



WORKSHOP AGENDA

Tuesday, March 31 | 11:00 am – 4:30 pm EDT

11:00 am Welcome and introductions – **Dusti Gallagher**, *Eversole Associates*

Session 1: Navigating the U.S. Regulatory System

Moderator: Dusti Gallagher

11:15 am U.S. Regulatory Agencies & Role within the Coordinated Framework

- USDA-APHIS – **Donna Lalli**
- EPA – **Shannon Borges**
- FDA – **Jason Dietz**

12:45 pm Q&A Discussion

1:45 pm Lunch Break

Session 2: Review & Discussion of Case Study #1: Canker-resistant Citrus and HLB-resistant Citrus

Moderator: Wayne Parrott

2:15 pm Case Study Overview: Canker-resistant Citrus and HLB-resistant Citrus – **Nian Wang**, *University of Florida*

2:45 pm APHIS response – **Rebecca Fletcher**

3:05 pm EPA response – **Amanda Pierce**

3:25 pm FDA response – **Charles Kanobe**

3:45 pm Q&A discussion

4:30 pm Wrap up & Adjourn Day 1 – **Dusti Gallagher**



Wednesday, April 1 | 11:00 am – 5:30 pm EDT

11:00 am Welcome and introductions – **Dusti Gallagher**, *Eversole Associates*

Session 3: Review and Discussion of Case Study #2: Insect Resistant and Herbicide Tolerant DP23211 Maize

Moderator: Chris Dardick

11:00 am Case Study #2 Overview – Insect Resistant and Herbicide Tolerant DP23211 Maize – **Jamie Staley**, *Corteva*

11:30 am EPA response – **Alex Blumenfeld**

11:50 am FDA response – **Jing Ning**

12:10 pm APHIS response – **Katharine Swoboda Bhattarai**

12:30 pm Q&A Discussion

1:15 pm **Lunch Break**

Session 4: Beyond the Trait: Field Trials and Marketing Strategies

Moderator: Wayne Parrott

1:45 pm The Nuances of Biotech Field Trials & Permitting – **Chris Dardick**, *ARS*

2:15 pm Marketing Strategies: How to Avoid Over Promising and Under Delivering New Product Value and Benefits – **Sarah Evanega**, *Okanagan Specialty Fruits*

2:45 pm Q&A Discussion

Session 5: Review & Discussion of Case Study #3: Gene-edited S4A Strawberry

Moderator: Wayne Parrott

3:15 pm Case Study #3 Overview: Gene-edited S4A Strawberry – **Muffy Koch**, *J.R. Simplot*

3:45 pm FDA response – **Matthew Fabian**

4:05 pm APHIS response – **Rebecca Fletcher**

4:25 pm EPA response – **Amanda Pierce**

4:45 pm Q&A Discussion

5:30 pm Wrap up & Adjourn Day 2 – **Dusti Gallagher**



Thursday, April 2 | 10:00 am – 2:00 pm EDT

11:00 am Welcome and introductions – **Dusti Gallagher**, Eversole Associates

Session 6: An International Regulatory Perspective

Moderator: Dusti Gallagher

10:00 am An Overview of Canada's Regulatory Frameworks for Genetically Engineered and Gene-Edited Crops – **Jordan Bean**, Health Canada

11:00 am Q&A Discussion

Session 7: Dissecting the U.S. Regulatory System

Moderator: Jennifer Rowland

12:00 pm Ask the Regulator: Common Mistakes and Pitfalls about Developing a Regulatory Plan for the U.S. Regulatory System.

Panel participants: **Jason Dietz and Jianmei (Jamie) Zhu**, FDA

Subray Hegde, APHIS

Mike Mendelsohn, EPA

1:45 pm Workshop Wrap up & Announcements – **Dusti Gallagher and Wayne Parrott**

2:00 pm Adjournment