DRAFT 9.26.2017

Thursday – Friday, November 2 - 3, 2017
USP Meeting Center: 12601 Twinbrook Parkway, Rockville, MD 20852

PQRI/USP Workshop on ICH Q3D Elemental Impurities Requirements – Recent Experience and Plans for Full Implementation in 2018

Day 1 – Thursday, November 2, 2017

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: Update on Recent US/EU/JP Regulatory Guidance and further ICH EI Initiatives**

REGULATOR PERSPECTIVE

- FDA Guidance & Current Experience with New Drug Submissions
  - Danae Christodoulou *(US Food and Drug Administration)*
- EMA Guideline & Current Experience with New Drug Submissions
  - Sven-Erik Hillver *(Medical Products Agency (MPA), ICH Q3D IWG)*
- Status of Q3D in Canada
  - Allison Ingham (*Health Canada*)
- Status of Q3D in Japan
  - Akihiko Hirose (*National Institute of Health Sciences (NIHS), ICH Q3D EWG*)

10:30 am Coffee Break

10:45 am **Session I (cont.): Update on Recent US/EU/JP Regulatory Guidance and further ICH EI Initiatives**

ICH PERSPECTIVE

- Global Developments for Elemental Impurity Requirements
  - Janeen Skutnik Wilkinson *(Biogen, ICH Q3D IWG)*
- What's Happening with Veterinary Medicines?
  - Michael R. Brent *(Center for Veterinary Medicine, FDA)*
- ICH – New Efforts on Topicals
  - Tim McGovern *(Food and Drug Administration, ICH Q3D Rapporteur)*

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DRAFT 9.26.2017

12:15 pm Lunch

1:00 pm **Session II: Recent Compendial Activities Related to Elemental Impurities**

- Specific Elements in Monographs
  - PhEur - Bruno Spieldenner (Latest PhEur Activities) & Cristian Sampaolesi (CEPs)
  - USP - Kahkashan Zaidi *(USP)*
- 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 – Diane Paskiet *(West Pharmaceutical Services, USP Packaging & Distribution Executive Committee)*
- USP <2232> - Dietary Supplements – USP's intent for the use of this chapter
  - USP Perspective - Dr. Gabriel Giancaspro *(USP)*
  - Industry Perspective – Tara Couch *(EAS Consulting Group)*

3:00 pm Coffee Break

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

3:15 pm **Breakout Session I: Topic: ICH, Regulatory Guidance and Compendial Issues – Areas Requiring Clarification**

Facilitators: ***Priscilla Zawislak (lead),*** Tim McGovern, Additional Moderators TBD

4:00 pm **Session III: Implementation of Q3D requirements for OTC and Existing Prescription Drugs in January 2018 – Challenges and Expectations**

- OTC Challenges
  - David Fillar (*Perrigo Co*)
- Existing Prescription Drug Challenges
  - Innovator Perspective – Mark Schweitzer (*ICH Q3D EWG, Novartis*)
  - Generic Perspective – Rajeev Mathur – *(Sun)*

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 White Flint Metro Station

Held at the Marriott North Bethesda
Salon A
5701 Marinelli Road, Rockville, MD

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DRAFT 9.26.2017

Day 2 – Friday, November 3, 2017

8:00 am **Continental Breakfast**

8:15 am **Spalding Auditorium**

8:15 am **Session IV: Company Experience with Implementation for New Drug Applications since June 2016**

- U.S. Industry Experience
  - ICH Q3D Risk Assessment: Regulatory Success and Standardized Methodology for New Filings - William Stevens *(Merck & Co., Inc.)*
  - Generic Perspective - Ravi Harapanhalli – *(Amneal)*
- EU Industry Experience
  - Innovator Perspective - Helmut Rockstroh (*Roche*)
  - Generic Perspective - Orit Schwartz – *(Teva)*
- Canadian Industry Experience
  - Canadian Submission – Parenteral Drug Product - Joy Mason (*Eli Lily and Company*)
  - Generic Perspective – Elisabeth Kovacs (*Apotex*)

10:15 am Coffee Break

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

10:30 am **Breakout Session II: Topic: Industry Experience with Previous Submissions on New Drugs and Concerns about Implementation for Existing Drugs (Includes Global Concerns)**

Facilitators: ***Kathy Ulman (lead),*** Mark Schweitzer, David Fillar, Moderator TBD

11:30 pm Lunch

12:15 pm **Session V: Acceptable Risk Assessment Strategies**

- Source of EI Data and Information
  - Limited Supplier Information – Varies from Supplier to Supplier
    - User Perspective - Mark Schweitzer *(Novartis)*
    - Maker Perspective - George Collins *(Vanderbilt Chemicals LLC)*
  - Literature and Database Information – How Applicable is it to the Grades of Ingredients used in YOUR Formulation??
    - Publications and Lhasa Database Update – John Glennon *(GSK)*
    - What do the regulators think about the use of this type of information? - EMA reviewer – Sven-Erik Hillver – *(MPA, ICH Q3D IWG)*

- EI Testing performed by the Pharmaceutical Company – Nancy Lewen *(BMS)*

1:55 pm **Session VI: Outstanding Analytical Challenges**

- PQRI Phase 2 Collaborative Study - Outcomes and Recommendations
  - Donna Seibert *(Perrigo)* & James Harrington *(RTI)*
- Key Issues Related to Sample Preparation, Interferences and Variability (Lab to Lab, Instrument to Instrument)
  - Timothy Shelbourn *(Eli Lilly)*
- Analytical Challenges for Q3D Implementation: Elemental Analysis by ICP-MS
  - Xiaodong Bu *(Merck & Co., Inc.)*
- Validation and Compliance – An Analytical Perspective
  - Francine Walker (*Chemical Solutions*)

3:25 pm Coffee Break

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

3:45 pm **Breakout Session III: Topic: Acceptable Risk Assessment Strategies & Outstanding Analytical Challenges**
Facilitators: ***Nancy Lewen (lead)***, *Tim Shelbourn*, Josh Foot, Moderator TBD

4:45 pm **Spalding Auditorium**

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

5:00 pm **Conference Ends**

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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, Evonik
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