2017 PQRI/USP Workshop on ICH Q3D Elemental Impurities Requirements – Recent Experience and Plans for Full Implementation in 2018

Welcome and Introductory Remarks

David R. Schoneker

Colorcon, IPEC-Americas, PQRI Steering Committee,

EI Coalition

PQRI

Product Quality Research Institute

usp™

Mission

The Product Quality Research Institute (PQRI) is a non-profit consortium of organizations working together to generate and share timely, relevant, and impactful information that advances drug product quality, manufacturing, and regulation

Housekeeping

- Cell Phones – please place on silent mode!
- Wi Fi Access
  - Network: USPMCGuest
  - No Password Needed
- Presentations
  - http://pqri.org/pqriusp3rdeiworkshop/
  - Click on Presentations
  - Password: PQRIEI2017

Housekeeping

- Networking Reception
  - 5:30 – 7:30 PM Tonight
  - Marriott North Bethesda -Salon A
  - Transportation will be provided from USP and Hilton Rockville
    - 5:15 PM USP to Bethesda North Marriott
    - 5:30 PM and 5:45 PM Hilton Rockville to Bethesda North Marriott
    - 7:30 PM, 7:45 PM and 8:00 PM Bethesda North Marriott to Hilton Rockville
- Issues/Comments/Concerns
  - See Dede Godstrey at Registration

Agenda – Day 1

- **Session I:** Update on Recent US/EU/JP Regulatory Guidance and further ICH EI Initiatives
- **Lunch Break**
- **Session II:** Recent Compendial Activities Related to Elemental Impurities
- **Breakout Session I:** ICH, Regulatory Guidance and Compendial Issues – Areas Requiring Clarification
- **Session III:** Implementation of Q3D requirements for OTC and Existing Prescription Drugs in January 2018 – Challenges and Expectations
- Reception at Marriott North Bethesda – Salon A

Agenda – Day 2

- **Session IV:** Company Experience with Implementation for New Drug Applications since June 2016
- **Breakout Session II**: Industry Experience with Previous Submissions on New Drugs and Concerns about Implementation for Existing Drugs (Includes Global Concerns)
- **Lunch Break**
- **Session V:** Acceptable Risk Assessment Strategies
- **Session VI:** Outstanding Analytical Challenges
- **Breakout Sessions III:** Acceptable Risk Assessment Strategies & Outstanding Analytical Challenges
- Summary of Feedback and Action Plans

Key Points

- The Workshop is designed to provide opportunities to share your experiences and learn from others about what challenges may exist in implementing ICH Q3D and what solutions may exist
- Therefore, **GET INVOLVED** in the discussions during the Breakout Sessions, Coffee Breaks, Lunches and Social Activities! - We need your Voice!
- PQRI will be publishing the Breakout Session Reports after the Workshop to summarize the discussions to assist industry during implementation
- This is a scientific workshop and **NOT** about developing commercial opportunities – **DO NOT** try to promote your company during the discussions if you offer testing services, etc. – take that off-site!

Q3D Basics

- **ICH Q3D applies to:**
  - Human drug products
  - New finished drug products & eventually existing drug products
  - **Emphasizes the use of risk assessment as opposed to testing wherever possible – unnecessary testing should be avoided!**
- **Does not apply to:**
  - Components, i.e. Drug Substance/ Excipients
  - However, improved two-way communication with suppliers will be important to determine what they may know or not know
  - **Successful Implementation** of Q3D will require all of us in the industry, the pharmacopeias and the global regulatory agencies to work closely together to identify the challenges and develop **rational** plans for resolution based on actual risk not precautionary thinking!

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Breakout Session Ground Rules

Each Session will have Key Questions to Discuss and a Note Taker from USP to document the discussions

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Breakout Session Ground Rules

- Each break-out session is only 45-60 minutes; therefore, there is limited time for discussion for each question (7 – 10 minutes per question). It is the intent of the program committee to get comments from as many attendees as possible, **so please**
  - **Be concise with your questions and comments**
  - **Allow time for other attendees in the breakout time to voice their comments and/or questions**
  - **Respect when the facilitator announces that it is time to move to the next question**

Breakout Session Ground Rules

- Name tags dots designate which breakout room you are assigned to each day.
- **See signs outside breakout rooms**
  - **SPALDING AUDITORIUM**
  - **BACHE/WOOD**
  - **MARSHALL/WILEY**

Thank You

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

All Breakout Session Facilitators & USP Note Takers

- Session 1: Priscilla Zawislak, Tim McGovern, Denise McClenathan
- Session 2: Kathy Ulman, Mark Schweitzer, David Fillar
- Session 3: Nancy Lewen, Tim Shelbourn, Josh Foote
- USP Note Takers: Antonio Hernandez Cardoso, Jenny Liu, Shankari Shivaprasad