



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



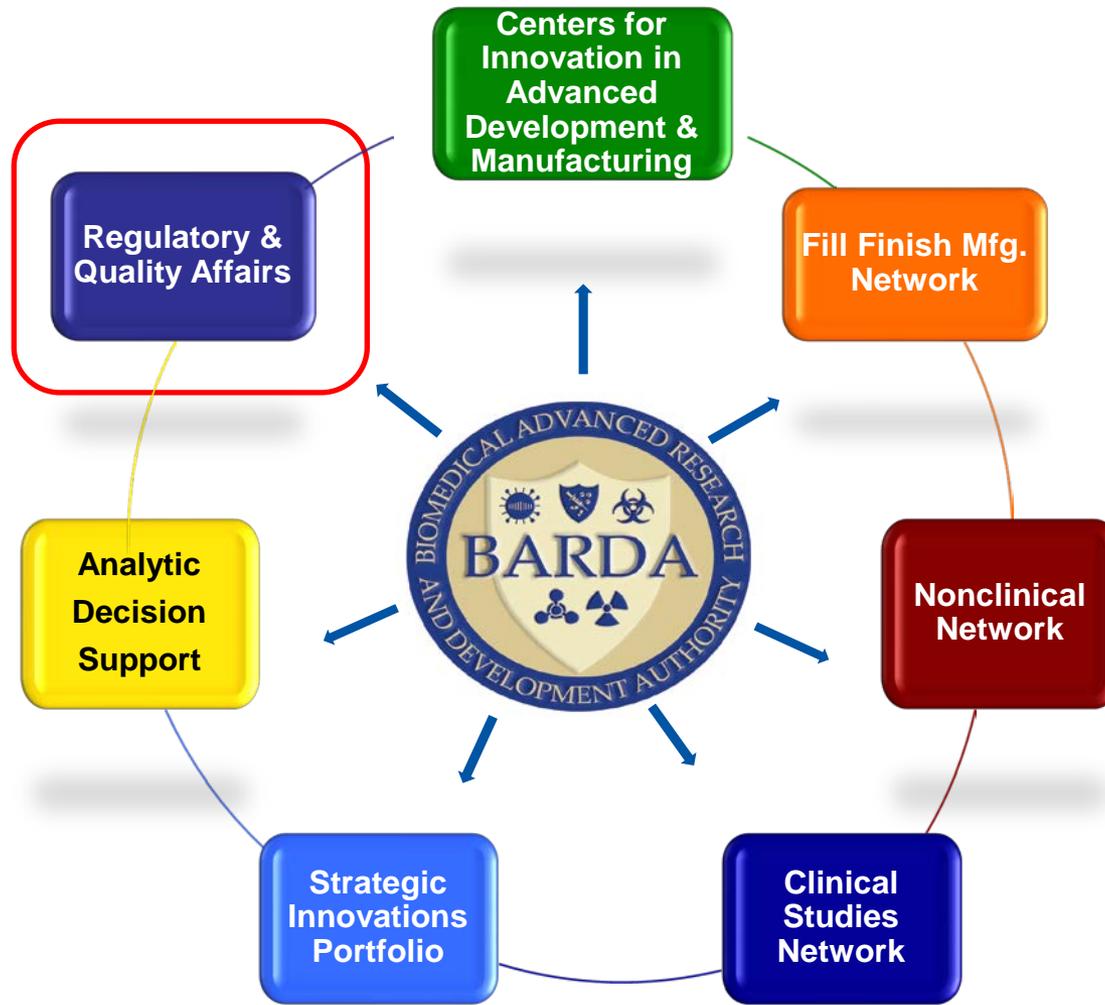
Regulatory & Quality Affairs Support

BARDA Industry Day 2014

**Debra A. Yeskey, Pharm.D.
Director, Regulatory & Quality Affairs Division**

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

RQA is a BARDA Core Service





The Division of Regulatory and Quality Affairs (RQA)



RQA provides comprehensive capabilities in Regulatory Affairs and Quality Assurance across all organizational activities within BARDA



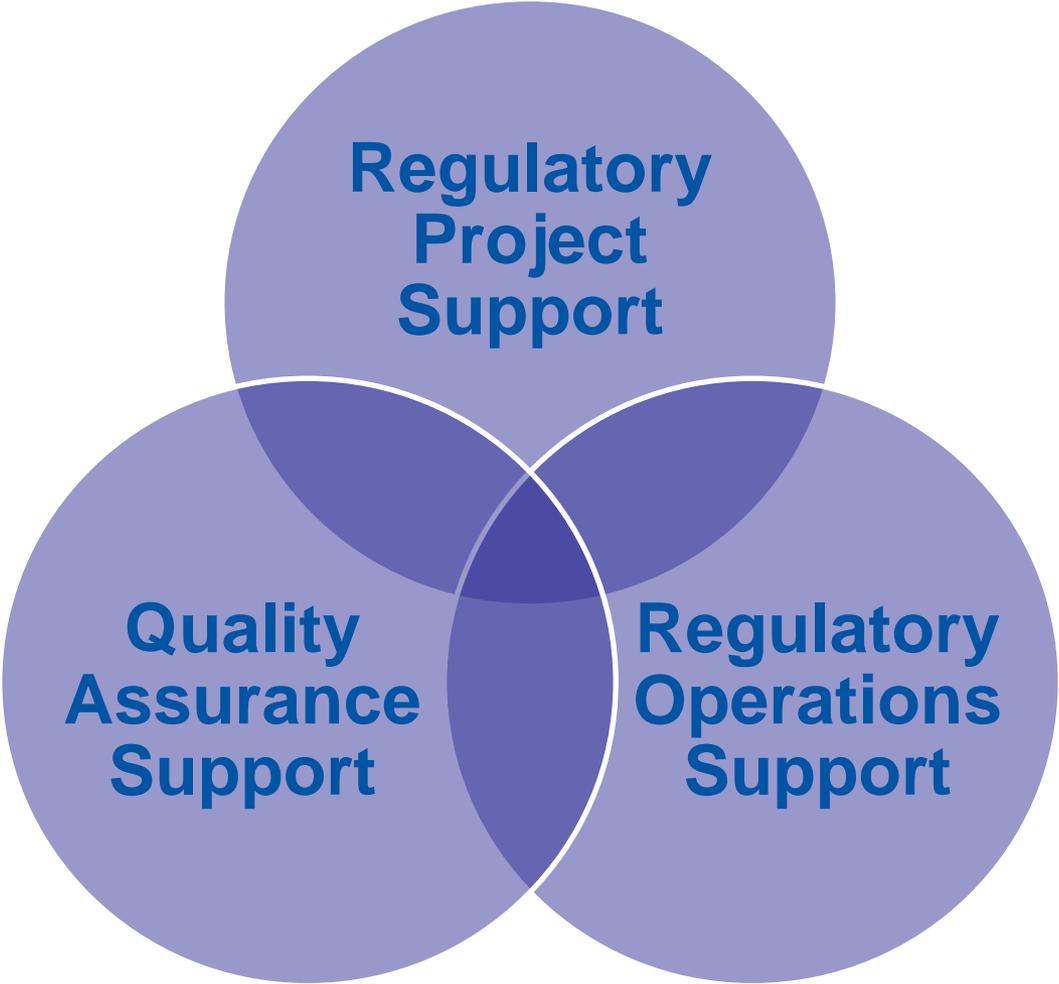
Who We Are



- 16 Professional Regulatory/Quality Staff Members
- 255+ years of experience in Regulatory Affairs and Quality Assurance
 - 18 Graduate or Professional degrees
 - Certifications in: RA (RAC – US and EU), GLPs (RQAP-GLP), Quality (CQA), Cytotechnology (SCT ASCP), Drug Development/Regulatory Science/Regulatory Compliance, Adult Learning
 - Backgrounds: Pharmacist, Nursing, Microbiologist, EMT, Cytotechnologist, FDA Reviewer, Training, Immunology, Toxicology, Neuroscience, Biochemistry, Physiology, Quality Assurance
 - Areas of Expertise: Biologics, Drugs, Antimicrobials, IVDs, Devices, Combination Products, Emergency Use Authorization, Regulatory Submissions/Operations, Clinical, CMC



RQA Role





RQA Initiatives



- Quality Audit Capability
 - GxP and Quality Systems Regulation Compliance and Remediation Auditing
 - Quality Systems Assessment and Improvement
 - PAI and Regulatory Audit Inspection Readiness and Training
- Regulatory Operations
 - eCDT capability
- FDA/BARDA contract with the United States Critical Illness and Injury Trials Group (USCIITG)