BARDA Innovation Initiatives:

Continuous Manufacturing of Pharmaceuticals

Resilient People. Healthy Communities. A Nation Prepared.
Challenges and Opportunities

- Pharmaceuticals with low commercial market (e.g. medical countermeasures against CBRN threats, personalized medicine, orphan drugs,) have reduced investment interest by pharma
  - CM will allow pharma to more efficiently utilize manufacturing facilities: sustainable smaller multi-product facilities

- Large scale production moving outside US due to reduced capital and operating costs and practices have become routine
  - Technology transfer ex-US may not be necessary with CM-enabled domestic pilot process development to smaller commercial scale-up and manufacturing
Continuous Manufacturing (CM) of Pharmaceuticals

• **Vision:**
  - Consistent with the Pandemic and All-Hazards Preparedness Act (PAHPA) to support innovations that lead to more cost-effective and faster production of MCMs with greater quality, BARDA and FDA partnered.
    • foster development of CM technologies in pharma
    • facilitate commercial adoption in the private sector
    • transfer technology to CIADMs to increase capabilities for domestic resilience and national security

• **Scope:**
  - Support enabling technologies for CM
  - Advance CM innovations into existing and new products
  - Transition realized technologies to increase domestic MCM response core capabilities
BARDA goals

- Speed the process for medical countermeasure (MCM) advanced development and manufacturing
- Increase efficiency and sustainability of MCM production
- Improve overall quality of MCMs
- Reduce total lifecycle development and operational costs

FDA goals

- Fund regulatory science research that addresses scientific, technical, operational CM challenges to evolve future regulatory practices
- Facilitate development of broadly-generalizable, product independent, CM enabling technologies and platforms that are interoperable
STAGE 1 (2015)

• BARDA – industry intel through private communications, targeted Tech Watch presentations

• BARDA/FDA established a joint working group and issued an RFI on April 21, 2015 entitled “Innovations in Medical Countermeasure Continuous Manufacturing” for conducting formal market research; responses analyzed

• White House National Science and Technology Council Subcommittee on Advanced Manufacturing: Sep. 17th

• PDA-FDA Joint Regulatory Conference: Sep. 28-30th

• BARDA Industry Day: Oct. 14-16th
STAGE 1 (2015)

Broad Agency Announcements

• BARDA Advanced Research and Development of Chemical, Biological, Radiological, and Nuclear Medical Countermeasures and Advanced Development of Medical Countermeasures for Pandemic Influenza (October 14, 2015)
  • BAA-16-100-SOL-00001 aims to develop MCMs for chemical, biological, radiological, and nuclear (CBRN) agents.
  • BAA-16-100-SOL-00002 will support development of MCMs for pandemic influenza.
    – Development of product candidates using CM technologies

• FDA Advanced Research and Development of Regulatory Science
  – CM-enabling technologies and innovations related to process control systems and process analytical technologies, CM instrumentation and equipment, etc.
STAGE 2 (2015- 2018)

• Funding projects through the BAAs:
  – Joint FDA-BARDA process established to review CM white papers and proposals that are received through the solicitation process

• Increase partnerships on potential projects through other interagency agencies:
  – Discussions on-going with DARPA, NIAID, NIH/NCATS
STAGE 3 (2017-2019)

• Transfer CM technology from industry partners to CIADMs for agile and scaled up production of selected MCMs to known and unknown threats

**Bottom Line:** Increased domestic resilience and response capabilities
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BACKUP SLIDES
What is Continuous Manufacturing?

Continuous manufacturing (CM) has been utilized in other sectors for decades:

- Food Industry
- Petroleum Industry
- Chemical Industry
- Paper Industry

For example: potato chips