REGULATORY & QUALITY AFFAIRS SUPPORT

BARDA Industry Day 2015

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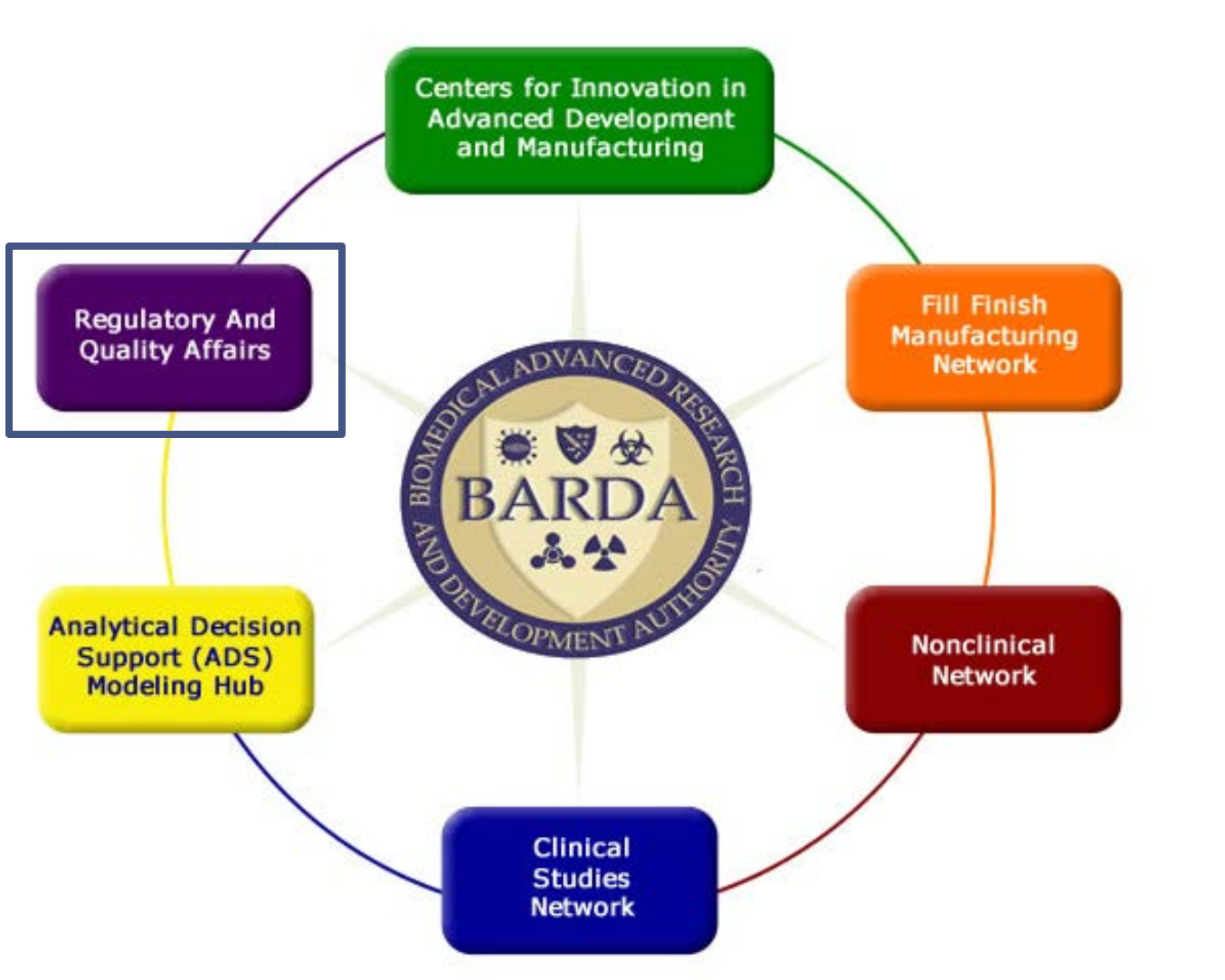
Resilient People. Healthy Communities. A Nation Prepared.

RQA is a BARDA Core Service



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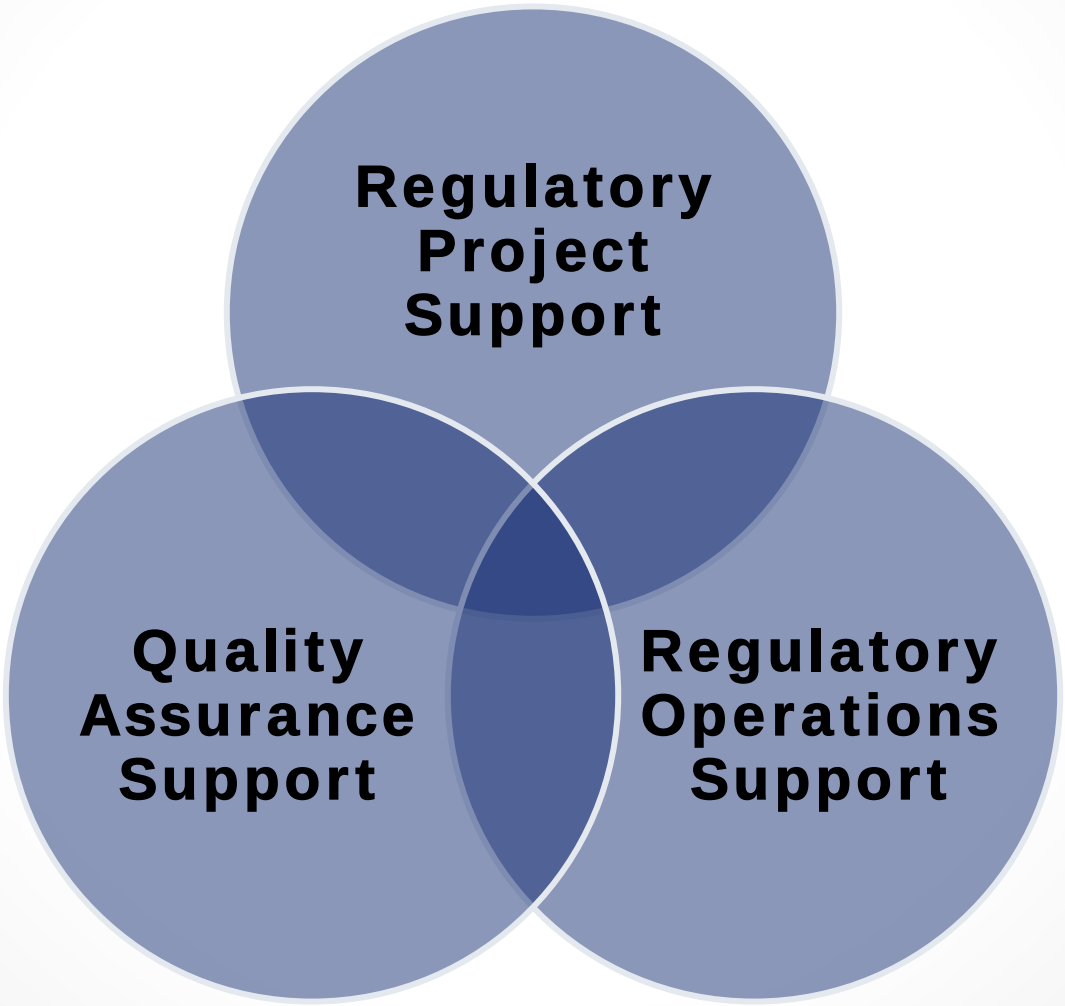


Regulatory Support

- Project Teams regulatory advice and guidance
- Monitor key regulatory milestones
- Track and analyze regulatory risks
- Review regulatory strategies
- Regulatory review of project documents
- Knowledge base for FDA current thinking
- FDA interactions
- Traditional Regulatory Affairs role in BARDA-sponsored development activities

Quality Support

- Project Teams quality advice and guidance
  - GxP regulations, applicable guidance, and industry standards
- Review and assess all quality issues related to BARDA projects
- Assess and track quality risk events
- Audit Program
- Manage Quality Acceptance of Procured MCMs
- Quality Management Plans for BARDA-sponsored development activities

Regulatory Operations Support

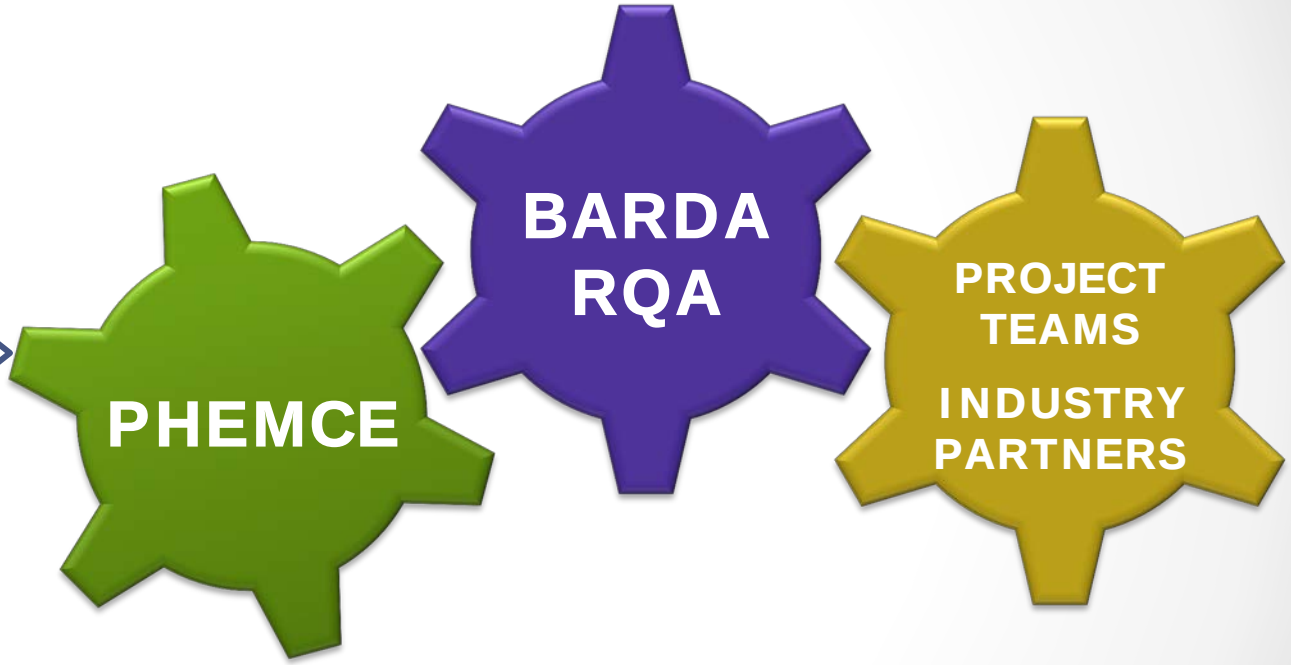
- Regulatory Documents and formal Regulatory Authority Communications
- Pre-EUAs and EUAs
- IND applications
- Pre-IND mechanism for nonclinical studies
- Other:
  - Letters of Intent
  - Official comments on FDA draft guidance documents
  - Requests for Expedited Review

Who We Are

- 16 Professional Staff
- 250+ Years Experience
- 18 Graduate and/or Professional Degrees
- Certifications
  - RAC (US and EU), RQAP-GLP, CQA, SCTASCP, DABT
- Background
  - Pharmacy, nursing, microbiology, EMT, Cytotechnology, FDA Reviewer, Training, Immunology, Toxicology, Bioengineering
- Expertise
  - Drugs, Biologics, Antimicrobials, IVDs, Devices, Combination Products, EUAs, Vaccines, Clinical, CMC

Advancing MCM Development

- FDA
- CDC
- NIH
- Integrated Project Teams
- Working Groups



Advancing MCM Development

Objective:

minimize inherent risks within the regulatory review and approval process for medical countermeasures