



---

# BARDA Regulatory and Quality Affairs Division: How We Are Here To Help

*BARDA Industry Day  
Boston, MA – October 18, 2011*



# Regulatory and Quality Affairs (RQA) BARDA



- RQA's Role

- Provide regulatory and quality support to BARDA Project Teams in development of vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies for contractors funded by BARDA

- RQA's Responsibilities

- Support PO/CO by monitoring key contracted activities with regulatory and quality implications
- Provide:
  - R/Q expertise on the project team
  - Input on regulatory and quality aspects of proposals and contracts
  - Assess regulatory strategies and regulatory risks of projects for Project Coordination Teams (PCT)



# REGULATORY AND QUALITY ASPECTS IN THE CONTRACT



## Understanding the regulatory approval requirements and applying them to BARDA contracts:

- Impact on project schedules
- Impact on budget, cost decisions, cost differentials
- Impact on regulatory strategy/pathway
- Contract and SOW modifications as needed during execution
- Awareness of GXP Requirements



# Regulatory and Quality Aspects of the Contract



- Regulatory Strategy, FDA Interactions, Submissions
- Understand Document Requirements
  - BARDA document review process
  - Appropriate document quality and compliance (SOPs, protocols, submissions, etc.)
- Compliance
  - Regulations: GXPs' – GLP, GCP, GMP
  - HHS: OHRP Requirements and Federal Wide Assurance (Human Studies); Office of Laboratory Animal Welfare (OLAW) Assurance requirements (Animal Studies)
  - Industry Standards: USP
- Subcontracts
  - Regulatory components of subcontracts
  - Quality Agreements with subcontractors
  - Regulatory submissions by subcontractors



# Pre-EUA Requests and EUA Submissions



- Not a regulatory pathway to market
- In general filings are made by USG, not by sponsor
- Reference Online Course: Emergency Use Authorization
  - Developed by FDA and CDC – A Great Resource

<http://emergency.cdc.gov/training/eua/index.html>



---

# REGULATORY STRATEGY



# Defining a Regulatory Pathway



- Challenges in defining a product pathway to approval, licensure, or clearance:
  - The “Animal Rule” - (21 CFR 314.600 for drugs; 21 CFR 601.90 for biological products) and animal models
  - Development of manufacturing process
  - Regulatory pathway for IVDs
  - Confounding Factors/Non-interference
  - Lifecycle issues
  - Many others



# Developing a Regulatory Strategy



(Adapted from "Developing an Effective Regulatory Strategy", Mark D. Kramer, *Regulatory Focus*, December 2010)

## **Step One: Ask Questions**

- What data is necessary to support desired claims? Lifecycle issues? Plans for Manufacture and GMP compliance? What will help assemble a complete picture of the scope of testing required to gain approval?

## **Step Two: Do Some Regulatory Information Gathering**

- Gather regulatory information and available data. Evaluate what could impact your strategy. Understand the regulatory landscape.

## **Step Three: Create a Draft Strategy Document**

- Key elements should be:
  - *Define objectives*
  - *Identify potential regulatory pathway*
  - *Outline plans for preclinical testing and clinical investigations*
  - *Lay out strategy for communicating with FDA (e.g. TPP)*

## **Step Four: Present and Confirm Strategy**

- Circulate draft strategy document for input among cross functional project team and obtain feedback. Is strategy sound and does it addresses objectives? Reasonable and practical strategy?
- Sound strategy informs expectations, evaluates potential hurdles and proposes proactive plans to address them.

## **Step Five: Consider It a Living Document**

- Set schedule for periodic review of Regulatory Strategy Document and update as necessary to reflect current status of development. Serves as a tracking, planning, and risk management tool.



---

# REGULATORY EXPERTISE ON THE PROJECT TEAM



# Regulatory: Integral To The Project Team



- The BARDA Team:
  - Project Officer, Contracting Officer, Program Management, SMEs, RQA
- The Sponsor Team: Build Your Team Wisely
  - Weak teams have negative consequences. Regulatory should be incorporated from the beginning and not be an afterthought
  - Build a strong regulatory foundation on your team and integrate into the development cycle
    - Take time to develop and discuss team regulatory processes
    - Establish ground rules for regulatory processes and communications within the project team
    - Maximize probability of regulatory and programmatic success by smart allocation of regulatory resources



# RQA Project Support Activities



## What we do everyday

### Participation

- Technical Evaluation Panels
- Pre-Award Activities
- Site Visits/Audits
- PCT Meetings
- IPR
- Interagency Coordination

### Document Review

- Requirements RFP
- Source Selection Plan
- Contract/SOW
- Project-Related Deliverables
- Sponsor Regulatory/Quality Documents

### Comments to Sponsor

- Records of Review
- RQA Comments to PO
- PO Forwards Comments to Sponsor
- Sponsor Response
- Issue Resolution



---

# HOW WE CAN HELP YOU IMPROVE YOUR INTERACTIONS WITH THE FDA AND FDA SUBMISSIONS



## Who We Are



- 13 staff members
- 240 years of experience in Regulatory Affairs and Quality
  - Mean = 19 years
- Product areas: biologics, drugs, IVDs, devices, and combination products
- 11 Graduate and Doctoral degrees in science
- Certifications in RA (RAC), GLPs (RQAP-GLP), Quality (CQA), and Acquisition



# Company Types



## Industry

- Start-up
- Midsize Pharma
- Large Pharma
- Testing Laboratory
- Clinical Research Organization

## Government/Academia

- FDA
- NIH
- CDC
- DOD
- University
- State Government
- UN/PAHO



## Scientific/Technical Areas



- ✓ Analytical Development
- ✓ Chemistry
- ✓ PK / Drug Metabolism
- ✓ Microbiology
- ✓ Toxicology
- ✓ Clinical Science
- ✓ Biologics and Biotechnology
- ✓ Risk Assessment and Management
- ✓ Compliance
- ✓ API, Oral Dosage Forms, Aseptic Manufacture
- ✓ Quality Management



# Therapeutic Areas



- Allergy
- Anti-inflammatory
- Anti-toxin
- Cardiovascular
- Endocrinology
- Epilepsy
- Gastroenterology
- Immunology
- Infectious disease
- Nephrology
- Neurology
- Oncology
- Ophthalmology
- Osteoarthritis
- Pain
- Pulmonary
- Reproduction
- Rheumatology
- Sepsis
- Urology

## MEDICAL COUNTERMEASURES

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



# Key Regulatory Documents



- Target Product Profile (TPP)
- Assurances of Compliance
  - Federal-wide Assurance (FWA)
  - Animal Welfare Assurance
- FDA Meeting Packages
- FDA Meeting Minutes
- IDEs, 510(k)s, PMAs, INDs, NDAs, BLAs, Amendments, Supplements,
- Annual Reports
- Safety Reports
- Product Labeling
- Study Reports
- Project Plans, Protocols, SOPs
- Pre-EUA Requests/EUA-supported data submissions



# Due Diligence Regarding Regulatory Consultants

---



Consider the following:

- Appropriateness of background and experience
- Cost appropriateness
- Projected number of hours for the task



## Improve Interactions with FDA



### BARDA RQA:

- Serves as resource for regulatory and quality information
  - Understands requirements and constraints for MCM development
- Stays up-to-date with FDA's current thinking through interactions with the Agency
- Understands FDA's focus for specific stages of drug development
- Is experienced with FDA review divisions for MCM indications
- Assists with meeting preparation



# FDA meetings



- Review of meeting package to insure that all required components are included
- Assist in identifying FDA meeting attendees
- Assure, with Subject Matter Experts, that necessary data and information are included
- Assure that regulatory questions are necessary and correct
- Assure that questions asked are appropriate
  - Scientific and development stage
- Assure that the FDA's time is not wasted
- Post-meeting assistance in interpreting FDA feedback
  - Independent viewpoint



# Thank You!



Suzanne M. Sensabaugh, MS, MBA  
Senior Regulatory Advisor

*CMI Consultant*

*supporting the office of the*

HHS/OS/ASPR/BARDA/RQA

Direct: 202-205-3723

Blackberry: 202-407-3920

suzanne.sensabaugh@hhs.gov

M. Lisa Borek, RAC  
Regulatory Affairs Specialist

*BARDA Regulatory and Quality  
Affairs Division*

HHS/OS/ASPR/BARDA/RQA

Office: (202) 205-1641

Blackberry: (202) 329-9131

lisa.borek@hhs.gov



# Interfacing with BARDA



- [www.phe.gov](http://www.phe.gov)
  - Program description, information, news, announcements
- [www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov)
  - Portal to BARDA
  - Register, request a meeting
  - Tech Watch
- [www.fedbizopps.gov](http://www.fedbizopps.gov)
  - Official announcements and detailed information about all government contract solicitations