PQRI Workshop:

TiO2 Use in Pharmaceuticals
Global Regulatory and Technical Challenges

June 13-14, 2023

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.

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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WORKSHOP OBJECTIVES

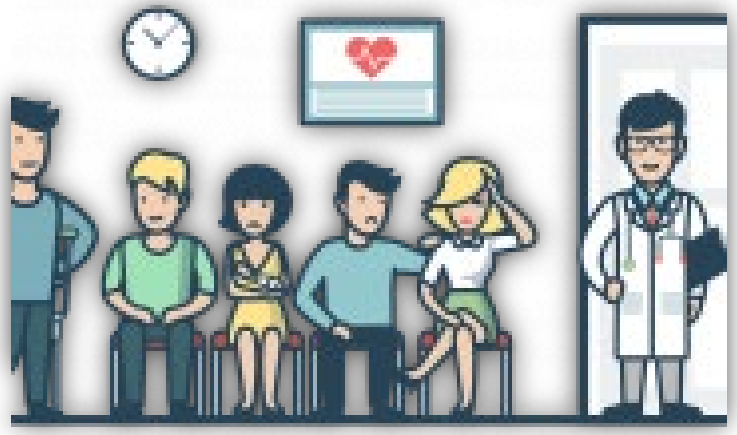
- The objective of this workshop is to bring together material suppliers, the pharmaceutical industry, and regulatory experts to discuss the safety profile of titanium dioxide (TiO2), based on the science, and the impact removing TiO2 would have, along with the benefits and challenges of the alternatives to TiO2 for use in solid oral dosage forms.

- You will hear from worldwide toxicology, regulatory and formulation experts with significant TiO2 experience.

- Workshop presentations and outcomes from the breakout sessions will be used to develop a white paper for submission to EMA by November 2023 to help support the continued use of TiO2 in pharmaceuticals in Europe.

Impact of a TiO2 Ban

Patients

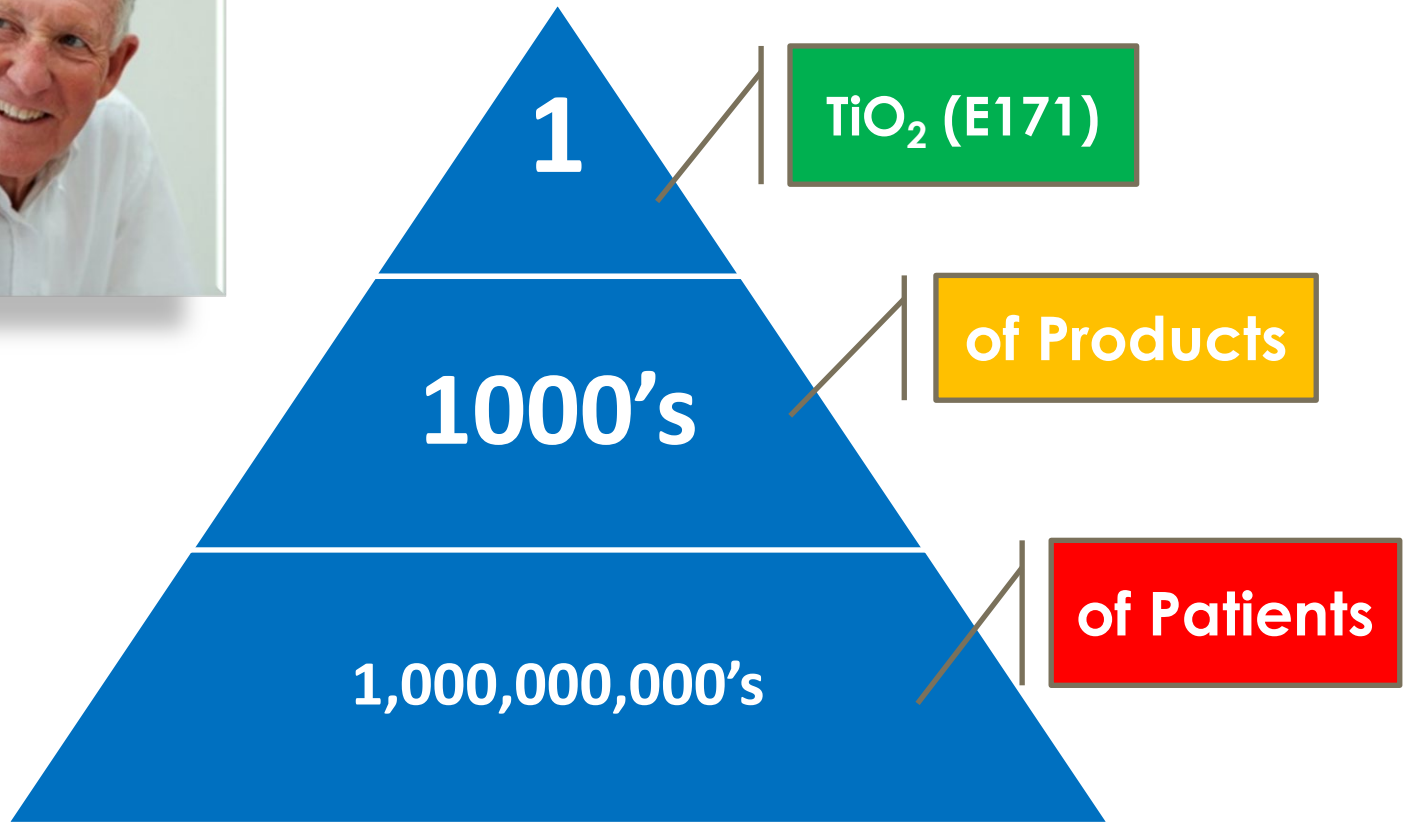


Regulators

Manufacturing

Drug Costs

Pharmaceutical Impact on Patients



Housekeeping I

- All Attendees are on mute.
- The Plenary Sessions are recorded.

- The Chat function has been disabled for Attendees. Type your question in the Q&A box.

Housekeeping II

- Survey
  - Results will be used in Day 2 Breakout Session and in the post-workshop white paper. Please complete the Survey by the end of Day 1 if you have not done so.
- Presentations
  - Go to Workshop webpage https://pqri.org/tio2-workshop-2023/ then scroll down to Presentations or Click here: https://pqri.org/tio2workshop-presentations/
  - Password: pqritio22023
- 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 following the Workshop.

Agenda - Day 1

- Welcome and Introductory Remarks
- Overview of the Potential EU Ban of TiO2 in Pharmaceuticals
- New TiO2 Safety Information since the EFSA Opinion
- Global Assessment of TiO2 Safety
- *Breakout Session I: Scientific Understanding and Awareness of the Safety of TiO2*
  - Breakouts for in person attendees only

Agenda - Day 2

- Welcome to Day 2 and review of Day 1 Breakouts
- TiO2 (E171) and Currently Available Alternatives
- The Impact of Replacing TiO2 on Product Quality, Resources and Availability
- What Could be Next
- *Breakout Session 2: Experiences When Evaluating Alternatives (Materials or Approaches) for Use in Pharmaceutical Drug Products*
  - Breakouts for in person attendees only

Key Points

- The Workshop is designed to provide opportunities to share your experiences and learn from others about TiO2 safety and the challenges that would result if a ban in pharma were to be implemented.
- Therefore, **GET INVOLVED** in the discussions during the 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 1 hour 15 minutes (Day 1) or 1 hour 30 minutes (Day 2); therefore, there is limited time for discussion for each question (approx. 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**

Thank You

Workshop Planning Committee

- David Schoneker, Chair – Workshop Org. Committee; Black Diamond Regulatory Consulting, LLC, IPEC Americas
- Dede Godstrey – PQRI Secretariat
- George Collins Jr. - Vanderbilt Chemicals LLC (IPEC-Americas)
- Priscilla Zawislak – IFF (IPEC-Americas)
- Sue Ann McAvoy – Sensient (IPEC-Americas)
- Kevin Hughes – Colorcon (IPEC Europe)
- Mahmud Yunis – BIOGRUND (IPEC Europe)
- Jason Melnick – Eli Lilly and Company (IQ Consortium)
- Joanne Wakeman – AbbVie (IQ Consortium)
- David Lockley – Venator (TDMA)
- Brett Pinker – Cefic (TDMA)
- Arnola Lilaj – Cefic (TDMA)
- Andreas Abend – Merck (PQRI)
- Uma Bruen – Organon (ELSIE)
- Richard Lostritto – Consultant (PDA)
- Wenlei Jiang – FDA (PQRI)
- Catherine Sheehan – USP
- Bram Baert, Lonza
- Thomas Broschard, EMD Serono Inc.

Breakout Session Moderators & Note Takers

Day 1 Breakouts:

Moderators:

Uma Bruen and George Collins

Note Takers:

Kevin Hughes and Courtney Callis

Day 2 Breakouts:

Moderators:

Jason Melnick and Andreas Abend

Note Takers:

Bram Baert and Rohit Tiwari