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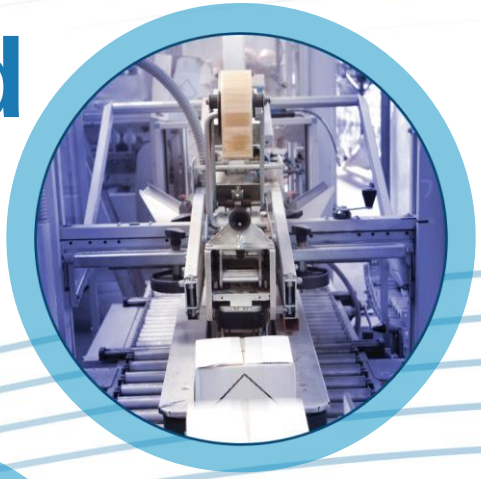
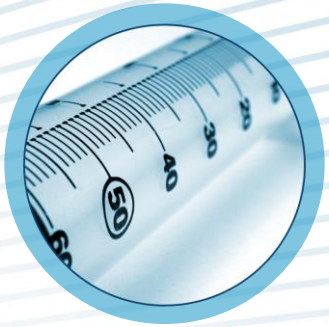
Regulatory Affairs and Quality Advisory Board



A Parenteral Drug Association (PDA) Advisory Board

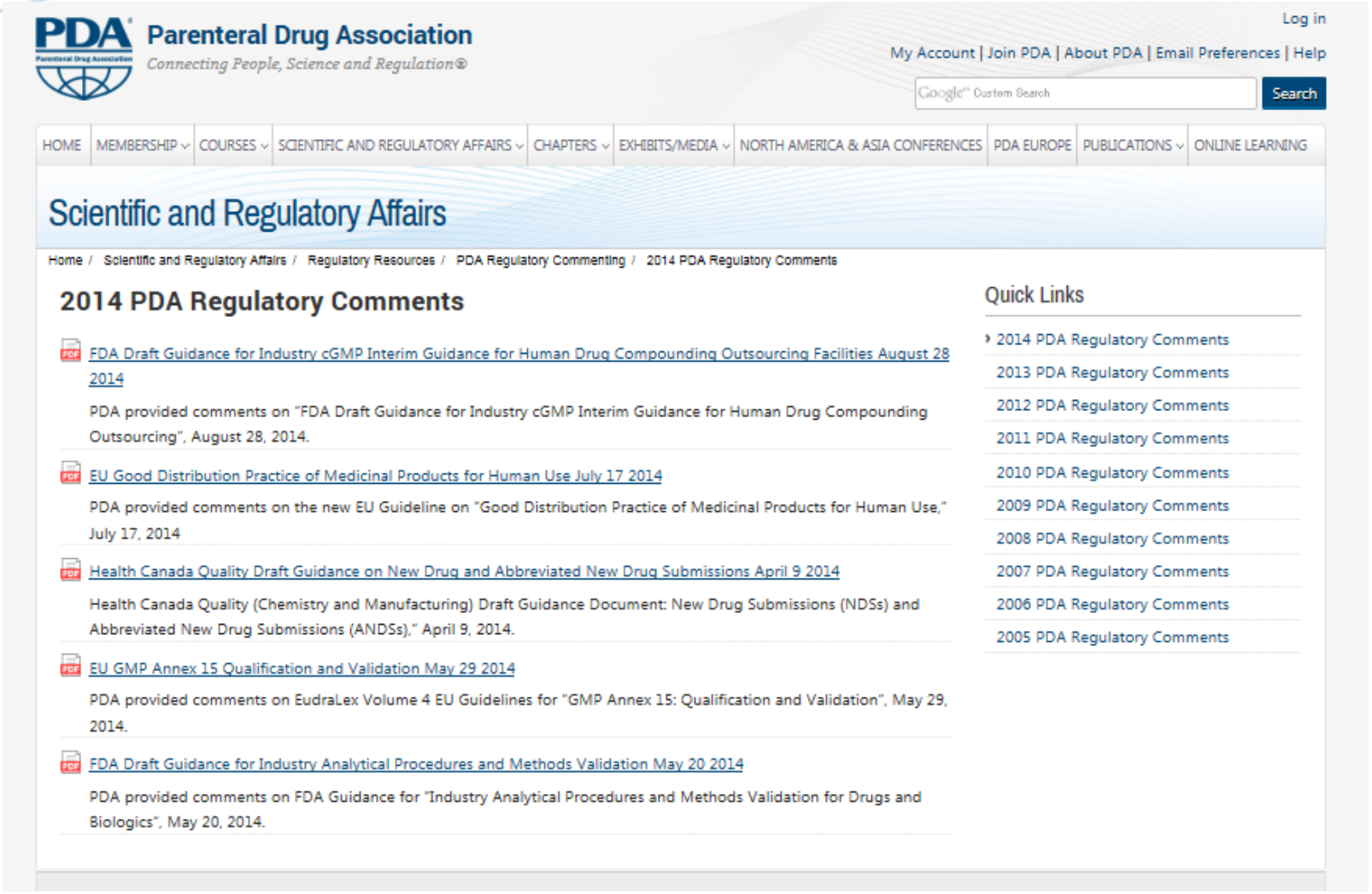


Introduction

- 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?



Parenteral Drug Association
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Scientific and Regulatory Affairs

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2014 PDA Regulatory Comments

FDA Draft Guidance for Industry cGMP Interim Guidance for Human Drug Compounding Outsourcing Facilities August 28 2014

PDA provided comments on "FDA Draft Guidance for Industry cGMP Interim Guidance for Human Drug Compounding Outsourcing", August 28, 2014.

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Health Canada Quality Draft Guidance on New Drug and Abbreviated New Drug Submissions April 9 2014

Health Canada Quality (Chemistry and Manufacturing) Draft Guidance Document: New Drug Submissions (NDSs) and Abbreviated New Drug Submissions (ANDSs)," April 9, 2014.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

PDA provided comments on EudraLex Volume 4 EU Guidelines for "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FDA Draft Guidance for Industry Analytical Procedures and Methods Validation May 20 2014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.

Quick Links

- 2014 PDA Regulatory Comments
- 2013 PDA Regulatory Comments
- 2012 PDA Regulatory Comments
- 2011 PDA Regulatory Comments
- 2010 PDA Regulatory Comments
- 2009 PDA Regulatory Comments
- 2008 PDA Regulatory Comments
- 2007 PDA Regulatory Comments
- 2006 PDA Regulatory Comments
- 2005 PDA Regulatory Comments

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

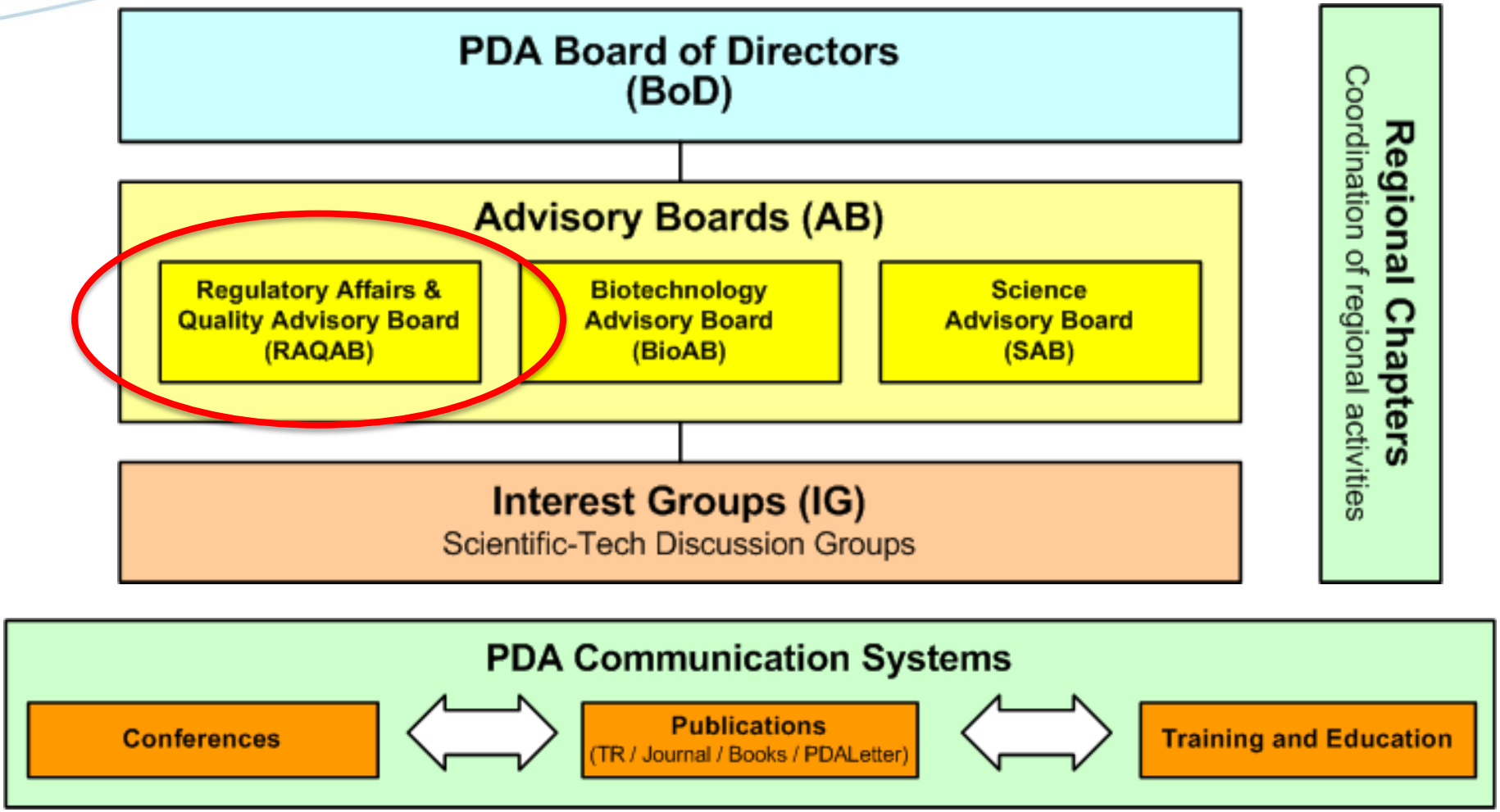
RAQAB Mission Statement

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



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
- Ultragenix


PDA
Parenteral Drug Association

RAQAB Liaisons

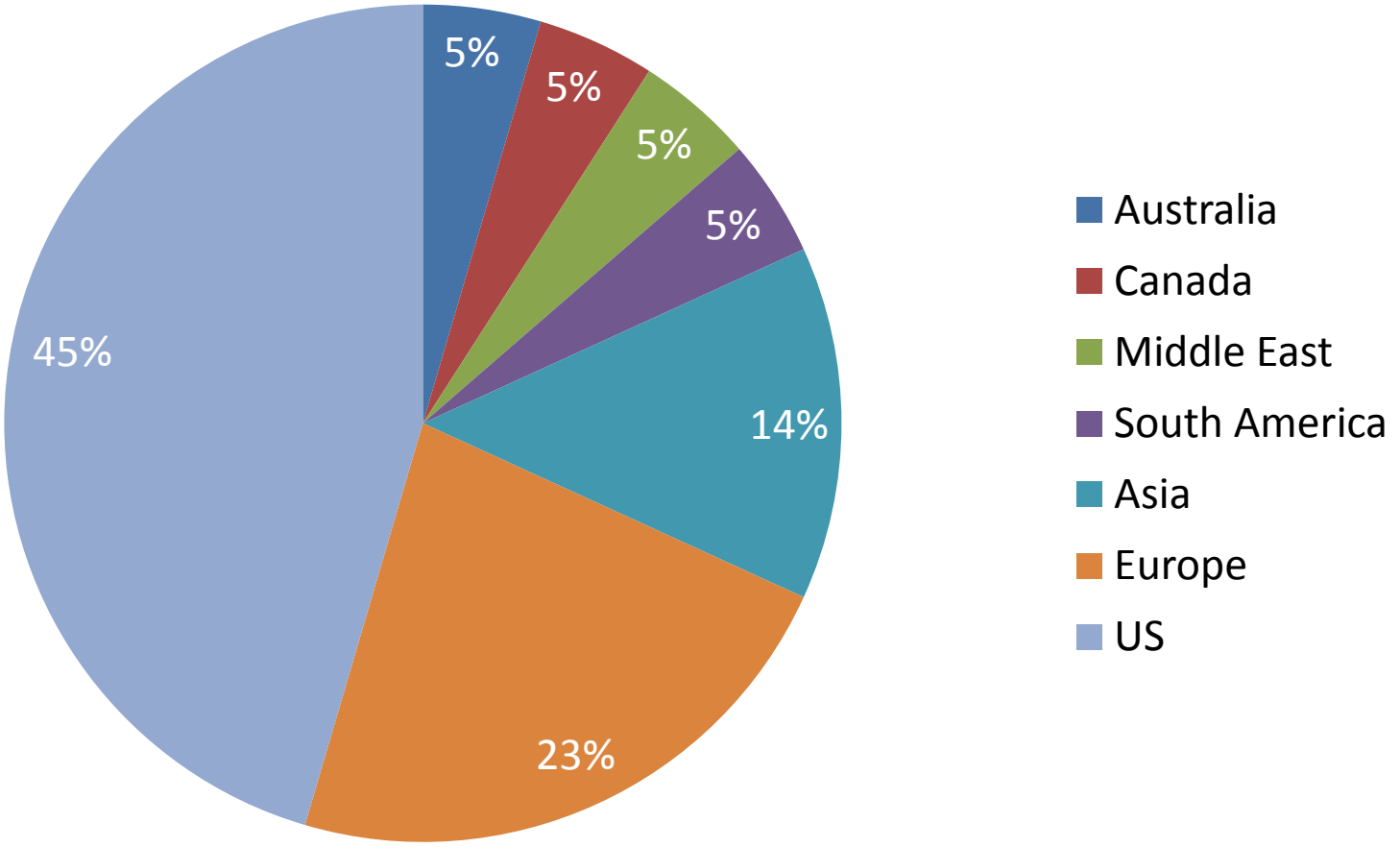
- RAQAB members serve as liaisons to the following:
  - Biotech Advisory Board (BioAB)
  - Science Advisory Board (SAB)
  - PDA Training and Research Institute (TRI)
  - Board of Directors
  - Technical Book Committee
  - PDA Letter Editorial Board
  - Portfolio Steering Committee
  - Many also serve on conference planning committees

RAQAB Membership (Continued)

- 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



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)

Member Selection Process (cont.)

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

RAQAB Member Responsibilities

- 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

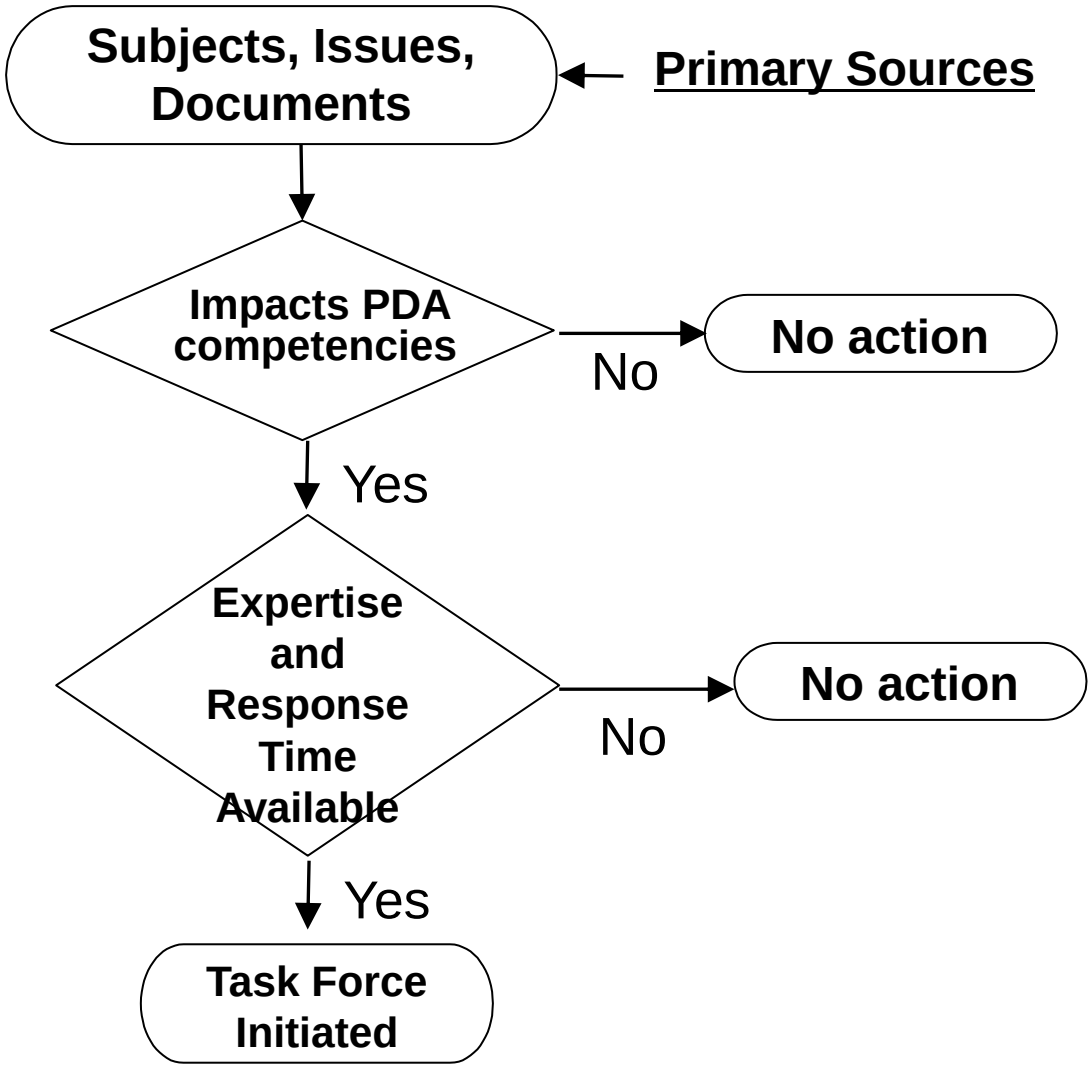
Products:

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

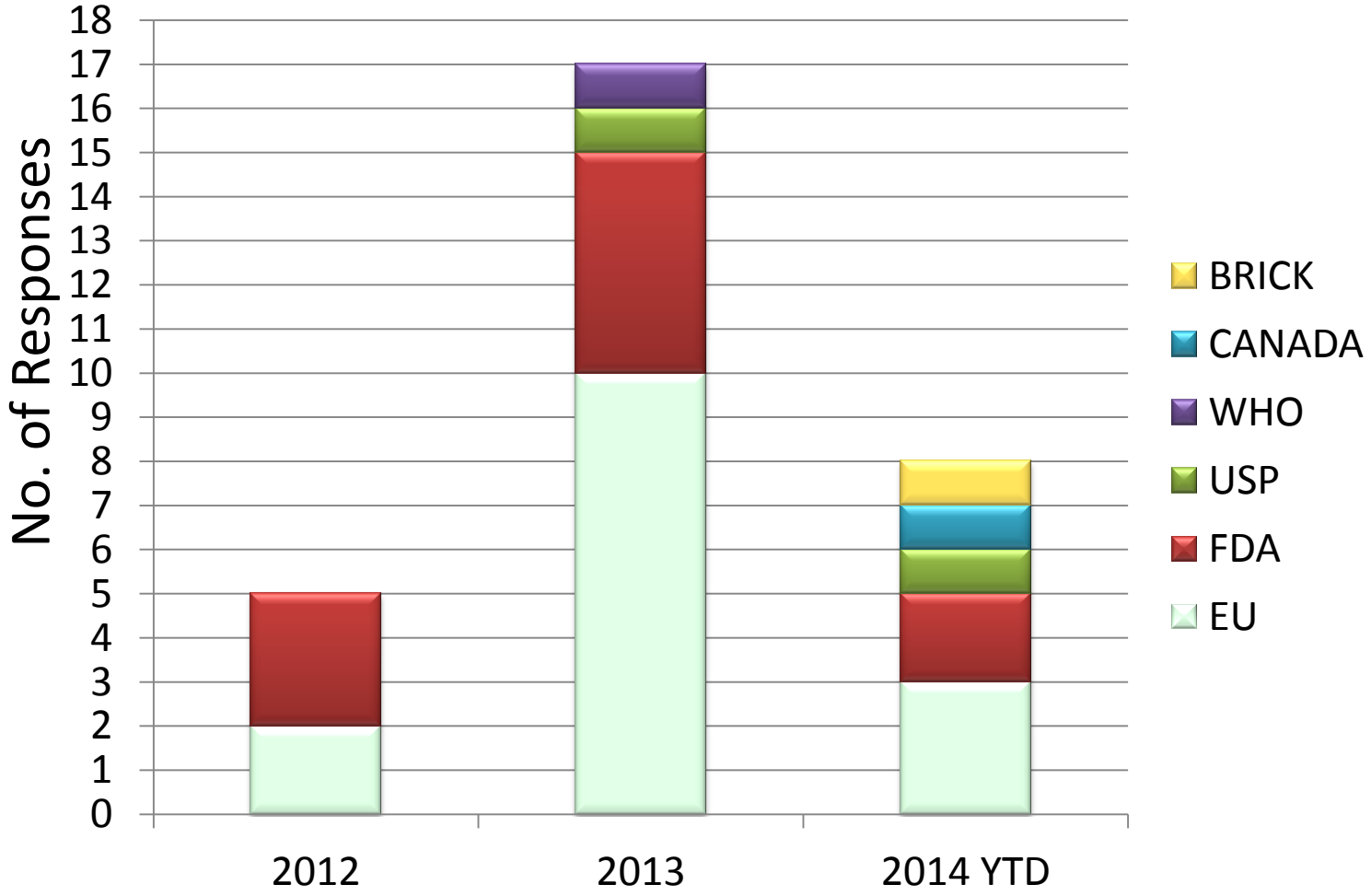
Not Typically in Scope:

- GCP, GLP, Labeling, Med Errors

PDA Decision to Comment



PDA Regulatory Commenting Activity



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?