



**2021 Association of Food and Drug Officials Drug and Medical
Products Virtual Conference
Update on Drug and Device Regulations
April 13 – 14, 2021**

Tuesday, April 13, 2021

1:00 – 1:10 **Welcome and Survey of Participants** – Steven Mandernach, Executive Director,
Association of Food and Drug Officials

Session Moderator: Nancy Singer, President, Compliance-Alliance, LLC

1:10 – 1:40 **FDA - Where We Are and Where We May Be Going in the Area of Drug Quality
in 2021 and Beyond**
Alonza Cruse, Director, Office of Pharmaceutical Quality Operations, Office of
Regulatory Affairs, U.S. Food and Drug Administration

1:40 - 2:10 **The Opportunities and Challenges of Using Real World Evidence to Support
FDA's Regulatory Decisions in the Area of Drug, Biologics and Devices**
John Concato, Associate Director for Real-World Evidence Analytics, Office of
Medical Policy, Center for Drug Evaluation and Research, U.S. Food and Drug
Administration

Pablo Morales, MD, Chief Medical Officer, Office of Clinical Evidence and
Analysis, Center for Devices and Radiological Health, U.S. Food and Drug
Administration

2:10 - 2:20 **Break**

Session Moderator: Cynthia Culmo, Principal Consultant, CC Consulting

2:20 – 2:50 **Managing and Preventing Drug and Device Shortages**
Emily Thakur, R.Ph., Team Leader Drug Shortages Staff, U.S. Food and Drug
Administration

- 2:50 – 3:20 **Managing and Selling Medical Devices in the UK and Northern Ireland**
Kimberly Trautman, Executive Vice President, Medical Device International Services, NSF Medical Devices
- 3:20 – 3:50 **Update on Canadian Regulation of Drugs and Medical Products**
Mary Morgan, Director, Health Product Compliance Risk Management, Health Canada
- Chad Sheehy, Acting Director, Medical Devices Compliance Program, Regulatory Operations and Enforcement Branch, Health Canada
- 3:50 to 4:00 **Closing Remarks:** Megan Snyder, Manager, Drugs and Medical Devices, Texas Department of State Health Services, AFDO Co- Chair of Drugs, Devices & Cosmetics Committee

Wednesday, April 14, 2021

- 1:00 – 1:10 **Welcome and Survey of Participants** – Steven Mandernach, Executive Director, Association of Food and Drug Officials

Session Moderator: Nancy Singer, President, Compliance-Alliance, LLC

- 1:10 – 1:40 **FDA Inspections and Enforcement Actions in This New Environment**
Elizabeth Miller, Pharma.D., Assistant Commissioner for Medical Products And Tobacco Operations, Office of Regulatory Affairs, U.S. Food and Drug Administration

- 1:40 – 2:10 **Update on Products Coming into the United States**
Dan Solis, Assistant Commissioner for Import Operations, U.S. Food and Drug Administration

- 2:10 – 2:20 **Break**

Session Moderator: Ballard Graham, Retired, U.S. Department of Food and Drug Administration

- 2:20 – 2:50 **CDRH Quality Pilot – Voluntary Medical Device Manufacturing and Product Quality**
Daniel Walter, Policy Analyst, Center for Devices and Radiological Health, Office of Product Evaluation and Quality, U.S. Department of Food and Drugs Administration

2:50 - 3:50 – Compliance/Interactive Session – Get Your Questions Answered

Moderator - Julie Larsen, Principal, Director of Inspection Readiness,
BioTeknica

Armando Zamora, Senior Advisor to the Associate Commissioner for Partnerships and Policy, Office of Partnerships and Operational Policy and Acting Director for the Division of Enforcement, Office of Partnerships and Operational Policy's Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, U.S. Food and Drug Administration

Dawne Hines, Division Director, Division of Northeast Imports, Office of Regulatory Affairs, U.S. Food and Drug Administration

Daniel Walter, Policy Analyst, Center for Devices and Radiological Health, Office of Product Evaluation and Quality, U.S. Department of Food and Drugs Administration

Mary Morgan, Director, Health Product Compliance & Risk Management, Health Canada

Chad Sheehy, Acting Director, Medical Devices Compliance Program, Regulatory Operations and Enforcement Branch, Health Canada

3:50 – 4:00 **Closing Remarks:** - Mark Sestak, AFDO President, Deputy Director, Division of Food, Milk, & Lodging, Alabama Department of Public Health

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