI) capacities for active pharmaceutical ingredients (APIs) used in medical countermeasure finished dose form (FDF) drug products. This scope includes providing a VMI as a service for the procurement, storage, management, conversion, and distribution of qualified (APIs from FDA-inspected suppliers with Drug Master Files on record; demonstration of analytical chemistry capabilities for acceptance and retesting of APIs; and storage, rotation, and replenishment of APIs under current good manufacturing practice (cGMP) conditions. This scope also includes the use of qualified laboratories for product verification, environmental and shelf-life testing, and adherence to industry-recognized consensus standards (e.g., ISO, ASTM). This scope also includes supply chain resilience activities.

Required capabilities include the establishment of a VMI service for real-time inventory management systems capable of verification, validation, and rapid reporting of on-hand stock across all product categories. Performers/sub-Performers must have a demonstrated ability to rapidly convert APIs to medical countermeasure FDF drug products within 30 days of notice to meet emergent demand. VMI capabilities include—though are not limited to—use of domestic and global purchase orders to secure and resell qualified APIs; maintain certified, specialized infrastructure for the procurement, storage, and management of DEA scheduled substances and APIs requiring cold chain storage with validated security and temperature monitoring systems; performing standard analytical testing using U.S. Pharmacopeia compendial methods; implement VMI practices using rotation and replenishment; enable spot/immediate inspection and reporting; maintaining FDF manufacturing capacity; and access/operate distribution networks capable of reaching more than 2,000 U.S. health systems and territories.

The USG's requirement is for a base and option-type contract award/subaward structure that may include more than one award or subawards, if determined to be in the best interests of the USG. Any additional funds added to this requirement can be used to add additional funds on an existing subaward, award new subawards, or add additional option years.

1.2. Introduction:

A key strategic goal of the Administration for Strategic Preparedness and Response (ASPR), Center for Industrial Base Management and Supply Chain (IBMSC), is to support, strengthen, modernize, and expand the Nation's medical countermeasure industrial base by increasing warm based manufacturing capacity for medical countermeasures, as well as ensuring capacity is available to rapidly manufacture products that are or may become qualified countermeasure.. This includes development of new materials, products, technologies, and manufacturing paradigms across pharmaceuticals, medical devices, PPE, and testing and diagnostic product categories.

For this requirement ASPR IBMSC is specifically seeking to develop VMI as a service to establish a strategic national reserve of APIs at population scale, including:

- Procurement, acceptance testing, retesting, and cGMP storage of APIs and FDF drug products;
- VMI-related services to include rotation and replenishment;
- Adherence to cGMP and FDA regulatory requirements
- Deployment of first in first out inventory-management and sales solutions applicable across all product classes;
- Rapid and agile conversion of API to medical countermeasure FDF drug products;
- Distribution capacity sufficient to simultaneously supply more than 2,000 U.S. health systems, distributors, or other designated endpoints;
- Replenishment capabilities.

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

2. REQUIREMENTS

2.1. General Objectives

The objective of this project is to establish VMI as a service to augment the actions the USG is taking to operationalize a strategic API reserve at population scale, including capabilities for procurement, acceptance testing and retesting, cGMP storage, inventory management capabilities, rapid and agile conversion of API to medical countermeasure FDF drug products, and an ability to distribute to more than 2000 health systems and/or other distribution centers simultaneously. It is anticipated that initial capabilities will be established in accordance with within 60 days of receipt of a subaward.

2.2. Specific Objectives

Objective 1: Establish VMI as a Service for USG-Selected APIs

Objective 1 is focused on the procurement, acceptance testing, cGMP storage, and retesting of APIs. The following incremental objectives are required:

I. Establish and operate a secure warehouse for receipt, storage and distribution of APIs in support of Executive Order 14366. Before API procurement authorization, the Performer must meet a comprehensive set of end-to-end infrastructure requirements. These include operational readiness, regulatory compliance, digital system integration, and adherence to corporate API minimum standards for procurement, acceptance and retest. These standards apply to the Performer and all sub-Performers. Facilities must be capable of securely storing, managing, and distributing APIs while maintaining full compliance with applicable regulatory and performance standards. All systems and processes must ensure the integrity and security of the pharmaceutical supply chain from receipt through distribution and replenishment. This includes robust controls for physical security, environmental monitoring, inventory traceability, and digital infrastructure to support real-time data visibility and audit readiness. Commercially available API rotation/replenishment and adherence to cGMP regulatory standards are requirements. Approaches that incorporate and guarantee first-in-first-out rotation are preferred. Specifically excluded non-cGMP compliant practices and the establishment of capacities that cannot provide end-to-end VMI as a service.

II. Examples of API/medical countermeasure quantity and storage requirements are included in the chart that follows. Actual requirements will be based on needs of the USG at the time of award:

API	Required (Kg)	Total Pallets	Ground-Level Positions (4-High)	Sq Ft Required
Amiodarone	30,660.00	153	38	817.40
Amoxicillin	387,345.00	1938	486	10,365.40
Atropine	4.1	1	1	21.3
Dexamethasone	155.9	1	1	21.3
Furosemide	14,600.00	73	19	405.2
Heparin	9.7	1	1	21.3
Ketamine (Schedule 3)	2,455.30	13	4	85.3
Levetiracetam	217,175	1,087	273	5,812
Linezolid	2,116.80	11	3	64
Lorazepam	127.8	1	1	21.3
Metoprolol	713,388.80	3,568	892	19,024.60
Metronidazole	18,062.50	91	23	490.5
Morphine (Schedule 2)	5,874.40	30	8	170.6
Moxifloxacin	3.3	1	1	21.3
Naloxone	4.8	1	1	21.3
Norepinephrine	7.6	1	1	21.3
Ondansetron	25.4	1	1	21.3
Piperacillin	55,405.00	278	70	1,493.00
Propofol	9,653.5	49	13	277.3
Tazobactam	13,851.3	71	9	192
Vancomycin	2103.8	11	3	64
Voriconazole	370.5	2	1	21.3

III. All Performers, including sub-performers, must be wholly U.S.- owned, U.S. - operated, and have their global headquarters located within the United States of America.

IV. No exceptions to the requirements of E.1 will be made for Performers. An Agreement Officer's Authorization (AOA) approval request is required for any proposed sub-Performer that does not meet the U.S.-owned and operated requirements specified in paragraph E.1. The supporting documents shall include the following, and additional information may be required at the discretion of the USG:

I. Competition activities, as well as technical and cost/price evaluation activities performed, in the selection of the sub-Performer(s);
II. The sub-Performer's qualifications/capabilities statement and past performance as they pertain to the activities included in the proposed subcontract;

III. The sub-Performer's willingness to perform under the Performer (i.e. commitment letters/preliminary agreements), with a list of specific duties included in the proposed subcontract;
IV. The priority that the work will be given and how it will relate to other work;
V. The amount of time and facilities available for the subject requirement; and
VI. A complete sub-Performer cost proposal or quote, in similar format as the Performer's cost proposal.
VII. Provide a detailed risk analysis of engaging a non-U.S.-owned or non-U.S.-operated sub-Performer, focusing on risks to national security, intellectual property protection, and supply chain resilience.
VIII. Provide documentation confirming that the non-U.S. sub-Performer complies with relevant U.S. regulations, such as FDA standards for APIs and export controls,
IX. Include certifications or third-party audits verifying the sub-Performer's adherence to quality, safety, and environmental standards

V. Staffing, Training & Infrastructure: Performer must ensure adequate personnel and training programs are in place. Performer will ensure the appropriate staff including chemists, engineers, facility managers, inventory managers, operations, logistics and business/management personnel are in place. Performer will also ensure that analytical chemists are in place and experienced and proficient in various instrumental techniques such as but not limited to HPLC, GC-MS, and Spectroscopy. Performer will ensure that the appropriate microbiologists (if applicable) are hired for APIs requiring microbial limit or sterility testing. Performer must also have access to and provide comprehensive training on United States Pharmacopeia (USP) monographs, specific analytical methods, instrument operation, data interpretation, current Good Manufacturing Practices (cGMP) and Good Laboratory Practice (GLP) regulations, and safety procedures.
VI. All facilities must be GXP (GMP, GDP, GLP) compliant and comply with all Federal, Local, and State laws and regulations, in addition to all FDA requirements.
VII. Performer must ensure end-to-end supply chain control and visibility, including establishing an inspectable dashboard infrastructure.
VIII. Warehouse Management System (WMS) Integration: Performer must be able to establish or interface with WMS for Procure-to-Pay, supplier management, inventory, barcoding/labeling, and quality assurance functionalities and provide a dashboard throughout the entire supply chain from procurement to storage.
IX. Performer and Sub-Performers must comply with 41 U.S.C. chapter 83, Buy American and FAR clauses regarding Nonavailability [FAR 25.103(b)], Trade Agreements [FAR 25.4], Prohibited Sources [FAR 25.7] in accordance with the contract.
X. ASPR retains the right to direct the inventory and distribution as determined to be in the best interests of the USG. .
XI. Performers shall already be, or partner with, Finished Dose Form (FDF) manufacturers and shall purchase only qualified APIs as part of this requirement. If partnering with an FDF manufacturer, evidence of the agreed partnership must be available. FDF Manufacturing processes must take place in an FDA approved cGMP domestic location.
XII. In addition to the requirements above, additional requirements for API procurement, facilities, staffing, quality and critical infrastructure include:
    a. Procurement Requirements.
        i. Demonstrated supplier qualification process that has established existing quality agreements in place with FDA-registered and inspected manufacturers, validated analytical testing methods, and a robust cGMP QA/QC processes.
        ii. Demonstrated ability to maintain approved supplier database (approved, rejected, reevaluation, etc.).

iii. Ability to restrict Purchase Request and Purchase Order from Approved Supplier at the inventory item level.
iv. Ability to achieve 4-way matching (PO, Goods Received Note (GRN), Inspection Report, Invoice)

b. Environmental & Climate Control Requirements.
   i. HVAC Systems
      - Must maintain validated pharmaceutical-grade temperature and humidity levels for ambient and cold storage per FDA guidelines (21 CFR Part 211.42).
      - Zoning controls for storage, sampling, and loading areas.
      - Integration with building automation systems for 24/7 monitoring. This system shall be routinely calibrated, inspected, or checked according to an approved and documented program designed to assure proper performance.
      - Failsafe of 20% redundant capacity required
   ii. Refrigerated Storage, as required
      - Cold Room: Performer must maintain a 2–8°C temperature range, with temperature logging and alarms.
      - Portable Chillers: Mobile units for emergency or overflow use.
      - Temperature mapping studies every six months, with alarms linked to ASPR reporting for critical APIs; include humidity alarms (30-60% RH) per USP <659> for hygroscopic APIs.
      - Failsafe of 20% redundant capacity required
   iii. Inert Gas Support, as required
      - Nitrogen gas line with industrial-grade bracket supports and safety regulators. Inline sensors for nitrogen purity (>99.999%) and flow rates, with automated shutdowns for deviations; integrate with 24/7 building automation for real-time alerts to prevent oxidation in API stockpiles.
      - Failsafe/backup systems one redundant tank with automatic switchover upon 80% depletion

c. Controlled Substance & DEA Compliance Requirements, as required for scheduled substances
   i. Support DEA/controlled substance management (vault storage, dual authorization)
   ii. Enhanced logging for controlled substances movement
   iii. Restricted access with role-based permissions
   iv. Audit reporting for controlled drug handling
   v. DEA Vault & Cages
      - Constructed to meet DEA physical security requirements under 21 CFR Part 1301.72.
      - Access-controlled vault for Schedule I–II substances.
      - DEA cage(s) for Schedule II–V materials with mesh enclosure and locking systems.

d. Security Requirements

Security Reporting Requirements

The performer facility shall notify the Government Security Team within 24-72 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products associated with this Agreement. The facts and circumstances associated with these incidents will be documented in writing for government review.

Security Audits

Description: The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both Performer and sub-Performers. Minimum length of notification is 10 business days.

Supply Chain Resiliency Plan

The Performer must develop and submit within 30 calendar days of contract award, a comprehensive Supply Chain Resiliency Program that provides identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods.

A critical component is defined as any material that is essential to the product or the manufacturing process associated with that product. Included in the definition are consumables and disposables associated with manufacturing. NOT included in the definition are facility and capital equipment.

Consideration of critical components includes the evaluation and potential impact of raw materials, excipients, active ingredients, substances, pieces, parts, software, firmware, labeling, assembly, testing, analytical and environmental componentry, reagents, or utility materials which are used in the manufacturing of a drug, cell banks, seed stocks, devices and key processing components and equipment. A clear example of a critical component is one where a sole supplier is utilized.

The Performer must identify key equipment suppliers, their locations, local resources, and the associated control processes at the time of award. This document shall address planning and scheduling for active pharmaceutical ingredients, upstream, downstream, component assembly, finished drug product and delivery events as necessary for the delivery of product.

a) Communication for these requirements shall be updated as part of an annual review, or as necessary, as part of regular contractual communications.
b) For upstream and downstream processing, both single-use and re-usable in-place processing equipment, and manufacturing disposables also shall be addressed. For finished goods, the inspection, labeling, packaging, and associated machinery shall be addressed taking into account capacity capabilities.
c) The focus on the aspects of resiliency shall be on critical components and aspects of complying with the contractual delivery schedule. Delivery methods shall be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries.

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

a) Production rates and lead times shall be understood and communicated to the Other Transaction Agreements Officer or the Other Transaction Agreements Officer or Project Agreement Representative (PAR) as necessary.
b) Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

Reports for critical items should include the following information:

a) Critical Material
b) Vendor
c) Supplier, Manufacturing / Distribution Location

d) Supplier Lead Time
e) Shelf Life
f) Transportation / Shipping restrictions

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

Manufacturing Data Requirements

The Performer must submit within 30 calendar days of contract award detailed data regarding project materials, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing, processing, and fill/finish sites; and location and nature of non-clinical and clinical studies sites. The Government may provide a table in tabular format for the Performer to be used to submit such data which would include but not be limited to the following:

- Storage/inventory of ancillary materials (vials, needles, syringes, etc.)
- Shipment of ancillary materials (vials, needles, syringes, etc.)
- Disposal of ancillary materials (vials, needles, syringes, etc.)
- Seed development or other starting material manufacturing
- Bulk drug substance and/or excipient production
- Fill, finish, and release of product or adjuvant
- Storage/inventory of starting materials, bulk substance, or filled/final product or adjuvant
- Stability information of bulk substance and/or finished product
- Shipment of bulk substance of final product
- Disposal of bulk substance or final product

Performer Locations

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

Performer will submit Work Locations Report:

- Within 5 business days of contract award
- Within 30 business days after a substantive location or capabilities change
- Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO

Operational Security (OPSEC)

The performer shall develop an OPSEC Standard Operating Procedure (SOP)/Plan within ninety (90)-calendar-days of project award to be reviewed and approved by the responsible Government OPSEC officer. This plan will be submitted to the PAR for coordination of approvals. This SOP/Plan will include identifying the critical information related to this contract, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.

Security Plan

The Performer must develop a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the Government requirement. This plan shall establish security practices and procedures that demonstrate how the Performer will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing, and shall be delivered to the Government within 30 calendar days of award. The Performer must also ensure all sub-Performers, researchers, etc. performing work on behalf of this effort, comply with all Government security requirements and Performer security plans.

a) The Government will review in detail and submit comments within ten (10) business days to the Other Transaction Agreements Officer (OTAO) to be forwarded to the Performer. The Performer must review the Draft Security Plan comments, and, submit a Final Security Plan to the U.S. Government within thirty (10) calendar days after receipt of the comments.
b) The Security Plan shall include a timeline for compliance of all the required security measures outlined by the Government.
c) Upon completion of initiating all security measures, the Performer must supply to the Other Transaction Agreements Officer a letter certifying compliance to the elements outlined in the Final Security Plan.

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

1. Facility Security Plan Description: As part of the partner facility's overall security program, the Performer must submit a written security plan with their proposal to the Government for review and approval by Government security subject matter experts. The performance of work under the contract will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:	
Security Administration	• organization chart and responsibilities • written security risk assessment for site • threat levels with identification matrix (High, Medium, or Low) • enhanced security procedures during elevated threats • liaison procedures with law enforcement • annual employee security education and training program
Personnel Security	• policies and procedures • candidate recruitment process • background investigations process • employment suitability policy • employee access determination • rules of behavior/ conduct • termination procedures • non-disclosure agreements

Physical Security Policies and Procedures	• internal/external access control • protective services • identification/badging • employee and visitor access controls • parking areas and access control • perimeter fencing/barriers • product shipping, receiving and transport security procedures • facility security lighting • restricted areas • signage • intrusion detection systems • alarm monitoring/response • closed circuit television • product storage security • other control measures as identified
Information Security	• identification and marking of sensitive information • access control • storage of information • secure transmission of data to the USG • document control procedures • retention/ destruction requirements
Information Technology/Cyber Security Policies and Procedures	• intrusion detection and prevention systems • threat identification • employee training (initial and annual) • encryption systems • identification of sensitive information/media • password policy (max days 90) • lock screen time out policy (minimum time 20 minutes) • removable media policy • laptop policy • removal of IT assets for domestic/foreign travel • access control and determination • VPN procedures • WiFi and Bluetooth disabled when not in use • system document control • system backup • system disaster recovery • incident response • system audit procedures

	• property accountability
2. Site Security Master Plan Description: The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; IT Server Room; Product Storage Freezer/Room; and bio-containment laboratories.	
3. Site Threat / Vulnerability / Risk Assessment Description: The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually.	
4. Physical Security Description:	
Closed Circuit Television (CCTV) Monitoring	a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored. b) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. c) Video recordings must be maintained for a minimum of 30 days. d) CCTV surveillance system must be on emergency power backup. e) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. f) Video recordings must be maintained for a minimum of 30 days. g) CCTV surveillance system must be on emergency power backup.
Facility Lighting	a) Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. b) Lighting must have emergency power backup. c) Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	a) Must have CCTV coverage and an electronic access control system. b) Must have procedures in place to control access and movement of drivers picking up or delivering shipments. c) Must identify drivers picking up Government products by government issued photo identification.
Access Control	a) Must have an electronic intrusion detection system with centralized monitoring. b) Responses to alarms must be immediate and documented in writing. c) Employ an electronic system (i.e., card key) to control access to areas where assets critical to the contract are located (facilities,

	laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.). d) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. e) Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of12 months. f) Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company. g) Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months. h) Should have written procedures to prevent employee piggybacking access i) to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. j) Must have a written manual key accountability and inventory process. k) Physical access controls should present a layered approach to critical assets within the facility.
Employee/Visitor Identification	a) Should issue company photo identification to all employees. b) Photo identification should be displayed above the waist anytime the employee is on company property. c) Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. d) Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises at all times.
Security Fencing	Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces	Requirements for security officers will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces Operations	a) Must have in-service training program. b) Must have Use of Force Continuum. c) Must have communication systems available (i.e., landline on post, cell phones, handheld radio, and desktop computer). d) Must have Standing Post Orders. e) Must wear distinct uniform identifying them as security officers.
5. Security Operations Description:	
Information Sharing	a) Establish formal liaison with law enforcement. b) Meet in person at a minimum annually. Document meeting notes and keep them on file for a, minimum of 12 months. POC information for LE Officer that attended the meeting must be documented.

	c) Implement procedures for receiving and disseminating threat information.
Training	a) Conduct new employee security awareness training. b) Conduct and maintain records of annual security awareness training.
Security Management	a) Designate a knowledgeable security professional to manage the security of the facility. b) Ensure sub-Performer compliance with all Government security requirements.
6. Personnel Security Description:	
Records Checks	Verification of social security number, date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, sex offender registry, credit check based upon position within the company; motor vehicle records check as appropriate; and local/national criminal history search.
Hiring and Retention Standards	a) Detailed policies and procedures concerning hiring and retention of employees, employee conduct, and off boarding procedures. b) Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network access.
7. Information Security Description:	
Physical Document Control	a) Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate government markings. b) Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended. c) Access to sensitive information should be restricted to those with a need to know.
Document Destruction	Documents must be destroyed using approved destruction measures (i.e, shredders/approved third party vendors / pulverizing / incinerating).
8. Information Technology & Cybersecurity Description:	
Identity Management	a) Physical devices and systems within the organization are inventoried and accounted for annually. b) Organizational cybersecurity policy is established and communicated. c) Asset vulnerabilities are identified and documented. d) Cyber threat intelligence is received from information sharing forums and sources.

	e) Threats, vulnerabilities, likelihoods, and impacts are used to determine risk. f) Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes. g) Users, devices, and other assets are authenticated (e.g., single-factor, multifactor) commensurate with the risk of the transaction (e.g., individuals' security and privacy risks and other organizational risks)
Access Control	a) Limit information system access to authorized users. b) Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access. c) Limit physical access to information systems, equipment, and server rooms with electronic access controls. d) Limit access to/ verify access to use of external information systems.
Training	a) Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.
Audit and Accountability	a) Create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate system activity. Records must be kept for minimum must be kept for 12 months. b) Ensure the actions of individual information system users can be uniquely traced to those users. c) Update malicious code mechanisms when new releases are available. d) Perform periodic scans of the information system and real time scans of files from external sources as files are downloaded, opened, or executed.
Configuration Management	a) Establish and enforce security configuration settings. b) Implement sub networks for publically accessible system components that are physically or logically separated from internal networks.
Contingency Planning	a) Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.
Incident Response	a) Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents. Exercise this capability annually.
Media and Information Protection	a) Protect information system media, both paper and digital. b) Limit access to information on information systems media to authorized users.

	c) Sanitize and destroy media no longer in use. d) Control the use of removable media through technology or policy.
Physical and Environmental Protection	a) Limit access to information systems, equipment, and the respective operating environments to authorized individuals. b) Intrusion detection and prevention system employed on IT networks. c) Protect the physical and support infrastructure for all information systems. d) Protect information systems against environmental hazards. e) Escort visitors and monitor visitor activity.
Network Protection	Employ intrusion prevention and detection technology with immediate analysis capabilities.
9. **Transportation Security** Description: Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.	
Drivers	a) Drivers must be vetted in accordance with Government Personnel Security Requirements. b) Drivers must be trained on specific security and emergency procedures. c) Drivers must be equipped with backup communications. d) Driver identity must be 100 percent confirmed before the pick-up of any Government product. e) Drivers must never leave Government products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency. f) Truck pickup and deliveries must be logged and kept on record for a minimum of 12 months.
Transport Routes	a) Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency. b) Transport routes should be continuously evaluated based upon new threats, significant planned events, weather, and other situations that may delay or disrupt transport.
Product Security	a) Government products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed. • Tamper resistant seals must be verified as "secure" after the product is placed in the transport vehicle. b) Government products should be continually monitored by GPS technology while in transport, and any deviations from planned routes should be investigated and documented. c) Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.
10. Security Reporting Requirements	

Description: The partner facility shall notify the Government Security Team within 24 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review.
11. Security Audits Description: The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and sub-Performer.

e. Structural & Natural Hazard Resilience Requirements.
   i. Safety Ratings (Facility must meet regional building codes and thresholds)
   ii. Hurricane resistance per ASCE 7-16 wind load standards
   iii. Tornado resistance with ICC 500-rated shelters
   iv. Seismic safety per FEMA P-749 and IBC standards
   v. Lightning protection per NFPA 780
   vi. Facility location must be confirmed to be outside any designated floodplain.
   vii. Structural Engineering
      - Seismic restraints for all critical equipment.
      - Pad layouts and equipment skids for vibration isolation and secure footing.

f. Warehouse Operations Zones Requirements
   i. Functional Areas
      - Sampling Room: Designated zone for repackaging, must include floor drain, appropriate ventilation, particle controls, and containment system.
      - Quarantine Area: Lockable, segregated, specific signage with specific temperature controls.
      - Stability Chambers
      - Downflow Booth: Required for material handling under GMP airflow control.
      - Staging Area: Designated “haul-off” zones for outbound goods.
      - Labeling Station: Barcode/RFID-enabled workstations. Limited accessibility
      - Shipping/Receiving: Temperature-controlled airlock zones.
      - Loading Dock:
         a. Min. two roll-up dock doors
         b. Adjustable dock levelers rated for 5,000+ lbs.
      - Special handling: High potency materials and flammable storage
      - Facilities must be located within the Continental United States

g. OSHA & Worker Safety Requirements.
   i. Personnel Facilities
      - Locker room with PPE storage and changing area
      - Safety showers and emergency eyewash stations
   ii. Caged ladder access per OSHA 29 CFR 1910.23
   iii. Fire suppression system: wet pipe or gas-based per NFPA 13
   iv. Gas bottle restraints and dedicated hazardous storage

h. Utilities & Facility Services Requirements.
   i. Infrastructure

- Electrical grid with redundant emergency backup
- Pharmaceutical-grade plumbing systems (minimum 304 SS (stainless steel) piping for fluid contact surfaces). Exception upon design if required.

ii. Integrated pest control program per FDA 21 CFR 211.56

i. Information Systems & Connectivity Requirements.
   i. Regulatory and Compliance
      - Must comply with GxP (GMP, GDP, GLP) requirements
      - System must be 21 CFR Part 210, Part 211, Part 11 compliant with electronic records and signatures
      - Full CSV validation package which includes validation protocol, URS, UAT, risk management assessments (GAMP 5), disaster recovery (RTO/RPO)
      - Must provide a validated audit trail (who/what/when/why) on all stages of process
      - Must enable role-based access control with segregation of duties
      - Must support data retention, archival, and retrieval per regulatory guidelines

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

k. Reporting and Analytics Requirements.
   i. Standard GMP-compliant reports (stock on hand, expiry, batch traceability)
   ii. Real-time dashboards for KPIs (inventory accuracy, warehouse utilization, picking efficiency).
   iii. Audit-ready reports for regulatory agencies
   iv. Configurable reporting and data export functionality

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

m. Equipment Procurement and Qualification Requirements.
   i. Prioritization: Based on the API list, identify the most frequently used instruments (e.g., HPLC, UV-Vis, FTIR)
   ii. Supplier Selection: Choose reputable suppliers for all instruments
   iii. Qualification (IQ/OQ/PQ): All new equipment must undergo Installation Qualification, Operational Qualification, and Performance Qualification to ensure it is installed correctly, operates as intended, and consistently produces accurate results
   iv. Require annual reviews of suppliers for single-source risks, prioritizing those with domestic supply chains to avoid foreign dependencies.

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

o. Reagent and Consumables Management Requirements.

i. Inventory Control: Maintain adequate stock of all necessary reagents, solvents, columns, and other consumables
ii. Quality Control: Ensure all reagents are of appropriate grade (e.g., HPLC grade solvents, USP grade chemicals)

p. Method Validation Requirements.
i. Verification/Validation: While USP methods are generally considered validated, their suitability for a specific laboratory's equipment and conditions must be verified. For non-compendial methods or significant modifications, full method validation (specificity, linearity, accuracy, precision, detection/quantitation limits, robustness) is required as per ICH Q2(R1) guidelines

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

r. Operations and Sustainment:
i. Sustain operations for a period of no less than 1 year with an uptime of >99.9%

Objective 2: Perform VMI as a service

XIII. Objective 2 requires securing, executing acceptance testing, managing, reporting, rotation/replenishment, retesting, and rapidly distributing inventories of APIs. Specific requirements include:

a. Inventory Management Requirements.
i. Support for multiple storage types (ambient, refrigerated, frozen, controlled substances)
ii. Real-time stock visibility (quantity, batch/lot, expiry, status).
iii. Full traceability by batch, lot, and serial number.
iv. Manage status control: Quarantine, released, rejected, returned, In-Transit.
v. FIFO/FEFO expiry-based picking logic.
vi. Location management (zones, racks, bins, cold rooms, cages etc.)
vii. Cycle counting and physical inventory support.

b. Material Receipt and Storage Requirements.
i. Electronic receipt against purchase orders
ii. Ability to scan and record incoming goods (barcode/RFID)
iii. Automate quality inspection upon receipt of goods
iv. Automatic quarantine receipt goods until QA release
v. Capture supplier CoA, temperature loggers, and supporting documents

c. Acceptance Testing Requirements.
i. Establish capabilities for non-invasive testing to minimize package opening, reduce contamination risks, and enabling real-time quality control.
ii. Develop and demonstrate rigorous method validation and a comprehensive, risk-based quality management system.
iii. Supplier Qualification and Reduced Testing: Source APIs from pre-qualified suppliers, meaning comprehensive testing has already been performed by the supplier. As a result,

your facility will implement reduced acceptance testing, focusing solely on Identity (ID) and Assay testing for incoming API lots.

iv. USP Monograph Reliance: All specified ID and Assay tests are based on United States Pharmacopeia (USP) monographs. Demonstrate adherence to the methods and specifications outlined within these monographs.

v. Method Validation/Verification: Implement the guidelines provided in USP General Chapter <1225> "Validation of Compendial Procedures" and USP General Chapter <1226> "Verification of Compendial Procedures".

vi. Essential Equipment Availability and Qualification: Procure spectroscopic chromatographic systems, physical testing equipment, microbiological testing equipment, and general laboratory equipment & consumables and undertake Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) on all equipment.

vii. Demonstrate ability to perform specific tests on incoming API lots to confirm they meet predefined quality standards before being released for use in manufacturing.

viii. Ensure API identity, purity, strength, and other critical attributes.

d. Retesting Requirements.

i. Facility must be equipped to conduct routine retesting of stored APIs as needed. Retesting: APIs have a defined retest period, which is the time during which they are expected to remain within specifications and can be retested to confirm their suitability for use. Retesting is performed if an API is held beyond its initial retest date but still within its proposed shelf life.

e. Vendor-Managed Inventory (VMI) Requirements

i. Propose a VMI plan/implementation program for the procurement, inventorying, rotating/replenishing to keep API reporting, and inspection of APIs to keep each API stored from never expiring.

ii. Performers will seek approval for routine use and replenishment of these inventories prior to utilizing and replenishing them.

iii. Provide a plan for spot-price procurement and replacement of APIs used as Vendor managed inventory.

Objective 3: VMI as a Service - Conversion, Distribution, and /Rotation/Replenishment

Objective 3 requires the establishment of a network of domestic conversion partners with the ability to rapidly convert qualified API into finished dose form drugs and distribute at the direction of ASPR. In addition, within 60 days of the subaward, Performers and sub-Performers must submit a plan that outlines how the Performer and sub-Performers will procure, manage, store, rotate/replenish a three to six month supply of the projected U.S. demand for selected active pharmaceutical ingredients (APIs), and already established conversion partners and distribution networks for these essential medicines. The plan must account for a storage period of at least 60 months. Explain VMI, replenishment, etc.

Objective 4*:* Option for Increased Quantity for Surge Support – Separately Priced Line Items 1002, and 1003.

The Government may have surge requirements in support of public health events (e.g. increased development requirements, additional security, SSA activities and unknown Federal mandates which are unpredictable and can initiate a workload surge) which would have a significant workload increase as it pertains to the Performer staffing. These events may result in increased workload for any of the remaining objectives listed in the SOO. At the time of exercising any optional task, the surge will apply.

The Performer must be capable of responding to unanticipated demands for increased capacity of services within existing capabilities covered under this SOO that may require a “surge” in service efforts and/or

resources. Surge requirements are demands primarily for 'emergency response' related services and/or accelerated or increased services, within existing activities identified in this SOO, subject to the availability of funding and program stakeholders need during a particular period of performance. Also, please note that this 'surge' need may be realized during the base year and/or any of the operating option years of the contract, based on Governments need.

3. PROGRAM MANAGEMENT:

A. The Performer is responsible for overall management and oversight of the work necessary to achieve the objectives of this effort. The Performer will provide VMI as a service and perform the overall management, integration, and coordination of all objective activities, including a technical and administrative organization that ensures the efficient planning, initiation, implementation, and direction of all activities.

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

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

4. DELIVERABLES

A. Objectives 1-4 deliverables include the following:

i. Monthly technical progress reports

ii. Detailed Project Plan (2 months after award).

- Plan should describe in detail the proposed plan to achieve each numbered step in sub-paragraph A above.
- Plan should include all analytical assumptions that will be employed in preparing and executing the model.
- Plan should include a range of assumptions/variables that can be used to assess various market conditions during Objectives 2 and 3.
- Plan should include metrics, variables, and milestones for gauging domestic market progress of required technologies and infrastructure that will be needed in real world scenarios.
- Plan should include all metrics, variables and milestones that define the various gates and decision points (distinct from the bullet above).
- Detailed security plan with specifics outlined in the "Milestone and Deliverables" table below.
- Plan should include identification of risks associated with execution of the plan.

v. Provide a complete description of the infrastructure and management structure, including but not limited to addressing all elements that will accomplish the program's goals and milestones.

vi. Provide a written briefing and oral presentation to the government team summarizing the technical approach and a plan for all Objectives.

vii. See also the Milestones and Deliverables Table and Appendix 1 for all other programmatic deliverables.

5. PHYSICAL PROPERTY

Title or interest in equipment and API originally acquired with USG funds must be established by agreement(s) for Performers and sub-Performers.

Title to Property: Fixed Price Project Agreements. Performer retains title to all property acquired as necessary to execute the work under the Project Agreement, unless otherwise dictated in the Project Agreement.

Title to Property: Expenditure Based (and other) Project Agreements. Items of property with an acquisition value equal to or less than $10,000 vest with the Performer upon acquisition. For items greater than $10,000, the Performer must obtain approval from the OTAO, through the CMF, prior to purchasing property using Government funds in order to retain title. Property listed in the cost proposal is considered as having received OTAO approval. For those items of real property or nonexpendable personal property having a unit acquisition cost of $10,000 or more, which will be acquired with Government funds received through the CMF, the Government reserves the right to transfer the title to the Federal Government or to a third Party named by the Government. If a Project Agreement includes the use of real property or equipment that is purchased with non-federal funds or that is donated by a third party to meet a portion of any required cost sharing or matching, the Government will have a financial interest in the property equal to the Federal funding in the project and such property shall be subject to this Article.

Disposition of Property. At the completion of Project Agreements containing property in which title does not vest with the Performer, property shall be disposed of in the following manner:

1. Purchased by the Project Awardee at an agreed-upon price, the price to represent fair market value, with the proceeds of the sale paid to the Government; or
2. Transferred to a Government research facility with title and ownership being transferred to the Government or to an eligible third party; or
3. Any other Government approved disposition procedures as approved by the Project OTAO, through the CMF. The Government shall provide disposition procedures within 120 days of being requested by the CMF to provide disposition.

Title or interest in API will remain with the Performers and sub-Performers. APIs will be acquired for VMI as a service using USG funds. The VMI must be rotated/replenished by the Performer/sub-Performer on a first in first out basis based on a VMI as a service plan presented to and approved by the USG. APIs may be distributed, converted and stored, and/or converted and distributed solely at the direction of the USG. Proceeds from the sale of APIs or converted APIs that are distributed must be used for API rotation/replenishment at levels established in the VMI as a service plan, subject to approval by the USG.

6. TERMS RELATED TO RECIPIENT'S CONSIDERATION FOR USG INVESTMENT

Terms related to consideration for USG investment must be established for Performers and sub-Performers. API will be directed by the USG from inventory management and storage to conversion and distribution following a triggering event that activates the Strategic API Reserve. Consideration will be given by the Performers following activation and access to API and Performers must replenish the inventory of API to levels directed by the USG.

7. Milestones and Deliverables:

The Government's preliminary schedule and high-level tasks (milestones) are expected to be as follows:

Milestones and Deliverables	***Due Date***
Objective 1	
Kickoff meeting	Within 30 days of award
Detailed project plan and a complete description of the infrastructure and management structure, including addressing all elements that will accomplish the program's goals and milestones.	Within 30 days of award
Procurement: 1. Ability to establish a supplier qualification process that has established existing quality agreements in place with FDA-registered and inspected manufacturers, validated analytical testing methods, and a robust cGMP QA/QC processes. 2. Ability to maintain approved supplier database (approved, rejected, reevaluation, etc.) 3. Ability to restrict Purchase Request and Purchase Order from Approved Supplier at the inventory item level. 4. Ability to achieve 4-way matching (PO, GRN, Inspection Report, Invoice)	Within 60 days of award
Environmental and Climate Control: 1. HVAC Systems a. Must maintain validated pharmaceutical-grade temperature and humidity levels for ambient and cold storage per FDA guidelines (21 CFR Part 211.42). b. Zoning controls for storage, sampling, and loading areas. c. Integration with building automation systems for 24/7 monitoring. This system shall be routinely calibrated, inspected, and/or checked according to an approved and documented program designed to assure proper performance. d. Failsafe of 20% redundant capacity required 2. Refrigerated Storage a. Cold Room: Performer must maintain a 2–8°C temperature range, with temperature logging and alarms. b. Portable Chillers: Mobile units for emergency or overflow use. c. Temperature mapping studies every six months, with alarms linked to ASPR reporting for critical APIs; include humidity alarms (30-60% RH) per USP <659> for hygroscopic APIs. d. Failsafe of 20% redundant capacity required 3. Inert Gas Support a. Nitrogen gas line with industrial-grade bracket supports and safety regulators. Inline sensors for nitrogen purity (>99.999%) and flow rates, with automated shutdowns for deviations; integrate with 24/7 building automation for real-time alerts to prevent oxidation in API stockpiles. d. Safe/backup systems: one redundant tank with automatic switchover upon 10% depletion	Within 6 months of award

DEA Storage: 1. Support DEA/controlled substance management (vault storage, dual authorization) 2. Enhanced logging for controlled substances movement 3. Restricted access with role-based permissions 4. Audit reporting for controlled drug handling 5. DEA Vault & Cages a. Constructed to meet DEA physical security requirements under 21 CFR Part 1301.72. b. Access-controlled vault for Schedule I–II substances. c. DEA cage(s) for Schedule II–V materials with mesh	Within 6 months of award
Security Requirements – security requirements specified under Section XII. d. must be addressed by the Performer and sub-Performers.	Within 30 days of award
Establishment of functional warehouse areas: 1. Sampling Room: Must include floor drain and containment system. 2. Quarantine Area: Lockable, segregated, specific signage with specific temperature controls. 3. Stability Chambers 4. Downflow Booth: Required for material handling under GMP airflow control. 5. Staging Area: Designated "haul-off" zones for outbound goods. 6. Sampling Area: Designated zone for repackaging, analytical testing and retesting. 7. Labeling Station: Barcode/RFID-enabled workstations. Limited accessibility 8. Shipping/Receiving: Temperature-controlled airlock zones. 9. Loading Dock: a. Min. two roll-up dock doors b. Adjustable dock levelers rated for 5,000+ lbs 10. Special handling: High potency materials and flammable storage 11. Facilities must be located within the Continental United States	Within 6 months of award
OSHA and Worker Safety: 1. Personnel Facilities a. Locker room with PPE storage and changing area b. Safety showers and emergency eyewash stations 2. Caged ladder access per OSHA 29 CFR 1910.23 3. Fire suppression system: wet pipe or gas-based per NFPA 13 4. Gas bottle restraints and dedicated hazardous storage	Within 6 months of award
Utilities and Facility Services: 1. Infrastructure a. Electrical grid with redundant emergency backup b. Pharmaceutical-grade plumbing systems 2. Integrated pest control program per FDA 21 CFR 211.56	Within 6 months of award
Environmental Monitoring and Compliance: 1. Monitoring of temperature, humidity, and other critical parameters. 2. Alerting and escalation for excursions 3. Integration with BMS (Building Management System)	Within 6 months of award
Reporting and Analytics: 1. Standard GMP-compliant reports (stock on hand, expiry, batch traceability) 2. Real-time dashboards for KPIs (inventory accuracy, warehouse utilization, picking efficiency).	Within 6 months of award

3. Audit-ready reports for regulatory agencies 4. Configurable reporting and data export functionality	
Facility Design and Layout: 1. Segregation: Dedicated areas for receipt/quarantine, sampling, testing laboratories (wet chemistry, instrumental, microbiology), sample retention, and approved material storage. 2. Environmental Control: Ensure HVAC systems can maintain appropriate temperature and humidity, especially in analytical areas and storage. 3. Safety: Incorporate fume hoods, emergency showers, eye wash stations, fire suppression systems, and appropriate chemical storage. 4. Provision for simplified permitting zones (e.g., pre-approved layouts for FDA/EPA reviews) to accelerate domestic facility upgrades, reducing build times	Within 6 months of award
Equipment Procurement and Qualification: 1. Prioritization: Based on the API list, identify the most frequently used instruments (e.g., HPLC, UV-Vis, FTIR) 2. Supplier Selection: Choose reputable suppliers for all instruments 3. Qualification (IQ/OQ/PQ): All new equipment must undergo Installation Qualification, Operational Qualification, and Performance Qualification to ensure it is installed correctly, operates as intended, and consistently produces accurate results 4. Require annual reviews of suppliers for single-source risks, prioritizing those with domestic supply chains to avoid foreign dependencies	Within 6 months of award
Reference Standards: 1. Procurement: Obtain USP Reference Standards for all APIs and their related compounds. 2. Storage and Tracking: Implement a robust system for storing, tracking inventory, and managing the expiration/retest of reference standards.	Within 6 months of award
Reagents and Consumables Management: 1. Inventory Control: Maintain adequate stock of all necessary reagents, solvents, columns, and other consumables 2. Quality Control: Ensure all reagents are of appropriate grade (e.g., HPLC grade solvents, USP grade chemicals)	Within 6 months of award
Quality Management: 1. SOPs: Develop and implement Standard Operating Procedures for all aspects of acceptance testing, retesting, stability testing, equipment operation, calibration, maintenance, sample management, data handling, and out-of-specification (OOS) investigations 2. Documentation System: Establish a robust document control system for all quality records 3. Change Control: Implement a change control system for any modifications to procedures, equipment, or specifications; establish expedited change control processes for the strategic active pharmaceutical ingredients reserve - impacted modifications, such as shifts in API suppliers to prioritize U.S.-based production or updates to the critical drug list. Require impact assessments on supply chain resilience, with mandatory notifications to HHS/ASPR for federally funded stockpiles 4. Audit Readiness: Be prepared for internal and external audits to ensure compliance with regulatory requirements (e.g., FDA)	Within 6 months of award
Operations and Sustainment: 1. Sustain operations for a period of no less than 1 year with an uptime of >99.9%	Within 6 months of award, sustained

	thereafter for 12 total months.
Interim presentations	Monthly. Bi-weekly
Objective 2	
Detailed project plan and a complete description of the infrastructure, management structure, reporting, audit and inspection capacities to adequately secure, perform acceptance testing, manage and report (in regular intervals and ad-hoc), rotation/replenishment, retest and rapidly distribute inventories of APIs.	Within 60 days of award
Interim presentations	Monthly, Bi-weekly
VMI inventory reports – available on cloud or remote access by ASPR	Daily
Spot and routine inspections with the USG	As needed, with 24 hour and no-notice
Establishment of multiple storage types (ambient, refrigerated, frozen, controlled substances)	Within 6 months of award
Inventory Management: 1. Real-time stock visibility (quantity, batch/lot, expiry, status). 2. Full traceability by batch, lot, and serial number. 3. Manage status control: Quarantine, released, rejected, returned, In-Transit. 4. FIFO/FEFO expiry-based picking logic. 5. Location management capacities (zones, racks, bins, cold rooms, cages etc.) 6. Cycle counting and physical inventory support.	Within 6 months of award
Material Receipt and Storage: 1. Electronic receipt against purchase orders 2. Ability to scan and record incoming goods (barcode/RFID) 3. Automate quality inspection upon receipt of goods 4. Automatic quarantine receipt goods until QA release 5. Capture supplier CoA, temperature loggers, and supporting documents	Within 6 months of award
Acceptance Testing: 1. Establish capabilities for non-invasive testing to minimize package opening, reduce contamination risks, and enabling real-time quality control. 2. Develop and demonstrate rigorous method validation and a comprehensive, risk-based quality management system. 3. Supplier Qualification and Reduced Testing: Source APIs from pre-qualified suppliers, meaning comprehensive testing has already been performed by the supplier. As a result, your facility will implement reduced acceptance testing, focusing solely on Identity (ID) and Assay testing for incoming API lots. 4. USP Monograph Reliance: All specified ID and Assay tests are based on United States Pharmacopeia (USP) monographs. Demonstrate adherence to the methods and specifications outlined within these monographs. 5. Method Validation/Verification: Implement the guidelines provided in USP General Chapter <1225> "Validation of Compendial Procedures" and USP General Chapter <1226> "Verification of Compendial Procedures". 6. Essential Equipment Availability and Qualification: Procure spectroscopic chromatographic systems, physical testing equipment, microbiological testing equipment, and general laboratory equipment & consumables and undertake Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) on all equipment. 7. Demonstrate ability to perform specific tests on incoming API lots to confirm they meet predefined quality standards before being released for use in manufacturing.	Within 6 months of award

8. Ensure API identity, purity, strength, and other critical attributes.	
Retesting: 1. Facility must be equipped to conduct routine retesting of stored APIs or drug products as needed. Retesting: APIs have a defined retest period, which is the time during which they are expected to remain within specifications and can be retested to confirm their suitability for use. Retesting is performed if an API is held beyond its initial retest date but still within its proposed shelf life.	Within 12 months from award
Vendor Managed Inventory Plan	Within 30 days from award
Vendor Managed Inventory: 1. Implement a VMI program that will establish and implement methods for procurement, inventorying, replenishing within current manufacturing capacities (to keep API inventories from never expiring), reporting, and inspection. 2. Provide a plan for spot-price procurement and replacement of APIs used as Vendor managed inventory.	Within 60 days from award
Final Report	30 days from completion
Objective 3	
1. Establish a network of conversion partners with the ability to rapidly convert qualified API into Finished Dose Form (FDF) drug(s) and distribute at the direction of ASPR. 2. Provide a plan within 60 days that outlines how the performer and sub-performers will procure, manage, and provide rotation/replenishment of a six-month supply of the projected U.S. demand for selected active pharmaceutical ingredients (APIs), and establish conversion partners and distribution networks for these essential medicines.	Within 60 days of award
Objective 4	
1. Upon activation for surge needs, establish a network of conversion partners with the ability to rapidly convert qualified API into Finished Dose Form (FDF) drug(s) and distribute at the direction of ASPR. 2. Provide a plan within 60 days that outlines how the performer and sub-performers will procure, manage, and provide rotation/replenishment of a six-month supply of the projected U.S. demand for selected active pharmaceutical ingredients (APIs), and establish conversion partners and distribution networks for these essential medicines.	Within 30 days of award

8. RISK MANAGEMENT OBJECTIVES

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

9. INTELLECTUAL PROPERTY:

Terms related to intellectual property must be established for Performers and sub-Performers. All rights to data, copyrights and inventions outlined in OTA 75A50123D00003 will be applicable to all Performers and sub-Performers.

10. TEAMING AND PARTNERSHIPS

It is anticipated that multi-disciplinary teams of performers and sub-performers will approach this program, and that successful implementation will be required through industrial collaborations. Teams of performers and sub-performers may be led by industrial, academic, or non-profit entities, and along with other organizations. It is expected that the proposed leadership team will include individuals with significant experience and expertise in pharmaceutical manufacturing and cGMP operations. These teams of performers and sub-performers will lead large and diverse cohorts with industrial partners and have significant experience in industrial process design and identify industrial and commercial partners to aid in achieving the milestones and implementing the deliverables outlined within this SOO. Efforts should be fully integrated and demonstrate that all components are necessary and inseparable. Teams will incorporate members with experience in diverse fields such as computer science, engineering, automation, regulatory, supply chain, industrial process development, chemistry/chemical engineering, cGMP manufacturing, and drug substance and drug product manufacturing, among others.

APPENDIX 1. Meetings, Site Visits and Reports

Deliverable Description	Content Requirements and Instructions[i]	Reporting Frequency[ii],[iii]
Kick Off Meeting	Recipient to develop Agenda and host an in-person or virtual kick-off meeting to discuss overall project objectives, key personnel, deliverables, risks, schedule and funding/payment procedures. Provide meeting minutes.	Kickoff meeting conducted within 5 days of award. Minutes to be submitted within 3 business days of meeting.
Ad-hoc Project Team Meetings	Recipient to schedule and create and agenda. Follows Agenda mutually agreed upon in advance of meeting. RECIPIENT to provide meeting minutes within 3 business days from date of meeting.	As needed for special topics, when specifically requested by the OTAO or OTTR.
Inventory Reports	Report of all APIs and FDF drugs in inventory provided on a daily basis - available on cloud or remote access by ASPR	Daily
Monthly Project Team Meetings	Purpose is to review monthly progress report findings, any changes since last month and any projected issues or challenges.	Virtual. Monthly, 5 business days after the monthly report deliverable. 1 hour duration, hosted by the recipient.

Deliverable Description	Content Requirements and Instructions[i]	Reporting Frequency[ii],[iii]
		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. Performer format acceptable, in PDF.
Quarterly In-Process Review (IPR)	Organized, scheduled and hosted by Recipient. May be virtual or physical at the Recipient's facilities based on USG preference. High level project progress review of overall objectives including, but not limited to Schedule, Budget, Quality, Cost Control (i.e. changes), Design, Construction, Validation, Regulatory. Projections against project expectations, including risks and mitigation plans.	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.	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

Deliverable Description	Content Requirements and Instructions[i]	Reporting Frequency[ii],[iii]
Project Documents and List(s)	Full listing of project, documentation organized by engineering discipline or other category (e.g. drawings list, specifications list, procurement packages list, instrument index, URS/FRS, etc.)	Submitted, uploaded and updated as required to USG specified site.
Project Documentation	Project Design, Procurement, Construction, Validation, Regulatory, and other related project execution related documents	When specifically requested via e-mail by USG Project Manager (or designee), post latest version of requested documents to shared documents site
Project Risk Register	Project risks identified throughout the project shall be tracked via a Risk Register Log (or similar list/tracking vehicle). Log should contain information regarding identification date, severity of risk, mitigation plan(s) and dates for implementation, risk owner, etc.	Updated monthly and submitted with Monthly Technical Progress Report and posted to USG identified document site.
Project Action Items List	Actions identified throughout the project, which are not tracked by some other project management tool, and which require follow up and monitoring for completion, will be captured in an Action Items List. (Or similar list/tracking tool.) List should contain information regarding identification date, target completion, responsible individuals/groups, etc.	Submitted if/as required with monthly technical progress report.
Site Visits	Host visits from USG following agenda/schedule mutually agreed upon with USG in advance of visits. Provide visit notes within 3 business days from date of visit.	Typically, quarterly, commensurate with quarterly IPR, ad-hoc and no-notice inspections will occur at the Agreements Officer's discretion.

Deliverable Description	Content Requirements and Instructions[i]	Reporting Frequency[ii],[iii]
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, comparing original schedule to final schedule; recommendations for path forward as applicable.	Initial submission to be submitted 30 days prior to the end of the period of performance. Within 15 days of receipt, the Government will provide review comments. The Respondent shall respond within 15 days of receipt of comments.
Security Plan	The Security Plan must detail how the RECIPIENT will adhere to established ASPR Informational Technology (IT) and Operational Security (OPSEC) policies and requirements. The Security Plan must include but is not limited to; • Internal management security measures that meet the ASPR, IT, and OPSEC security requirements • Plan to ensure Project Agreement security compliance, to include roles and responsibilities • Plan to manage Consortium member physical, IT, and OPSEC security compliance as a contingency of Consortium membership	Submission within 60 days post-award, updated as necessary.

[i] 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.

[ii] 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.

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