BioMaP Consortium
Biopharmaceutical Manufacturing Preparedness - Consortium

Virtual Collaboration Event RPP-24-01-SmallMol

January 17, 2024

Administrative Information

- All participants are muted, speakers are on mute until its their turn
- Slides for this presentation are also posted in Events page
  - https://www.biomap-consortium.org/events/
- Q&A capability is enabled, questions will be captured and posted
  - Use Q&A feature to submit any questions (do not use chat feature for questions)
  - Please use chat function for assistance with the zoom meeting or troubleshooting
  - Q&A will also be posted following the event
- 1-on-1's this afternoon: use the link provided in confirmation email

Agenda

- 11:00 – 11:05: Opening Comments & Administrative Information
- 11:05 – 11:15: BARDA BioMaP Program Office Introduction
- 11:15 – 11:30: RPP-24-01-SmallMol Informational Brief
- 11:30 – 12:00: ASPR IBMSC Program Office Introduction & Technology Roadmap Overview
- 12:00 – UTC: Questions
- 1:00 – 4:00: 1-on-1s hosted by ASPR IBMSC & BARDA BioMaP Program Office

BioMaP-Consortium Overview and Focus Areas

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Agreements mechanism that will leverage BARDA's Other Transaction Authorities (OTAs) to fund vaccine manufacturing and supply chain industrial base expansion and advanced manufacturing technology innovations.

KEY DOMAINS:

Industrial Base Expansion of Biomanufacturing Supply Chain

Engaging providers of goods and services that support the entire biomanufacturing process to strengthen the domestic supply chain (raw materials, consumables, etc.)

Biomanufacturing Capacity Expansion and Reservation

Establishing, expanding, and reserving drug substance and drug product to prepare timely and sufficient MCMs in response to emerging pathogens with pandemic potential

Advanced Biomanufacturing Technologies

Addressing technologies that:

- Are new, emerging, and innovative
- Enhance existing technologies
- Increase the speed, quality, safety, yield, and efficiency of the biomanufacturing process

ASPR's Office of Industrial Base Management and Supply Chain (IBMSC) Overview and Advanced Pharmaceutical Update

January 17, 2024

Administration for Strategic Preparedness & Response

ASPR's mission: Assist the country in **preparing for, responding to,** and **recovering from** public health emergencies and disasters.

ASPR Key Priorities

1

Prepare for future public health emergencies and disasters

2

Manage the federal **response** to and recovery from public health emergencies and other disasters

3

Improve and leverage **partnerships** with health care and public health stakeholders

4

Ensure **workforce readiness** through development of innovative workplace practices

Evolution of The Public Health Industrial Base Through COVID-19

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Pre COVID-19
before Jan 2020

Limited public health industrial base to address pandemic needs

- Reliant on “just-in-time" manufacturing inputs that were vulnerable to supply disruptions
- High dependency on a consolidated, geographically limited foreign supply, e.g.,
  - 90%+ gloves, syringes, needles from Asia
  - 95%+ generic drugs made in India and China

Peak COVID-19
2020-2022

Inadequate availability of critical medical supplies;
USG & industry responded

- Accelerated global transport and domestic allocation of critical raw materials and medical countermeasures in shortage
- Increased domestic production capacities for PPE, vaccines, diagnostics, and pharmaceuticals

Today
January 2024

Demand & supply stabilizing, continued manufacturing investments required

- Addressing new increased demand from virus variants, additional vaccinations, global support for vaccines
- Establishing acquisition workforce to actively manage supply and production capacities
- Ensuring investments are sustainable for long term competitiveness and needs

Future
(next 24 months)

Build resilient industrial base to respond to future pandemics

- Actively manage health and resiliency of our domestic public health industrial base
- Preserve production capacities in US supply chain as demand wanes
- Expand professional acquisition workforce
- Expand supply chain monitoring & industrial base analysis capabilities

U.S. Department of Health and Human Services Administration for Strategic Preparedness and Response (ASPR)

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Immediate Office

Assistant Secretary for Preparedness and Response Principal

Deputy Assistant Secretary and Chief Operating Officer

- Office of Strategy, Policy, and Requirements
- Executive Secretariat
- Office of External Affairs
- Office of Legislative Affairs
- Office of Public Affairs

Office of Administration

- Head of Contracting Activity*
- Finance
- Human Capital
- Information Technology

Office of Preparedness

- Health Care Readiness
- Medical Reserve Corps
- Security and Intelligence
- Information Management Data and Analytics
- Critical Infrastructure Protection
- Planning and Exercises
- Continuity
- Secretary's Operations Center

Office of Response

- National Disaster Medical System
- Regional Response
- Response Logistics
- Community Mitigation and Recovery

Biomedical Advanced Research and Development Authority

- Medical Countermeasures Program Support Services
- Medical Countermeasures Program
- Deputy Head of Contracting Activity

Office of Industrial Base Management and Supply Chain

- Personal Protective Equipment and Durable Medical Equipment
- Testing and Diagnostics
- Advanced Manufacturing Technologies
- Supply Chain Optimization
- Defense Production Act and Emergency Response Authorities

Strategic National Stockpile

- Management and Business Operations
- Logistics
- State Tribal Local and Territories Preparedness
- National Readiness and Response
- Supply Chain Alliance and Development
- Science

HHS Coordination Operations and Response Element

- Supply, Production, and Distribution
- Planning and Operational Coordination
- Operations Technical Assistance
- Analytics, Data, and IT*
- Security and Assurance*

ASPR Industrial Base Management & Supply Chain (IBMSC) Office

A permanent capability within ASPR to enhance preparedness and save lives by building a resilient domestic public health industrial base with the following key focus areas:

- Personal Protective Equipment
- Testing and Diagnostics
- Advanced Manufacturing Technologies
- Supply Chain Optimization
- Defense Production Act & Emergency Response Authorization

Our Areas of Interest

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Advanced Manufacturing	Supply Chain Optimization	PPE Manufacturing	Testing and Diagnostics Manufacturing
Advanced manufacturing technologies for drug substance and drug product manufacturing Distributed manufacturing of drug substances and drug products Additive manufacturing biologically-derived manufacturing of drug substances or drug products	Identify the PHIB supply chains most vulnerable to disruption, and in most need of optimization. Provide solutions to optimize the PHIB supply chains, such as logistics technologies and innovations, manufacturing process improvements, raw materials improvements, data systems and decision support tools. Provide manufacturing approaches for multi-functional and multi-product capabilities in production lines.	PPE manufacturing expansion Novel sub-tier manufacturing capabilities Materials science applications for PPE reuse of innovative materials to lower costs and increase capacities.	Testing and diagnostic manufacturing expansion Novel sub-tier manufacturing capabilities Next-generation sequencing and multi-omic approaches Antibodies/antigens proteins/peptides/proteomic Metabolic/metabolomic predictive analytics Next generation diagnostics for novel agents

IBMSC Strategic Objectives

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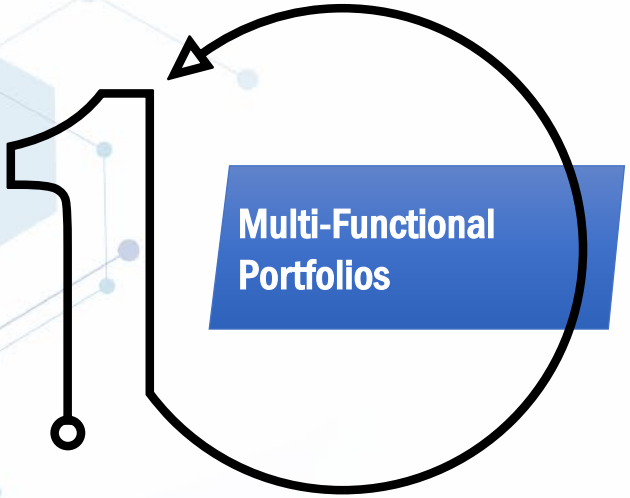
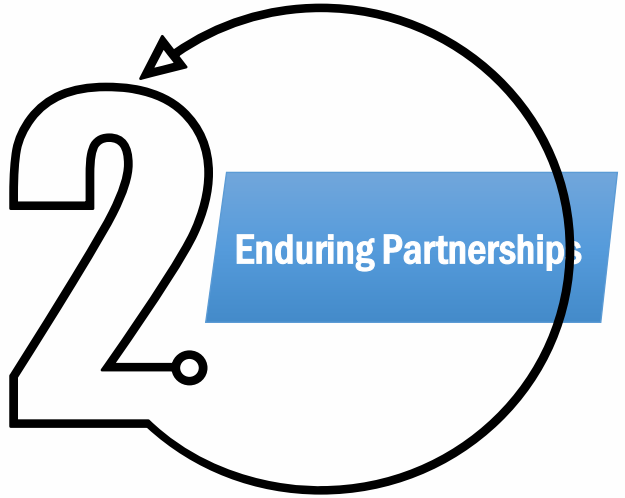
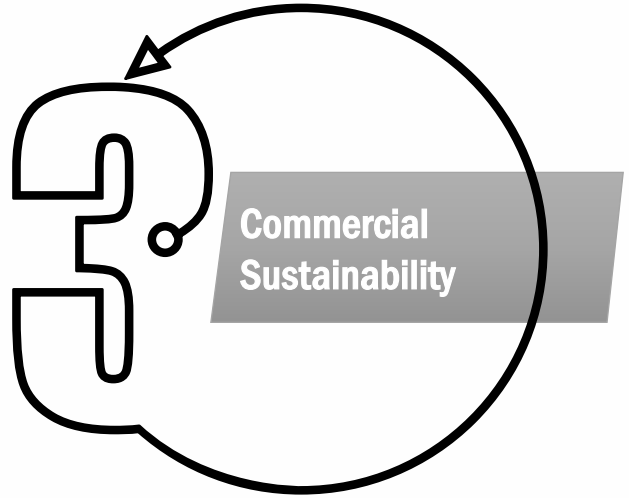
The U.S. government (USG) is committed to enhancing preparedness to save lives through investing in and advancing the domestic industrial base for public health and medical countermeasures through:



Promoting multi-functional capabilities that ensure access to necessary raw materials and components for domestic manufacturing



Establishing innovative and sustainable partnerships with biotech, pharma, distributors, healthcare, non-profit, and for-profit organizations



Prioritizing long-term, viable, adaptable domestic industrial base infrastructure to sustain commercial markets

What IBMSC is Currently Managing

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KEY ACTIVITIES

- **$18B in investments in domestic production and products to-date**
  - PPE - $982M
  - Advanced Manufacturing - $325M
  - Testing - $3.37B IBX; $9.33B Procurement
  - Vaccines manufacturing & materials- $1.87B
- Establishing innovative manufacturing technologies and fill-finish capacities to better avail drug products and vaccines
- Distribute tests to thousands of LTCFs, CHCs, Schools, Food Banks and CL Centers

INVESTMENTS & EXPECTED CAPACITY

N95 respirators

+83m / month

Surgical masks

+44m / month

Gloves

+1.5B / month

Gowns

+125k / month

Drug products*

+200m doses for 6 meds in shortage

Lab-based Tests

+72m / month

Point-of-care Tests

+73m / month

At home Tests

+80M / month

Vaccine production & supplies**

Up to 600M doses / month

POC and OTC Test Procurements

+1.39B Tests

** Including active pharmaceutical ingredients (API)*

*** Includes consumables and raw materials, fill-finish capacity, vials, and needles & syringes*

Not exhaustive

Advanced Manufacturing Technologies At-a-Glance

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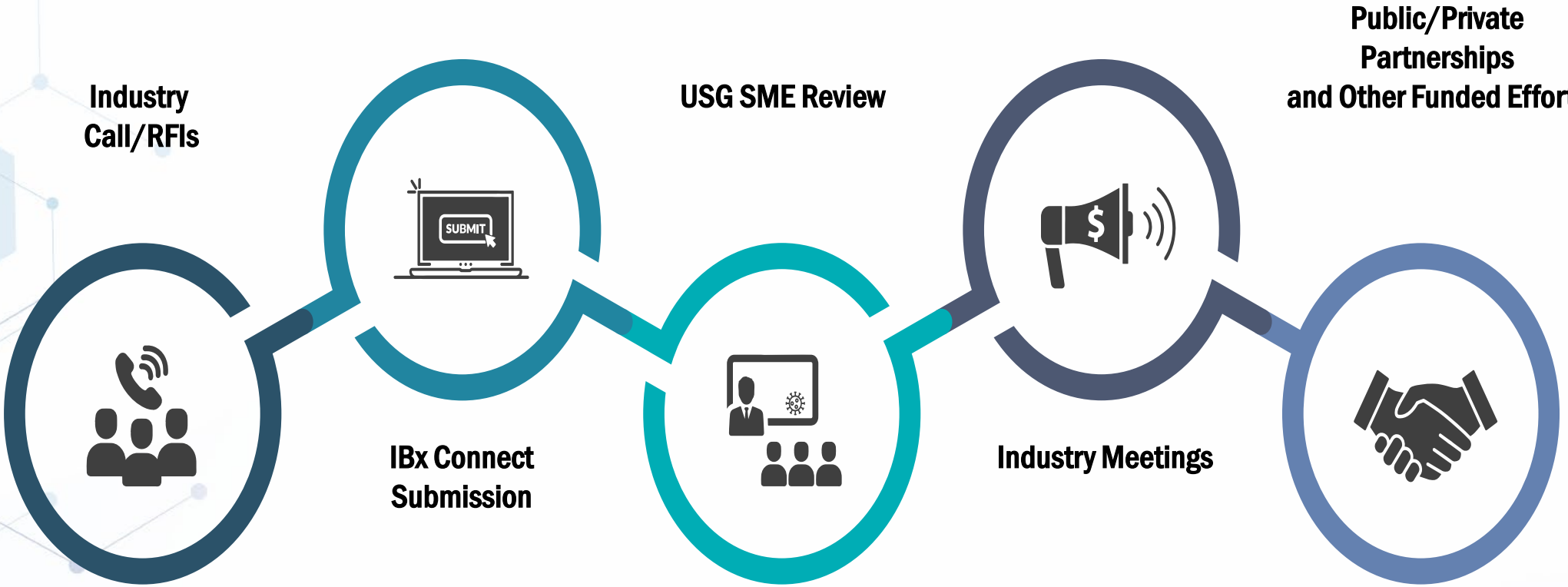
- Small molecule drug production
  - Continuous manufacturing and cGMP validation of sedatives, neuromuscular blocking agents and analgesics in shortage
- Saline manufacturing
  - Development and validation of saline-on-demand technologies
- Fill-Finish
  - Development of novel population scale fill-finish capabilities for small molecule and biologic injectables
- Aero mobility solutions for supply chain optimization- EVTOL
- Supply chain optimization efforts with the Advanced Regenerative Manufacturing Institute, Inc (ARMI) Foundry for American Biotechnology (NextFAB)

IBx Connect

- Advanced manufacturing efforts for drug substances and drug products
- Supply chain optimization
- Testing and diagnostic devices and consumables and
- Personal protective equipment

https://aspr.hhs.gov/ibxconnect/

How IBx Connect Works



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Production of Biologically Derived Small Molecule Regulatory Starting Materials and/or Active Pharmaceutical Ingredients at Commercial Scale

Solicitation At-a-Glance

The Goal

- ASPR IBMSC is seeking to develop a biological design-build-test cycle, beginning with an analytical paper and demonstration of production of small molecule drug substances at commercial scale.
- This will support ASPR IBMSC's broader long-term goal of developing and commercializing infrastructure that will be accessible to a broad community of users for the purpose of producing drug substances, creating a new manufacturing paradigm that can be competitive in the global market and to onshore drug production.

Technical Objectives

Objective A:
Design a study phase to allow the performer to explore, develop and refine an infrastructure design and technical approach, including management, logistics, pricing/costing and other non-technical elements necessary to achieve the primary goal of enabling population scale manufacturing of up to 3 small molecule drug substances.

Objective B:
Develop and execute a biologically derived analytical model of small molecule drug substance development from MRL 3 to MRL 10, including compliance with all Federal, State and Local regulations.

Solicitation Approach

- Stage 1: Enhanced White Paper
- Stage 2: Presentation followed by Statement of Work and Full Cost Proposal

Enhanced White Paper Specifics

- Enhanced White Paper submissions must be submitted by the date and time on the cover page of the RPP
  - Responses received after the time and date specified may not be evaluated
    - Currently Feb 1st, 2024 at 1pm ET
  - Responses must be submitted to the following website: https://secure.ati.org/BioMaP/24-01-SmallSub/
  - Responses should include the Solicitation Number on each Proposal submitted
- Do not submit any classified information in the submission
- The Enhanced White Paper must follow the mandatory template in Attachment A, and is limited to 15 pages excluding Cover Page, Data Rights Appendix, and Relevant Experience Appendix. The section headers in Attachment A are mandatory
- ZIP files and other application formats are not acceptable. All files must be print-capable and without a password required. Filenames shall contain the appropriate filename extension (.docx or .doc)

Oral Presentation Logistics

- **Presentation Date for invited proposers:** Week of Feb 26 – Mar 1
- **Location: Virtual:** MS Teams links to be provided after down select
- **Duration:** 90 minutes (60 minutes for presentation and 30 minutes for Q&A)

Include the following in your presentation:

- **Executive summary:**
  - 10 to 15 slides
  - Technical approach overview
  - Facilities and personnel qualification

- **Oral proposal presentation criteria:**
  - 25 to 30 slides
  - Detailed technical approach
  - Detailed risks and mitigation plan
  - Details of the cGMP manufacturing facility (can include video)
  - Budget estimation
  - Teaming/subcontractors
  - Data Rights Assertions

Note: the cost of participating in the Oral Presentation is not considered a direct charge to any resulting award or any other contract.

Oral Presentations – Process and Basis of Evaluation

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1. **Technical Approach**
   a. The proposed technical approach is reasonable, feasible, and innovative.
   b. The approach demonstrates an innovative yet feasible approach to address the identified technical risks and challenges and meet program metrics.
   c. The proposed technical understanding accurately reflects goals of the solicitation, and key technical challenges and risks are identified.
   d. The proposer's team and organization can realize the technology and process informatics model for real-time qualification of drug products produced via agile pharmaceutical manufacturing from domestic commodity chemicals or precursors.
2. **Risks and Mitigation Plan**
   a. Ability to identify potential risks to performance schedule, addressing with business and technical mitigation plans to address possible delays or performance impacts.
3. **Relevant Qualifications**
   a. Personnel and/or company experience and qualifications are accurate, relevant, and demonstrate the ability of the proposer to meet the technical goals of the program.
4. **Budget**
   a. The proposed costs are reasonable, realistic, and affordable for the technical approach and accurately reflect the technical goals and objectives of the solicitation.

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Questions

- Who can respond to a BioMaP-Consortium Request for Project Proposals (RPP)?
- What are the rules around collaborating with the government for this RPP?
- How do we work with the USG on Draft SOO's before the sponsor formalizes as a RPP?
- How do we respond to a BioMaP-Consortium RPP?
- Are there any more 1-on-1 slots available this afternoon?

Available Resources

- **BioMaP-Consortium website:** https://www.biomap-consortium.org
- **BioMaP-Consortium Mailbox:** biomap-consortium@ati.org
- **BioMaP-Consortium Contracts team (ATI):** biomap-contracts@ati.org

Thank you for attending today's webinar!