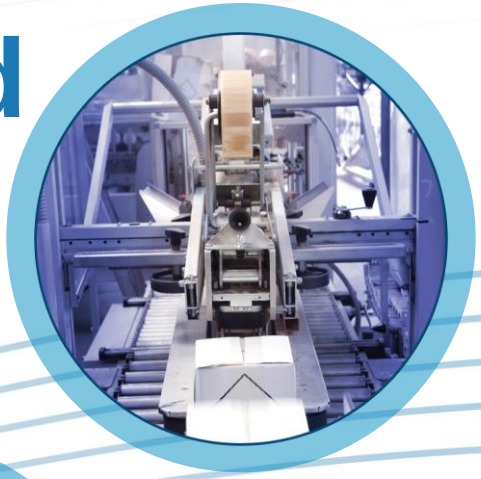
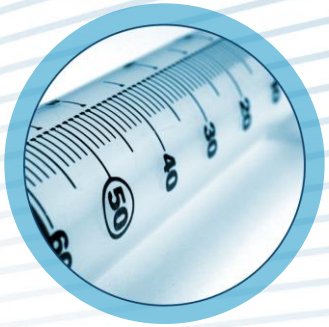
Connecting People, Science and Regulation®

Regulatory Affairs & Quality Advisory Board



A Parenteral Drug Association (PDA) Advisory Board



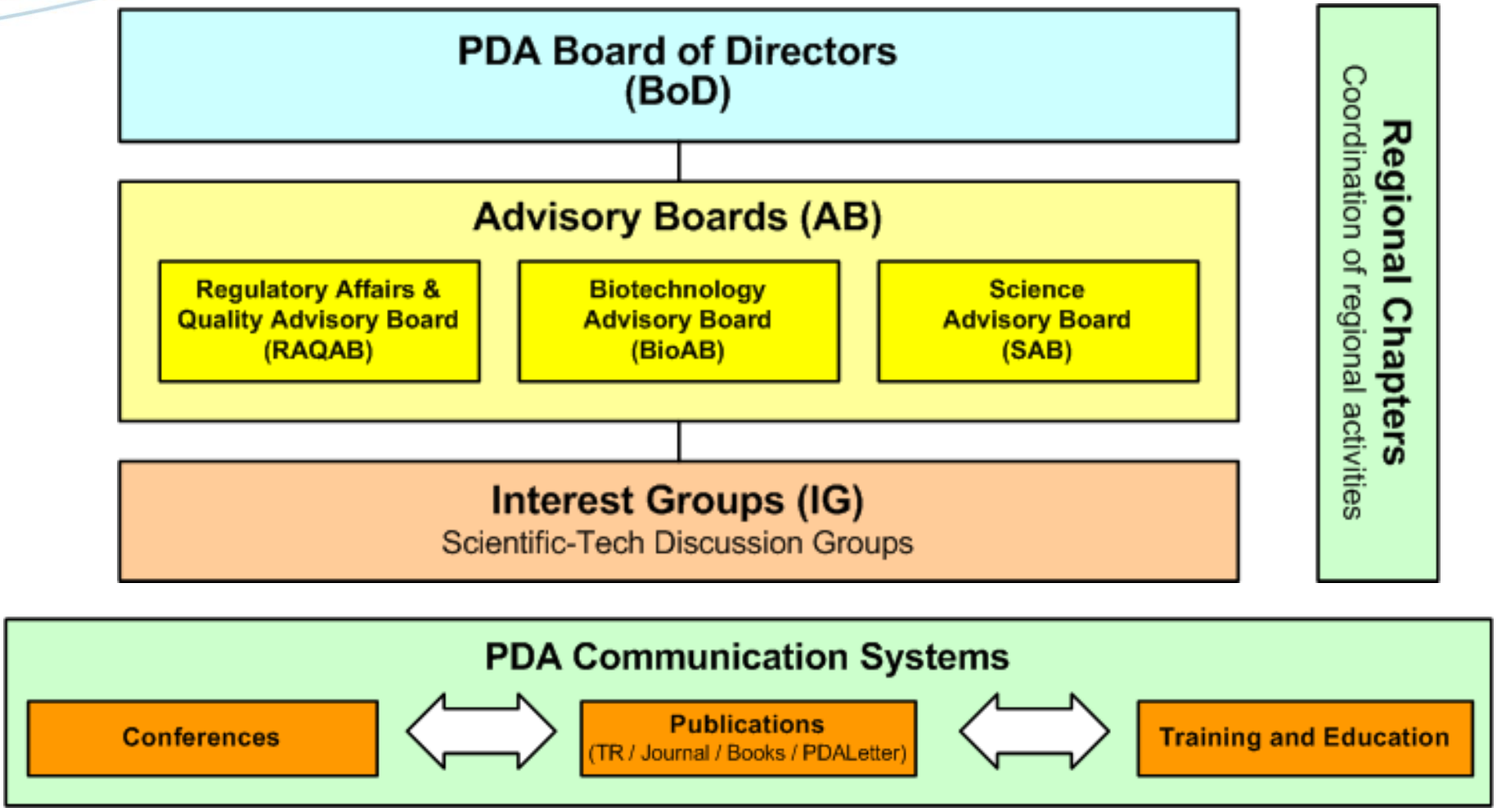
Purpose of Presentation

- RAQAB has a goal of improving communication of RAQAB activities to the membership
- RAQAB Members will attempt to attend PDA Chapter meetings on an ongoing basis to provide updates on activities
- Today's presentation will
  - Introduce the Mission, Roles & Responsibilities
  - Discuss how members are selected
  - Provide an overview of the commenting process and highlight metrics as one example

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.

Where RAQAB Fits in PDA Structure



RAQAB Role: What We Do

The Regulatory Affairs and Quality Advisory Board (RAQAB):

1. Identifies current regulatory and quality issues affecting development, manufacturing and quality of healthcare products
2. Advises PDA on the impact of such issues
3. Recommends a plan of action for PDA response
4. Sponsors projects to improve communication or responses

What We Do (cont.)

- Typical issues may include evaluation of proposed regulations, technical guidance documents, inspection procedures, policy statements, Pharmacopoeia proposals, Standards activities and 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 considering Regional Representatives for certain areas of the world and other members for technical background and expertise
- Two (2) consecutive, 3 year terms may be held.
- Members may reapply again after taking a year away.

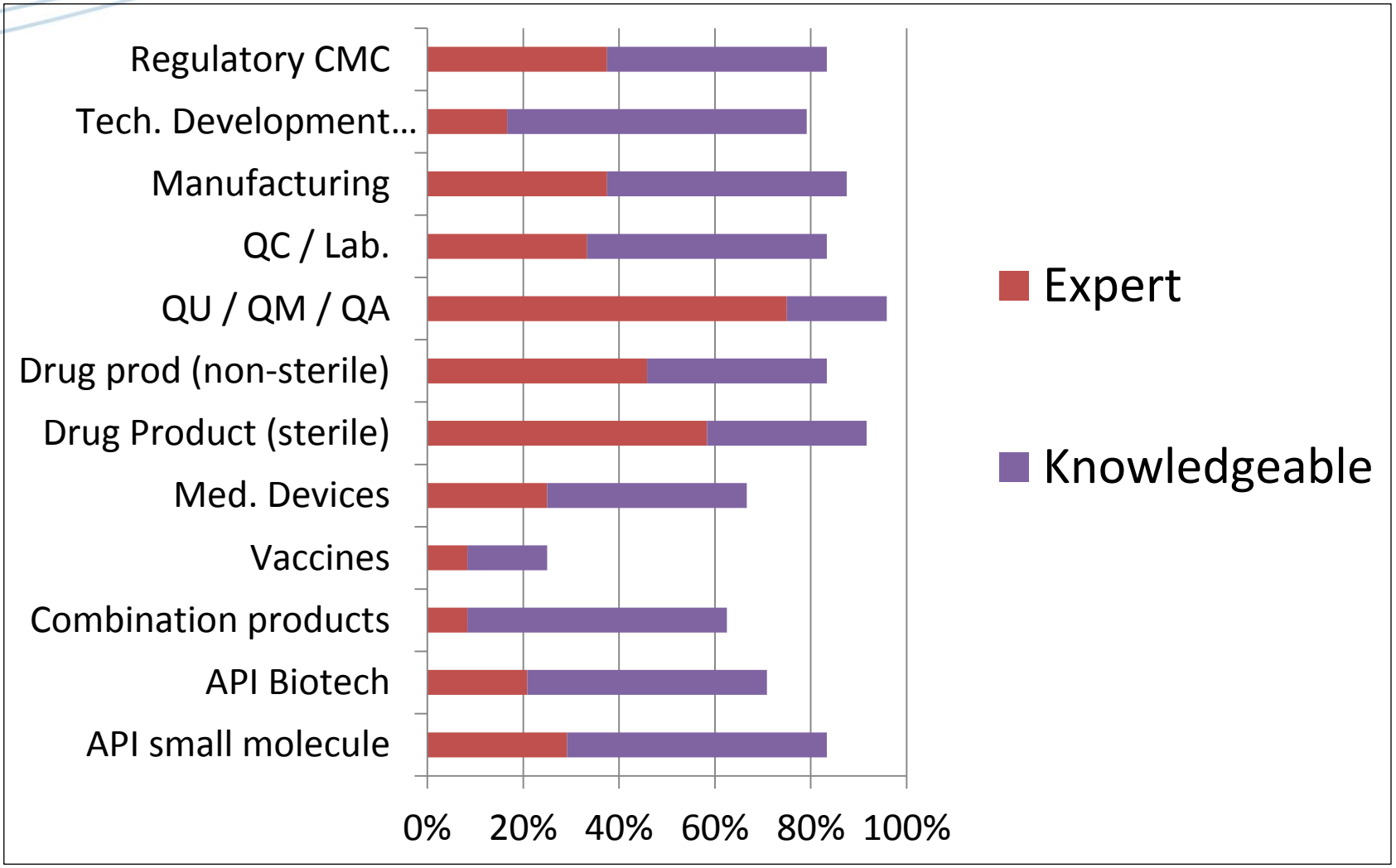
Current RAQAB Members

- Ruhi Ahmed
- Jeff Broadfoot
- Alan Burns
- Robert Caunce
- Claudio Correa Cappai
- Veronique Davoust
- John Finkbohner
- Jeff Hartmann
- Hongyang Li
- Barbara Jentges
- Lauren Melton
- Elisabeth Meyers
- Shin-ichiro Mohri
- Haley Park
- 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
- Alnylam
- Amgen
- Dainippon Sumitomo
- Emergent
- Hospira
- Johnson & Johnson
- Kyowa Hakko Kirin
- MedImmune/Astra Zeneca
- Merck
- Novartis
- Paraxel
- Pfizer
- PhACT GmbH
- Roche
- Sanofi
- Ultragenix

RAQAB Members Expertise



RAQAB Liaisons

RAQAB members serve as liaisons to the following:

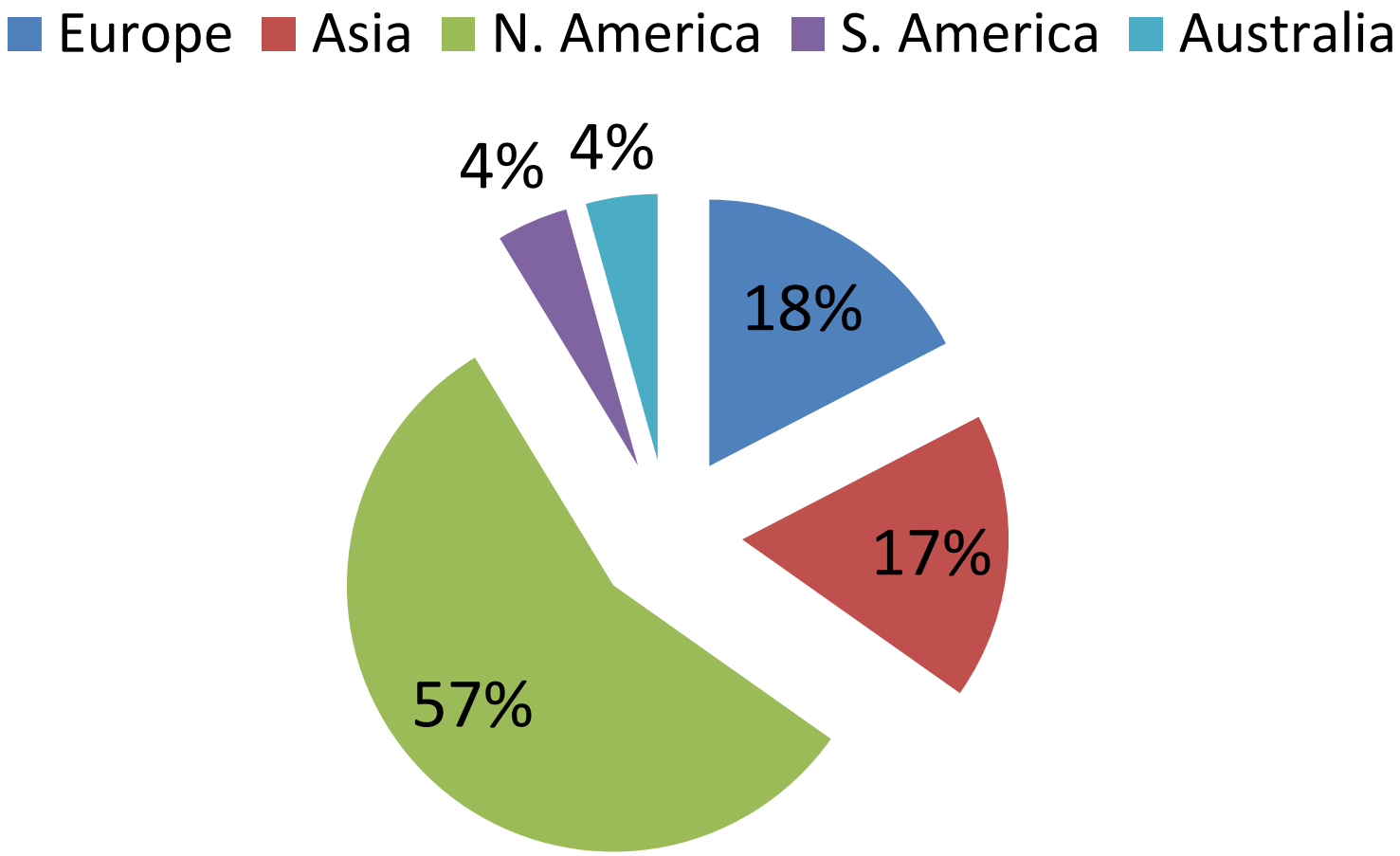
- Biotech Advisory Board
- Science Advisory Board
- PDA Training and Research Institute (TRI)
- Board of Directors- Stephan R.
- Book Committee
- PDA Letter Editorial Board
- Portfolio Steering Committee

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)
- 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

2. **Assessment process of potential new members:**

   – Commitment to PDA / volunteering e.g. length of membership, PDA activities experience, other outside experience

   – Broad & diverse group of experts:
   By Expertise / Knowledge, By Region; 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 interested members
- Solicit updated information and confirm the candidates are still interested

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

Responsibilities & 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 to 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

1. Attendance/participation 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*)
2. Provide input & comments as part of RAQAB commenting process and complete ballot once comments are drafted.
3. 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

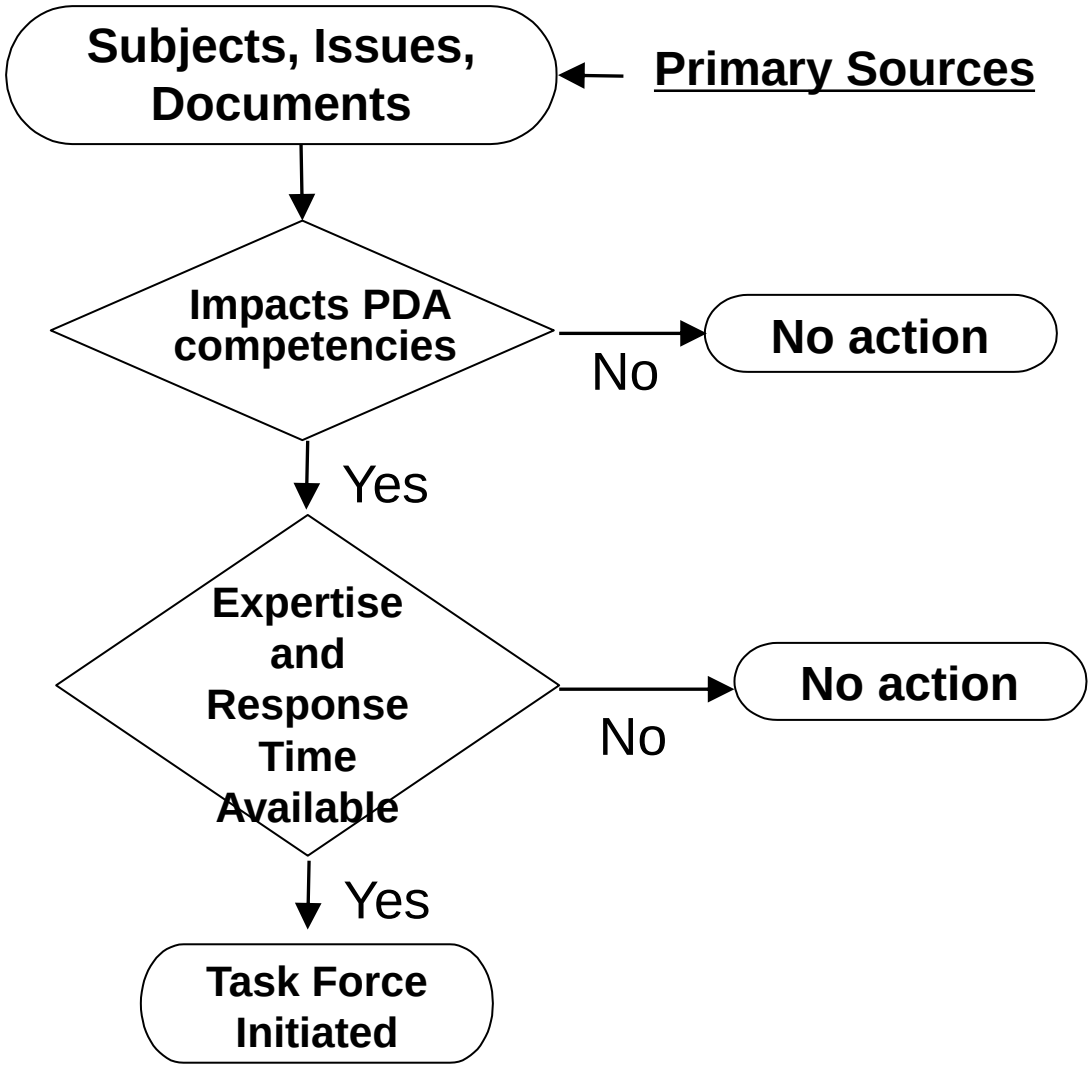
Products:

- 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



Pharmaceutical Quality Metrics

PDA Commenting and Influence

FDA Drug Shortages Task Force Requests Metrics Input Feb 2013

- What metrics to manufacturers currently use to monitor production quality?
- To what extent do purchasers and prescribers use information about manufacturing quality when deciding how to purchase or utilize products?
- What kind of manufacturing quality metrics might be valuable for manufacturers when choosing a contract manufacturer?
- How frequently would such metrics need to be updated?

PDA Responds March 2013

See PDA.org for complete response

March 13, 2013

Division of Docket Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

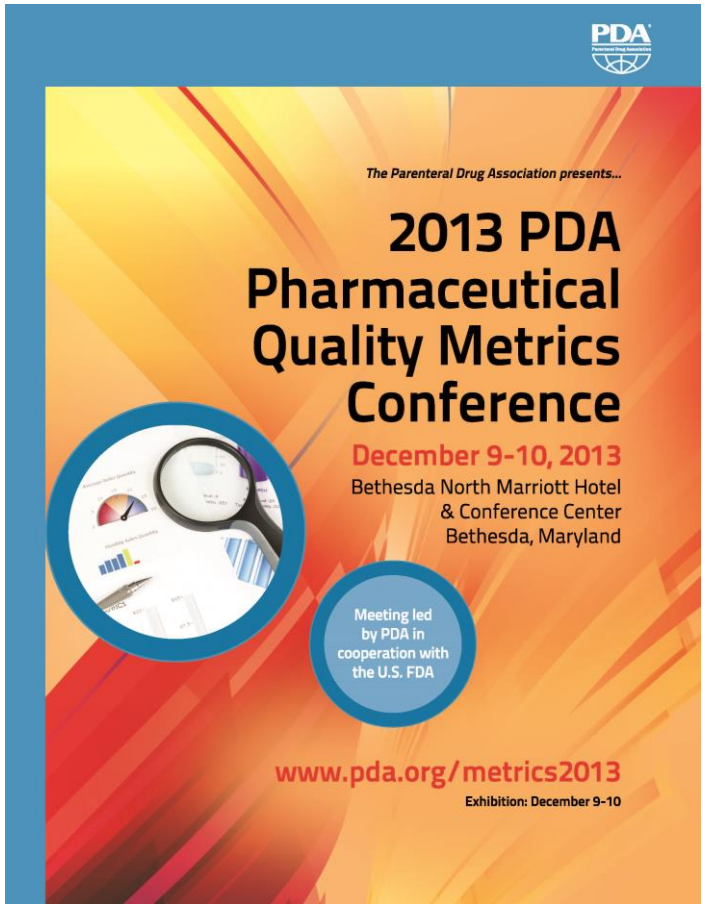
Reference: FDA Drug Shortages Strategic Plan Docket No. FDA-2013-N-0124)

Dear Sir/Madam,

PDA appreciates FDA initiating this important dialog with industry regarding the drug shortage issue. PDA recognizes the seriousness of the current situation and supports efforts on the agency's part to address it. New and innovative concepts should be discussed with the goal of establishing mechanisms which will promote an industry wide sustainable quality culture that can guarantee high-quality products are consistently manufactured with no disruption to the patient. …

PDA Dialogue with FDA on Metrics

- PDA Representatives Invited to Meet with Dr. Janet Woodcock, CDER Center Director
- FDA agrees to work with PDA to plan Metrics Conference



Metrics Conference - December 2013

300+ participants from more than 150 companies
Co-chaired with FDA; approximately 20 attended

Participants gave Direct Input to Recommendations

Panel Discussion with Global Quality Heads

Conference Outputs

- PDA Points to Consider Document
- Metrics Definitions
- Pilot/Survey
- Future Metrics Conference