PQRI Workshop:

TiO2 Use in Pharmaceuticals
Global Regulatory and Technical Challenges

Breakout Session 2: June 14, 2023

Experiences when Evaluating Alternatives (Materials or Approaches) for use in Pharmaceutical Drug Products

Moderators:

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Breakout Session Ground Rules

- Day 2 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**

Breakout Questions

1. Which alternatives to TiO2 are you evaluating and why were those specific alternative(s) chosen?
2. Are you concerned with the safety of any of the currently employed alternatives to TiO2? If so which alternatives and why?
3. What decision/acceptance criteria are being used to say an alternative is considered acceptable?
4. What specific technical challenges are being encountered during your evaluations of TiO2 alternatives?
5. Is a change in appearance considered a barrier for introduction of an alternative to TiO2 for your marketed product?
6. What unit dosage marking techniques do you currently employ and how does removal of TiO2 and use of alternatives impact those unit dose marking capabilities?