Welcome and Introductory Remarks – David Schoneker (Colorcon, PQRI-USP EI Workshop Planning Committee)

Update on Recent US/EU/JP Regulatory Guidance and Further ICH EI Initiatives

- FDA Guideline & Current Experience with New Drug Submissions
  - Danae Christodoulou (FDA)
- EMA Guideline & Current Experience with New Drug Submissions
  - Sven-Erik Hilver (EMA Representative, ICH Q3D IWG)
- Status of Q3D in Japan
  - Akihiko Hirose (NIHS, ICH Q3D EWG)
- Global Developments for Elemental Impurity Requirements
  - Janeen Skutnik Wilkinson (Biogen, ICH Q3D IWG)
- What’s happening with Veterinary Medicines?
  - Michael Brent (FDA – CVM)
- ICH – New efforts on Topicals
  - Timothy McGovern (FDA, ICH Q3D Rapporteur)

Recent Compendial Activities Related to Elemental Impurities

- Specific Elements in Monographs
  - USP - Kahkashan Zaidi (USP)
  - PhEur – Speaker Invited
- USP <661.1>, <381> and <665> and other related chapters – Container/Closure Requirements – Differences from <232> concepts
  - Industry Perspective – Timothy Shelbourn (Eli Lilly, IQ Consortium)
  - USP Perspective - Desmond Hunt (USP)
- USP <2232> - Dietary Supplements – USP’s intent for the use of this chapter
  - USP Perspective - Gabriel Giancaspro (USP)
  - Industry Perspective – Tara Lin Couch (EAS Consulting Group, LLC)
Company Experience with Implementation for New Drug Applications since June 2016

- U.S. Industry Experience
  - Innovator Perspective - Speaker Invited
  - Generic Perspective - Speaker Invited

- EU Industry Experience
  - Innovator Perspective – Helmut Rockstroh (Roche)
  - Generic Perspective - Speaker Invited

- Canada Industry Experience
  - Innovator Perspective – Joy Mason (Eli Lilly and Company)
  - Generics Perspective – Elisabeth Kovacs (Apotex)

Implementation of Q3D Requirements for OTC and Existing Prescription Drugs in January 2018 – Challenges and Expectations

- OTC Challenges – David Fillar (Perrigo)
- Existing Prescription Drug Challenges
  - Innovator Perspective – Mark Schweitzer (Novartis, ICH Q3D EWG)
  - Generic Perspective – Speaker Invited

Acceptable Risk Assessment Strategies

- Source of EI Data and Information
  - Limited Supplier Information – Varies from Supplier to Supplier – Industry Reps.
    - User Reps. – Speaker Invited
    - Maker Perspective – Speaker Invited
  - Literature and Database Information – How Applicable is it to the Grades of Ingredients used in YOUR Formulation??
    - Publications and Lhasa Database Update
      - Andrew Teasdale, Ph.D. (Astra Zeneca)
  - What do the regulators think about the use of this information?
    - FDA Speaker Invited
    - EU Speaker Invited
  - EI Testing performed by the Pharmaceutical Company
    - Nancy Lewen (BMS)

PQRI Phase 2 Collaborative Study - Outcomes and Recommendations

- Donna Seibert (Perrigo) James. Harrington (RTI)
  - Review of Study Protocol
  - Learnings from Study Outcomes
  - Planned Actions
Outstanding Analytical Challenges

- Key Issues Related to Sample Preparation, Interferences and Variability (Lab to Lab, Instrument to Instrument)
  - Timothy Shelbourn *(Eli Lilly and Company)*
- Analytical Challenges for Q3D Implementation: Elemental Analysis by ICP-MS
  - Xiadong Bu *(Analytical Research & Development, Merck Research Laboratories)*
- Validation and Compliance – An Analytical Perspective
  - Francine Walker *(Chemical Solutions Ltd.)*

BREAKOUT SESSIONS

- ICH, Regulatory Guidance and Compendial Issues – Areas Requiring Clarification
- Industry Experience with Previous Submissions on New Drugs and Concerns about Implementation for Existing Drugs (Includes Global Concerns)
- Acceptable Risk Assessment Strategies
- Outstanding Analytical Challenges & Questions about the PQRI Phase 2 Study

Workshop Planning Committee

- David R. Schoneker, Chair, Colorcon, IPEC Americas, and PQRI
- Timothy McGovern, Ph.D., US Food and Drug Administration
- Kahkashan Zaidi, Ph.D., US Pharmacopeia
- Priscilla S. Zawislak, The Dow Chemical Company
- William Dale Carter, JM Huber
- Katherine L. Ulman, Consultant
- Donna Seibert, Perrigo
- Andrew Teasdale, Ph.D., Astra Zeneca
- Phyllis Walsh, Merck & Co. Inc.
- Nancy Lewen, Bristol-Myers Squibb
- Timothy Shelbourn, Eli Lilly and Company
- Jean Poulos, Lachman Consultants