

9/3/2024



DAY 2 - October 9, 2024

Safety and Quality

- 8:30- 8:35** **Welcome/ Opening Remarks**
Salon 3 Alexandra Kowcz, EVP of Science, PCPC
- 8:35- 9:20** **MoCRA Implementation Activities and Agency Priorities (Safety & Quality)**
Salon 3 Dr. Linda M. Katz, Director, Office of Cosmetics & Colors, FDA
- 9:20- 10:00** **FDA Inspection Readiness (Safety & Quality)**
Salon 3 CDR Chad Thompson, Director, Investigations Branch, Office of Pharmaceutical Quality, Division 1, FDA
- 10:00- 10:30** **Coffee Break in EXPO area**
- 10:30 -11:15** **From Titanium Dioxide to BPA: Have We Entered an Era of Chemophobia? (Safety)**
Salon 3 Dr. Norbert Kaminski, Director, Center for Research on Ingredient Safety and Institute for Integrative Toxicology, Michigan State University
- Cosmetic vs. Drug: How to Manage Dual Facilities (Quality)**
 Roundtable with Industry Quality Experts
Salon 1 Don Ye, Vice President, Global Corporate and R&D Quality, Estee Lauder
 Liam Jablesnik, Vice President, Quality & Regulatory, Mana Products
 Cathleen Owen, Director, Pharmaceutical and Personal Care Services, Q Laboratories
 Steve Riedell, Director, Corporate Quality Assurance, Procter & Gamble
- 11:15 -12:00** **Detailed Aggregate Exposure Analysis Shows that Exposure to Fragrance Ingredients in Consumer Products Is Extremely Low (Safety)**
Salon 3 Dr. Anne Marie Api, President, The Research Institute for Fragrance Materials (RIFM)
- Salon 1 **Change Management (Quality)**
 Melissa Schneider, Associate Director of Regulatory Compliance, Compliance Insights
- 12:00 -1:30** **Lunch / EXPO Break**
Plaza Ballroom

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1:30- 2:15

Building your Evidence Base: Approaches and Tools for Identification, Selection, Evaluation, and Assembly of Existing Data for Ingredient Safety Substantiations (Safety)

Salon 3

Dr. Daniele Wikoff, Chief Scientific Officer, ToxStrategies

Salon 1

FDA Update (Quality)

Alonza Cruse, Director, Office of Pharmaceutical Quality Operations, FDA

2:15- 3:00

Use of Post Consumer Resin (PCR) in Cosmetic Packaging: Balancing Safety and Sustainability (Safety)

Salon 3

Dr. Ramez Labib, Principal Toxicologist, Venebio Consulting

Salon 1

Quality Agreements (Quality)

Paula R. Katz, Of Counsel, Covington

3:00- 3:20

EXPO break

3:20- 4:00

OTC Monograph Activities (Safety)

Salon 3

Dr. Theresa Michele, Director, Office of Nonprescription Drugs, CDER, FDA

3:20-4:15

Case Study and Panel Discussion: Featuring Regulatory Adventure Stories – Myths or Facts (Quality)

Salon 1

Alonza Cruse, Director, Office of Pharmaceutical Quality Operations, FDA

Paula R. Katz, Of Counsel, Covington

Melissa Schneider, Associate Director of Regulatory Compliance, Compliance Insights

CDR Chad Thompson, Director, Investigations Branch, Office of Pharmaceutical Quality, Division 1, FDA

Alexandra Kowcz, EVP of Science, PCPC

4:00- 4:40

How AI will Transform Toxicology: Focus on Cosmetic Safety Assessment (Safety)

Salon 3

Dr. Thomas Hartung, Doerenkamp-Zbinden Chair Professor, Center for Alternatives to Animal Testing (CAAT), Johns Hopkins Bloomberg School of Public Health

4:40-4:45

Closing Remarks

Salon 3

Alexandra Kowcz, EVP of Science, PCPC