



“Change: Collaborating Today for a Safer Tomorrow”

SATURDAY, JUNE 17, 2017

8:00 am – 12:00 pm	<p>Environmental Assessment at Retail Location: Ballroom of the Americas “F” – Level 2</p> <p>This half-day workshop will focus on the role of an environmental assessment within the context of a foodborne disease outbreak investigation and food safety system. The skills needed to participate in an outbreak investigation are different from those needed to inspect food service operations and the role of environmental health staff is critical. You will learn when and how to use the National Environmental Assessment Reporting System (NEARS) environmental assessment tool and its components during the workshop. It is recommended that before you take this half day workshop, you register and take CDC’s (free) e-Learning on Environmental Assessments of Foodborne Illness Outbreaks. It is available at https://www.cdc.gov/nceh/ehs/elearn/ea_fio/index.htm.</p> <p><i>Erik Coleman, MPH, Health Scientist, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Environmental Health</i> <i>Vince Radke, Sanitarian, Centers for Disease Control and Prevention</i></p>
9:00 am – 12:00 pm	<p>Effective Communication Skills Location: Ballroom of the Americas “D” – Level 2</p> <p>In a recent study of 1000 employers, 81% of those surveyed believed that their perception of a person’s management ability is directly affected by the quality of the person’s participation in meetings. To increase your effectiveness in meetings and in other challenging situations in the workplace, join Nancy Singer of Compliance-Alliance, Dr. Daniela Drago from GW University, and prominent retired AFDO alumnae and current members* in an interactive session where you will learn skills and practice techniques to make you more effective in in the workplace, and improve your chances for promotion.</p> <p>Moderator: <i>Nancy Singer, President, Compliance Alliance</i> <i>Dr. Candace Jacobs, Assistant Director, Washington State Department of Agriculture, Food Safety & Consumer Services</i> <i>Mark Reed, Project Manager, AFDO</i> <i>Steve Steingart, Retired, Allegheny County Health Department</i> <i>Bill Teeter, Retired, Canadian Food Inspection Agency</i></p>
9:30 am – 11:30 am	<p>FoodSHIELD: Document Control Working Session Location: 335C – Level 3</p> <p>This session will be focused on enabling and extending the functionality of document control in FoodSHIELD. Help work through the best features and capabilities to support your needs by attending this working session. Potential discussions of the Alerts tool and Task Management apps to review current and suggested functionality for next versions as time allows. Feel free to bring your laptops and questions.</p> <p><i>Eric Hoffman, President, Datastream Connexion</i> <i>Ted Steinmann, IT Manager, National Center for Food Protection and Defense</i></p>
10:00 am – 10:30 am	<p>Break / Exhibitor Showcase Location: Ballroom of the Americas Prefunction – Level 2</p>
<p>AFDO Committee Meetings are open to all Conference Attendees</p>	
12:30 pm – 2:30 pm	<p>Food Committee Location: Ballroom of the Americas “E” – Level 2</p> <p>Guest Speakers/Presentations:</p> <p>Update on Partnership for Food Protection, <i>Barbara Cassens, Director for the Office of Partnerships, U.S. Food and Drug Administration</i></p> <p>Update on the National Food Safety Data Exchange, <i>Lisa Creason, Director, Information Systems Management Office of Regulatory Affairs, U.S. Food and Drug Administration</i></p> <p>Update on Produce Rule Implementation, <i>Byron Beerbower, Consumer Safety Officer, ORA – PSN, U.S. Food and Drug Administration</i></p> <p>State and Territory Food Safety Regulation of Leased Commercial Kitchens (LCKs), <i>Odeisa Hichez, Food Inspector, New York State Department of Agriculture & Markets</i></p> <p>Corrections after FDA and Wisconsin Manufactured Food Inspections Show Comparable Compliance Rates, <i>Skya Murphy, Program And Policy Analyst, Wisconsin Department of Agriculture, Trade & Consumer Protection</i></p>
2:15 pm – 3:00 PM	<p>Break / Exhibitor Showcase Location: Ballroom of the Americas Prefunction – Level 2</p>
2:30 pm – 5:00 pm	<p>Retail Food Committee Location: Ballroom of the Americas “E” – Level 2</p> <p>Guest Speakers/Presentations:</p> <p>Making the Grade: Do Current Restaurant Grading Systems Fulfill Stakeholder Expectations?, <i>Jessica Egan, Research Scientist, New York State Department of Health</i></p> <p>Control of Behavior-Centric Risk Factors Between Two Management Groups, <i>Renita Stroupe, Health Educator, DeKalb County Board of Health</i></p> <p>E Commerce – Pick and Pack Delivery, <i>Liz Duffy, Director, Walmart Food Safety and Regulatory Compliance Global eCommerce</i></p> <p>USDA Update, <i>Shaun Smith, Regional Director, OIEA, U.S. Department of Agriculture</i></p> <p>CFP Update, <i>Patrick Guzzle, CFP Conference Chair, and Food Protection Program Manager, Idaho Department of Health and Welfare</i></p> <p>Commercial / Shared Kitchen, <i>Angela Montalbano, Supervisor, NY State Department of Agriculture and Markets</i></p>
5:00 pm – 6:00 pm	<p>AFDO Committee Chairs and Co-Chairs Meeting Location: 335C – Level 3</p>

6:00 pm	Saturday Night Event Sponsored by Computer Aid, Inc. - Meet in the hotel lobby at approximately 5:45 pm
	Computer Aid will be sponsoring a social networking event as part of the AFDO conference on Saturday, June 17 th from roughly 6:00 p.m. - 11:00 p.m. that is open to all AFDO conference attendees. A bus will be picking up attendees at the Hilton Americas-Houston Hotel at 6:00 p.m. and taking them to a historical section of town. The main attraction will be Barringer Bar and Lounge, which is in the historic part of downtown Houston. The lounge resides on the first floor of the Brewster building, the 11th oldest building in Houston, built in 1873. Inside the dimly lit, shotgun style restaurant, the laid-back vibe is accented by antique furniture and black and white photos of Houston's past. CAI will be providing a beverage ticket along with a spread of finger foods and appetizers. The bus will pick us up at the Barringer Lounge location at around 10:45 p.m. so attendees are welcome to explore downtown or stay and mingle at Barringer. We look forward to seeing you there.
SUNDAY, JUNE 18, 2017	
7:30 am – 9:30 am	Continental Breakfast Location: Ballroom of the Americas Prefunction – Level 2
AFDO Committee Meetings are open to all Conference Attendees	
8:00 am – 9:00 am	Endowment Foundation Location: Ballroom of the Americas “A” – Level 2
8:00 am – 9:30 am	Food Protection & Defense Committee Location: Ballroom of the Americas “E” – Level 2 Guest Speaker/Presentation: FDA Intentional Adulteration , Colin Barthel, Policy Analyst, U.S. Food and Drug Administration Project Trends and Updates from FPDI , Ted Steinmann, IT Manager, National Center for Food Protection and Defense Guest Speaker , Nathaniel C. Rice, Ph.D., Behavioral Toxicologist, ORISE Postdoctoral Fellow, U. S. Army Medical Research Institute of Chemical Defense
9:00 am – 10:00 am	Industry Associate Membership Committee Location: Ballroom of the Americas “A” – Level 2
9:00 am – 10:00 am	Administrative Committee Location: 335C – Level 3
10:00 am – 3:00 PM	Break / Exhibitor Showcase Location: Ballroom of the Americas Prefunction – Level 2
9:30 am – 11:00 am	Foodborne Outbreak & Emergency Response Committee Location: Ballroom of the Americas “E” – Level 2 Guest Speaker/Presentation: CoE Updates , Vince Radke, Sanitarian, Centers for Disease Control and Prevention InFORM Updates , Carrie Rigdon, Response and Compliance Supervisor, Minnesota Department of Agriculture CIFOR Updates , Ernie Julian, Chief of Food Protection, Rhode Island Department of Health Community Size and Retail Risk Factors in Iowa Retail Food Establishments , Sherri Sigwarth, Food Safety Specialist, Iowa Department of Inspection & Appeals CORE Updates , Karen Blickenstaff, Team Lead, Coordinated Outbreak Response and Evaluation Network, U.S. Food and Drug Administration
10:30 am – 12:00 pm	Drugs, Devices & Cosmetics Committee Location: Ballroom of the Americas “F” – Level 2 Guest Speaker/Presentation: USP Update , Alissa D. Jijon, Senior Counsel, Global Legal Affairs - Standards, United States Pharmacopeial Convention Bio-north Texas Update , David Musgrave, Chairman, Texas Healthcare and Bioscience Institute ASQ Update , Fatma Ali, President, FMA Consulting, LLC FDMIC Update , Karen Daugherty, Director, Investigations Branch, U.S. Food and Drug Administration; Former Regulatory Co-Chair, FMDIC
11:00 am – 12:00 pm	Professional Development Committee Location: Ballroom of the Americas “A” – Level 2 Guest Speakers/Presentations: Indiana Food Safety Regulator Enumeration , JoAnna Beck, Food Safety Farm Consultant, Indiana State Department of Health Inspector Use of Chinese Language Retail Food Safety Training Tools , Autumn Schuck, Food Safety and Lodging Program, Kansas Department of Agriculture
11:00 am – 12:30 pm	Laboratory, Science and Technology Committee Meeting Location: Ballroom of the Americas “C” – Level 2 Guest Speaker/Presentation: Laboratory Curriculum Framework Project , Craig Kaml, EdD, Senior Vice President, International Food Protection Training Institute Estimating Risk by Measuring Coliform on Common Touch Surfaces , Jo-Ann Xiong-Mercado, Environmental Health Specialist, Marion County Public Health Department
11:30 pm – 1:00 pm	Lunch On Your Own - Cash-N-Carry Lunches will be Available Location: Ballroom of the Americas Prefunction – Level 2
12:00 pm – 1:30 pm	FoodSHIELD: Resource Libraries & More Location: Ballroom of the Americas “B” – Level 2 This presentation will focus on the new Resource Library and the ability to search across documents, photos, videos, links, news, and meetings to find information. Discussions about how to best manage content and learning more about how these features can be used. Feel free to bring your laptops and questions. Also presenting information on Conference and Training Manager tools recently released. Eric Hoffman, President, Datastream Connexion Ted Steinmann, IT Manager, National Center for Food Protection and Defense

12:30 pm – 2:30 pm	<p>Tattoo Demonstration – Presented by the Body Art Sub-Committee Location: Ballroom of the Americas “D” – Level 2</p> <p>The demonstration will feature the current tattooing industry best practices. This will be an opportunity for AFDO members to observe the typical tattooing experience from start to finish along with commentary. AFDO members in attendance will be encouraged to provide constructive feedback and ask questions for discussion. This collaboration of professionals in the tattoo industry and regulators will be used to support the on-going work of the AFDO Body Art Sub-Committee. Specifically, information gathered during this demonstration will be used in the continuing development of comprehensive educational, training and safety/risk-mitigation strategies for use in the tattooing and related industries. This event will be licensed by the Texas Department of State Health Services.</p> <p>Guest Speaker/Presentation: <i>Sean Brown, Eternal Ink and Director for Eternal Republic Tattoo Company</i> <i>Featured Artist, Liz Cook, Rebel Muse Tattoo Studio</i></p>
1:30 pm – 3:00 pm	<p>Seafood Committee Location: Ballroom of the Americas “E” – Level 2</p> <p>Guest Speaker/Presentation: Use of Critical Control Points (CCPs) In Florida Seafood HACCP Plans, <i>Matthew Coleman, Environmental Manager, Florida Department of Agriculture & Consumer Services</i> Highlights of Revised Protocol, <i>Courtney Mickiewicz, Regional Manager, Virginia Department of Agriculture and Consumer Services</i> Catfish Rule, <i>Roberta Wagner, Deputy Assistant Administrator, U.S. Department of Agriculture</i> Seafood Fraud, <i>Lisa Weddig, National Fisheries Institute</i></p>
1:30 pm – 3:00 pm	<p>Laws & Regulations Committee Location: Ballroom of the Americas “C” – Level 2</p> <p>Guest Speaker/Presentation: Spice Lead Levels and Blood Lead Levels in Maryland Children, <i>Kyle Shannon, Rapid Response Team Coordinator, Maryland Department of Health & Mental Hygiene</i> Current Trends in State Laws Related to Food, <i>Doug Farquhar, Program Director for Environmental Health, National Conference of State Legislatures</i></p>
2:00 pm – 3:00 pm	<p>Alumni Committee Location: 335C – Level 3</p> <p>Join your fellow AFDO alumni and participate in a lively discussion about ways alumni can play a more active role in the association. Ideas to be discussed include educational sessions delivered by alumni and opportunities for mentoring, networking and outreach to other organizations.</p> <p>Session Leader: <i>Nancy Singer, President, Compliance Alliance</i></p>
2:30 pm – 4:00 pm	<p>Body Art Sub-Committee Location: Ballroom of the Americas “F” – Level 2</p>
3:00 pm – 4:30 pm	<p>International & Government Relations Committee Location: Ballroom of the Americas “C” – Level 2</p> <p>Moderators: <i>Ken Moore, Director, Health Product Compliance and Risk Management, Health Canada</i> <i>LaTonya Mitchell, District Director, U.S. Food and Drug Administration</i></p> <p>Guest Speaker/Presentation: International Capacity Building in Seafood, <i>Brett Koonse, Consumer Safety Officer, Aquaculture and Source Control Specialist, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition</i> Systems Recognition: Canada and New Zealand, <i>Camille Brewer, Director, International Affairs, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition</i> Health Canada GMP Transformation, <i>Alexis Grolla, Manager GMP Inspection East/West, Health Canada</i></p>
4:30 pm – 6:00 pm	<p>Opening Session Location: Ballroom of the Americas “AB” – Level 2 <i>Steven Mandernach, AFDO President and Bureau Chief for Food and Consumer Safety, Iowa Department of Inspection & Appeals</i></p> <p>Welcome from MCAFDO <i>Jason Guzman, Training, Standardization, and Quality Assurance Officer, Texas Department of State Health Services</i></p> <p>IFPTI: Cohort V Graduation Ceremony <i>Gerald Wojtala, Executive Director, International Food Protection Training Institute (IFPTI)</i></p> <p>Endowment Foundation Address <i>John Young, Chair, AFDO Endowment Foundation, and Partner, Young & Associates</i></p> <p>President’s Address <i>Steven Mandernach, AFDO President and Bureau Chief for Food and consumer Safety, Iowa Department of Inspection & Appeals</i></p> <p>Glenn W. Kilpatrick Memorial Address <i>Joseph A. Levitt, Partner, Hogan Lovells US LLP</i></p>
6:00 pm – 7:30 pm	<p>Welcome Reception Location: Ballroom of the Americas “DE” – Level 2</p> <p>Sponsored by the AFDO Associate Members and the Mid-Continental Association of Food and Drug Officials (MCA) Thank you to all our contributing Industry Sponsors. All are welcome to attend!</p>
8:00 pm – 10:00 pm	<p>AFDO Bingo Location: Ballroom of the Americas “F” – Level 2</p> <p><i>Sponsored by General Mills</i></p> 

Food Sessions

MONDAY, JUNE 19, 2017

MORNING JOINT SESSION


Moderator: Laurie Farmer, Director State Cooperative Programs, SE Region, U.S. Food and Drug Administration

7:00 am - 9:00 am	Continental Breakfast Location: Ballroom of the Americas Prefunction – Level 2
8:00 am - 8:15 am	Announcements & Awards Location: Ballroom of the Americas “ABC” – Level 2 <i>Steven Mandernach, AFDO President and Bureau Chief for Food and Consumer Safety, Iowa Department of Inspection & Appeals</i>
8:15 am - 9:30 am	U.S. Food and Drug Administration Regulatory Affairs Update Location: Ballroom of the Americas “ABC” – Level 2 ORA’s senior leaders will provide an update and overview of the changes to ORA’s organizational structure under the program alignment initiative. They will also share information about significant operational changes and key programmatic initiatives, as well as participate in a panel discussion with attendees <i>Melinda Plaisier, Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration</i> <i>Ellen Morrison, Assistant Commissioner for Medical Product and Tobacco Operations, U.S. Food and Drug Administration</i> <i>Michael Rogers, Assistant Commissioner for Human and Animal Food Operations, U.S. Food and Drug Administration</i>
9:30 am - 10:00 am	Preview - Cannabis: New Horizons in Food and Drug Regulations Location: Ballroom of the Americas “ABC” – Level 2 Introduction to Wednesday’s session
10:00 am - 10:30 am	Break / Exhibitor Showcase Location: Ballroom of the Americas Prefunction – Level 2

Moderator: Laurie Farmer, Acting Office Director, Office of State Cooperative Programs, U.S. Food and Drug Administration

10:30 am - 11:15 am	How can third party auditing drive change in Food Safety Culture? Location: Ballroom of the Americas “ABC” – Level 2
This interactive session will open a National discussion of third party auditing as it impacts food safety culture throughout the global food supply. Regulatory and industry participants will understand the role that they play in the influence of food safety culture as it relates to third party audits and what they can control and what they can influence to protect public health and their brands. Moderator: <i>Tara Paster, CEO & President of Paster Training, Inc.</i> Panelist: <i>Stan Hazan, MPH Sr. Director, Scientific & Regulatory Affairs NSF International</i> <i>Melissa Vaccaro, MS, CP-FS, VP of PTI and Consulting Group</i> <i>Darrell Newell Retail Food Safety & QA Director for Comprehensive Food Safety</i>	

11:15 am - 12:00 pm	Be A Bloodhound! Traceback Fundamentals for a Foodborne Outbreak Location: Ballroom of the Americas “ABC” – Level 2
An energetic audience participation session about foodborne illness outbreak traceback investigations from simple to complex. In addition, this session will address the challenges of traceback. Participants will be able to better understand flow diagrams appropriately paired with timelines and how all stakeholders work together. Learn about investigations from the perspectives of all levels of government in the retail and manufactured environments; as well as, the importance of industry involvement during traceback. You will be entertained and educated by FDA’s principle Traceback Investigations Instructor Allen Gelfius and trainer extraordinaire Tara Paster. <i>Allen Gelfius, Consumer Safety Officer, U.S. Food and Drug Administration</i> <i>Tara Paster, CEO & President of Paster Training, Inc</i>	

12:00 pm - 1:30 pm	Lunch On Your Own - Cash-N-Carry Lunches will be Available Location: Ballroom of the Americas Prefunction – Level 2
12:00 pm - 1:30 pm	Burditt Lunch Location: Ballroom of the Americas “E” – Level 2  Take a fun filled journey into AFDO’s past, present and future. Your first stop will be in the year 1910 where you will meet prominent members and supporters and hear their exact words delivered at the 14th Annual Conference that was held at the Hotel Grunewald in New Orleans. This Convention took several important actions including the association’s support for weights and measures laws, a Resolution calling for the appointment by the President of the United States of a “food standard” commission, support for sanitary laws, and support for uniformity in state and national laws. The next stop will be the year 1997 where you will hear portions of an important speech delivered that first promoted an integrated food safety system. And finally, join us as we explore the future AFDO of 2096.

Moderator: Randy Treadwell, Animal Feed/Rapid Response Program Manager, Washington State Department of Agriculture

1:30 pm - 2:15 pm	The Culture of Clean Location: Ballroom of the Americas “ABC” – Level 2
An industry perspective of sanitizers and disinfectants <i>Tracy Graham, Manager of Regulatory Affairs, Ecolab, Inc.</i>	
2:15 pm - 2:45 pm	Fellowship Select Presentations Location: Ballroom of the Americas “ABC” – Level 2
Use of Critical Control Points (CCPs) In Florida Seafood HACCP Plans <i>Matthew Coleman, Environmental Manager, Florida Department of Agriculture & Consumer Services</i>	
State and Territory Food Safety Regulation of Leased Commercial Kitchens (LCKs) <i>Odeisa Hichez, Food Inspector, New York State Department of Agriculture & Markets</i>	
2:45 pm - 3:30 pm	Fellowship Poster Session Location: Ballroom of the Americas Prefunction – Level 2

The poster session features the research projects carried out by the Cohort 6 IFPTI Fellows. Explore the research and discuss findings with the authors. The focus of the Fellows' research is on current food safety or regulatory issues describing the impact on the U.S. Food Safety System.

3:00 pm – 3:30 pm

Break / Exhibitor Showcase | Location: Ballroom of the Americas Prefunction – Level 2

BREAKOUTS (CHOOSE 1)

3:30 pm – 5:00 pm

U.S. Strategies for Improving the Safety of Imported Food | Location: Ballroom of the Americas “AB” – Level 2

The safety of imported food is a global concern due to the great variety and cultural diversity of the foods and ingredients that are imported into the country. Programs that regulate food safety in countries around the world vary in their scope and effectiveness. They may lack adequate funding, expertise, or laboratory resources. Although food safety issues exist in this country as well, there are new legal approaches and innovative efforts designed to assure food imported into this country have met the same strenuous oversight and control mandated for domestic manufacturers as well. Panelists will offer perspectives on a variety of regulatory approaches to food safety at the federal and state levels in the United States, as well as in selected countries and within the food industry itself. Insights into the nature and use of 3rd party audits and verification will also be addressed.

Moderator: *Joe Corby, Executive Director, AFDO*

Stephen Stich, Division Director, New York Department of Agriculture & Markets, Division of Food Safety & Inspection

Todd Cato; Director, FDA Southwest Import District, Office of Regulatory Affairs

Karil Kochenderfer, Principal, Linkages

3:30 pm – 5:30 pm

Learn how YOU can make Advances in Implementation of the Retail Food Program Standards | Location: Ballroom of the Americas “F” – Level 2

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*

Pete Salisbury, Project Manager, CFSAN, Retail Food Protection Staff, U.S. Food and Drug Administration

Deanna Copeland, Manager, Food & Neighborhood Nuisance, Harris County Public Health

Scott Holmes, Manager, Environmental Public Health, Lincoln-Lancaster County Health Department

Lane Brager, Consumer Protection Program Coordinator, Boulder County Public Health

Melissa Ham, Regional Environmental Health Specialist, North Carolina Department of Health and Human Services

Donna Wanucha, REHS, Retail Food Specialist, State Cooperative Programs

Steven Mandernach, President, AFDO and Bureau Chief for Food and Consumer Safety, Iowa Department of Inspection & Appeals

Ruth Clay, MPH, Health Director, City of Melrose

6:15 pm – 10:00 pm

MONDAY NIGHT EVENT: TRAVEL TO THE MOON AT THE HOUSTON SPACE CENTER – LIMITED SPACE AVAILABLE



Your Mission starts with a short film that chronicles the events leading up to the formation of NASA and beyond. Next, enjoy dinner in the Starship Gallery surrounded by one-of-a kind space artifacts including the last Command Module to land on the moon and touch a 3.8 billion years old moon rock.

Sponsored in part by the National Restaurant Association.




TUESDAY, JUNE 20, 2017

MORNING JOINT SESSION

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

7:30 am - 9:00 am	Continental Breakfast Location: Ballroom of the Americas Prefunction – Level 2
8:00 am - 8:15 am	Announcements & Awards Location: Ballroom of the Americas “ABC” – Level 2 <i>Steven Mandernach, AFDO President and Bureau Chief for Food and Consumer Safety, Iowa Department of Inspection & Appeals</i>
8:15 am – 9:00 am	Achieving Foreign Inspection Equivalence Location: Ballroom of the Americas “ABC” – Level 2 <i>Camille Brewer, Director, International Affairs, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition</i>
9:00 am - 10:00 am	Flint Water Crisis – Lessons Learned Location: Ballroom of the Americas “ABC” – Level 2 The Flint, MI water crisis has been the most noteworthy recognition of public water supply contamination to date, but it is not alone in that respect and there are fears that maybe it is only the “tip of the iceberg” when it comes to water supply safety. The Michigan Department of Agriculture and Rural Development (MDARD) was closely involved with consumer health protection as it related to food safety of retail and processing food establishments during this crisis; similarly, the food industry is also very much concerned about water supply safety and the impact it can have on public health. These presentations will focus on MDARD actions during that crisis, and actions that The Coca-Cola Company takes to help protect our water supplies. <i>Sandra Walker, Food Program Manager, Michigan Department of Agriculture & Rural Development</i> <i>Jon Radtke, Manager, Sustainability, The Coca-Cola Company</i>
10:00 am – 10:30 am	Break / Exhibitor Showcase Location: Ballroom of the Americas Prefunction – Level 2
Moderator: Peter Salsbury, Project Manager, CFSAN, U.S. Food And Drug Administration	
10:30 am – 11:15 am	U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition Update Location: Ballroom of the Americas “ABC” – Level 2
Included will be a talk on the integration of CORE, a CFSCAN priorities update and an update on the new Office of Dietary Supplements <i>Ted Elkin, Deputy Director for Regulatory Affairs, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration</i>	
11:15 am – 12:00 pm	Emerging Issues with Shellfish Location: Ballroom of the Americas “ABC” – Level 2
According to the most recent available estimates made by the Food and Drug Administration (FDA), molluscan shellfish--oysters, clams, mussels, and scallops--cause more than 100,000 illnesses annually. To address this public health concern, the Interstate Shellfish Sanitation Conference (ISSC) was formed in 1982 to foster and promote shellfish sanitation through the cooperation of state and federal control agencies, the shellfish industry, and academia. This organization is at the forefront of dealing with food safety issues dealing with shellfish as they provide the guidance and counsel on such matters to State regulatory authorities and the shellfish industry as well. This agenda topic is designed to provide an update on the oversight strategies in place to assure the safe harvesting and marketing of shellfish and address any emerging issues that exist. <i>Ken B. Moore, Executive Director, Interstate Shellfish Sanitation Conference (ISSC)</i>	
12:00 pm – 1:30 pm	Lunch On Your Own - Cash-N-Carry Lunches will be Available Location: Ballroom of the Americas Prefunction – Level 2
12:20 pm – 1:20 pm	Raw Milk Lunch and Learn Location: Ballroom of the Americas “E” – Level 2
An informal primer for the main session raw milk panel at 4:15 PM. A relaxed small group conversation about experiences with raw milk bills and available resources for State Officials	
BREAKOUTS (CHOOSE 1)	
1:30 pm – 3:00 pm	Disaster Response and Lessons Learned Location: Ballroom of the Americas “F” – Level 2
Learn about tools, best practices and real world experiences in emergency response and outbreaks in the retail food setting. Moderator: <i>Steven Mandernach, President, AFDO and Bureau Chief for Food and Consumer Safety, Iowa Department of Inspection & Appeals</i> <i>Carrie Rigdon, PhD, Response Training and Outreach Supervisor, Minnesota Department of Agriculture</i> <i>Lane Drager, Consumer Protection Program Coordinator, Boulder county Public Health</i> <i>Deanna Copeland, Manager, Food & Neighborhood Nuisance, Harris County Public Health</i> <i>Scott Jeansonne, Supervisor, Food & NNA Programs, Harris County Public Health</i>	
1:30 pm – 3:00 pm	Implementing the Produce Safety Rule Location: Ballroom of the Americas “AB” – Level 2
The Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption establishes mandatory food safety practices for farms, both foreign and domestic. With the exception of specific commodities that are rarely eaten raw or will be treated for pathogens later during processing, most fresh produce will be covered. The new requirements resemble the voluntary Good Agriculture Practices (GAPs). Recently, FDA announced that \$21.8 million in federal money will go to 42 states for use in implementing the new regulation. Panelists will discuss initiatives and roles as federal and state agencies collaborate with university and produced industries leaders to implement the FSMA Produce Safety Rule. Moderator: <i>Erik Bungo, Program Supervisor, Produce Safety Program, Virginia Department of Agriculture & Consumer Services</i> Challenges and Opportunities with Implementing New On-Farm Regulatory Program <i>Timothy Slawinski, Food Safety Modernization Unit Manager, Food and Dairy Division, Michigan Department of Agriculture and Rural Development</i> FDA Funding Available for States, NASDA Pilots and Guidance <i>Bob Ehart, Senior Policy & Science Advisor, National Association of State Departments of Agriculture (NASDA)</i> FDA Activities and Plans Highlighting Areas for Collaboration and Complementary Aspects of FDA, NASDA, Industry and State Efforts <i>Stephen Hughes, Team Leader, Produce Safety Network, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration</i> Outreach/Training and Efforts to Conduct Applied Research to Address Scientific Gaps Important for Managing National or Regional Regulatory Issues <i>Don Stoeckel, PH.D. PSA Midwest Regional Extension Associate, Department of Food Science, Cornell University</i>	

3:00 pm – 3:30 pm	Break / Exhibitor Showcase Location: Ballroom of the Americas Prefunction – Level 2
BREAKOUTS (CHOOSE 1)	
3:30 pm – 4:30 pm	Using Social Media to Improve Foodborne Illness Reporting Location: Ballroom of the Americas “F” – Level 2
<p>Twitter and other social media are widely used by the public and are sometimes used by the public to complain about food poisoning. Given the low rates of reporting foodborne illness by the public, Twitter may be a promising new source of data for both surveillance of foodborne illness and connecting constituents with health departments for foodborne illness reporting and response. The HealthMap team at Boston Children’s Hospital developed the FoodBorne Dashboard to collect tweets in a geographic area and display them for food safety professionals to review and reply to. This presentation will describe the functionality of the Dashboard and the results of its implementation and use in the City of St. Louis Department of Health.</p> <p>Moderator: <i>Tara Paster, CEO & President of Paster Training, Inc</i> <i>Dr. Jenine Harris, Associate Professor, Washington University in St Louis</i> <i>Candace DaSilva, Food Establishment Inspector, City of St. Louis Department of Health</i> <i>Kara Sewalk, Program Coordinator, HealthMap, Boston Children’s Hospital</i></p>	
3:30 pm – 4:15 pm	When the Government Comes Knocking: How Pathogens in your Plant Can Lead to Criminal Charges Location: Ballroom of the Americas “AB” – Level 2
<p>The vast majority of foodborne illnesses in the CDC’s PulseNet database remain unsolved. This means that, every day, there are food companies unknowingly processing and selling contaminated foods that are making people sick. To determine if sanitation is adequate, FDA and state regulators frequently swab food processing environments during routine inspections. When a positive food sample collected from a food facility matches a human isolate in the PulseNet database, the consequences can be drastic. Learn about the new potential for criminal liability for firm management when a firm is linked to an outbreak.</p> <p>Moderator: <i>Erik Bungo, Program Supervisor, Produce Safety Program, Virginia Department of Agriculture & Consumer Services</i> <i>Shawn Stevens, Attorney, Food Industry Counsel LLC</i> <i>Donald W Plunkett, J.D., J.M., Food Safety Consultant, Center for Science in the Public Interest</i></p>	
BREAKOUTS (CHOOSE 1)	
4:30 pm – 5:30 pm	Food Safety Culture Location: Ballroom of the Americas “F” – Level 2
<p>How to create a culture of food safety in a highly diverse workforce.</p> <p>Moderator: <i>Dionne Crawford, US Food Safety Supervisor, McDonald’s Corporation</i> <i>Rogercarole Rogers, RcRogers & Associates, LLC</i></p>	
4:15 pm – 5:30 pm	Tools for State Programs Facing Raw Milk Legislation Location: Ballroom of the Americas “AB” – Level 2
<p>Proposed State legislation to legalize the sale of raw unpasteurized milk is becoming a more common bill in states. Have we forgotten the public health reasons for pasteurization? The following panel will discuss the scope of raw milk trends and illnesses, the health risk and tools for state programs.</p> <p>Moderator: <i>Kim Stryker, Env. Program Manager, Alaska Department of Environmental Conservation</i></p> <p>The Scope and Trends of Raw Milk in the US & Illness Data <i>Doug Farquhar, J.D., Program Director for Environmental Health, National Conference of State Legislatures</i> <i>Vince Radke, Sanitarian, Centers for Disease Control and Prevention</i></p> <p>Why Raw Milk? <i>Mary McGonigle Martin, M.S., Public Health Advocate</i></p> <p>Public Health Success Stories and Tools for State Programs <i>Brad Legreid, Executive Director, Wisconsin Dairy Products Association</i></p>	
6:30 pm – 7:30 pm	President’s Reception Location: Ballroom of the Americas Prefunction – Level 2
7:30 pm – 9:30 pm	Wiley Award Banquet Location: Ballroom of the Americas “E” – Level 2 



WEDNESDAY, JUNE 21, 2017

7:00 am - 9:00 am | **Continental Breakfast** | **Location:** Ballroom of the Americas Prefunction – Level 2

BREAKOUTS (CHOOSE 1)

Retail Breakout Sessions | **Location:** Ballroom of the Americas “F” – Level 2

8:00 am – 9:30 am | **Three Health Inspectors Walk Into a Bar**

You might expect they order three different drinks and hilarious antics ensue, but what really happens is that, often, three slight different inspection reports are filed. It’s no joke – in fields that rely on decentralized decisions and regulatory authority, consistency from one professional to another is a challenge, and inconsistency breeds mistrust. Becky Elias from Seattle & King County (WA) Public Health’s Food Protection Program will share what it might take to make public servants more consistent. (Spoiler alert: it’s peer review and can be adapted to the myriad of federal, state, and local government units with decentralized decision-making.)

Moderators: *Joseph Graham, Food Safety Program Supervisor, Washington Department of Health*
Becky Elias, Food & Facilities Section Manager, Environmental Health, Public Health – Seattle & King County

10:00 am – 10:30 am | **Break** | **Location:** Ballroom of the Americas Prefunction – Level 2

10:00 am – 11:30 am | **Potential Hazards Associated with Fermented Foods**

Many fermented foods from exotic locations are now making it onto the culinary scene in the US. These include items such as kimchi, tempe, and kombucha. Traditionally, these have been made in small batches but what are the potential risks when preparing these foods commercially? Please join Dr. Neal and Chef Tyler Henderson in this interactive presentation/demonstration to help inspectors learn the preparation process and identify potential hazards in the preparation, storage and serving of these fermented foods as well as what to look for during health inspections.

Moderator: *Donna Wanucha, Regional Retail Food Specialist, State Cooperative Programs, U.S. Food and Drug Administration*
Jay Neal, PhD, Assistant Provost - Sugar Land, Associate Professor, University of Houston
Tyler Henderson, Chef, Featured on the TV Food Network “Chopped” in 2016

11:30 am – 12:00 pm | **AFDO Business Meeting** | **Location:** Ballroom of the Americas Prefunction – Level 2

Cannabis: New Horizons in Food and Drug Regulations | **Location:** Ballroom of the Americas “AB” – Level 2

8:00 am – 3:00 pm | **Moderator:** *Lezli Engelking, Founder, Foundation of Cannabis Unified Standards (FOCUS)*

8:15 am | **The Credence of Cannabis as Medicine: A Historical Perspective**

Lezli Engelking, Founder, Foundation of Cannabis Unified Standards (FOCUS)

9:00 am | **Introduction to Cannabis, Extractions, Concentrates and Infused Products**

Thuy Vu, Founder & CEO, Thuy Vu Consulting, LLC

10:00 am | **Break**

10:30 am | **What Regulators need to know about Lab Testing**

Jeremy Appen, Vice Chairman of the ASTM D37 Cannabis Standard Committee

11:00 am | **Regulatory Laboratory Perspective on Colorado Cannabis**

Keith Wegner, Laboratory Services Section Chief, Colorado Department of Agriculture

12:45 pm | **Assessing the landscape for successful implementation of marijuana legalization**

Lewis Koski, Co-founder, Freedman & Koski

1:15 pm | **Changes and Issues - Panel Discussion**

Jeff Lawrence, the Division Director of the Colorado Department of Public Health and Environment

Dr. Candace Jacobs, Assistant Director, Washington State Department of Agriculture, Food Safety & Consumer Services

Kevin Armbrust, Professor and Chair Department of Environmental Sciences, College of the Coast and Environment, Louisiana State University

Lewis Koski, Co-founder, Freedman & Koski

2:30 pm | **ASTM Global Cannabis Standards**

Robert Morgan, Director, Technical Committee Operations, ASTM International

11:45 am – 12:45 pm | **Lunch On Your Own – Grab-N-Go Lunches will be Available** | **Location:** Ballroom of the Americas Prefunction – Level 2

12:00 pm – 4:00 pm | **AFDO Board of Directors Meeting** | **Location:** 335C – Level 3

Drug & Medical Device Sessions


MONDAY, JUNE 19, 2017

MORNING JOINT SESSION

Moderator: Laurie Farmer, Director State Cooperative Programs, SE Region, U.S. Food and Drug Administration



7:00 am - 9:00 am	Continental Breakfast Location: Ballroom of the Americas Prefunction – Level 2
8:00 am - 8:15 am	Announcements & Awards Location: Ballroom of the Americas “ABC” – Level 2 <i>Steven Mandernach, AFDO President and Bureau Chief for Food and Consumer Safety, Iowa Department of Inspection & Appeals</i>
8:15 am – 9:30 am	U.S. Food and Drug Administration for Regulatory Affairs Update Location: Ballroom of the Americas “ABC” – Level 2 ORA’s senior leaders will provide an update and overview of the changes to ORA’s organizational structure under the program alignment initiative. They will also share information about significant operational changes and key programmatic initiatives, as well as participate in a panel discussion with attendees <i>Melinda Plaisier, Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration</i> <i>Ellen Morrison, Assistant Commissioner for Medical Product and Tobacco Operations, U.S. Food and Drug Administration</i> <i>Michael Rogers, Assistant Commissioner for Human and Animal Food Operations, U.S. Food and Drug Administration</i>
9:30 am – 10:00 am	Preview - Cannabis: New Horizons in Food and Drug Regulations Location: Ballroom of the Americas “ABC” – Level 2 Introduction to Wednesday’s session
10:00 am - 10:30 am	Break Location: Ballroom of the Americas Prefunction – Level 2





Moderator: Dennis Baker, Retired, U.S. Food and Drug Administration

10:30 am - 10:35 am	Welcome Location: Ballroom of the Americas “D” – Level 2 <i>David Musgrave, Chairman, Texas Healthcare and Bioscience Institute</i>
10:30 am - 11:15 am	Warning Signs that Data Integrity Issues Exist Location: Ballroom of the Americas “D” – Level 2 In this session, you will learn how to get firms to acknowledge that data without integrity leads to dangerous product decisions. To quickly determine if data integrity problems exist at a firm you are auditing, you will learn about the key records to request, the critical questions to ask, and areas for you to focus on when inspecting an audit trail. <i>John Avellanet, Managing Director & Principal, Cerulean Associates Inc</i> <i>Nancy Singer, President, Compliance-Alliance, LLC</i>
11:15 am - 12:00 pm	Embracing a Culture of Self Correction - making the most of your internal audit program Location: Ballroom of the Americas “D” – Level 2 Although Drug and Device manufacturers are all required to have internal audit programs in place, most are ineffective. This presentation explores challenges for internal audit programs and potential solutions to truly drive internal audits to their full potential. <i>Julie Larsen, Senior Partner, BioTeknica, Inc</i>
12:00 pm – 1:30 pm	Lunch On Your Own – Grab-N-Go Lunches will be Available Location: Ballroom of the Americas Prefunction – Level 2
12:00 pm - 1:30 pm	Burditt Lunch Location: Ballroom of the Americas “E” – Level 2  Take a fun filled journey into AFDO’s past, present and future. Your first stop will be in the year 1910 where you will meet prominent members and supporters and hear their exact words delivered at the 14th Annual Conference that was held at the Hotel Grunewald in New Orleans. This Convention took several important actions including the association’s support for weights and measures laws, a Resolution calling for the appointment by the President of the United States of a “food standard” commission, support for sanitary laws, and support for uniformity in state and national laws. The next stop will be the year 1997 where you will hear portions of an important speech delivered that first promoted an integrated food safety system. And finally, join us as we explore the future AFDO of 2096.

Moderator: Cynthia Culmo, Principal Consultant, CC Consulting

1:30 pm - 2:15 pm	Supply by Design - Good Supply Practices for the 21st Century Location: Ballroom of the Americas “D” – Level 2 Industry manufacturers, suppliers, and FDA officials have been working together since 2012 with Xavier University to uncover true root causes to supply chain challenges experienced throughout the pharmaceutical and medical device industries. This team is solidifying practical, business-smart solutions that are commensurate with the needs of your supply chain. Leave this session with tools you can implement immediately for measurable differences in your supply chain effectiveness. <i>Dr. Marla Phillips, Director, Xavier Health, Xavier University</i>
2:15 pm - 3:00 pm	FDA Training Initiatives Location: Ballroom of the Americas “D” – Level 2 To ensure that its employees have the necessary skills to do their jobs, FDA offers numerous training programs. During this session you will learn about the training courses that FDA employees are required to take and the online courses that are available to state and local regulators. <i>Jane Kreis, Captain, U.S. Public Health Service, Acting Deputy Pacific Regional Food and Drug Director</i>
3:00 pm – 3:30 pm	Break Location: Ballroom of the Americas Prefunction – Level 2

3:30 pm - 4:15 pm	FDA Alumni Panel Location: Ballroom of the Americas “D” – Level 2
<p>Ever have a burning question for FDA but could never get a straightforward answer? This may be your opportunity! Participate in a conversational one-on-one discussion with Dennis Baker and Ballard Graham, two of AFDO’s esteemed alumni, as they share their wisdom, opinions and experiences gained through decades in leadership positions within the FDA, state government and industry.</p> <p>Moderator: <i>John Misock, Chair, AFDO Drugs, Devices, and Cosmetics Committee and Food Technologist, U.S. Food and Drug Administration</i> <i>Dennis Baker, Retired, U.S. Food and Drug Administration</i> <i>Ballard Graham, Retired, U.S. Food and Drug Administration</i></p>	
4:15 pm - 5:00 pm	Import Controls: Explaining the Process Location: Ballroom of the Americas “D” – Level 2
<p>FDA’s Import Operations Branch oversees the process for FDA regulated products that are trying to come into the United States. During this session, you will learn how the process works and the steps to take if your products are stopped at a port.</p> <p><i>Dan Solis, Director of the Los Angeles District, Import Operations Branch, U.S. Food and Drug Administration</i></p>	
6:15 pm – 10:00 pm	<p>Monday Night Event: Travel to the Moon at the Houston Space Center – LIMITED SPACE AVAILABLE </p> <p>Your Mission starts with a short film that chronicles the events leading up to the formation of NASA and beyond. Next, enjoy dinner in the Starship Gallery surrounded by one-of-a kind space artifacts including the last Command Module to land on the moon and touch a 3.8 billion years old moon rock.</p> <p>Sponsored in part by the National Restaurant Association.</p> 
TUESDAY, JUNE 20, 2017	
MORNING JOINT SESSION	
Moderator: Peter Salsbury, Project Manager, CFSAN, U.S. Food And Drug Administration	
7:30 am - 9:00 am	Continental Breakfast Location: Ballroom of the Americas Prefunction – Level 2
8:00 am - 8:15 am	<p>Announcements & Awards Location: Ballroom of the Americas “ABC” – Level 2</p> <p><i>Steven Mandernach, President, AFDO and Bureau Chief for Food and Consumer Safety, Iowa Department of Inspection & Appeals</i></p>
8:15 am – 9:00 am	<p>Achieving Foreign Inspection Equivalence Location: Ballroom of the Americas “ABC” – Level 2</p> <p><i>Camille Brewer, Director, International Affairs, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition</i></p>
9:00 am - 10:00 am	<p>Flint Water Crisis – Lessons Learned Location: Ballroom of the Americas “ABC” – Level 2</p> <p>The Flint, MI water crisis has been the most noteworthy recognition of public water supply contamination to date, but it is not alone in that respect and there are fears that maybe it is only the “tip of the iceberg” when it comes to water supply safety. The Michigan Department of Agriculture and Rural Development (MDARD) was closely involved with consumer health protection as it related to food safety of retail and processing food establishments during this crisis; similarly, the food industry is also very much concerned about water supply safety and the impact it can have on public health. These presentations will focus on MDARD actions during that crisis, and actions that The Coca-Cola Company takes to help protect our water supplies.</p> <p><i>Sandra Walker, Food Program Manager, Michigan Department of Agriculture & Rural Development</i> <i>Jon Radtke, Manager, Sustainability, The Coca-Cola Company</i></p>
Moderator: Ken C. Stevenson, II, Vice President Regulatory Affairs, Ceutical Laboratories, Inc	
10:30 am - 11:15 am	Modernizing the Regulation of Self-care Products in Canada Location: Ballroom of the Americas “D” – Level 2
<p>Health Canada is looking to modernize its approach to regulating self-care products. These products are available for purchase without a prescription and include cosmetics, natural health products and non-prescription drugs. Canadians use self-care products every day to maintain health, treat minor ailments and improve appearance. Lipstick, vitamins, sunscreen and pain relievers are examples of self-care products.</p> <p>The different types of self-care products appear to be very similar and are presented in the same way on stores shelves – but right now, there are three different sets of rules that apply to these products, each with its own set of requirements. A new approach is being proposed that would make it easier for Canadians to make informed choices about the right products for them. Health Canada is proposing that:</p> <ul style="list-style-type: none"> • self-care products would be regulated according to risk to consumers; • self-care products making similar claims would require similar evidence; and • it would have appropriate powers to address safety concerns and non-compliance <p>To ensure that any new approach is informed by a broad range of perspectives, Health Canada has been consulting extensively. An online consultation in fall 2016 attracted significant interest. Informed by the feedback received through the fall 2016 consultation, Health Canada has refined the proposal. Health Canada is undertaking a series of in-person and online consultations throughout spring 2017 to seek feedback on the refined proposal.</p> <p><i>Emily Contreras, Cosmetics Unit Head, Health Canada</i> <i>Amanda Moir, Health Canada</i></p>	
11:15 am - 12:00 pm	FDA Program Alignment Location: Ballroom of the Americas “D” – Level 2
<i>Barbara Cassens, Director for the Office of Partnerships, U.S. Food and Drug Administration</i>	

12:00 pm - 1:30 pm	Working Lunch Presentation* Location: Ballroom of the Americas "D" – Level 2 
<p>Join us for a delicious lunch of Texas barbeque and cherry cobbler and mingle with FDA and industry officials. Discuss with your lunch companions innovative ways to handle challenging situations during an FDA inspection and then listen as a panel of experts provide their advice.</p> <p><i>Nancy Singer, President, Compliance-Alliance</i> <i>Courtland Imel, CEO, Ceutical Labs</i> <i>Julie Larsen, Senior Partner, BioTeknica, Inc</i> <i>Jane Kreis, Captain, U.S. Public Health Service, Acting Deputy Pacific Regional Food and Drug Director</i> <i>Dan Solis, Director of the Los Angeles District, Import Operations Branch, U.S. Food and Drug Administration</i> <i>Dr. Daniela Drago, Director of Regulatory Affairs Program, George Washington University School of Medicine and Health Sciences</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-around; align-items: center;">  <div data-bbox="565 388 1068 415">*Sponsored by Ceutical Laboratories, Inc and BioTeknica</div>  </div>	
Moderator: Ballard Graham, Retired, U.S. Food and Drug Administration	
1:30 pm - 2:15 pm	New Look of ISO 13485: 2016 Location: Ballroom of the Americas "D" – Level 2
<p>A brief history of the changes will be shared before exploring the overview of the new changes to include maintaining effectiveness, continuing suitability and adequacy of the management system; Standard risk management using ISO 14971; Tight control on supply chain; Importance of identification and traceability; Control of documents and records; Software validation (when used in QMS and processes); Statistically and scientifically sound sampling plans; Preventive action won't go away; Robust design and rigorous testing; End use focus along with customer satisfaction; Postmarket surveillance/Continue monitoring product usability (usability standard); and Multiple audits</p> <p><i>Fatma Ail, President, FMA Consulting, LLC; Lead Auditor for ISO 13485 and 9001</i></p>	
2:15 pm - 3:00 pm	Changes Affecting Medical Device Manufacturers—Going from Directive to Regulation in Europe Location: Ballroom of the Americas "D" – Level 2
<p>The new European medical device regulations (MDR) and in vitro diagnostic regulations (IVDR) will come into force in May 2017, with full implementation deadlines now set for May 2020 and May 2022, respectively. The MDR will replace the EU's current Medical Device Directive (93/42/EEC) and the EU's Directive on active implantable medical devices (90/385/EEC). Learn about major changes in the regulatory framework and ways in which device manufacturers are developing plans to meet these changes and to determine the impact on their business.</p> <p><i>Tamas Borsai, Division Manager of non-active medical devices, TÜV SÜD America</i></p>	
3:00 pm - 3:30 pm	Break Location: Ballroom of the Americas Prefunction – Level 2
3:30 pm - 4:15 pm	Medical Device Single Audit Program and the Changing Regulatory Environment Location: Ballroom of the Americas "D" – Level 2
<p>On January 1, 2017, following a three-year pilot, the MDSAP became operational and is gaining strength in the medical device community as more jurisdictional areas, e.g. the European Union (EU) and the World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Program, are taking interest. The MDSAP is being used by manufacturing companies as an important model in the pathway to global compliance, but with it brings deadlines of which manufacturer's must be aware.</p> <p><i>Brian Ludovico, Executive Director, MDSAP Regulatory Certification, Medical Device International Services</i></p>	
4:15 pm - 5:00 pm	Medical Device Cybersecurity - The Marriage between Product Safety and Security Location: Ballroom of the Americas "D" – Level 2
<p>Protecting patient safety through product security is one of today's top imperatives for Medical Device Manufactures, Healthcare Delivery Organizations, and Regulatory Compliance stakeholders. This session will provide an overview of the topic and discuss the state of the industry, challenges ahead, and recommendations for continual improvement.</p> <p><i>Armin Torres, Principal/Senior Software Consultant, BioTeknica, Inc.</i></p>	
6:30 pm - 7:30 pm	President's Reception Location: Ballroom of the Americas Prefunction – Level 2
7:30 pm - 9:30 pm	Wiley Award Banquet Location: Ballroom of the Americas "C" – Level 2 

WEDNESDAY, JUNE 21, 2017

7:00 am – 9:00 am **Continental Breakfast** | Location: Ballroom of the Americas Prefunction – Level 2

Cannabis: New Horizons in Food and Drug Regulations | Location: Ballroom of the Americas “AB” – Level 2

8:00 am – 3:00 pm **Moderator:** Lezli Engelking, Founder, Foundation of Cannabis Unified Standards (FOCUS)

8:15 am **The Credence of Cannabis as Medicine: A Historical Perspective**

Lezli Engelking, Founder, Foundation of Cannabis Unified Standards (FOCUS)

9:00 am **Introduction to Cannabis, Extractions, Concentrates and Infused Products**

Thuy Vu, Founder & CEO, Thuy Vu Consulting, LLC

10:00 am **Break**

10:30 am **What Regulators need to know about Lab Testing**

Jeremy Applen, Vice Chairman of the ASTM D37 Cannabis Standard Committee

11:00 am **Regulatory Laboratory Perspective on Colorado Cannabis**

Keith Wegner, Laboratory Services Section Chief, Colorado Department of Agriculture

12:45 pm **Assessing the landscape for successful implementation of marijuana legalization**

Lewis Koski, Co-founder, Freedman & Koski

1:15 pm **Changes and Issues - Panel Discussion**

Jeff Lawrence, the Division Director of the Colorado Department of Public Health and Environment

Dr. Candace Jacobs, Assistant Director, Washington State Department of Agriculture, Food Safety & Consumer Services

Kevin Armburst, Professor and Chair Department of Environmental Sciences, College of the Coast and Environment, Louisiana State University

Lewis Koski, Co-founder, Freedman & Koski

2:30 pm **ASTM Global Cannabis Standards**

Robert Morgan, Director, Technical Committee Operations, ASTM International

11:45 am – 12:45 pm **Lunch On Your Own – Grab-N-Go Lunches will be Available** | Location: Ballroom of the Americas Prefunction – Level 2

