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

FDA ⇔ BARDA CM Partnership

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:
  - BARDA is supporting a CM project in partnership with Janssen for the advanced development of an influenza antiviral, JNJ872 (aka Vertex 787), awarded (Sept.25, 2015

    http://www.hhs.gov/news/press/2015pres/09/20150928a.html

  - 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

Acknowledgments
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BACKUP SLIDES

What is Continuous Manufacturing?

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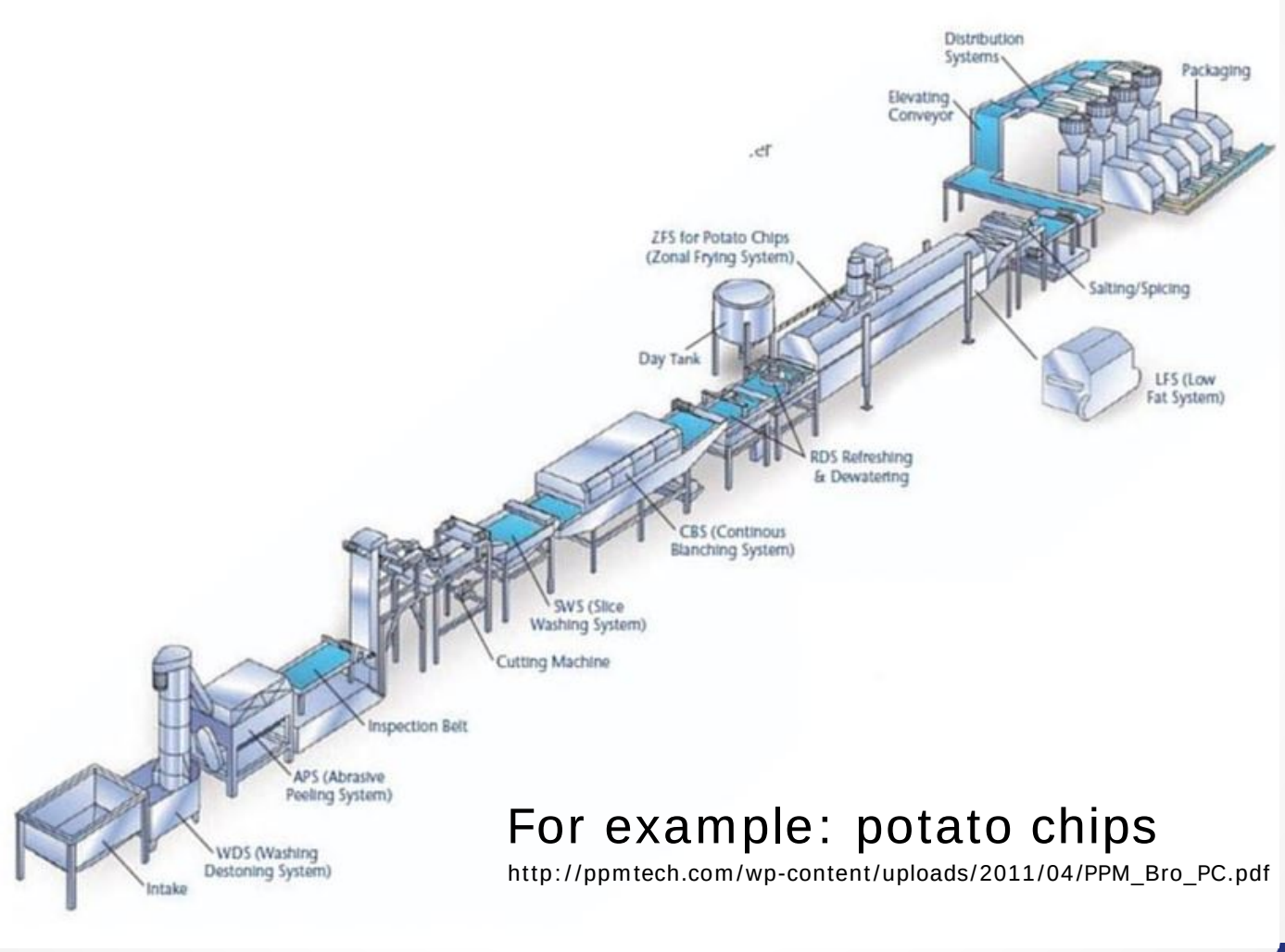

For example: potato chips

http://ppmtech.com/wp-content/uploads/2011/04/PPM_Bro_PC.pdf