

DAY ONE: October 10, 2018

- 8:00 a.m. – 8:45 a.m. **Registration, Continental Breakfast**
- 8:45 a.m. – 9:00 a.m. **Welcome and Introduction**
- 9:00 a.m. – 10:00 a.m. **The Basics of FDA Food-Contact Regulation – an Overview**
- Defining a Food Additive
 - Clearance Options and Exemptions
 - FDA’s Food Contact Notification Program
- 10:00 a.m. – 10:45 a.m. **Understanding Food Additive Regulatory Clearances**
- Interpreting Scope and Limitations
 - Cross-References
- 10:45 a.m. – 11:15 a.m. **Break**
- 11:15 a.m. – 12:00 p.m. **An Update from the U.S. Food and Drug Administration**
Guest Speaker Invited: U.S. Food and Drug Administration
- 12:00 p.m. – 1:15 p.m. **Lunch**
- 1:15 p.m. – 2:15 p.m. **The Basics of European Food-Contact Regulation – an Overview**
- Framework Regulation
 - GMP Regulation
 - Plastics Regulation
 - Non-Harmonized Materials
- 2:15 p.m. – 2:45 p.m. **Break**
- 2:45 p.m. – 3:45 p.m. **Technical Considerations – USA and EU: Similarities and Differences**
- Migration Calculations and Testing
 - Toxicity Considerations
- 3:45 p.m. – 4:30 p.m. **Impurities and Non-Intentionally Added Substances**
- Suitable Purity Assessments under FDA GMP Regulation
 - Regulation of NIAS under EU Plastics Regulation
 - Case Studies
- 4:30 p.m. – 4:45 p.m. **Q&A**
- 5:30 p.m. – 9:00 p.m. **Cocktail Reception and Networking Dinner**
Join the presenters and your colleagues for cocktails at the hotel followed by dinner at Ruth’s Chris Steak House in Crystal City.
(both events are complimentary; RSVP is required for dinner at Ruth’s Chris Steak House)

DAY TWO: October 11, 2018

- 8:00 a.m. – 8:30 a.m. **Continental Breakfast**
- 8:30 a.m. – 9:15 a.m. **Customer Assurance Considerations**
- U.S. and EU Approaches to Customer Assurance
 - Types of Assurances/Warranties/Contracts
 - Providing Suitable Assurance Statements
- 9:15 a.m. – 10:00 a.m. **Good Manufacturing Practices: What are They? What to Do When Something Goes Wrong!**
- GMP Requirements
 - GMP Problems – Assessing the Situation/Scope
 - Customer Communications
 - Recalls
- 10:00 a.m. – 10:30 a.m. **Break**
- 10:30 a.m. – 11:15 a.m. **Regulation of Food Packaging under MERCOSUR**
- Regulatory Framework
 - Sector-specific Legislation
 - Update to Revision of Positive List of Additives
- 11:15 a.m. – 12:00 p.m. **Food Packaging Regulations in Japan**
Guest Speaker: Mitsuhiro Shigekura, Executive Director, Japan Hygienic Olefin and Styrene Plastics Association
- 12:00 p.m. – 1:15 p.m. **Lunch**
- 1:15 p.m. – 2:00 p.m. **Regulation of Food Packaging in China**
- Updates on China's Food Safety Law and Hygienic Standards
 - Petitioning for New Substances in China
- 2:00 p.m. – 2:30 p.m. **California's Proposition 65**
- Overview of Requirements
 - Impact of New Warning Requirements
- 2:30 p.m. – 3:00 p.m. **Overview of Recent Developments Affecting Food Contact Materials**
- U.S. State Law Activities, Current FCN Challenges
 - Impact of Brexit in the EU
 - Other Issues of Current Interest
- 3:00 p.m. – 3:15 p.m. **Closing Remarks**
- 3:15 p.m. **Seminar Adjourns**