Regulatory Affairs and Quality Advisory Board

A Parenteral Drug Association (PDA) Advisory Board
Introduction

• Ladies and Gentlemen, I am happy to be here with you tonight
• NE Chapter Member since 1986
• Work in Bethesda, home in MA

Richard V. Levy, Ph.D.
Member of PDA for 28 years
Member, PDA Board of Directors 1999-2005
Treasurer and Chair-elect before joining PDA staff in September of 2005
Currently Senior VP of Scientific and Regulatory Affairs
Did you ever wonder how PDA’s Regulatory Comments were developed?

2014 PDA Regulatory Comments


- EU Good Distribution Practice of Medicinal Products for Human Use July 17, 2014
  PDA provided comments on the new EU Guideline on “Good Distribution Practice of Medicinal Products for Human Use,” July 17, 2014.

  Health Canada Quality (Chemistry and Manufacturing) Draft Guidance Document: New Drug Submissions (NDSs) and Abbreviated New Drug Submissions (ANDSs)” April 9, 2014.

- EU GMP Annex 15 Qualification and Validation May 29, 2014

- FDA Draft Guidance for Industry Analytical Procedures and Methods Validation May 20, 2014
  PDA provided comments on FDA Guidance for “Industry Analytical Procedures and Methods Validation for Drugs and Biologics”, May 20, 2014.
It helps by understanding more about one of PDA’s Advisory Boards: RAQAB

• Today’s presentation will
  – Introduce the Mission, Roles & Responsibilities
  – Discuss how members are selected
  – Discuss Activities
  – Provide an overview of the regulatory commenting process
The mission of the PDA Regulatory Affairs & Quality Advisory Board (RAQAB) is to serve the PDA membership by influencing scientific-based regulations and providing interpretation on quality and regulatory issues affecting the development, manufacturing, and control of healthcare products.
RAQAB Outreach Project

• RAQAB has a goal of improving communication of RAQAB activities to the membership
• RAQAB Members will attend PDA Chapter meetings on an ongoing basis to provide updates on activities
• This is the first such presentation at the NE Chapter
• Anil Sawant who presented before me is an RAQAB member
Where RAQAB Fits in PDA Structure

- PDA Board of Directors (BoD)
- Advisory Boards (AB)
  - Regulatory Affairs & Quality Advisory Board (RAQAB)
  - Biotechnology Advisory Board (BioAB)
  - Science Advisory Board (SAB)
- Interest Groups (IG)
  - Scientific-Tech Discussion Groups
- PDA Communication Systems
  - Conferences
  - Publications (TR / Journal / Books / PDA Letter)
  - Training and Education
RAQAB Role: What We Do

- Identifies current regulatory and quality issues affecting development, manufacturing and quality of healthcare products
- Advises PDA on the impact of such issues
- Recommends a plan of action for PDA response
- Sponsors projects to improve communication or responses
RAQAB: What We Do (continued)

• Typical board activities may include evaluation of:
  – Proposed regulations
  – Technical guidance documents
  – Inspection procedures
  – Policy statements
  – Pharmacopoeia proposals
  – Standards activities
  – Other related items developed by the e.g. US FDA, EMA, WHO, other global Regulatory Authorities and/or bodies

• As appropriate, the RAQAB develops and makes recommendations to PDA Board on proposed Association positions
RAQAB Membership

• RAQAB is led by a Chair and Vice-Chair
• The RAQAB Chair and Vice-Chair are approved by the Board of Directors of PDA and assume the post for a period of three (3) years.
• The RAQAB is comprised of up to 25 voting and non-voting members.
• Membership is intentionally diverse
  – Regional Representatives for certain areas of the world
  – Other members for technical background and expertise
• Two (2) consecutive, 3 year terms may be held
  – Members may reapply again after taking at least a year away
Current RAQAB Members

- Ruhi Ahmed
- Jeff Broadfoot
- Robert Caunce
- Claudio Correa Cappai
- Veronique Davoust
- John Finkbohner
- Mirko Gabriele
- Karen Ginsbury
- Jeff Hartmann
- Hongyang Li
- Elisabeth Meyers

- Shin-ichiro Mohri
- Emma Ramnarine
- Edwin Rivera
- Stephan Rönninger
- Junko Sasaki
- Anil Sawant
- Siegfried Schmitt
- Susan J. Schniepp
- Jackie Vevia-Panter
- Wendy Zwolenski-Lambert
Company Affiliations of RAQAB Members

- Allergy Labs
- Amgen
- Astra Zeneca
- Dainippon Sumitomo
- Emergent
- Genentech
- Hospira
- Johnson & Johnson
- Kyowa Hakko Kirin
- Merck

- Novartis
- NSF Health Sciences
- PAREXEL
- Patheon Italia
- PCI
- Pfizer
- Roche
- Sanofi
- Ultragenerix
RAQAB Liaisons

- RAQAB members serve as liaisons to the following:
  - Biotech Advisory Board (BioAB)
  - Science Advisory Board (SAB)
  - PDA Training and Research Institute (TRI)
  - Board of Directors
  - Technical Book Committee
  - PDA Letter Editorial Board
  - Portfolio Steering Committee
  - Many also serve on conference planning committees
RAQAB is also supported by non-voting PDA staff members and the leaders of the associated PDA Interest Groups (IG)

Some IGs coordinated by RAQAB

- Outsourced Operations
- Supply Chain Management
- Quality Risk Management
- Inspection Trends
- Pharmacovigilance
- Clinical Trial Material
- Pharmacopeial
- Quality Systems
- Regulatory Affairs
RAQAB Membership is Global

- Australia: 14%
- Canada: 5%
- Middle East: 5%
- South America: 5%
- Asia: 5%
- Europe: 23%
- US: 45%
Member Selection Process

1. **Assess the need for new RAQAB members**
   - Prompted by expiration of specific terms, members resigning from advisory board or the need to expand the advisory board skills, knowledge and expertise

2. **Assessment process of potential new members:**
   - AB recommendations, member recommendations or requests, review of member database
     - Demonstrate commitment to PDA / volunteering
     - e.g., length of membership, PDA activities experience, other outside experience, ability to serve
   - Meet objective of a broad & diverse group of experts: by expertise / knowledge; by region; and by employment (small and large firms; consultancies)
3. **Screening Process**
   - RAQAB Leadership team (Chair, Vice-Chair, Immediate Past Chair & PDA Staff) review a pool of candidate members
   - Solicit updated information and confirm the candidates are interested and able to serve

4. **Selection process**
   - RAQAB to approve the nomination of new member and returning members (vote taken)
   - BoD to approve new chair and vice-chair
   - Approach individuals for RAQAB membership
RAQAB Member Expectations

• Participation in the RAQAB requires a commitment on the part of every member of the advisory board
• Much of the work undertaken by the RAQAB has very specific time constraints and requires adherence to strict schedules
• Ensure that comments are prepared, reviewed and approved in a timely manner for submission to Regulatory authorities and/or other bodies by specified deadlines
• Attend/participate in RAQAB meetings
  • Face to Face Strategy Meetings (Target 2 times year, PDA Annual Meeting, PDA/FDA or PDA/EMA Meeting)
  • Monthly Teleconferences (about 1.5 h; required unless time zone restrictions)

• Provide input & comments as part of RAQAB commenting process and complete ballot once comments are drafted.

• Share current regulatory news or hot topics from your region.
PDA Regulatory Commenting
Primary Sources of Draft Documents

- FDA
- EMA
- MHLW/PMDA
- ICH
- PIC/S
- WHO
- BRICK Countries
- If PDA input requested
PDA Commenting Competencies

Applied Sciences:
- Aseptic Processing
- Manufacturing and Testing
- Process Engineering
- Biotechnology
- Microbiology
- Process Validation

Quality and Regulatory:
- Compliance and GMP
- Supply Chain
- Quality Systems
- Submission Content and Format

Products:
- API and DP for Parenteral and Other Drugs (primary)
- Combination Products, Vaccines, Veterinary (if in topic area)

Not Typically in Scope:
- GCP, GLP, Labeling, Med Errors
PDA Decision to Comment

- Subjects, Issues, Documents
  - Primary Sources
  - Impacts PDA competencies
    - No action
    - Yes
      - Expertise and Response Time Available
        - No action
        - Yes
          - Task Force Initiated
PDA Regulatory Commenting Activity

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In summary: RAQAB…

- Comprised of PDA Volunteers
- Identifies current regulatory and quality issues affecting development, manufacturing and quality of healthcare products
- Advises PDA on the impact of such issues
- Recommends a plan of action for PDA regulatory responses
- Manages sponsored Interest Groups
- Sponsors projects to improve quality and regulatory industry practices
Questions?