4th PQRI Workshop on ICH Q3D Elemental Impurities Requirements November 9-10, 2020

Welcome

Presented by:

David Schoneker, Black Diamond Regulatory Consulting, LLC

PQRI

Product Quality Research Institute

Product Quality Research Institute (PQRI)

Mission:

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.

CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

FDA U.S. FOOD & DRUG ADMINISTRATION

INTERNATIONAL PHARMACEUTICAL EXCIPIENTS COUNCIL IPEC AMERICAS

PDA Parenteral Drug Association

Health Canada

USP U.S. Pharmacopeial Convention™

PQRI Product Quality Research Institute

What Does PQRI Do ?

- Unites thought leaders from regulatory agencies, standard setting bodies, industry and academia to conduct research and share knowledge on emerging scientific and regulatory quality challenges
- Provides a unique, neutral forum to develop broad consensus among a diverse collection of industry organizations and regulatory bodies
- Creates opportunities to accomplish mutual goals that cannot be achieved by individual organizations
- Impacts global regulatory guidance and standards, bringing maximum value to members and patients

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Introductory Remarks

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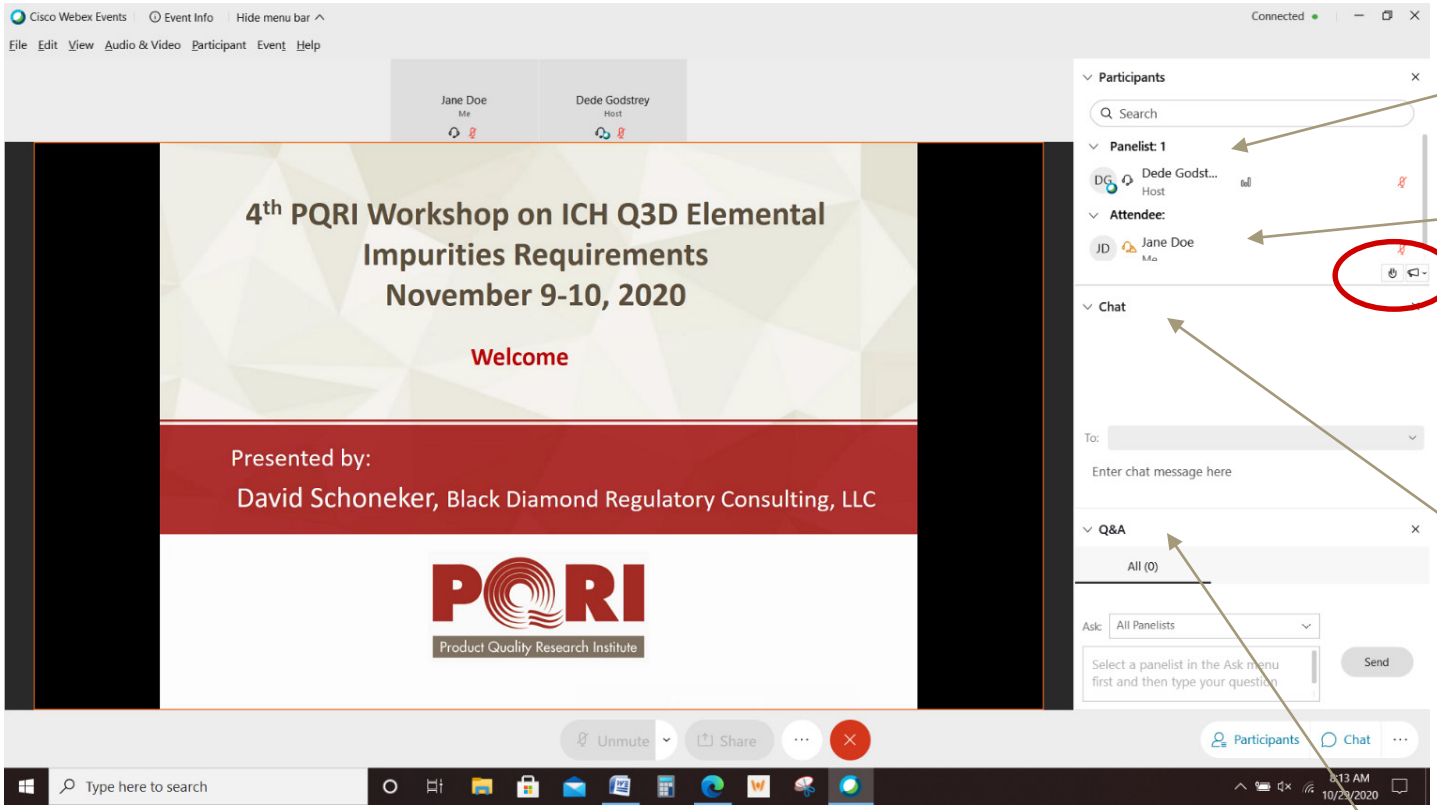
Housekeeping I



- Panelists will be listed here.
- The Attendee list is only available to Panelists and Host. (You will only see your name listed.)
- The Chat function has been disabled for Attendees. You may receive chats from the Host, but you cannot reply.
- Type your question in the Q&A box or raise your hand to be unmuted.

- All Attendees are on mute

Housekeeping II

- Presentations
  - [add link]
  - Click on Presentations
  - Password: PQRIEI2020
- Recordings
  - The recordings will be posted after the Workshop has concluded. We will send out a notice to attendees with the link to view the recordings.
  - NOTE: Breakouts will be not be recorded, but the summaries will be posted with the presentations post –Workshop.

Agenda – Day 1

- **Welcome and Introductory Remarks**
- **Current State of Implementation of ICH Q3D Globally**
  - Results of Pre-Workshop Survey and Global Experience
  - Implementation of ICH Q3D in Japan and India
- **Regulator Experience – Quality of Risk Assessments and Supporting Data**
  - US FDA and Swedish Medical Products Agency
- **Industry Experience – Implementation Challenges**
- **Pharmacopeia Approaches to Element Specific requirements in Monographs**
  - USP and EDQM
  - Industry Perspective and Consequences
- **Breakout Session I: Implementation Problems and Future Needs**

Agenda – Day 2

- **Welcome to Day 2 and Review of Day 1**
- **Ongoing ICH Q3D Activities**
  - Update on Transdermal Limits
  - Lhasa Database Update
- **PQRI Phase 2 Elemental Impurity Collaborative Study Results**
  - Purpose and Study Design
  - Method Development and Laboratory Participant Perspective
  - Results Review and Publication
  - Main Take-Aways
  - Implications for Analytical Testing in Laboratories for EI
  - Implications for Risk Assessments
- **Breakout Session II: Explore the Impact of the Phase 2 Study on Industry and Regulators**
- **Closing Remarks**

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 Virtual Breakout Sessions! - We need your Voice!
- PQRI will be publishing the Breakout Session Notes after the Workshop on the PQRI website to summarize the discussions and to assist industry in the future
- The Phase 2 PQRI Collaborative Study results will be published in the near future. However, you will be able to get a sneak peek at this information since you signed up for this workshop. The results are quite interesting!

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
  - **Continued 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 additional 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 to document the discussions

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Breakout Session Ground Rules

- Each break-out session is only 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 session 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

- Join the Breakout session by clicking on the Webex Meeting link below (or in the calendar invite).
  - [add link]
- Once you join, you will be placed in a breakout room.
- We will not reconvene in the main meeting room on Day 1 after the breakouts. The moderators in each breakout will excuse you for the day.

Thank You

Workshop Planning Committee

- David R. Schoneker, Chair, Black Diamond Regulatory Consulting
- Dale Carter, Evonik
- Danae Christodoulou, US Food and Drug Administration
- Dede Godstrey, PQRI Secretariat
- James Harrington, RTI
- Nancy Lewen, Consultant
- Timothy McGovern, US Food and Drug Administration
- Doug Muse, Eli Lilly and Company
- Donna Seibert, Perrigo
- Timothy Shelbourn, Eli Lilly and Company
- Janeen Skutnik Wilkinson, Biogen
- Andrew Teasdale, Astra Zeneca
- Katherine Ulman, Consultant
- Matthew Vera, US Food and Drug Administration
- Kahkashan Zaidi, US Pharmacopeia
- Priscilla Zawislak, Dupont

Breakout Session Facilitators & Note Takers

Day 1 Breakouts:
Facilitators:
Kathy Ulman, Doug Muse and Janeen Skutnik Wilkinson

Note Takers:
George Collins, Tom Farrell, Priscilla Zawislak

Day 2 Breakouts:
Facilitators:
James Harrington, Donna Seibert, Denise McClenathan

Note Takers:
Josh Foote, Kelly Smith, Miranda De Boskey