

**PQRI Workshop:**  
***TiO<sub>2</sub> Use in Pharmaceuticals***  
***Global Regulatory and Technical Challenges***

June 13-14, 2023

**Day 2 - Welcome and Review of Day 1**

Presented by:

David Schoneker, Black Diamond Regulatory Consulting, LLC



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**Introductory Remarks**

Presented by:

David Schoneker, Black Diamond Regulatory Consulting, LLC



# Housekeeping I

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

You are viewing Faegre Drinker's screen View Options

## 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



Mute Chat Raise Hand Q&A Show Captions Leave

- 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.

- 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 2

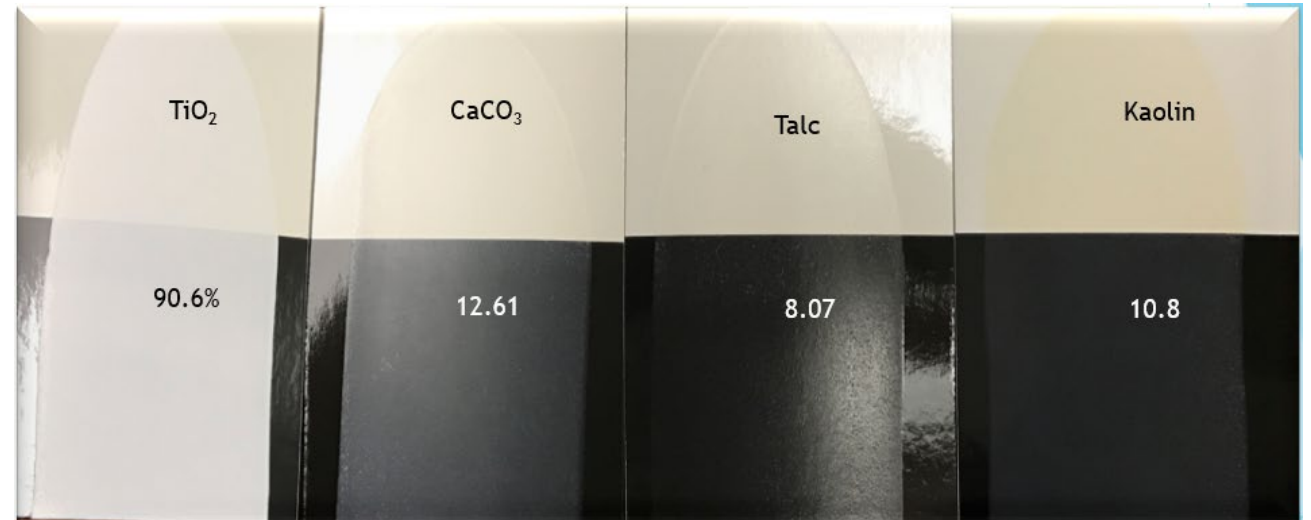
- Welcome to Day 2 and review of Day 1 Breakouts
- TiO<sub>2</sub> (E171) and Currently Available Alternatives
- The Impact of Replacing TiO<sub>2</sub> on Product Quality, Resources and Availability
- What Could be Next
- *Breakout Session 2: Experiences When Evaluating Alternatives (Materials or Approaches)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



# What can be used if E171 cannot?

## Alternate Opacifiers for E171?

- ▶ **There is NO really good alternative to  $\text{TiO}_2$  which can provide similar pigment/opacity properties!**
- ▶ **Calcium Carbonate** can sometimes provide certain useful properties, **but it is not an equivalent opacifier to  $\text{TiO}_2$ .**
- ▶ Some other options exist such as **Tricalcium phosphate, Isomalt, Starches** and a few others which may work in some limited applications.





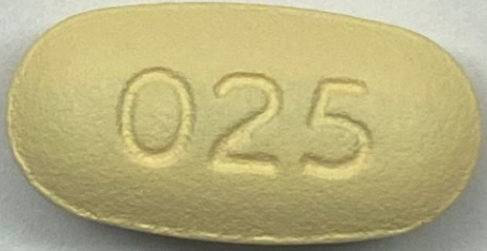
Control Group

Supplier 1  
TiO<sub>2</sub> Free PVA

Supplier 1  
TiO<sub>2</sub> Free HPMC

Supplier 2  
TiO<sub>2</sub> Free HPMC

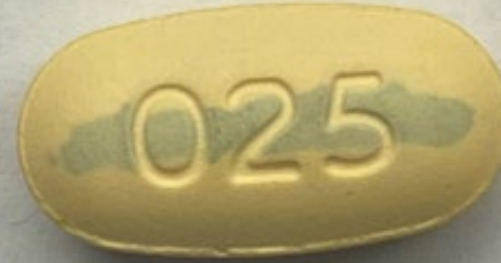
3% TiO<sub>2</sub> HPMC coating



3%



3%



3%



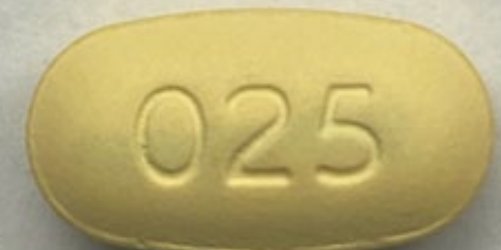
uncoated



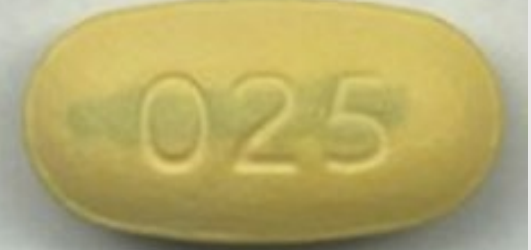
9%



8%



10%



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**Breakout Session Ground Rules**

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





# Breakout Session Ground Rules

- Today's break-out session is 1 hour 30 minutes; 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**



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**SUMMARY OF DAY 1 BREAKOUTS**



Product Quality Research Institute