

“Pathways to Global Unity”

SATURDAY, JUNE 9, 2018

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| 8:00 am – 12:00 pm | Environmental Sampling as a Tool for Solving Outbreaks at the Retail Food Level Location: Environmental samples can often link an illness to establishment for a period of time after food is no longer available. Learn more about how to conduct environmental sampling in retail food (restaurants, grocery, etc) for outbreak investigations including practical exercises. |
| 9:00 am – 12:00 pm | The Effective Regulator: A Workshop on Improving Your Communication Skills Location: Join Nancy Singer, JD, LLM, RAC and Daniela Drago, PhD, RAC assistant professors at George Washington School of Medicine and Health Sciences, prominent retired AFDO alumni, and current members in an interactive session where you will discover key communication skills that will improve your performance in the workplace. Topics to be covered include: the essentials skills required by regulators; how to project an image of authority and competence; ways to handle difficult situations gracefully; and email techniques to motivate people to take action. <i>Daniela Drago, PhD, RAC, Assistant Professor, George Washington School of Medicine and Health Sciences</i> <i>Nancy Singer, President, Compliance Alliance</i> |
| 8:00 am – 12:00 pm | HACCP System Implementation, A Guide for Inspectors Location: Once a HACCP plan has been approved, what must a restaurant/retailer engaging in a specialized processing method do to implement the plan successfully? In this workshop, we dive into HACCP record keeping requirements and verification activities and discuss how to overcome challenges posed by limited resources, seasonal menus and rotating suppliers. Deliverables from this workshop include strategies for enforcement of HACCP requirement and deeper understanding of HACCP system implementation in the retail/food service environment. <i>Charlie Kalish, Managing Member, Food Safety Guides</i> <i>Michael Kalish, Managing Member, Food Safety Guides</i> |
| 10:00 am – 10:30 am | Break / Exhibitor Showcase Location: |

AFDO Committee Meetings are open to all Conference Attendees


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| 12:30 pm – 2:00 pm | Food Committee Location: Guest Speakers/Presentations: |
| 2:00 pm – 3:30 pm | Retail Food Committee Location: Guest Speakers/Presentations: An innovative hands-on approach to food safety training - Robert Mancini, Environmental Health Officer, Health Canada |
| 3:30 pm – 5:00 pm | Produce Committee Location: Guest Speakers/Presentations: |
| 5:00 pm – 6:00 pm | AFDO Committee Chairs and Co-Chairs Meeting Location: |

SUNDAY, JUNE 10, 2018

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| 7:30 am – 9:30 am | Continental Breakfast Location: |
| AFDO Committee Meetings are open to all Conference Attendees | |
| 8:00 am – 9:00 am | Endowment Foundation Location: |
| 8:00 am – 9:30 am | Food Protection & Defense Committee Location: Guest Speaker/Presentation: |
| 9:00 am – 10:00 am | Industry Associate Membership Committee Location: |
| 9:00 am – 10:00 am | Administrative Committee Location: |
| 10:00 am – 3:00 PM | Break / Exhibitor Showcase Location: |
| 9:30 am – 11:00 am | Foodborne Outbreak & Emergency Response Committee Location: Guest Speaker/Presentation: |

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| 10:30 am – 12:00 pm | Drugs, Devices & Cosmetics Committee Location: Guest Speaker - Dr. Ali K. Yetisen, Harvard University - Dermal Abyss: Tattoos as medical condition monitors |
| 11:00 am – 12:00 pm | Professional Development Committee Location: Guest Speakers/Presentations: |
| 11:00 am – 12:00 pm | Laboratory, Science and Technology Committee Meeting Location: Guest Speaker/Presentation: |
| 11:30 pm – 12:30 pm | Seafood Committee Location: Guest Speaker/Presentation: Welcome and Updates Rita Johnson, Florida Department of Agriculture and Courtney Mickiewicz, Virginia Department of Agriculture and Consumer Services Control of Pathogens in Ready-to-Eat Seafood Products: Introduction to Industry Manual Lisa Weddig, National Fisheries Institute Updates from U.S. Food and Drug Administration Steven Bloodgood, U.S. Food and Drug Administration Questions/Discussion |
| 12:00 pm – 12:30 pm | Lunch On Your Own - Cash-N-Carry Lunches will be Available Location: |
| 12:30 pm – 1:30 pm | Cannabis Committee Location: Guest Speaker/Presentation: |
| 12:30 pm – 1:30 pm | Laws & Regulations Committee Location: Guest Speaker/Presentation: |
| 12:30 pm – 3:30 pm | Body Art Committee Location: Guest Speaker/Presentation: |
| 1:30 pm – 3:30 pm | International & Government Relations Committee Location: Moderators: Ken Moore, Director, Health Product Compliance and Risk Management, Health Canada LaTonya Mitchell, District Director, U.S. Food and Drug Administration Guest Speaker/Presentation: |
| 2:00 pm – 3:00 pm | Alumni Committee Location: Session Leader: Nancy Singer, President, Compliance Alliance |
| 1:30 pm – 3:30 pm | Partners with a Common Purpose Location: The concept of “Partners with a Common Purpose” recognizes that establishing equal partnerships and collaborating at meetings and forums will generate greater input for continuously improving food safety and public health. One of AFDO’s primary roles in this initiative is to ensure there is broad agreement on the common purpose and that all stakeholders are engaged. During this session, industry food safety professionals and regulatory officials will engage with each other in a facilitated “safe-harbor” environment as they examine their ability to impact food safety control through self-examination, discussions and forums. Discussions might include, but are not limited to the elements of successful programs, barriers in implementing intervention strategies, lessons learned, sharing of best practices, and future challenges and opportunities. Guest Speaker/Presentation: |
| 3:30 pm – 4:20 pm | First Time Attendee Orientation Location: Guest Speaker/Presentation |



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| 4:30 pm – 6:00 pm | <p>Opening Session Location: <i>Pamela Miles, AFDO President and Program Supervisor, Virginia Department of Agriculture and Consumer Services</i></p> <p>Invocation <i>T.B.D.</i></p> <p>Welcome from Burlington <i>T.B.D.</i></p> <p>Welcome from NEFDOA <i>T.B.D.</i></p> <p>Endowment Foundation Address <i>John Young, Chair, AFDO Endowment Foundation, and Partner, Young & Associates</i></p> <p>President's Address <i>Pamela Miles, AFDO President and Program Supervisor, Virginia Department of Agriculture and Consumer Services</i></p> <p>Glenn W. Kilpatrick Memorial Address <i>Sandra Eskin, Director, Food Safety, The Pew Charitable Trusts</i></p> |
| 6:00 pm – 7:30 pm | <p>Welcome Reception Location: Sponsored by the AFDO Associate Members and the North East Food and Drug Officials Association (NEFDOA) Thank you to all our contributing Industry Sponsors. All are welcome to attend!</p> |
| 8:00 pm – 10:00 pm | <p>AFDO Trivia & Karaoke Location: <i>Sponsored by General Mills</i></p>  |


Food Sessions

MONDAY, JUNE 11, 2018

MORNING JOINT SESSION

Moderator:

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| 7:30 am - 9:00 am | Continental Breakfast Location: |
| 8:00 am - 8:15 am | <p>Announcements & Awards Location: <i>Pamela Miles, AFDO President and Program Supervisor, Virginia Department of Agriculture and Consumer Services</i></p> |
| 8:15 am – 9:30 am | <p>U.S. Food and Drug Administration Regulatory Affairs Update Location: <i>Melinda Plaisier, Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration</i></p> |
| 9:30 am – 10:00 am | <p>Hurricane Maria and Puerto Rico's Response to Regulated Food and Drug Firms Location: Hurricane Maria is regarded as the worst natural disaster on record in Puerto Rico. The tenth-most intense Atlantic hurricane on record and the most intense tropical cyclone worldwide of 2017. This session focuses on the challenges presented in the FDA regulated products arena during this hurricane. <i>T.B.D.</i></p> |
| 10:00 am - 10:30 am | Break / Exhibitor Showcase Location |
| Moderator: Randy Treadwell, Program Manager, Rapid Response & Emergency Management, Washington State Department of Agriculture | |
| 10:30 am - 11:15 am | <p>FSIS Update Location: <i>Roberta Wagner, Assistant Administrator, Office of Policy and Program Development, U.S. Department of Agriculture</i></p> |
| 11:15 am – 12:00 pm | <p>Meet Irma and Harvey Location: Hurricane Harvey is tied with Hurricane Katrina as the costliest tropical cyclone on record, inflicting at least \$125 billion (2017 USD) in damage, primarily from catastrophic rainfall-triggered flooding in the Houston metropolitan area. Hurricane Irma is one of the most powerful Atlantic hurricanes ever recorded in the Caribbean and Florida. This session with focus on best practices learned during the response to Irma & Harvey.</p> <p>Moderators: Randy Treadwell, Washington Department of Agriculture Alida Sorenson, Minnesota Department of Agriculture</p> <p>Panelists: Brenda Morris, Florida Department of Agriculture Tishara Coleman, Texas Department of State Health Services U.S. Food and Drug Administration – T.B.D.</p> |


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| 12:00 pm – 1:30 pm | Lunch On Your Own - Cash-N-Carry Lunches will be Available Location: |
| 12:00 pm - 1:30 pm | Burditt Lunch Location:  Take a fun filled journey into AFDO's past, present and future. Your first stop will be 1915 where you will meet prominent AFDO members and supporters and hear their exact words that were delivered at the 19th Annual Conference held in Berkeley, California. A number of important actions and Resolutions came out of this conference including the association's expression of concern for misleading packaging, continued support for federal state cooperation, and a Resolution recommending states enact food safety requirements for all public eating establishments. Following a short visit to 1917 and 1943, we will salute all former and current Women who served as AFDO Presidents. Finally, we take a journey into the AFDO future to witness some very entertaining and interesting events. |

BREAKOUTS (CHOOSE 1)

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| Food Breakout Location: | | Retail Breakout Location: | |
| 1:30 pm – 2:30 pm | Food Safety on the Little Screen | 1:30 pm – 2:45pm | Investigators' Discoveries: Digging Deeper for Food Safety |
| Examine compliance with recommended food safety practices in television cooking shows and learn first-hand about the safety experiences from the 7 th season of Food Networks "The Great Food Truck Race" winners. | | | |
| 2:30 pm – 3:15 pm | What's Ready-to-Eat? | | |
| Flour, frozen vegetables and other products that have not traditionally been consider ready to eat food have recently resulted in massive nationwide recalls. Join this panel to explore the question of "what is ready-to-eat"? <i>Courtney Bidney, Director, Global Scientific and Regulatory Affairs, General Mills</i> <i>Sanjay Gummalla, PhD., Vice President, Scientific and Regulatory Affairs, American Frozen Food Institute (AFFI)</i> <i>U.S. Food and Drug Administration – T.B.D.</i> | | | |
| 3:15 pm – 3:45 pm | Break / Exhibitor Showcase Location: | 2:45 pm – 3:15 pm | Break / Exhibitor Showcase Location: |

BREAKOUTS (CHOOSE 1)

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| 3:45 pm – 4:30 pm | Local Food Process Authority – Evaluating Unusual Foods | 3:15 pm – 5:30 pm | Retail "Speed dating" session |
| <i>Dr. Brian Nummer, Food Safety Specialist, Associate Professor, Utah State University Food Safety Extension</i> | | Join us in celebrating the successful implementation of the Retail Program Standards and you can get tips on how they did it. FDA and CFSAN, along with State and local governments will exhibit projects and tools developed to help implement and conform to the Retail Program Standards. You will have the opportunity to visit numerous tables, each representing a different Retail Standard or different stage of implementation of the Standards. There is something for everyone, from the newly enrolled to those who have made some progress and who are working toward continuous improvement. Moderator: Cathy Hosman, Project Officer, Office of Partnerships, U.S. Food and Drug Administration <i>Pete Salisbury, Project Manager, CFSAN, Retail Food Partnerships, U.S. Food and Drug Administration</i> <i>Gary Coggins, Environmental Health Manager, Sr., New River Health District, Virginia Department of Health</i> <i>Jayne Smith, Berkshire Public Health Coalition</i> <i>Ron Honeycutt, Director of Environmental Health, Pitt County Health Department</i> <i>Dawn Beck, Associate Director of Public Health, Olmsted County Public Health Services, Minnesota</i> <i>Katie Lott, RS, Program Manager, Food & Community Safety, Tacoma-Pierce Health Department, Washington</i> <i>Mark Speltz, Retail Program Lead/Training Specialist, Iowa Department of Inspection & Appeals</i> <i>Adam Inman, Education, Training and Enforcement Manager, Kansas Department of Agriculture</i> <i>Summer Williams, Emergency Response Coordinator, Division of Food Safety, Florida Department of Agriculture & Consumer Services</i> <i>Jayne E Smith, RS, Berkshire Public Health Alliance Inspector, Egremont, Massachusetts</i> | |
| 4:30 pm – 5:30 pm | Food Recovery Systems | | |
| <i>Mitzi Baum, M.Sc, Managing Director of Food Safety, Feeding America</i> <i>Jason Maring, Chief Operations Officer, Vermont Foodbank+⁻</i> -- | | | |

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| 6:00 pm – 10:00 pm | MONDAY NIGHT EVENT: “ENJOY THE JOURNEY”  Join us for a Sunset Dinner Cruise on Lake Champlain aboard the Spirit of Ethan Allen. A sumptuous buffet dinner, music, and a memorable evening awaits. The dining area is enclosed and fully climate controlled, but there is plenty of room on deck to enjoy the views of the Adirondack’s, Green Mountains, Burlington and possibly a sighting of our lake monster “Champ.” Be sure to have your camera ready. “It’s always a beautiful day on the lake.” |
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TUESDAY, JUNE 12, 2018

MORNING JOINT SESSION

Moderator: Peter Salsbury, Project Manager, U.S. Food and Drug Administration

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| 7:30 am - 9:00 am | Continental Breakfast Location: |
| 8:00 am - 8:15 am | Announcements & Awards Location: <i>Pamela Miles, AFDO President and Program Supervisor, Virginia Department of Agriculture and Consumer Services</i> |
| 8:15 am – 8:45 am | Public Health Crisis of Opioid Addiction Communities all across the country have been facing the challenge of opioid addiction. Learn more about the four-year-old Hub and Spoke system in Vermont that has made a significant positive impact in many important personal and public health and safety indicators, and how this evidence-based work relates to regional and national public health efforts. <i>Mark Levine, MD, Commissioner, Vermont Department of Health</i> |
| 8:45 am - 9:15 am | Medical Marijuana |
| 9:15 am - 10:15 am | Data Integrity FDA depends heavily on the integrity of data generated in support of pre-approved applications and to confirm that medical products are manufactured in a manner to ensure their safety and effectiveness. This presentation will discuss the critical element of data integrity, data integrity and 21 CFR Part 11, FDA’s increasing interest focusing on data reviews during surveillance inspections and recent FDA findings of data integrity issues. <i>Mike Chappell, Principal, Regulatory Compliance, Greenleaf Health LLC</i> |

Break / Exhibitor Showcase | Location:

Moderator: Peter Salsbury, Project Manager, U.S. Food and Drug Administration


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| 10:30 am – 11:00 am | U.S. Food and Drug Administration’s Food Program Update Location: <i>Dr. Stephen Ostroff, Deputy Commissioner for Foods and Veterinary Medicine, Office of Foods and Veterinary Medicine, U.S. Food and Drug Administration</i> |
| 11:00 am – 12:00 pm | Why??? Location: Understanding why a breakdown in the food system occurred is an emerging trend in foodborne illness and food incident investigations. Learn about multiple projects focused on getting to “WHY” the incident happened. <i>Dr. Laura Brown, Behavior Scientist, National Center for Environmental Health, Centers for Disease Control and Prevention</i> <i>Carol Conroy, Associate, Safe Food Project, The Pew Charitable Trusts</i> <i>Carla Tuite, MS, LCDR, US Public Health Service, Human and Animal Food Policy Branch, Office of Strategic Planning and Operational Policy, ORA, FDA</i> |

12:00 pm – 1:30 pm **Lunch On Your Own - Cash-N-Carry Lunches will be Available** | Location:

BREAKOUTS (CHOOSE 1)

| Food Breakout Location: | | Retail Breakout Location: | |
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| 1:30 pm – 2:00 pm | Moving Towards a Public Health Systems Approach | 1:30 pm – 3:00 pm | Millennials/Communication |
| FDA’s public health mandate, an overview of a public health inspection process. This session will also include an update on new developments on Sanitary Transportation and Intentional Adulteration rules. <i>Joann Givens, U.S. Food and Drug Administration (Invited)</i> | | <i>Benjamin Chapman, Ph.D., Associate Professor, Food Safety Specialist, Department of Agricultural and Human Sciences, North Carolina State University</i> | |
| 2:00 pm – 3:00 pm | A Conversation with the Experts on Produce Safety | | |
| This panel includes experts from FDA, States and the Produce Safety Alliance. | | | |

3:00 pm – 3:30 pm **Break / Exhibitor Showcase | Location:**

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| 3:30 pm – 4:00 pm | FSMA and Imports | 3:30 pm – 5:30 pm | Home Meal Kits |
| 4:00 pm – 4:15 pm | Third Party Accreditation & Systems Recognition | | |
| <i>Ellen Buchanan, U.S. Food and Drug Administration</i> | | | |
| 4:15 pm – 5:30 pm | Preventive Controls: Moving Food Safety into 21st Century | | |
| This panel includes FDA, State and Industry Representative discussing the implementation and lessons learned. | | | |
| 6:30 pm – 7:30 pm | President's Reception Location: | | |
| 7:30 pm – 9:30 pm | Wiley Award Banquet Location:  | | |
| WEDNESDAY, JUNE 13, 2018 | | | |
| 7:30 am - 9:00 am | Continental Breakfast Location: | | |
| BREAKOUTS (CHOOSE 1) | | | |
| Retail Breakout Sessions Location: | | | |
| 8:00 am – 9:15 am | Outbreaks | | |
| 9:15 am – 10:00 am | Entomophagy - An Introduction | | |
| Back when I was a kid, there was this saying: “Nobody likes me, everybody hates me, I’m going to the garden to eat worms”. Back then, it had an obvious negative connotation, but maybe the times have changed! Entomophagy – it’s what’s for breakfast (and lunch, and dinner)! This presentation will give you a basic understanding of entomophagy, as well as a look into its popularity, nutritional value, and economic potential. It may even make you pause and think a bit. | | | |
| <i>Jim Dingman, Environmental Health Manager, Plano</i> | | | |
| 10:00 am – 10:30 am | Break Location: | | |
| 10:00 am – 12:00 am | Sushi – Special Processes | | |
| <i>Thomas W. Nerney, Retail Food Specialist, U.S. Food and Drug Administration Dr. Larry Payton, Corporate Director of Quality Assurance, Sushic, LLC</i> | | | |
| 11:30 am – 12:00 pm | AFDO Business Meeting Location: | | |
| Cannabis: Location: | | | |
| 8:00 am – 9:00 am | Status of Cannabis Legalization | | |
| 9:00 am – 10:00 am | Tour of Edibles – What’s out there; What’s prohibited | | |
| 10:00 am – 10:15 am | Break Location: | | |
| 10:15 am – 11:45 am | Regulatory Panel on Challenges on Implementing a Cannabis Edibles Program | | |
| Discussion to touch on Lessons Learned, Mislabeling and Misbranding, Trade Secrets, and Manufacturing Challenges | | | |
| 11:45 am – 12:15 pm | Lunch On Your Own - Cash-N-Carry Lunches will be Available Location: | | |
| 12:15 pm – 2:00 pm | Edibles and Laboratory Testing: Dosing, Contaminants and Adulterants | | |

Drug & Medical Device Sessions

MONDAY, JUNE 11, 2018

MORNING JOINT SESSION

Moderator

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| 7:30 am - 9:00 am | Continental Breakfast Location: |
| 8:00 am - 8:15 am | Announcements & Awards Location: <i>Pamela Miles, AFDO President and Program Supervisor, Virginia Department of Agriculture and Consumer Services</i> |
| 8:15 am - 9:30 am | U.S. Food and Drug Administration Regulatory Affairs Update Location: <i>Melinda Plaisier, Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration</i> |
| 9:30 am - 10:00 am | Hurricane Maria and Puerto Rico's Response to Regulated Food and Drug Firms Location: Hurricane Maria is regarded as the worst natural disaster on record in Puerto Rico. The tenth-most intense Atlantic hurricane on record and the most intense tropical cyclone worldwide of 2017. This session focuses on the challenges presented in the FDA regulated products arena during this hurricane. <i>T.B.D.</i> |
| 10:15 am - 10:30 am | Break Location: |
| Moderator: | |
| 10:30 am - 10:35 am | Welcome Location: |
| 10:30 am - 11:15 am | Using Artificial Intelligence to Advance Quality Operations Location: Representatives from Xavier University's 2017 Artificial Intelligence Summit working teams will explain how companies can use artificial intelligence to identify signals that can predict product failures. Participants will be engaged in discussing how they can realistically employ artificial intelligence solutions within their organizations using a crawl, walk, run scheme. <i>Charlene Banard, Senior Vice President, Shire</i> <i>Mac McKeen, Fellow, Regulatory Science, Boston Scientific</i> <i>Marla Phillips, Director, Xavier Health, Xavier University</i> |
| 11:15 am - 12:00 pm | Post Market Management of Non-Conformances in Medical Devices Location: |
| 12:00 pm - 1:30 pm | Lunch On Your Own – Cash-N-Carry Lunches will be Available Location: |
| 12:00 pm - 1:30 pm | BURDITT LUNCH LOCATION:  Take a fun filled journey into AFDO's past, present and future. Your first stop will be 1915 where you will meet prominent AFDO members and supporters and hear their exact words that were delivered at the 19th Annual Conference held in Berkeley, California. A number of important actions and Resolutions came out of this conference including the association's expression of concern for misleading packaging, continued support for federal state cooperation, and a Resolution recommending states enact food safety requirements for all public eating establishments. Following a short visit to 1917 and 1943, we will salute all former and current Women who served as AFDO Presidents. Finally, we take a journey into the AFDO future to witness some very entertaining and interesting events. |
| Moderator: | |
| 1:30 pm - 2:15 pm | Drug Supply Chain Security Act – FDA Update Location: <i>Shanika Booth, Supervisory Consumer Safety, Center for Devices and Radiological Health, Office of Compliance, U.S. Food and Drug Administration</i> |
| 2:15 pm - 3:00 pm | Supply Chain Control Location: <i>Robert SeEVERS, Senior Advisor, Pearl Pathways</i> |
| 3:00 pm - 3:30 pm | Break Location: |
| 3:30 pm - 4:15 pm | Structured Product Labeling & Supply Chain Management Location: <i>Ken Coleman Stevenson II, VP Regulatory Affairs, Ceutical Laboratories, Inc</i> |

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| 4:15 pm - 5:00 pm | Enforcement Trends in Drugs, Devices & Compounding Pharmacy Inspections Location: |
| <p>What emerging compliance issues are likely to lead to regulatory action? Leadership from FDA's District and Division Offices will share the most notable trends in drug and device compliance including how inspection results drive compliance outcomes such as recalls, warning letters and related regulatory actions.</p> <p><i>Joseph Matrisciano, New England District Director, Office of Medical Device and Radiological Health Operations Program Division / Director, U.S. Food & Drug Administration</i> <i>Diane Amador-Toro, New Jersey District Director, Pharma Program Division I Director, Office of Regulatory Affairs, U.S. Food & Drug Administration</i> <i>Maya Davis, Compliance Officer, U.S. Food and Drug Administration</i></p> | |
| 6:00 pm - 10:00 pm | Monday Night Event: "ENJOY THE JOURNEY"  <p>Join us for a Sunset Dinner Cruise on Lake Champlain aboard the Spirit of Ethan Allen. A sumptuous buffet dinner, music, and a memorable evening awaits. The dining area is enclosed and fully climate controlled, but there is plenty of room on deck to enjoy the views of the Adirondack's, Green Mountains, Burlington and possibly a sighting of our lake monster "Champ." Be sure to have your camera ready. "It's always a beautiful day on the lake."</p> |
| TUESDAY, JUNE 12, 2018 | |
| MORNING JOINT SESSION | |
| Moderator: | |
| 7:30 am - 9:00 am | Continental Breakfast Location: |
| 8:00 am - 8:15 am | Announcements & Awards Location: <i>Pamela Miles, AFDO President and Program Supervisor, Virginia Department of Agriculture and Consumer Services</i> |
| 8:15 am - 8:45 am | Public Health Crisis of Opioid Addiction <p>Communities all across the country have been facing the challenge of opioid addiction. Learn more about the four-year-old Hub and Spoke system in Vermont that has made a significant positive impact in many important personal and public health and safety indicators, and how this evidence-based work relates to regional and national public health efforts.</p> <p><i>Mark Levine, MD, Commissioner, Vermont Department of Health</i></p> |
| 8:45 am - 9:15 am | Medical Marijuana |
| 9:15 am - 10:15 am | Data Integrity <p>FDA depends heavily on the integrity of data generated in support of pre-approved applications and to confirm that medical products are manufactured in a manner to ensure their safety and effectiveness. This presentation will discuss the critical element of data integrity, data integrity and 21 CFR Part 11, FDA's increasing interest focusing on data reviews during surveillance inspections and recent FDA findings of data integrity issues.</p> <p><i>Mike Chappell, Principal, Regulatory Compliance, Greenleaf Health LLC</i></p> |
| 10:15 am - 10:30 am | Break Location: |
| Moderator: | |
| 10:30 am - 11:00 am | Canadian MDSAP Location: |
| <p>The Medical Devices Single Audit Program (MDSAP) is a program that allows the conduct of a single regulatory audit of a medical device manufacturer's quality management system to satisfy the requirements of multiple regulatory jurisdictions. Audits are conducted by auditing organizations authorized by participating regulatory authorities to audit under MDSAP requirements. Using MDSAP, medical device manufacturers can be audited for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States. Health Canada has established MDSAP as mandatory for market access starting January 2019. This presentation will highlight MDSAP challenges and opportunities along with the Canadian experience to date with some lessons that could inform convergence activities elsewhere.</p> <p><i>Carey Agnew, LL.B., Associate Director, Medical Devices Bureau, Health Canada</i></p> | |
| 11:00 am - 12:00 pm | International Compliance - Industry Perspective Location: |
| <p><i>Rob Ruff, Executive Director, Medical Device Certification and Training, NSF International</i></p> | |



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| 12:00 pm - 1:30 pm | Working Lunch Presentation* Location:  |
| <p>Handling Regulatory Challenges with Grace Under Pressure During this session, attendees will be divided into teams. The teams will discuss how to handle both potential regulatory challenges and intra-office conflicts. Then a panel of seasoned professionals will comment on the attendees' responses.</p> <p><i>Nancy Singer, President, Compliance-Alliance</i> <i>Courtland Imel, CEO, Ceutical Labs</i> <i>Daniela Drago, PhD, George Washington School of Medicine and Health Sciences</i> <i>Julie Larson, Senior Partner, BioTeknica</i> <i>Joseph Matrisciano, New England District Director, Office of Medical Device and Radiological Health Operations Program Division I Director, U.S. Food & Drug Administration</i> <i>Diane Amador-Toro, New Jersey District Director, Pharma Program Division I Director, Office of Regulatory Affairs, U.S. Food & Drug Administration</i> <i>Adam E. Saltman, M.D., Ph.D. Medical Officer, Center for Devices and Radiological Health, Office of Compliance, U.S. Food and Drug Administration</i></p> <p style="text-align: right;">*Lunch provided only for registered attendees of the Drug & Device Conference Track</p> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;">  <p>Ceutical Labs cGMP COMPLIANCE SPECIALISTS</p> </div> <div style="text-align: center;"> <p>*Sponsored by Ceutical Laboratories, Inc and BioTeknica</p> </div> <div style="text-align: center;">  <p>BIOTEKNICA ENGINEERING & REGULATORY SERVICES</p> </div> </div> | |
| Moderator: | |
| 1:30 pm - 2:15 pm | Aligning Hygienic Design Requirements with Inspections Location: |
| <i>Angela Anandappa Ph.D., Director, Alliance for Advanced Sanitation, University of Nebraska-Lincoln</i> | |
| 2:15 pm - 3:00 pm | Design Controls for Combination Products Location: |
| <i>Nazia Rahman, Lead Consumer Safety Office, Center for Devices and Radiological Health, Office of Compliance, U.S. Food and Drug Administration</i> | |
| 3:00 pm - 3:30 pm | Break Location: |
| 3:30 pm - 4:15 pm | Using Benefit Risk in Making Post Market Decisions Location: |
| <p>CDRH's mission is to protect and promote the public health, while assuring that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. This means that the benefit of device use should outweigh the risk. However, after a device is approved or cleared for the market, unforeseen circumstances can change the benefit-risk balance. Determinations regarding the best way to manage the problem can be helped by a consistent, transparent, and harmonized benefit-risk assessment. In this session, Dr. Saltman will discuss FDA's current thinking about using benefit-risk assessments in the post market arena, using medical device recalls as a working example.</p> <p><i>Adam E. Saltman, M.D., Ph.D. Medical Officer, Office of Compliance, Center for Devices and Radiological Health, Office of Compliance, U.S. Food and Drug Administration</i></p> | |
| 4:15 pm - 5:00 pm | Compliance Question Panel Location: |
| <p>The compliance question and answer panel is made up of three distinguished representatives from the U.S. Food and Drug Administration and Health Canada who will answer compliance questions from industry participants. This is an excellent opportunity for industry to ask questions about their more difficult decisions, interpretations and applications of the regulations to their products. Questions will be answered directly by those who are decision makers in interpreting what practices are considered compliant and what is considered acceptable according to the regulations</p> <p><i>Joseph Matrisciano, New England District Director, Office of Medical Device and Radiological Health Operations Program Division I Director, U.S. Food & Drug Administration</i> <i>Diane Amador-Toro, New Jersey District Director, Pharma Program Division I Director, Office of Regulatory Affairs, U.S. Food & Drug Administration</i> <i>Mark Bailey, Supervisor, Medical Devices Inspection Program, Health Canada</i></p> | |
| 6:30 pm - 7:30 pm | President's Reception Location: |
| 7:30 pm - 9:30 pm | Wiley Award Banquet Location:  |
| WEDNESDAY, JUNE 13, 2018 | |
| 7:30 am - 9:00 am | Continental Breakfast Location: |
| Cannabis: Location: | |
| 8:00 am - 2:00 pm | Moderator: Lezli Engelking, Founder, Foundation of Cannabis Unified Standards (FOCUS) |