



United States Department of

**Health & Human Services**

Office of the Assistant Secretary for Preparedness and Response



# **BARDA Regulatory & Quality Affairs Division**

**BARDA Industry Day**

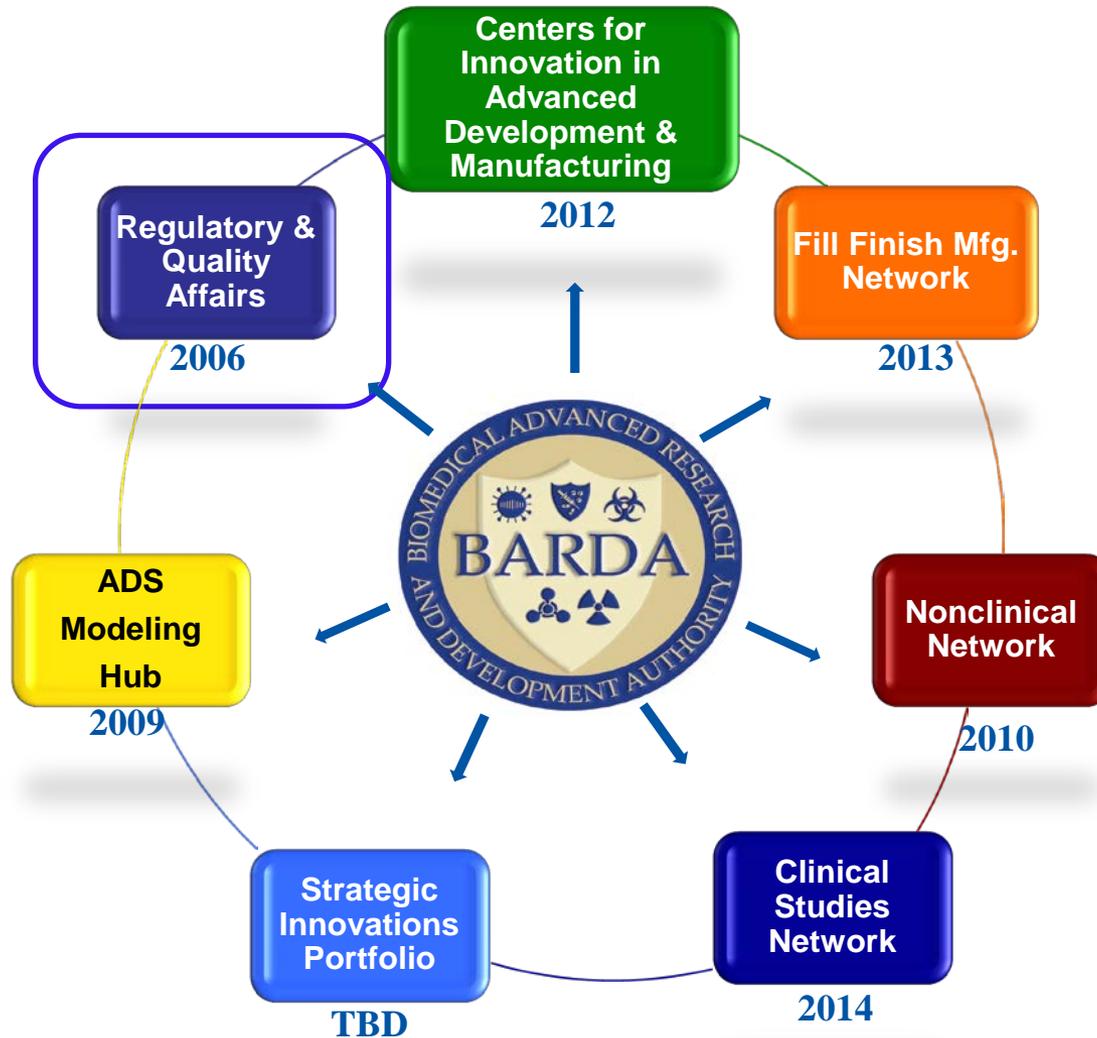
November 13, 2013

**Debra A. Yeskey, Pharm.D.**

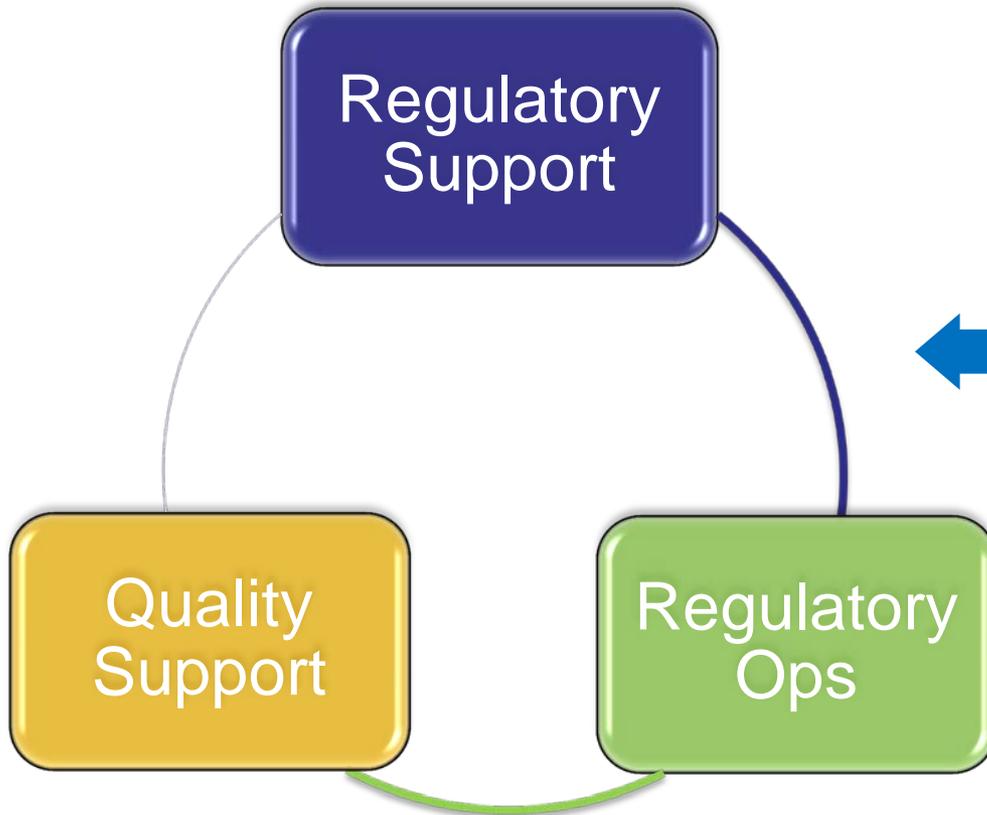
**Director of Regulatory & Quality Affairs**

*ASPR: Resilient People. Healthy Communities. A Nation Prepared.*

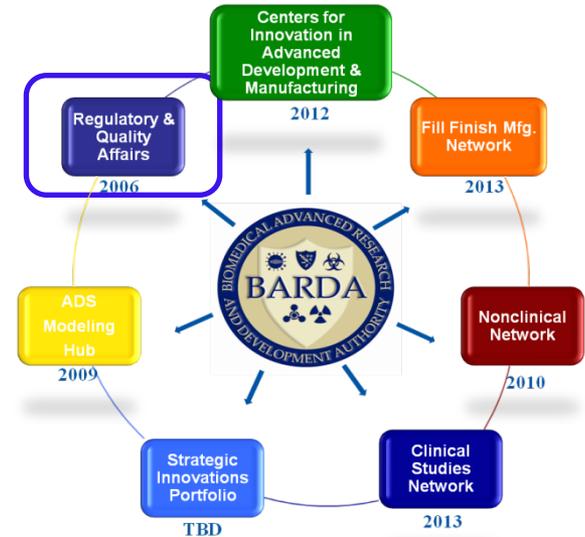
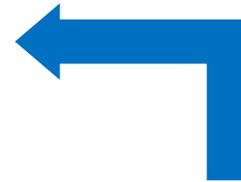
# Regulatory and Quality Affairs is a BARDA Core Service



# RQA Capabilities



*We provide BARDA and our Sponsors comprehensive capabilities in regulatory affairs and quality monitoring.*





# 2014 Initiatives



- Quality Branch:
  - Quality Audit Capability
    - GxP and Quality Systems regulatory compliance and remediation auditing
    - Quality Systems assessment and improvement
    - PAI and regulatory audit inspection readiness and training
- Regulatory Operations:
  - eCDT capability
  - Looking at rapid mechanisms for data collection during a public health emergency event