PQRI/USP Workshop on Implementation Status of ICH Q3D Elemental Impurity Requirements - Analytical and Risk Assessment Challenges

Day 1 – Wednesday, November 9, 2016

8:00 am – 8:15 am  Registration Check In

8:15 am  Spalding Auditorium

Welcome and Introductory Remarks
David R. Schoneker
Colorcon, IPEC-Americas,
PQRI Steering Committee
EI Coalition

8:30 am  Session I: Regulatory Filing Observations for New Drugs – Industry and Regulator Perspectives

Industry Perspective

➢ ICH Q3D Risk Assessment for New Filings – Examples and Regulatory Interactions
  ▪ Andre Hermans (Merck & Co, Inc.)
➢ Generic Industry Perspective - Experience with a drug filed after June 1, 2016. Questions from FDA and EMA and how the situation was resolved.
  ▪ Marjorie Coppinger (Teva)
➢ ICH Q3D Guideline - Impact on the Users: Perspective of a Finished Product Manufacturer
  ▪ John Glennon (GlaxoSmithKline)

9:30 am  Coffee Break
9:45 am Session I: Regulatory Filing Observations for New Drugs – Industry and Regulator Perspectives (Cont.)

**REGULATOR PERSPECTIVE**

- FDA Experience When Reviewing NDAs and ANDAs for Q3D Elemental Impurity Compliance
  - Danae Christodoulou (*US Food and Drug Administration, EI Implementation Working Group*)
- EMA Experience When Reviewing NDAs and ANDAs for Q3D Elemental Impurity Compliance
  - Diana van Riet-Nales (*Member Quality Working Party (QWP) European Medicines Agency (EMA) | Senior Assessor department of Chemical Pharmaceutical Assessments (CFB)*)
- Health Canada's Implementation Plans for ICH Q3D Elemental Impurity Compliance
  - Alison Ingham (*Health Canada*)

11:00 am Session IIA: Data Sharing and Collaborative Studies – Key Learnings and Ongoing Efforts

- Data Sharing Initiatives
  - Andrew Teasdale (*Astra Zeneca*) (By Video)
- PQRI Phase 2 Collaborative Study – Current Status and Learnings
  - Donna Seibert (*Perrigo*)

11:45 am Lunch

12:45 pm Session IIB: Analytical Testing Considerations

- Strategies for Determination of Elemental Impurities in Difficult Sample Matrices
  - Denise McClenathan (*Procter & Gamble*)
- Fundamentals of the ICP-MS technique and How to Resolve Issues for Pharmaceutical Materials
  - Tim Shelbourn (*Eli Lilly*)
- Analytical Challenges Seen at a Contract Lab and How to Develop a Project Appropriately
  - Samina Hussain (*Exova Labs*)
- API Testing Requirements to Support the Risk Assessment
  - Elisabeth Corbett (*Bristol-Myers Squibb*)
- A Supplier’s Strategy for Elemental Testing and Risk Assessment
  - Kathy Ulman (*Dow*)
- Use of Alternative Testing Methods for Elemental Analysis of Pharmaceutical Samples (XRF, etc.)
  - Glenn Williams (*Rigaku*)
Breakout Sessions – there will be four concurrent rooms utilized to discuss the topic to facilitate small group discussion

3:00 pm  Breakout Session I
Topic: Regulatory Filing Observations for New Drugs
Facilitators: Kathy Ulman (lead), Tim Shelbourn, David Schoneker, Phyllis Walsh

- What section of the filings should EI information be submitted and what additional hyperlinks are required?
- Differences in requirements/guidance from region to region?
- Differences between CDER and CBER in the U.S.?
- What questions have sponsors been getting from regulators on current submissions?
- How much information should go into the filing and how much should be available on-site?

4:00 pm  Breakout Session II
Topic: Analytical Testing Considerations - Data Sharing ad Collaborative Studies
Facilitators: Nancy Lewen (lead), Josh Foote, Donna Seibert, Denise McClenathan

- Analytical/Screening Techniques which are being used and what level of validation is needed
- Analytical considerations regarding the component summation vs. drug product
- How to decide which elements to test for and at what concentrations for components?
- How to address difficult samples?
- Collaborative Study and Data Sharing

5:00 pm  Spalding Auditorium
Closing Remarks
David R. Schoneker
Colorcon, IPEC-Americas, PQRI Steering Committee, EI Coalition

5:30 – 7:30 pm  Reception
Please note location is offsite and adjacent to the Twinbrook Metro Station
Held at the Hilton Hotel and Executive Meeting Center
1750 Rockville Pike, Rockville, Maryland  20852
Day 2 – Thursday, November 10, 2016

8:00 am        Registration
8:15 am        Spalding Auditorium

Summary of Day 1, Goals for Day 2
David R. Schoneker, Colorcon, IPEC-Americas, PQRI Steering Committee // EI Coalition

8:25 am     Session III: Risk Assessment Approaches that Work
(Speakers will relate the use of the ICH Training Module Case Studies and how this worked in a real situation where possible)

- Case study - Oral Solid & Liquid Dosage Forms Which Contains Excipients Derived from Natural and Mined Excipients
  - Josh Foote (Perrigo Co.)
- Case study - Topical dosage form
  - David Fillar (Perrigo Co.)
- Case study - Parenteral dosage form- Approaches and Challenges
  - Joy Mason (Eli Lilly and Company)
- Case study - Biological dosage form
  - Peter Colvin (Merck & Co., Inc.)

9:45 am     Coffee Break

10:00 am    Session IV: Preparing for Existing Drug Product Implementation in January 2018

- Final Implementation Plans for USP and PhEur Pharmacopeial Chapters and Notices on Elemental Impurities
  - Kahkashan Zaidi (USP)
  - Bruno Spieldenner (PhEur)
- Regulatory filing implications that will be expected for existing products
  - Danae Christodoulou (US Food and Drug Administration, EI Implementation Working Group)
- Life-cycle management
  - Phyllis Walsh (Merck & Co., Inc.)
- Industry Readiness for Implementation of Q3D and Pharmacopeial Chapters to Existing Products
  - Siva Vaithiyalingam (CIPLA)
- Implementation Outside of the U.S. and EU
  - I-Chen Sun (Deputy Director, Center for Drug Evaluation, Taiwan)
12:30 pm  Lunch

Breakout Sessions – there will be four concurrent rooms utilized to discuss the topic to facilitate small group discussion

1:30 pm  Breakout Session III
Topic: Risk Assessment Approaches that Work
Facilitators: Priscilla Zawislak (lead), David Schoneker, Dave Fillar, Joy Mason
- Should you use a finished product or component assessment?
- How much data/information is needed to perform a scientifically valid risk assessment?
- Acceptable sources of data – literature, historical, supplier information, databases, actual testing
- Number of Batches needed where testing is required
- Worst Case approaches and Predictability

2:30 pm  Breakout Session IV
Topic: Preparing for Existing Drug Product Implementation in January 2018
Facilitators: Phyllis Walsh (lead), Kahkashan Zaidi, Neil Schwarzwalder, Nancy Lewen
- Lifecycle Management
- U.S./EU Regulatory Filings, Annual Reports, International Filings
- Removal of Heavy Metals Test in Pharmacopeias
- Removal of Specific Metal Tests/Limits in Monographs

3:30 pm  Coffee Break

3:45 pm  Spalding Auditorium

Breakout Summary Reports
Breakout Session I:  Katherine Ulman, Dow
Breakout Session II:  Nancy Lewen, Bristol-Myers Squibb
Breakout Session III:  Priscilla Zawislak, Consultant
Breakout Session IV:  Phyllis Walsh, Merck & Co. Inc.

4:45 pm  Summary of Feedback and Action Plans
David R. Schoneker
Colorcon, IPEC-Americas, PQRI Steering Committee, EI Coalition

5:00 pm  Conference Ends
Workshop Planning Committee

David R. Schoneker, Chair, Colorcon, IPEC Americas, and PQRI
John F. Kauffman, Ph.D., US Food and Drug Administration
Kahkashan Zaidi, Ph.D., US Pharmacopeia
Priscilla S. Zawislak, Consultant
William Dale Carter, JM Huber
Katherine L. Ulman, Dow
David J. Fillar, Perrigo
Donna Seibert, Perrigo
Andrew Teasdale, Ph.D., Astra Zeneca
Phyllis Walsh, Merck & Co. Inc.
Nancy Lewen, Bristol-Myers Squibb
Neil Schwarzwelder – Eli Lilly
Timothy Shelbourn – Eli Lilly
Jean Poulos – Rising Pharma