



International Generic and Biosimilar Medicines Association 25th Annual Meeting

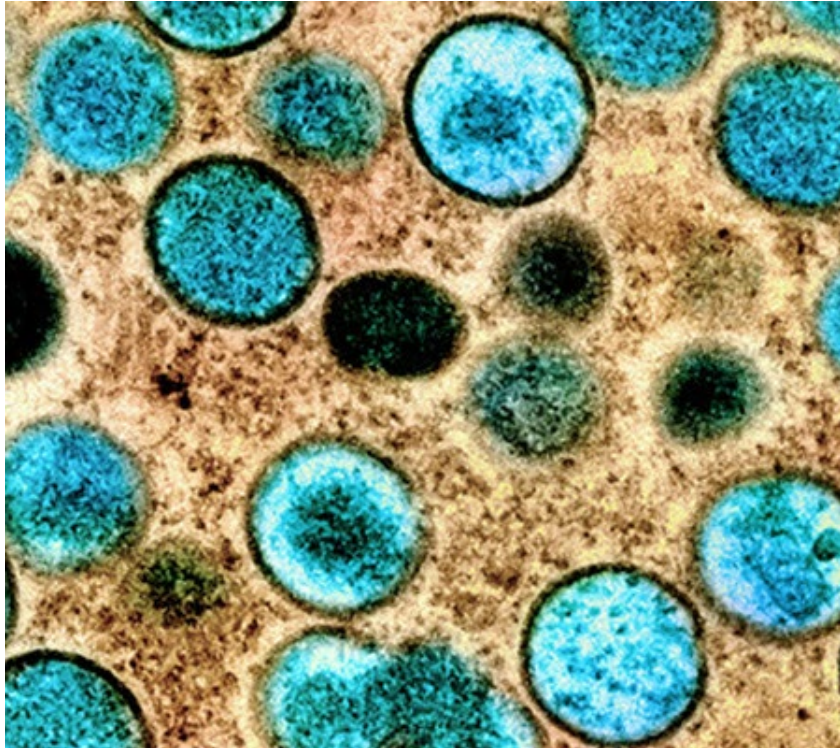
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Administration for Strategic Preparedness and Response
February 15, 2023**

Unclassified/For Public Distribution

About ASPR

The Administration for Strategic Preparedness and Response leads the nation's medical and public health preparedness for, response to, and recovery from disasters and public health emergencies. ASPR collaborates with hospitals, healthcare coalitions, biotech firms, community members, state, local, tribal, and territorial governments, and other partners across the country to improve readiness and response capabilities.

ASPR at Work



MonkeyPox Response



Operation Fly Formula

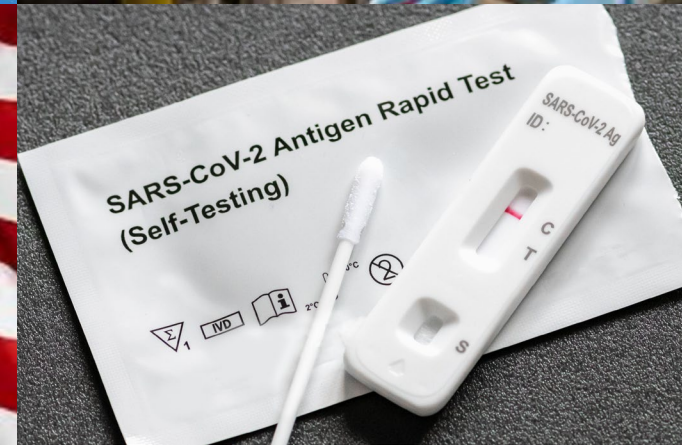


Ebola Response Efforts

Industrial Base Management and 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:

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

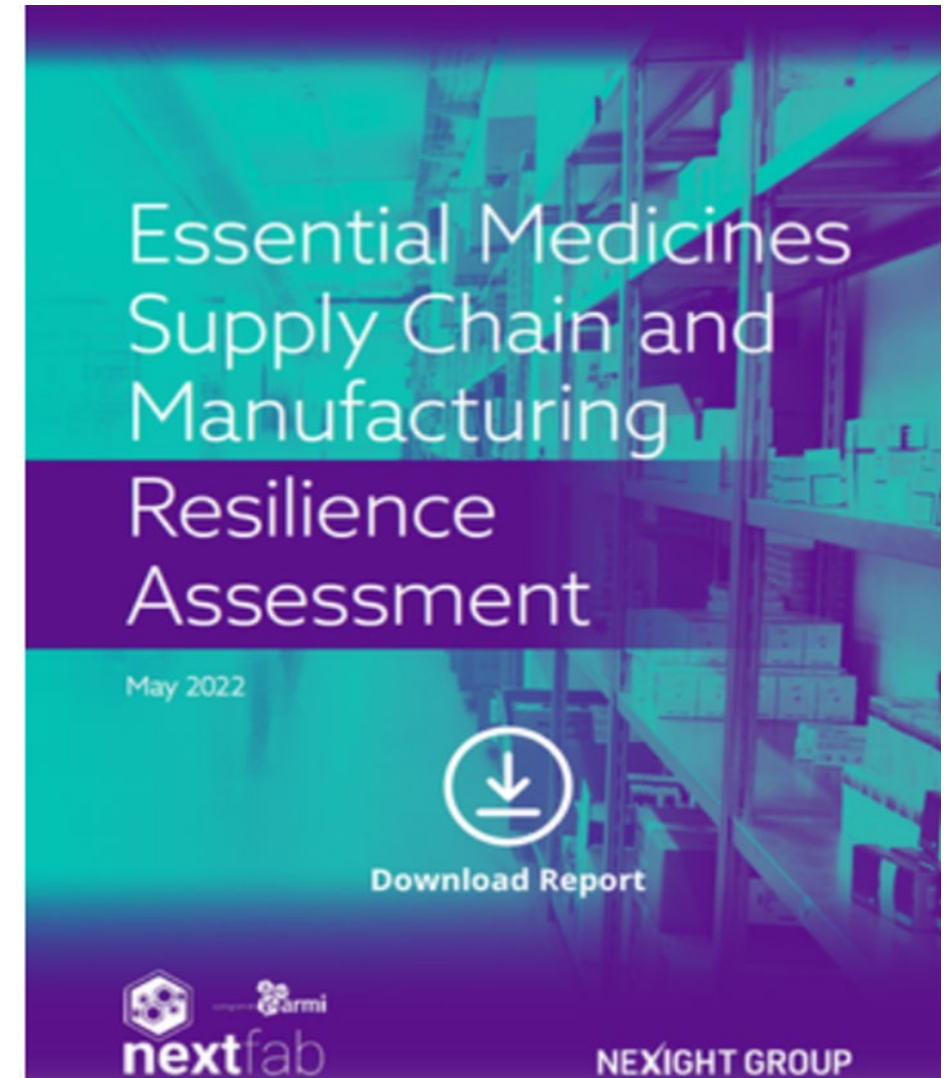


Essential Medicines

Medicines, Medical Countermeasures and Critical Inputs under EO13944

Essential Medicines Supply Chain and Manufacturing Resilience Assessment (Ongoing analysis)

- Narrowed and prioritized list of Essential Medicines (n= 86)
- Supply Chain Challenges (6) illuminated and Strategies Identified (5)
- Developed the “Essential Medicines Supply Chain and Manufacturing Resilience Assessment” Action Report

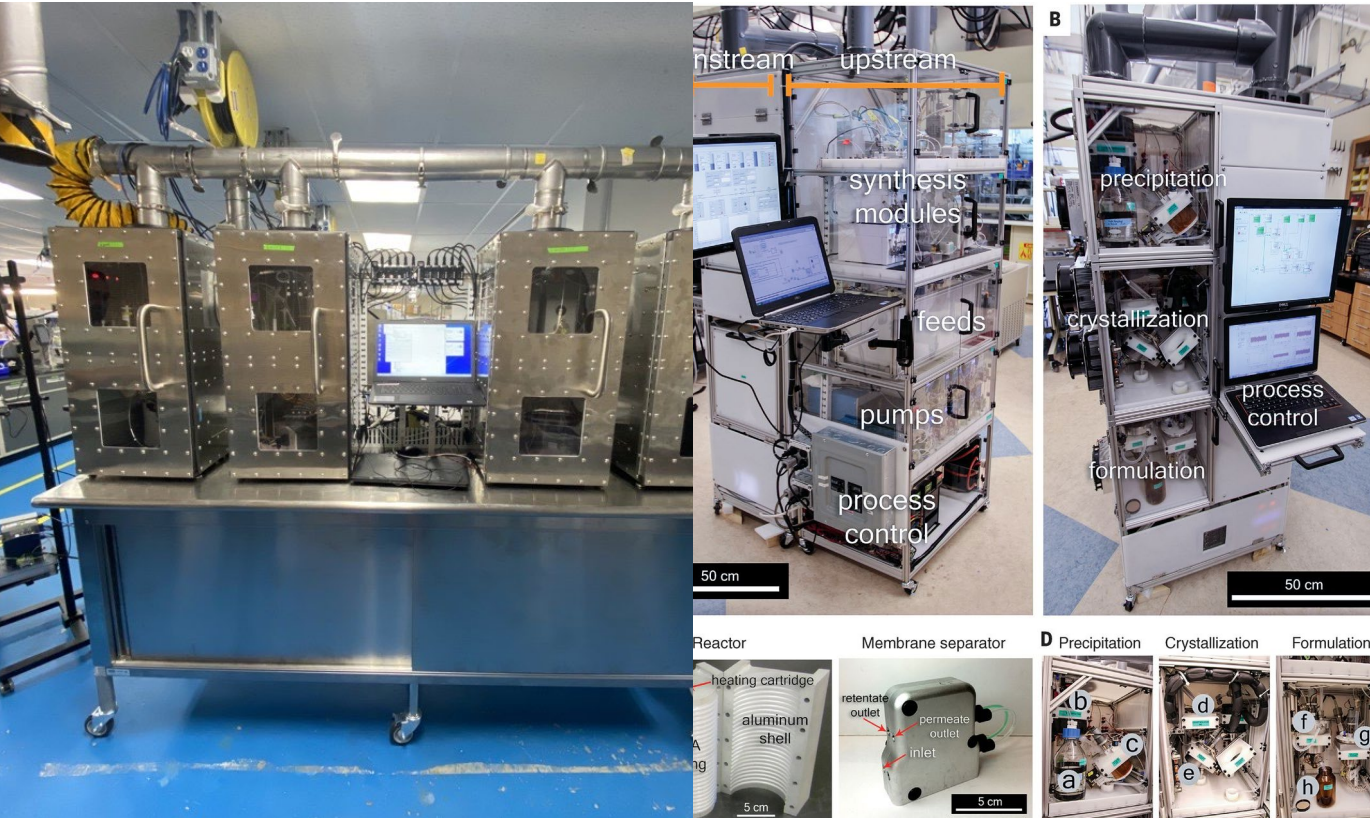


IBMSC (Dialysate)

New dialysis technology that used tap water and standard power outlets to treat patients that required kidney care across the US.



IBMSC (On Demand Pharmaceuticals)



- On Demand Pharmaceuticals is an innovative technology company transforming how medicines are made so they can be produced on demand—whenever and wherever medicines are needed.
- The breakthrough manufacturing technology platform, the Pharmacy on Demand (PoD)TM, allows medicines to be made in small machines instead of a factory. Using a modular approach, the PoD can be quickly customized to produce anything from key starting materials, to active pharmaceutical ingredients (API), and final formulated drugs.

What IBMSC is Currently Managing

Key activities

- **\$14.54B in investments in domestic production and products to-date**
 - PPE - \$908M
 - Advanced Manufacturing - \$459M
 - Testing - \$3.37B IBx; \$7.93B Procurement
 - Vaccines manufacturing & materials- \$1.87B
- Establishing innovative manufacturing technologies and fill-finish capacities to better avail drug products and vaccines
- Oversee Test Stockpile Mission and Operation Fly Formula
- Distribute tests to thousands of LTCFs, CHCs, Schools, Food Banks and CL Centers

Investments & expected capacity

Not exhaustive

 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

IBMSC Blow Fill Seal Technology

Contract to develop and produce high-speed, high-volume drug packaging solution for inexpensive prefilled syringes, to give the USG, ASPR and specifically the Strategic National Stockpile (SNS), the capability to rapidly fill and finish up to 330 million prefilled syringes per month to respond quickly and efficiently to national (or smaller scale) health emergencies.



IBMSC

NextFab, Foundry for American Technology



The mission of NextFab is to produce technological solutions that help the United States protect against and respond to health-security threats, enhance daily medical care and add to the U.S. bioeconomy.

IBx Connect

IBx Connect

Connecting industry and ASPR to bolster resiliency across the entire public health and medical industrial base



IBx Connect Focus Areas

- 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/>



Thank you!