

# 121st AFDO Annual Educational Conference

# IN HOUSTON

HILTON-AMERICAS HOUSTON

June 17-21, 2017



Change: Collaborating Today for a Safer Tomorrow



# Greetings from the President of the Association of Food and Drug Officials . . . .

Welcome to the 121st Annual Educational Conference of the Association of Food and Drug Officials (AFDO)! This year's conference will be both exciting and informative. Once again we will offer a choice of concurrent manufactured foods, retail foods, and drug and device sessions. Please take a look at the agenda and scheduled speakers. I hope you will agree we are in for an excellent conference!

For more than a century, AFDO and its annual educational conference have **connected** food and medical products professionals in the public and private sectors, providing them a forum for **sharing** various disciplines and perspectives with the goal of **impacting** the regulatory environment to **protect** the health and welfare of the global community.

This year's conference continues in this tradition with a theme of "Change: Collaborating Today for a Safer Tomorrow." The Program Planning Committee, together with our sponsors from the Mid-Continental Association of Food and Drug Officials (MCAFDO) and U.S. Food and Drug Administration (FDA), have developed an outstanding program centered around this theme. Our joint sessions cover issues of interest to both the food and drug and device attendees.

This year's conference will include a few first time events:

- On Sunday, the Body Art Sub-Committee will be presenting a live tattoo demonstration with a discussion of key regulatory requirements throughout; and
- On Wednesday, a special day-long session on introducing the regulation of cannabis providing lessons learned from the pioneering cannabis regulatory programs.

With this being the first major meeting after the implementation of FDA's Office of Regulatory Affairs (ORA) program alignment, we will learn firsthand from ORA's leaders about the final implementation and how the changes will impact the food and medical products communities in the future. Imported products discussions and presentations also are a common theme throughout the conference.

For the third year, the retail food track continues with another exciting line-up including the ever popular "speed dating" session on program standards, emergency response, program improvement, and fermentation.

Our Drugs, Devices, and Cosmetics Committee have put together a two-day seminar designed for all drug and medical device stakeholders. Sessions include presentations on FDA program alignment, imports, metrics, and data integrity.

I know you will take advantage of the extensive educational, professional, and networking opportunities available at this Conference to **connect** with your colleagues, **share** your knowledge and experiences, to **impact** and **protect** the public health. Also, this should be a great opportunity to explore the Houston area and the many attractions near the conference site.

Thank you for your attendance and support of AFDO.  
Steven Mandernach



2016-2017 AFDO Board and Advisors to the Board

# *Thank you* 2017 AFDO Sponsors

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AFDO is pleased to permit a diverse assortment of exhibitors and sponsors at its Annual Educational Conference. AFDO does not, however, endorse any product or service exhibited, with the exception of its Affiliate Organizations and Endowment Foundation. Third party trademarks, trade names, and logos, contained in these materials may be the trademarks or registered trademarks of their respective owners.



# AFDO SPECIAL EVENTS & ACTIVITIES AT A GLANCE

## REGISTRATION

Location: Ballroom of Americas  
Prefunction – Level 2

Friday, June 16, 2017  
12:00pm – 3:00pm

Saturday, June 17, 2017  
7:30am – 5:00pm

Sunday, June 18, 2017  
7:30am – 5:00pm

Monday, June 19, 2017  
7:30am – 5:00pm

Tuesday, June 20, 2017  
7:30am – 5:00pm

Wednesday, June 21, 2017  
7:30am – 12:00pm



## Saturday, June 17, 2017

5:30 pm: AFDO Committee Chairs & Co-Chairs Meeting


## Sunday, June 18, 2017

12:00 pm: Silent Auction Opens  
12:30 pm: Tattoo Demonstration  
6:30 pm: Welcome Reception  
8:00 pm: Bingo 

## Monday, June 19, 2017

12:00 pm: Burditt Luncheon   
6:00 pm: Monday Night Event 

## Tuesday, June 20, 2017

5:45 pm: Silent Auction Closes  
6:30 pm: President's Reception  
7:30 pm: Wiley Award Banquet 

## Wednesday, June 21, 2017

11:30 am: AFDO Business Meeting

## Committee Meeting

Committee Meetings are open to all attendees and will be held on Saturday, June 17, 12:30pm – 5:00pm and Sunday, June 18, 8:00am – 4:30pm.

## AFDO Ticketed Events

Please stop by the registration desk to purchase tickets to any of our ticketed events. Tickets will be sold on a first come, first serve basis.

**AFDO Silent Auction** – Opens: Sunday, June 18 at 12:00 pm ♦ Closes: Tuesday, June 20 at 5:45 pm

You will find almost every item imaginable. You will have the opportunity to silently bid on as many items as you desire, and to bid as often as you like in this fun and competitive event.

Help make this year's Silent Auction a huge success by donating a souvenir, keepsake gift or novelty item – or by bidding on items in the Auction. Please check with the staff at the AFDO Registration Desk if you wish to donate an item. All proceeds of this auction will benefit the **AFDO Scholarship Fund**.

**AFDO BINGO** – Sunday, June 18 at 8:00 pm

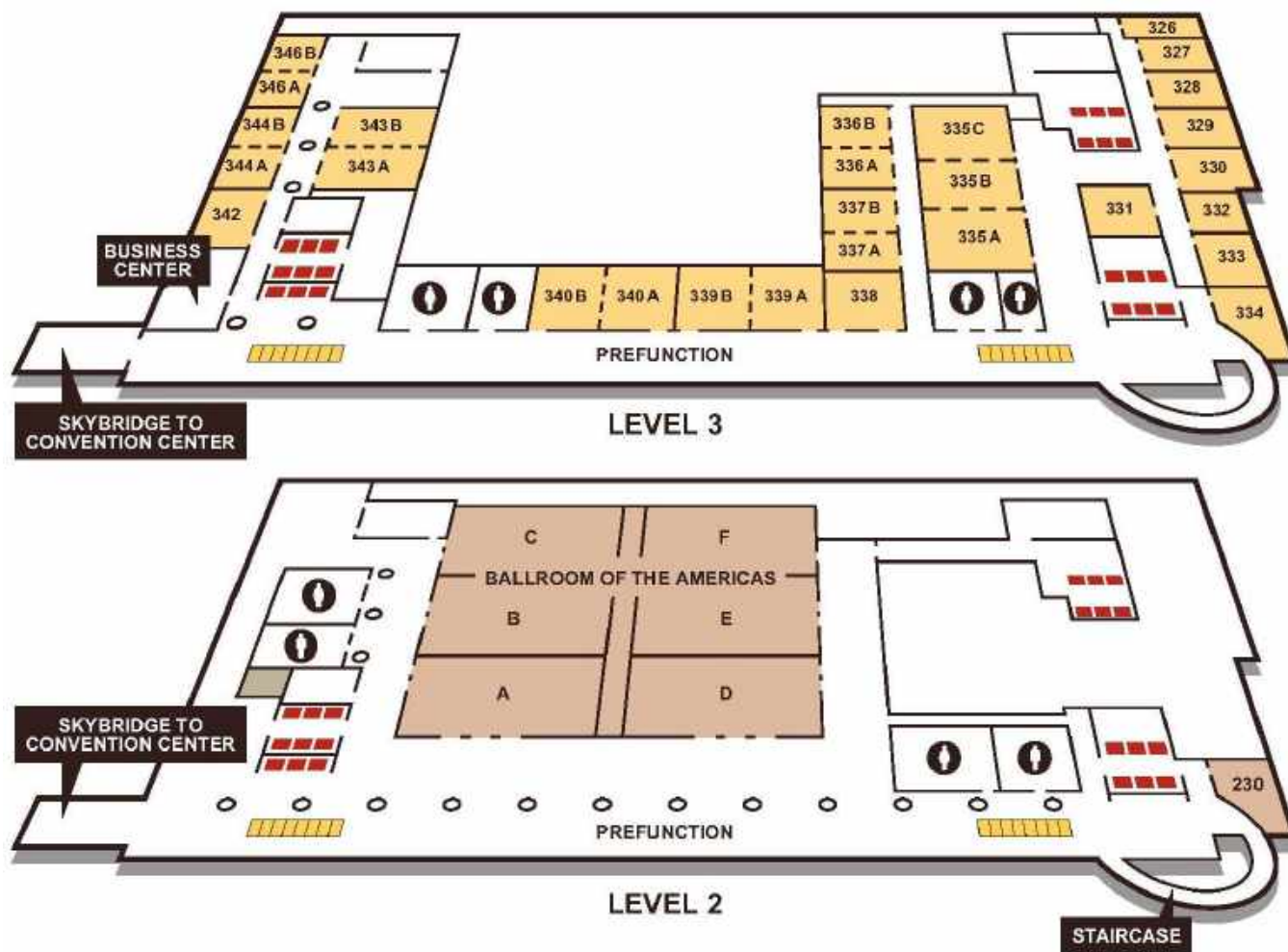
Join your fellow AFDO members for a unique Bingo night where pictures of your favorite members will now become the call numbers. You will learn some new names, potentially win some valuable prizes and, of course, raise money for the AFDO Endowment Foundation. Cards will be sold for \$25 per card. Don't miss out on the fun!

**Endowment Fund** – Make Donations at the Endowment Foundation Table in the Ballroom of Americas Prefunction during the Conference. The Endowment Foundation was established in 1993 by the Board of Directors with the express purpose of raising a permanent endowment fund, to provide support to AFDO's educational and scientific mission. Separated from the general operating budget, the endowment fund is administered by its own Board of Trustees consisting of 10 AFDO members from the private sector or former government employees.

*Funding for this conference was made possible, in part, by the Food and Drug Administration through grant 1R13FD005352. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government.*



## Floorplans






 Meeting/Function Rooms
  Escalator
  Elevator
  Coat Room

# "Change: Collaborating Today for a Safer Tomorrow"

SATURDAY, JUNE 17, 2017

8:00 am – 12:00 pm	<b>Environmental Assessment at Retail   Location:</b> Ballroom of the Americas "F" – Level 2 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 <a href="https://www.cdc.gov/nceh/ehs/learn/ea_fio/index.htm">https://www.cdc.gov/nceh/ehs/learn/ea_fio/index.htm</a> . <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>
9:00 am – 12:00 pm	<b>Effective Communication Skills   Location:</b> Ballroom of the Americas "D" – Level 2 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 the workplace, and improve your chances for promotion. <b>Moderator:</b> Nancy Singer, President, Compliance Alliance <i>Dr. Candace Jacobs, Assistant Director, Washington State Department of Agriculture, Food Safety &amp; 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>
9:30 am – 11:30 am	<b>FoodSHIELD: Document Control Working Session   Location:</b> 335C – Level 3 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. <i>Eric Hoffman, President, Datastream Connexion</i> <i>Ted Steinmann, IT Manager, National Center for Food Protection and Defense</i>
10:00 am – 10:30 am	<b>Break / Exhibitor Showcase   Location:</b> Ballroom of the Americas Prefunction – Level 2
<b>AFDO Committee Meetings are open to all Conference Attendees</b>	
12:30 pm – 2:30 pm	<b>Food Committee   Location:</b> Ballroom of the Americas "E" – Level 2 <b>Guest Speakers/Presentations:</b> <b>Update on Partnership for Food Protection</b> , Barbara Cassens, Director for the Office of Partnerships, U.S. Food and Drug Administration <b>Update on the National Food Safety Data Exchange</b> , Lisa Creason, Director, Information Systems Management Office of Regulatory Affairs, U.S. Food and Drug Administration <b>Update on Produce Rule Implementation</b> , Byron Beerbower, Consumer Safety Officer, ORA – PSN, U.S. Food and Drug Administration <b>State and Territory Food Safety Regulation of Leased Commercial Kitchens (LCKs)</b> , Odeisa Hichez, Food Inspector, New York State Department of Agriculture & Markets <b>Corrections after FDA and Wisconsin Manufactured Food Inspections Show Comparable Compliance Rates</b> , Skya Murphy, Program And Policy Analyst, Wisconsin Department of Agriculture, Trade & Consumer Protection
2:15 pm – 3:00 PM	<b>Break / Exhibitor Showcase   Location:</b> Ballroom of the Americas Prefunction – Level 2
2:30 pm – 5:00 pm	<b>Retail Food Committee   Location:</b> Ballroom of the Americas "E" – Level 2 <b>Guest Speakers/Presentations:</b> <b>Making the Grade: Do Current Restaurant Grading Systems Fulfill Stakeholder Expectations?</b> , Jessica Egan, Research Scientist, New York State Department of Health <b>Control of Behavior-Centric Risk Factors Between Two Management Groups</b> , Renita Stroupe, Health Educator, DeKalb County Board of Health <b>E Commerce – Pick and Pack Delivery</b> , Liz Duffy, Director, Walmart Food Safety and Regulatory Compliance Global eCommerce <b>USDA Update</b> , Shaun Smith, Regional Director, OIEA, U.S. Department of Agriculture <b>CFP Update</b> , Patrick Guzzle, CFP Conference Chair, and Food Protection Program Manager, Idaho Department of Health and Welfare <b>Commercial / Shared Kitchen</b> , Angela Montalbano, Supervisor, NY State Department of Agriculture and Markets
5:00 pm – 6:00 pm	<b>AFDO Committee Chairs and Co-Chairs Meeting   Location:</b> 335C – Level 3




6:00 pm	<b>Saturday Night Event Sponsored by Computer Aid, Inc.</b> - 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 <sup>th</sup> 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.
<b>SUNDAY, JUNE 18, 2017</b>	
7:30 am – 9:30 am	<b>Continental Breakfast</b>   <b>Location:</b> Ballroom of the Americas Prefunction – Level 2
<b>AFDO Committee Meetings are open to all Conference Attendees</b>	
8:00 am – 9:00 am	<b>Endowment Foundation</b>   <b>Location:</b> Ballroom of the Americas “A” – Level 2
8:00 am – 9:30 am	<b>Food Protection &amp; Defense Committee</b>   <b>Location:</b> Ballroom of the Americas “E” – Level 2 <b>Guest Speaker/Presentation:</b> <b>FDA Intentional Adulteration</b> , Colin Barthel, Policy Analyst, U.S. Food and Drug Administration <b>Project Trends and Updates from FPD</b> , Ted Steinmann, IT Manager, National Center for Food Protection and Defense <b>Guest Speaker</b> , 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	<b>Industry Associate Membership Committee</b>   <b>Location:</b> Ballroom of the Americas “A” – Level 2
9:00 am – 10:00 am	<b>Administrative Committee</b>   <b>Location:</b> 335C – Level 3
10:00 am – 3:00 PM	<b>Break / Exhibitor Showcase</b>   <b>Location:</b> Ballroom of the Americas Prefunction – Level 2
9:30 am – 11:00 am	<b>Foodborne Outbreak &amp; Emergency Response Committee</b>   <b>Location:</b> Ballroom of the Americas “E” – Level 2 <b>Guest Speaker/Presentation:</b> <b>CoE Updates</b> , Vince Radke, Sanitarian, Centers for Disease Control and Prevention <b>InFORM Updates</b> , Carrie Rigdon, Response and Compliance Supervisor, Minnesota Department of Agriculture <b>CIFOR Updates</b> , Ernie Julian, Chief of Food Protection, Rhode Island Department of Health <b>Community Size and Retail Risk Factors in Iowa Retail Food Establishments</b> , Sherri Sigwarth, Food Safety Specialist, Iowa Department of Inspection & Appeals <b>CORE Updates</b> , Karen Blickenstaff, Team Lead, Coordinated Outbreak Response and Evaluation Network, U.S. Food and Drug Administration
10:30 am – 12:00 pm	<b>Drugs, Devices &amp; Cosmetics Committee</b>   <b>Location:</b> Ballroom of the Americas “F” – Level 2 <b>Guest Speaker/Presentation:</b> <b>USP Update</b> , Alissa D. Jijon, Senior Counsel, Global Legal Affairs - Standards, United States Pharmacopeial Convention <b>Bio-north Texas Update</b> , David Musgrave, Chairman, Texas Healthcare and Bioscience Institute <b>ASQ Update</b> , Fatma Ali, President, FMA Consulting, LLC <b>FDMIC Update</b> , Karen Daugherty, Director, Investigations Branch, U.S. Food and Drug Administration; Former Regulatory Co-Chair, FMDIC
11:00 am – 12:00 pm	<b>Professional Development Committee</b>   <b>Location:</b> Ballroom of the Americas “A” – Level 2 <b>Guest Speakers/Presentations:</b> <b>Indiana Food Safety Regulator Enumeration</b> , JoAnna Beck, Food Safety Farm Consultant, Indiana State Department of Health <b>Inspector Use of Chinese Language Retail Food Safety Training Tools</b> , Autumn Schuck, Food Safety and Lodging Program, Kansas Department of Agriculture
11:00 am – 12:30 pm	<b>Laboratory, Science and Technology Committee Meeting</b>   <b>Location:</b> Ballroom of the Americas “C” – Level 2 <b>Guest Speaker/Presentation:</b> <b>Laboratory Curriculum Framework Project</b> , Craig Kaml, EdD, Senior Vice President, International Food Protection Training Institute <b>Estimating Risk by Measuring Coliform on Common Touch Surfaces</b> , Jo-Ann Xiong-Mercado, Environmental Health Specialist, Marion County Public Health Department
11:30 pm – 1:00 pm	<b>Lunch On Your Own - Cash-N-Carry Lunches will be Available</b>   <b>Location:</b> Ballroom of the Americas Prefunction – Level 2
12:00 pm – 1:30 pm	<b>FoodSHIELD: Resource Libraries &amp; More</b>   <b>Location:</b> 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	<b>Tattoo Demonstration – Presented by the Body Art Sub-Committee   Location:</b> Ballroom of the Americas “D” – Level 2 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.  <b>Guest Speaker/Presentation:</b> <i>Sean Brown, Eternal Ink and Director for Eternal Republic Tattoo Company</i> <i>Featured Artist, Liz Cook, Rebel Muse Tattoo Studio</i>
1:30 pm – 3:00 pm	<b>Seafood Committee   Location:</b> Ballroom of the Americas “E” – Level 2 <b>Guest Speaker/Presentation:</b> <b>Use of Critical Control Points (CCPs) In Florida Seafood HACCP Plans,</b> <i>Matthew Coleman, Environmental Manager, Florida Department of Agriculture &amp; Consumer Services</i> <b>Highlights of Revised Protocol,</b> <i>Courtney Mickiewicz, Regional Manager, Virginia Department of Agriculture and Consumer Services</i> <b>Catfish Rule,</b> <i>Roberta Wagner, Deputy Assistant Administrator, U.S. Department of Agriculture</i> <b>Seafood Fraud,</b> <i>Lisa Weddig, National Fisheries Institute</i>
1:30 pm – 3:00 pm	<b>Laws &amp; Regulations Committee   Location:</b> Ballroom of the Americas “C” – Level 2 <b>Guest Speaker/Presentation:</b> <b>Spice Lead Levels and Blood Lead Levels in Maryland Children,</b> <i>Kyle Shannon, Rapid Response Team Coordinator, Maryland Department of Health &amp; Mental Hygiene</i> <b>Current Trends in State Laws Related to Food,</b> <i>Doug Farquhar, Program Director for Environmental Health, National Conference of State Legislatures</i>
2:00 pm – 3:00 pm	<b>Alumni Committee   Location:</b> 335C – Level 3 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. <b>Session Leader:</b> <i>Nancy Singer, President, Compliance Alliance</i>
2:30 pm – 4:00 pm	<b>Body Art Sub-Committee   Location:</b> Ballroom of the Americas “F” – Level 2
3:00 pm – 4:30 pm	<b>International &amp; Government Relations Committee   Location:</b> Ballroom of the Americas “C” – Level 2 <b>Moderators:</b> <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>  <b>Guest Speaker/Presentation:</b> <b>International Capacity Building in Seafood,</b> <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> <b>Systems Recognition: Canada and New Zealand,</b> <i>Camille Brewer, Director, International Affairs, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition</i> <b>Health Canada GMP Transformation,</b> <i>Alexis Grolla, Manager GMP Inspection East/West, Health Canada</i>
4:30 pm – 6:00 pm	<b>Opening Session   Location:</b> Ballroom of the Americas “AB” – Level 2 <i>Steven Mandernach, AFDO President and Bureau Chief for Food and Consumer Safety, Iowa Department of Inspection &amp; Appeals</i>  <b>Welcome from MCAFDO</b> <i>Jason Guzman, Training, Standardization, and Quality Assurance Officer, Texas Department of State Health Services</i>  <b>IFPTI: Cohort V Graduation Ceremony</b> <i>Gerald Wojtala, Executive Director, International Food Protection Training Institute (IFPTI)</i>  <b>Endowment Foundation Address</b> <i>John Young, Chair, AFDO Endowment Foundation, and Partner, Young &amp; Associates</i>  <b>President’s Address</b> <i>Steven Mandernach, AFDO President and Bureau Chief for Food and consumer Safety, Iowa Department of Inspection &amp; Appeals</i>  <b>Glenn W. Kilpatrick Memorial Address</b> <i>Joseph A. Levitt, Partner, Hogan Lovells US LLP</i>
6:00 pm – 7:30 pm	<b>Welcome Reception   Location:</b> Ballroom of the Americas “DE” – Level 2 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. <b>All are welcome to attend!</b>
8:00 pm – 10:00 pm	<b>AFDO Bingo   Location:</b> Ballroom of the Americas “F” – Level 2 Sponsored by General Mills





Food Sessions	
MONDAY, JUNE 19, 2017	
MORNING JOINT SESSION	
<b>Moderator:</b> Laurie Farmer, Director State Cooperative Programs, SE Region, U.S. Food and Drug Administration	
7:00 am - 9:00 am	<b>Continental Breakfast   Location:</b> Ballroom of the Americas Prefunction – Level 2
8:00 am - 8:15 am	<b>Announcements &amp; Awards   Location:</b> Ballroom of the Americas “ABC” – Level 2 <i>Steven Mandernach, AFDO President and Bureau Chief for Food and Consumer Safety, Iowa Department of Inspection &amp; Appeals</i>
8:15 am – 9:30 am	<b>U.S. Food and Drug Administration Regulatory Affairs Update   Location:</b> 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	<b>Preview - Cannabis: New Horizons in Food and Drug Regulations   Location:</b> Ballroom of the Americas “ABC” – Level 2 Introduction to Wednesday’s session
10:00 am - 10:30 am	<b>Break / Exhibitor Showcase   Location:</b> Ballroom of the Americas Prefunction – Level 2
<b>Moderator:</b> Laurie Farmer, Director State Cooperative Programs, SE Region, U.S. Food and Drug Administration	
10:30 am - 11:15 am	<b>How can third party auditing drive change in Food Safety Culture?   Location:</b> 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. <b>Moderator:</b> Tara Paster, CEO & President of Paster Training, Inc. <b>Panelist:</b> Stan Hazan, MPH Sr. Director, Scientific & Regulatory Affairs NSF International <i>Melissa Vaccaro, MS, CP-FS, VP of PTI and Consulting Group</i> <i>Darrell Newell Retail Food Safety &amp; QA Director for Comprehensive Food Safety</i>	
11:15 am – 12:00 pm	<b>Be A Bloodhound! Traceback Fundamentals for a Foodborne Outbreak   Location:</b> 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 &amp; President of Paster Training, Inc</i>	
12:00 pm – 1:30 pm	<b>Lunch On Your Own - Cash-N-Carry Lunches will be Available   Location:</b> Ballroom of the Americas Prefunction – Level 2
12:00 pm - 1:30 pm	<b>Burditt Lunch   Location:</b> 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.
<b>Moderator:</b> Randy Treadwell, Animal Feed/Rapid Response Program Manager, Washington State Department of Agriculture	
1:30 pm – 2:15 pm	<b>The Culture of Clean   Location:</b> 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	<b>Fellowship Select Presentations   Location:</b> Ballroom of the Americas “ABC” – Level 2
<b>Use of Critical Control Points (CCPs) In Florida Seafood HACCP Plans</b> <i>Matthew Coleman, Environmental Manager, Florida Department of Agriculture &amp; Consumer Services</i>	
<b>State and Territory Food Safety Regulation of Leased Commercial Kitchens (LCKs)</b> <i>Odeisa Hichez, Food Inspector, New York State Department of Agriculture &amp; Markets</i>	



2:45 pm – 3:30 pm	<b>Fellowship Poster Session</b>   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	<b>Break / Exhibitor Showcase</b>   Location: Ballroom of the Americas Prefunction – Level 2
<b>BREAKOUTS (CHOOSE 1)</b>	
3:30 pm – 5:00 pm	<b>U.S. Strategies for Improving the Safety of Imported Food</b>   Location: Ballroom of the Americas "AB" – Level 2
<p>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.</p> <p><b>Moderator:</b> Joe Corby, Executive Director, AFDO  Stephen Stich, Division Director, New York Department of Agriculture &amp; Markets, Division of Food Safety &amp; Inspection  Todd Cato, Director, FDA Southwest Import District, Office of Regulatory Affairs  Karil Kochenderfer, Principal, Linkages</p>	
3:30 pm – 5:30 pm	<b>Learn how YOU can make Advances in Implementation of the Retail Food Program Standards</b>   Location: Ballroom of the Americas "F" – Level 2
<p>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.</p> <p><b>Moderator:</b> Cathy Hosman, Project Officer, Office of Partnerships, U.S. Food and Drug Administration  Pete Salsbury, Project Manager, CFSAN, Retail Food Protection Staff, U.S. Food and Drug Administration  Deanna Copeland, Manager, Food &amp; 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 &amp; Appeals  Ruth Clay, MPH, Health Director, City of Melrose</p>	
6:15 pm – 10:00 pm	<b>MONDAY NIGHT EVENT: TRAVEL TO THE MOON AT THE HOUSTON SPACE CENTER – LIMITED SPACE AVAILABLE</b>  <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> 

<b>TUESDAY, JUNE 20, 2017</b>	
<b>MORNING JOINT SESSION</b>	
<b>Moderator:</b> Peter Salsbury, Project Manager, CFSAN, U.S. Food And Drug Administration	
7:30 am - 9:00 am	<b>Continental Breakfast</b>   Location: Ballroom of the Americas Prefunction – Level 2
8:00 am - 8:15 am	<b>Announcements &amp; Awards</b>   Location: Ballroom of the Americas "ABC" – Level 2 Steven Mandernach, AFDO President and Bureau Chief for Food and Consumer Safety, Iowa Department of Inspection & Appeals
8:15 am – 9:00 am	<b>Achieving Foreign Inspection Equivalence</b>   Location: Ballroom of the Americas "ABC" – Level 2 Camille Brewer, Director, International Affairs, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition
9:00 am - 10:00 am	<b>Flint Water Crisis – Lessons Learned</b>   Location: Ballroom of the Americas "ABC" – Level 2 <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>Sandra Walker, Food Program Manager, Michigan Department of Agriculture &amp; Rural Development  Jon Radtke, Manager, Sustainability, The Coca-Cola Company</p>
10:00 am – 10:30 am	<b>Break / Exhibitor Showcase</b>   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  
*Ted Elkin, Deputy Director for Regulatory Affairs, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration*

**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.

*Ken B. Moore, Executive Director, Interstate Shellfish Sanitation Conference (ISSC)*

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

*Carrie Rigdon, PhD, Response Training and Outreach Supervisor, Minnesota Department of Agriculture*

*Lane Drager, Consumer Protection Program Coordinator, Boulder county Public Health*

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

*Scott Jeansonne, Supervisor, Food & NNA Programs, Harris County Public Health*

**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:** Erik Bungo, Program Supervisor, Produce Safety Program, Virginia Department of Agriculture & Consumer Services

**Challenges and Opportunities with Implementing New On-Farm Regulatory Program**

*Timothy Slawinski, Food Safety Modernization Unit Manager, Food and Dairy Division, Michigan Department of Agriculture and Rural Development*

**FDA Funding Available for States, NASDA Pilots and Guidance**

*Bob Ehart, Senior Policy & Science Advisor, National Association of State Departments of Agriculture (NASDA)*

**FDA Activities and Plans Highlighting Areas for Collaboration and Complementary Aspects of FDA, NASDA, Industry and State Efforts**

*Stephen Hughes, Team Leader, Produce Safety Network, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration*

**Outreach/Training and Efforts to Conduct Applied Research to Address Scientific Gaps Important for Managing National or Regional Regulatory Issues**

*Don Stoeckel, PH.D. PSA Midwest Regional Extension Associate, Department of Food Science, Cornell University*

**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

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.


**Moderator:** Tara Paster, CEO & President of Paster Training, Inc

*Dr. Jenine Harris, Associate Professor, Washington University in St Louis*

*Candace DaSilva, Food Establishment Inspector, City of St. Louis Department of Health*

*Kara Sewalk, Program Coordinator, HealthMap, Boston Children’s Hospital*



3:30 pm – 4:15 pm	<b>When the Government Comes Knocking: How Pathogens in your Plant Can Lead to Criminal Charges   Location:</b> 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><b>Moderator:</b> Erik Bungo, Program Supervisor, Produce Safety Program, Virginia Department of Agriculture &amp; Consumer Services  Shawn Stevens, Attorney, Food Industry Counsel LLC  Donald W Plunkett, J.D., J.M., Food Safety Consultant, Center for Science in the Public Interest</p>	
<b>BREAKOUTS (CHOOSE 1)</b>	
4:30 pm – 5:30 pm	<b>Food Safety Culture   Location:</b> Ballroom of the Americas “F” – Level 2
<p>How to create a culture of food safety in a highly diverse workforce.</p> <p><b>Moderator:</b> Dionne Crawford, US Food Safety Supervisor, McDonald's Corporation  Roger Carole Rogers, RCG Rogers &amp; Associates, LLC</p>	
4:15 pm – 5:30 pm	<b>Tools for State Programs Facing Raw Milk Legislation   Location:</b> 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><b>Moderator:</b> Kim Stryker, Env. Program Manager, Alaska Department of Environmental Conservation</p> <p><b>The Scope and Trends of Raw Milk in the US &amp; Illness Data</b>  Doug Farquhar, J.D., Program Director for Environmental Health, National Conference of State Legislatures  Vince Radke, Sanitarian, Centers for Disease Control and Prevention</p> <p><b>Why Raw Milk?</b>  Mary McGonigle Martin, M.S., Public Health Advocate</p> <p><b>Public Health Success Stories and Tools for State Programs</b>  Brad Legreid, Executive Director, Wisconsin Dairy Products Association</p>	
6:30 pm – 7:30 pm	<b>President’s Reception   Location:</b> Ballroom of the Americas Prefunction – Level 2
7:30 pm – 9:30 pm	<b>Wiley Award Banquet   Location:</b> Ballroom of the Americas “C” – Level 2 
<b>WEDNESDAY, JUNE 21, 2017</b>	
7:00 am - 9:00 am	<b>Continental Breakfast   Location:</b> Ballroom of the Americas Prefunction – Level 2
<b>BREAKOUTS (CHOOSE 1)</b>	
<b>Retail Breakout Sessions   Location:</b> Ballroom of the Americas “F” – Level 2	
8:00 am – 9:30 am	<b>Three Health Inspectors Walk Into a Bar</b>
<p>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 &amp; 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.)</p> <p><b>Moderators:</b> Joseph Graham, Food Safety Program Supervisor, Washington Department of Health  Becky Elias, Food &amp; Facilities Section Manager, Environmental Health, Public Health – Seattle &amp; King County</p>	
10:00 am – 10:30 am	<b>Break   Location:</b> Ballroom of the Americas Prefunction – Level 2
10:00 am – 11:30 am	<b>Potential Hazards Associated with Fermented Foods</b>
<p>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.</p> <p><b>Moderator:</b> Steven Mandernach, AFDO President and Bureau Chief for Food and Consumer Safety, Iowa Department of Inspection &amp; Appeals  Jay Neal, PhD, Assistant Provost - Sugar Land, Associate Professor, University of Houston  Tyler Henderson, Chef, Featured on the TV Food Network “Chopped” in 2016</p>	
11:30 am – 12:00 pm	<b>AFDO Business Meeting   Location:</b> Ballroom of the Americas Prefunction – Level 2





<b>Cannabis: New Horizons in Food and Drug Regulations   Location: Ballroom of the Americas “AB” – Level 2</b>	
<b>8:00 am – 3:00 pm</b>	<b>Moderator:</b> <i>Lezli Engelking, Founder, Foundation of Cannabis Unified Standards (FOCUS)</i>
8:15 am	<b>The Credence of Cannabis as Medicine: A Historical Perspective</b> <i>Lezli Engelking, Founder, Foundation of Cannabis Unified Standards (FOCUS)</i>
9:00 am	<b>Introduction to Cannabis, Extractions, Concentrates and Infused Products</b> <i>Thuy Vu, Founder &amp; CEO, Thuy Vu Consulting, LLC</i>
10:00 am	<b>Break</b>
10:30 am	<b>What Regulators need to know about Lab Testing</b> <i>Jeremy Appen, Vice Chairman of the ASTM D37 Cannabis Standard Committee</i>
11:00 am	<b>Certification of Testing Facilities in Colorado</b> <i>Keith Wegner, Laboratory Services Section Chief, Colorado Department of Agriculture</i>
12:45 pm	<b>Hemp Regulation</b> <i>Laura VanWagenen, Federal Manufactured Foods and Recall Program Coordinator, Colorado Department of Public Health &amp; Environment</i>
1:15 pm	<b>Changes and Issues Panel Discussion</b> <i>Lewis Koski, Co-founder, Freedman &amp; Koski</i> <i>Dr. Candace Jacobs, Assistant Director, Washington State Department of Agriculture, Food Safety &amp; Consumer Services</i> <i>Kevin Armbrust, Professor and Chair Department of Environmental Sciences, College of the Coast and Environment, Louisiana State University</i>
2:30 pm	<b>ASTM Global Cannabis Standards</b> <i>Robert Morgan, Director, Technical Committee Operations, ASTM International</i>
<b>11:45 am – 12:45 pm</b>	<b>Lunch On Your Own – Grab-N-Go Lunches will be Available   Location: Ballroom of the Americas Prefunction – Level 2</b>
<b>12:00 pm – 4:00 pm</b>	<b>AFDO Board of Directors Meeting   Location: 335C – Level 3</b>



# 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	<b>Continental Breakfast</b>   <b>Location:</b> Ballroom of the Americas Prefunction – Level 2
8:00 am - 8:15 am	<b>Announcements &amp; Awards</b>   <b>Location:</b> Ballroom of the Americas “ABC” – Level 2 <i>Steven Mandernach, AFDO President and Bureau Chief for Food and Consumer Safety, Iowa Department of Inspection &amp; Appeals</i>
8:15 am - 9:30 am	<b>U.S. Food and Drug Administration for Regulatory Affairs Update</b>   <b>Location:</b> 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	<b>Preview - Cannabis: New Horizons in Food and Drug Regulations</b>   <b>Location:</b> Ballroom of the Americas “ABC” – Level 2 Introduction to Wednesday’s session
10:00 am - 10:30 am	<b>Break</b>   <b>Location:</b> Ballroom of the Americas Prefunction – Level 2



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

10:30 am - 10:35 am	<b>Welcome</b>   <b>Location:</b> Ballroom of the Americas “D” – Level 2 <i>David Musgrave, Chairman, Texas Healthcare and Bioscience Institute</i>
10:30 am - 11:15 am	<b>Warning Signs that Data Integrity Issues Exist</b>   <b>Location:</b> 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 &amp; Principal, Cerulean Associates Inc</i> <i>Nancy Singer, President, Compliance-Alliance, LLC</i>
11:15 am - 12:00 pm	<b>Embracing a Culture of Self Correction - making the most of your internal audit program</b>   <b>Location:</b> 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	<b>Lunch On Your Own – Grab-N-Go Lunches will be Available</b>   <b>Location:</b> Ballroom of the Americas Prefunction – Level 2
12:00 pm - 1:30 pm	<b>Burditt Lunch</b>   <b>Location:</b> 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	<b>The World of Quality Metrics Across Pharma and Device</b>   <b>Location:</b> Ballroom of the Americas “D” – Level 2 CDRH and CDER launched metrics initiatives in 2011 and 2012, respectively. These two initiatives have different drivers, have taken different approaches, but yet have similar outcomes. Now the question is – how is FDA going to use these metrics, and how has that been influenced by the authority given to them through FDASIA (the 2012 FDA Safety & Innovation Act)? Importantly, learn what your organization can do today to manage these differences, and advance the quality of your own products. <i>Dr. Marla Phillips, Director, Xavier Health, Xavier University</i>
2:15 pm - 3:00 pm	<b>FDA Training Initiatives</b>   <b>Location:</b> 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	<b>Break</b>   <b>Location:</b> Ballroom of the Americas Prefunction – Level 2



3:30 pm - 4:15 pm	<b>FDA Alumni Panel   Location:</b> 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><b>Moderator:</b> <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	<b>Import Controls: Explaining the Process   Location:</b> 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>Dan Solis, Director of the Los Angeles District, Import Operations Branch, U.S. Food and Drug Administration</p>	
6:15 pm – 10:00 pm	<p><b>Monday Night Event: Travel to the Moon at the Houston Space Center – LIMITED SPACE AVAILABLE</b> </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> 
<b>TUESDAY, JUNE 20, 2017</b>	
<b>MORNING JOINT SESSION</b>	
<b>Moderator:</b> Peter Salsbury, Project Manager, CFSAN, U.S. Food And Drug Administration	
7:30 am - 9:00 am	<b>Continental Breakfast   Location:</b> Ballroom of the Americas Prefunction – Level 2
8:00 am - 8:15 am	<p><b>Announcements &amp; Awards   Location:</b> 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 &amp; Appeals</i></p>
8:15 am – 9:00 am	<p><b>Achieving Foreign Inspection Equivalence   Location:</b> 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><b>Flint Water Crisis – Lessons Learned   Location:</b> 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 &amp; Rural Development</i>  <i>Jon Radtke, Manager, Sustainability, The Coca-Cola Company</i></p>
<b>Moderator:</b> Ken C. Stevenson, II, Vice President Regulatory Affairs, Ceutical Laboratories, Inc	
10:30 am - 11:15 am	<b>Modernizing the Regulation of Self-care Products in Canada   Location:</b> 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"> <li>• self-care products would be regulated according to risk to consumers;</li> <li>• self-care products making similar claims would require similar evidence; and</li> <li>• it would have appropriate powers to address safety concerns and non-compliance</li> </ul> <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	<b>FDA Program Alignment   Location:</b> 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	<b>Working Lunch Presentation*   Location:</b> 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>Dr. Daniela Drago, Director of Regulatory Affairs Program, George Washington University School of Medicine and Health Sciences</i></p> <p style="text-align: right;"><b>Lunch provided only for registered attendees of the Drug &amp; Device Conference Track</b></p> <div style="display: flex; justify-content: space-around; align-items: center;">  <div> <p><b>*Sponsored by Ceutical Laboratories, Inc and BioTeknica</b></p>  </div> </div>	
<b>Moderator:</b> Ballard Graham, Retired, U.S. Food and Drug Administration	
1:30 pm - 2:15 pm	<b>New Look of ISO 13485: 2016   Location:</b> 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	<b>Changes Affecting Medical Device Manufacturers—Going from Directive to Regulation in Europe   Location:</b> 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	<b>Break   Location:</b> Ballroom of the Americas Prefunction – Level 2
3:30 pm - 4:15 pm	<b>Medical Device Single Audit Program and the Changing Regulatory Environment   Location:</b> 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	<b>Medical Device Cybersecurity - The Marriage between Product Safety and Security   Location:</b> 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	<b>President's Reception   Location:</b> Ballroom of the Americas Prefunction – Level 2
7:30 pm - 9:30 pm	<b>Wiley Award Banquet   Location:</b> 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 Appen, Vice Chairman of the ASTM D37 Cannabis Standard Committee*
- 11:00 am **Certification of Testing Facilities in Colorado**  
*Keith Wegner, Laboratory Services Section Chief, Colorado Department of Agriculture*
- 12:45 pm **Hemp Regulation**  
*Laura VanWagenen, Federal Manufactured Foods and Recall Program Coordinator, Colorado Department of Public Health & Environment*
- 1:15 pm **Changes and Issues Panel Discussion**  
*Lewis Koski, Co-founder, Freedman & Koski*  
*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*
- 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



# AFDO EXHIBITORS



Global Food Law  
MICHIGAN STATE UNIVERSITY  
COLLEGE OF LAW

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**Superior Laboratory  
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## Exhibitor #6

**Win Wam**



**NSF International**

## Exhibitor #7

**NSF International**



## Exhibitor #8

**Safe Quality Food  
Institute (SQFI)**

**PROMETRIC**



## Exhibitor #9

**Prometric**



## Exhibitor #10



**Computer Aid**



## Exhibitor #11

**Sani Station**



**Food Protection and Defense Institute**  
A Homeland Security Center of Excellence

## Exhibitor #12

**Food Protection and  
Defense Institute**



## Exhibitor #13

**USDA Food Safety and  
Inspection Service**

For more details regarding our exhibitors, visit our website at [Houston.afdo.org](http://Houston.afdo.org)

**Don't forget to check them out in the Ballroom of Americas Prefunction**



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