**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)*
- Health Canada's Experience When Implementing the ICH Q3D Elemental Impurity Guidance for NDSs and ANDSs
  - Alison Ingham (*Health Canada*)
- Current Status and Experience with New Drug Submissions 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 *(Biogen, ICH Q3D IWG)*
- Elemental Impurities and Animal Drugs – An Update from CVM
  - Michael R. Brent *(Center for Veterinary Medicine, FDA)*
- ICH Q3D Expert Working Group: Update on Cutaneous and Transdermal Routes
  - Timothy McGovern *(Food and Drug Administration, ICH Q3D Rapporteur)*

**12:15 pm Lunch**

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

- Specific Elements in Monographs
  - Implementation of the ICH Q3D Guideline in the Ph.Eur. - Bruno Spieldenner *(EDQM)*
  - Implementation of ICH Q3D in the Certification Procedure -Cristian Sampaolesi (*EDQM*)
  - USP – Nancy Lewen *(Bristol-Myers Squibb)*
- USP <661.1>, <381> and <665> and Other Related Chapters
  - Industry Perspective – Timothy Shelbourn (*Eli Lilly and Company, 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 – Kit S. Goldman *(USP)*
  - Elemental Impurities Testing Challenges – Tara Lin Couch *(EAS Consulting Group, LLC)*

**3:00 pm Coffee Break**

**Breakout Sessions** – *there will be three 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, Denise McClenathan

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

- OTC Lifecycle Program – Implementation Strategy & Challenges
  - David Fillar (*Perrigo Co*)
- Existing Prescription Drug Challenges
  - Development of Elemental Impurity Risk Assessments for Existing Prescription Products – Mark Schweitzer (*Novartis, ICH Q3D EWG*)
  - Elemental Impurities Program in Teva – Challenges and Expectations – Orit Schwartz – *(Teva Pharmaceutical Industries Ltd.)*

**5:00 pm** **Closing Remarks** **(Spalding Auditorium)**

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**

## 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 Industry Experience with Implementation for New Drug Applications since June 2016 - Ravi Harapanhalli – *(Amneal Pharmaceuticals)*
- EU Industry Experience
  - Innovator Perspective - Helmut Rockstroh (*F. Hoffmann-La Roche Ltd*)
- Canadian Industry Experience
  - Canadian Submission – Parenteral Drug Product - Joy Mason (*Eli Lily and Company*)
  - Generic Industry Perspective – Elisabeth Kovacs (*Apotex Inc.*)

**10:15 am Coffee Break**

**Breakout Sessions** – *there will be three 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

**11:30 am Lunch**

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

- Source of EI Data and Information
  - Limited Supplier Information – Varies from Supplier to Supplier
    - Approaches to Elemental Impurity Product Risk Assessments with Limited Supplier Information - 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??
    - Lhasa Database Update – John Glennon *(GlaxoSmithKline)*
    - What Do 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 Technical Analytical Challenges Round 2 Interlaboratory Study: Progress and Early Findings
  - Donna Seibert *(Perrigo)* & James Harrington *(RTI International)*
- Key Issues Related to Sample Preparation, Interferences and Variability
  - Timothy Shelbourn *(Eli Lilly and Company)*
- 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 Ltd.*)

**3:25 pm** **Coffee Break**

***Breakout Sessions*** *– there will be three 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 Foote

**4:45 pm** **Summary of Feedback and Action Plans** **(Spalding Auditorium)**
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
Timothy McGovern, US Food and Drug Administration
Kahkashan Zaidi, US Pharmacopeia
Priscilla S. Zawislak, The Dow Chemical Company
William Dale Carter, Evonik
Katherine L. Ulman, Consultant
Donna Seibert, Perrigo
Andrew Teasdale, Astra Zeneca
Phyllis Walsh, Merck & Co., Inc.
Nancy Lewen, Bristol-Myers Squibb
Timothy Shelbourn, Eli Lilly and Company
Jean Poulos, Lachman Consultants