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

BARDA Industry Day
Boston, MA – October 18, 2011
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
Regulatory and Quality 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: GXP’s – 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*)

<table>
<thead>
<tr>
<th>Step One: Ask Questions</th>
<th>• 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?</th>
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<td>Step Two: Do Some Regulatory Information Gathering</td>
<td>• Gather regulatory information and available data. Evaluate what could impact your strategy. Understand the regulatory landscape.</td>
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| 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

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!

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Interfacing with BARDA

• www.phe.gov
  — Program description, information, news, announcements

• www.medicalcountermeasures.gov
  — Portal to BARDA
  — Register, request a meeting
  — Tech Watch

• www.fedbizopps.gov
  — Official announcements and detailed information about all government contract solicitations