PQRI Workshop:

Managing Excipient and API Impact on Continuous Manufacturing

May 17 – 18, 2022

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
Taking healthcare personally.

FDA U.S. FOOD & DRUG ADMINISTRATION

Health Canada

PDA® Parenteral Drug Association

IPAC-RS International Pharmaceutical Aerosol Consortium on Regulation & Science

INTERNATIONAL PHARMACEUTICAL EXCIPIENTS COUNCIL IPEC AMERICAS

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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 alone, by leveraging the energy, resources, and intelligence of leading global organizations
- Impacts global regulatory guidance and standards, bringing maximum value to members and patients

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Introductory Remarks

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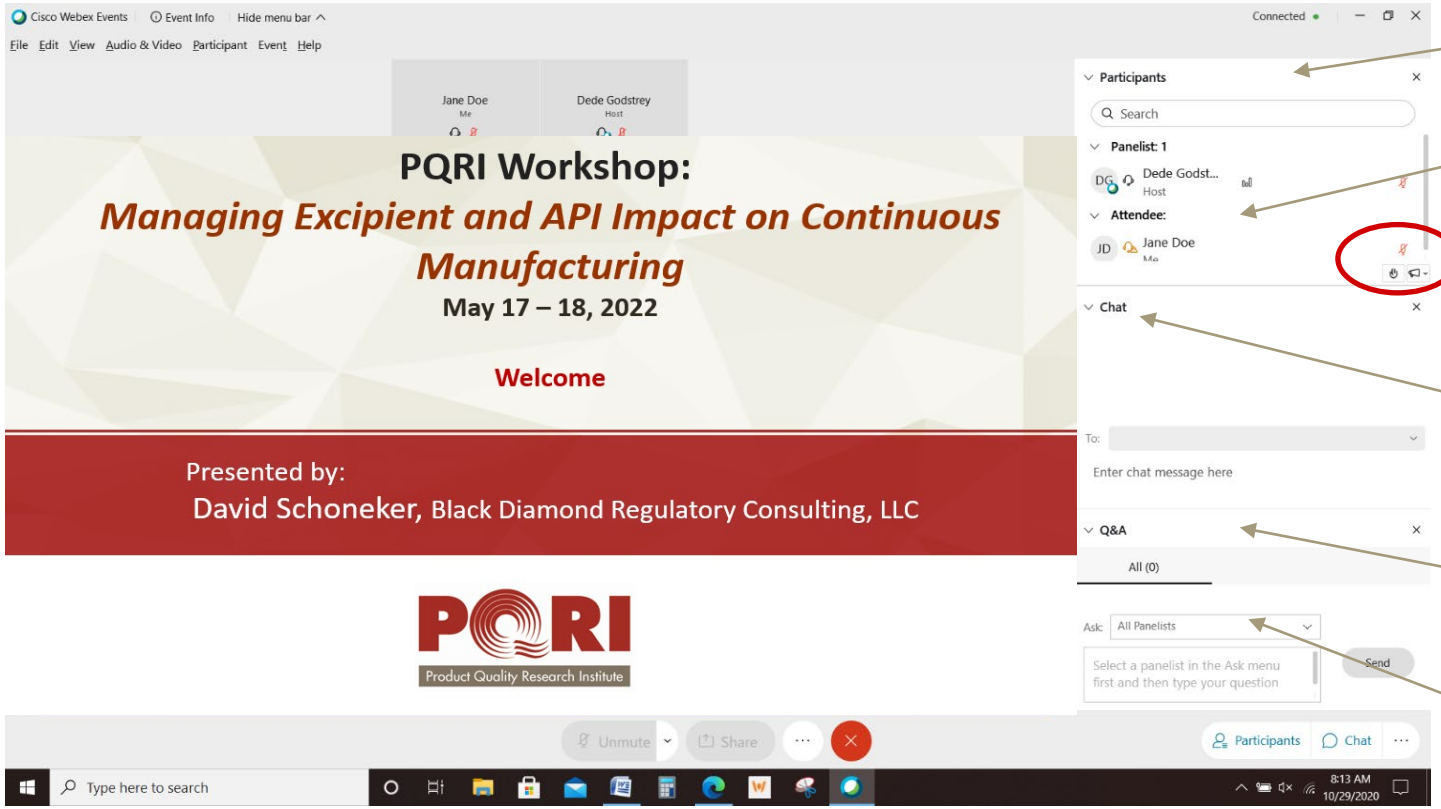
Housekeeping



- 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.
- Be sure your Q&A is set to ASK All Panelists.

- All Attendees are on mute

Housekeeping II

- Presentations
  - Go to Workshop webpage https://pqri.org/cm_workshop/, then scroll down to Presentations or Click here: https://pqri.org/cm_workshop_abstracts/
  - Password: PQRICM2022
- 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
- Introduction of Continuous Manufacturing and Excipient/API Impact
- Regulator and Industry Input on API and Excipient Impact on CM Drugs – Risks and Mitigation?
  - US FDA and Industry
  - Panel Discussion
- Impact of Material Properties and Variability on CM
- *Breakout Session I:* What are the Challenges You've Experienced Related to Material Impact on CM Processes?

Agenda - Day 2

- Welcome to Day 2 and review of Day 1 Breakouts
- Risk Mitigation in Continuous Manufacturing
- Material Property Impact on CM Processes and Equipment
- The Need for Novel Materials and Processes
  - Panel Discussion: What Types of Mate3rials and Processes Might be Needed to Support CM Developments over the next 5 to 10 years?
- *Breakout Session 2:* What Types of Characterization Techniques and Novel Excipients are Needed to Enhance CM Going Forward?

Key Points2

- The Workshop is designed to provide opportunities to share your experiences and learn from others about what challenges may exist in utilizing excipients and APIs in Continuous Manufacturing related to their material properties.
- 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.

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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 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 session time to voice their comments and/or questions**
  - **Respect when the facilitator announces that it is time to move to the next question**

To Join Breakout Session

- Join the Breakout session by clicking on the Webex Meeting link that was provided to you by email (or in the calendar invite).
- Please join right away and then take your break.
- During the break, you will be placed in a breakout room and we will begin the breakout at 4:00 PM ET.
- 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, LLC; IPEC-Americas
- Edmond Biba, USP
- Brian Carlin, Carlin Pharma Consulting
- George Collins, Vanderbilt Minerals LLS
- Sebastian Escotet, Merck & Co., Inc.
- Tom Farrell, Colorcon Inc.
- Dede Godstrey, PQRI Secretariat
- Yong Hu, FDA
- Krizia Karry, BASF
- Chris Moreton, FinnBrit Consulting
- Himanshu Patel, BASF
- Shailesh Singh, Merck
- Janeen Skutnik-Wilkinson, Biogen
- Elizabeth Tocce, IFF
- Katherine Ulman, KLU Consulting
- Priscilla Zawislak, IFF
- Joseph Zeleznik, IMCD US Pharma

Breakout Session Facilitators & Note Takers

Day 1 Breakouts:

Moderators:

Joseph Zeleznik, Brian Carlin, Shailesh Singh

Note Takers:

Yong Hu, Kathy Ulman, Janeen Skutnik-Wilkinson

Day 2 Breakouts:

Moderators:

Krizia Karry, Priscilla Zawislak, Kathy Ulman

Note Takers:

Chris Moreton, Edmond Biba, Sebastian Escotet

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