FINAL Program as of 6/7/23

June 13-14, 2023 (Hybrid Event)

Bethesda Marriott - 5151 Pooks Hill Rd, Bethesda, MD 20814

PQRI Workshop:

TiO2 Use in Pharmaceuticals – Global Regulatory and Technical Challenges

Day 1 – June 13, 2023 8:00 AM – 5:00 PM US ET	
7:30 – 8:00 AM **7:45 – 8:00 AM**	***Continental Breakfast (in person)*** ***Pre-Workshop Check Connections (virtual)***
8:00 - 8:15 AM ET	***Welcome and Introductory Remarks*** David Schoneker IPEC-Americas, Black Diamond Regulatory Consulting LLC; Chair - PQRI Workshop Organizing Committee
Overview of the Potential EU Ban of TiO2 in Pharmaceuticals	
8:15 – 9:00 AM	***Update on the History and Current Status of TiO2 (E171) in Europe (Foods and Pharmaceuticals) and Concerns Related to Excipients Containing Nanoparticles*** Kevin Hughes, Colorcon Ltd (IPEC Europe) and Bram Baert, Lonza
9:00 – 9:45 AM	***Critical Considerations About the Basis for EFSA's Opinion on TiO2 Safety in Foods*** David Lockley, Venator (TDMA)
9:45 – 10:00 AM	**BREAK**
New TiO2 Safety Information since the EFSA Opinion	
10:00 – 10:45 AM	***A Review of the Genotoxicity of Titanium Dioxide (TiO2)*** David Kirkland, Kirkland Consulting
10:45 – 11:30 AM	***A Weight of Evidence Review of the Carcinogenicity of TiO2*** Samuel Cohen, University of Nebraska Medical Center
11:30 AM – 12:00 PM	***Evaluation of the Immunologic and Intestinal Effects of Dietary E 171 (Food Grade Titanium Dioxide) Consumption*** Lance K. Blevins, Institute for Integrative Toxicology, Michigan State University
12:00 – 1:00 PM	**LUNCH BREAK**

1:00 – 1:30 PM	***Panel Discussion and Q&A*** Moderator: David Schoneker Panelists: Kevin Hughes, Bram Baert, David Lockley, David Kirkland, Sam Cohen, Lance Blevins
Global Assessment of TiO2 Safety	
1:30 – 2:15 PM	***FDA and other Regulator Perspective on TiO2 Safety – Current Global Status*** David Schoneker, IPEC-Americas, Black Diamond Regulatory Consulting, LLC
2:15 – 3:00 PM	***Efforts in the US to Ban TiO2 in Various States and Through a Color Additive Petition*** Jay West, Titanium Dioxide Stewardship Council
3:00 – 3:30 PM	***TDMA's New Science Program for TiO2*** David Kirkland, Kirkland Consulting & David Lockley, Venator (TDMA)
3:30 – 3:45 AM	**BREAK**
3:45 – 5:00 PM	***Breakout Session 1 – Scientific Understanding & Awareness of the Safety of TiO2*** *There will be two concurrent breakouts utilized to discuss the topic to facilitate small group discussion.* Moderators: Uma Bruen, Organon and George Collins Jr, Vanderbilt Chemicals LLC Notetakers: Kevin Hughes, Colorcon and Courtney Callis, Eli Lilly and Company
5:00 PM	***Day 1 Closing Remarks*** *- In breakout sessions*
5:30 – 6:30 PM	***Networking Reception***

PQRI Workshop:

TiO2 Use in Pharmaceuticals – Global Regulatory and Technical Challenges

Day 2 – June 14, 2023 8:15 AM – 5:30 PM US ET	
8:15 – 8:30 AM US ET	***Pre-Workshop Check Connections***
8:30 – 9:00 AM	***Welcome to Day 2 and Review of Day 1 Breakouts*** David Schoneker IPEC-Americas, Black Diamond Regulatory Consulting, LLC; Chair - PQRI Workshop Organizing Committee
TiO2 (E171) and Currently Available Alternatives	
9:00 – 9:30 AM	***Overview of Pharmaceutical Uses of TiO2 and Technical Challenges with the Use of Alternatives*** Mike Tobyn, Bristol Myers Squibb
9:30 – 10:00 AM	***Technical Challenges Substituting TiO2 from Different Coating Producers' Point of View*** Charlie Cunningham, Colorcon
10:00 – 10:30 AM	***Replacing TiO2: Challenges and Opportunities From a Capsule Shell Producer Point of View*** Bram Baert, Lonza
10:30 – 10:45 AM	**BREAK**
The Impact of Replacing TiO2 on Product Quality, Resources and Availability	
10:45 – 11:15 AM	***Examples of Technical Challenges in Drug Products with Titanium Dioxide Alternatives*** Jason Melnick, Eli Lilly and Company
11:15 – 11:45 AM	***Data and Analytical Requirements and Resource Impact of Switching to TF-film Coats: From One Product to Thousands*** Andreas Abend, Merck
11:45 – 12:15 PM	***Impact on a Large Global Pharmaceutical Manufacturer: Manufacturing, Supply, & Patient Implications of a TiO2 Ban in Pharmaceuticals*** Bruno Hancock, Pfizer Inc.
12:15 – 1:00 PM	**LUNCH BREAK**

1:00 – 1:30 PM	***Panel Discussion and Q&A*** Moderator: David Schoneker Panelists: Mike Tobyn, Charlie Cunningham, Bram Baert, Jason Melnick, Andreas Abend, Bruno Hancock
1:30 – 2:15 PM	***Challenges to Providing Essential Drugs if a TiO2 Ban Takes Place: Generic Drug Manufacturer Perspective*** David Cragin, Teva
What Could be Next	
2:15 – 2:45 PM	***Potential for Expansion of Similar Concerns in Europe to Many Other Important Excipients based on the French ANSES list of Food Additives that May Contain Nanoparticles (Update on E172)*** Thomas Broschard, EMD Serono Inc./EI72 Consortium
2:45 – 3:00 PM	**BREAK**
3:00 – 4:30 PM	***Breakout Session 2 – Experiences when Evaluating Alternatives (Materials or Approaches) for Use in Pharmaceutical Drug Products*** *There will be two concurrent breakouts utilized to discuss the topic to facilitate small group discussion.* Moderators: Jason Melnick, Eli Lilly and Company and Andreas Abend, Merck Notetakers: Bram Baert, Lonza and Rohit Tiwari, Eli Lilly and Company
4:30 – 4:45 PM	**BREAK** – To reconnect from breakout rooms
4:45 – 5:00 PM	***Review of Day 2, Summary of Key Points and Actions Needed and Closing Remarks*** David Schoneker IPEC-Americas, Black Diamond Regulatory Consulting, LLC; Chair - PQRI Workshop Organizing Committee

Workshop Faculty

Andreas Abend, Ph.D., Director, Merck & Co., Inc.
Bram Baert, Ph.D., Associate Director Regulatory Affairs, Lonza
Lance K. Blevins, Ph.D., Assistant Professor, Institute for Integrative Toxicology, Michigan State University
Thomas Broschard, Ph.D., ERT, Senior Toxicologist, Chemical and Preclinical Safety Department, EMD Serono/Merck Healthcare KGaA
Uma Bruen, Ph.D., Director, Lead Toxicology and Quality Support, Organon
Samuel M. Cohen, MD, Ph.D., Professor, University of Nebraska Medical Center
David W. Cragin, Ph.D., DABT, Senior Director, Teva Pharmaceutical
Charlie Cunningham, Technical Director, NALAN, Colorcon
George Collins, Jr., BS, Vice President, Vanderbilt Chemicals LLC
Bruno C. Hancock, Ph.D., Head of Materials Science, Pfizer Inc.
Kevin Hughes, BSc, QA/RA Manager, Colorcon Ltd and IPEC Europe
David Kirkland, Ph.D., Consultant, Kirkland Consulting
David Lockley, Ph.D., ERT, Toxicology & Regulatory Defence Director, Venator and Chair of the Titanium Dioxide Manufacturers Association (TDMA) Scientific Committee and Regulatory Task Force
Jason Melnick, MS, Senior Director, Eli Lilly and Company
David Schoneker, Black Diamond Regulatory Consulting LLC; Chair - PQRI Workshop Organizing Committee; IPEC-Americas
Mike Tobyn, Ph.D, Senior Scientific Director, Bristol Myers Squibb
Jay West, Executive Director, Titanium Dioxide Stewardship Council

Workshop Organizing 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.