

**SATURDAY, JUNE 20, 2015**


12:00 pm – 2:00 pm	<b>FSMA Primer   Location:</b> Plaza A First part of a three-part series: Plans for Implementation <i>Joann M. Givens, Acting Food and Feed Program Director, Office of Regulatory Affairs, U.S. Food and Drug Administration</i>
2:00 pm - 2:15 pm	<b>BREAK   LOCATION:</b> Plaza Ballroom Foyer
2:15 pm – 5:15 pm	<b>Food Committee   Location:</b> Plaza A <b>Guest Speakers/Presentations:</b> Compliance assistance in food safety inspections of small-scale food processors in Michigan. Ethnographic research on food safety inspection practice in Michigan suggests that inspectors’ efforts to educate and build relationships with facility personnel improved compliance. This presentation describes the skills and tactics that inspectors employed and offers their observations on this approach. <i>Jenifer Buckley</i> National trends in state cottage food regulations <i>Mark Miklos, Sr. Manager Program Compliance, National Restaurant Association</i> Overview of the DelMarVa sampling project currently underway in three East Coast States. <i>Ernest Julian, Ph.D., Chief, Office of Food Protection, Rhode Island Department of Health</i> Evaluating Manufactured Food Inspection Program New Hire Training Costs and Staff Turnover in Select AFDOSS States <i>Matt Colson, Florida Department of Agriculture</i> Sub-Committee Reports <i>Erik Bungo, RRT Coordinator, Virginia Department of Agriculture &amp; Consumer Services</i> <i>Roxanne Hill, Supervising Food Inspector, New York Department of Agriculture &amp; Markets</i>
5:30 pm – 6:30 pm	<b>AFDO COMMITTEE CHAIRS AND CO-CHAIRS MEETING   LOCATION:</b> PLAZA D
6:30 pm – Midnight	<b>IN-joy Indy</b> On behalf of Computer Aid Inc./USAFoodSafety, we officially invite all AFDO conference attendees to join us on a ride to downtown Indy to explore the local restaurants and entertainment. The Go Express bus will take us from the Sheraton to Yard House, 15 W Maryland St., and will pick up at the same location. There are plenty of delicious and fun restaurants within walking distance of the Yard House. We hope you can join us! Departure times from the Sheraton: 6:30pm & 7:30pm. Pick-up times from W. Maryland St.: 10:00pm & 12:00am



**SUNDAY, JUNE 21, 2015**

7:00 am – 9:00 am	<b>CONTINENTAL BREAKFAST   Location:</b> Plaza Ballroom Foyer
7:00 am – 8:00 am	<b>FIRST TIME ATTENDEE BREAKFAST (FIRST TIME ATTENDEES AND MENTORS – TICKET REQUIRED)   Location:</b> Clearwater Ballroom
8:00 am – 4:00 pm	<b>AFDO COMMITTEE MEETINGS</b>
8:00 am – 9:00 am	<b>Endowment Foundation   Location:</b> Suite 4 & 5
8:00 am – 9:30 am	<b>Food Protection &amp; Defense Committee   Location:</b> Plaza A <b>Guest Speakers/Presentations:</b> Factors Influencing Multi-Jurisdictional Collaboration Within State Food Emergency Rapid Response Teams (RRTs) <i>Randy Treadwell, Washington State Department of Agriculture</i>
8:30 am – 9:30 am	<b>Information Sharing with State and Local Government Officials   Location:</b> Metro Suite The Office of Partnerships is presenting a new training session on information sharing vehicles including commissioning and 20.88 agreements. Questions that will be addressed include what these vehicles are, when they are used, and what are the benefits to public health. <i>Ryan Cates, Office of Regulatory Affairs, Office of Partnerships, U.S. Food and Drug Administration</i>
9:00 am – 10:00 am	<b>Associate Membership Committee   Location:</b> Suite 4 & 5
9:30 am – 11:00 am	<b>Foodborne Outbreak &amp; Emergency Response Committee   Location:</b> Plaza A <b>Guest Speakers/Presentations:</b> State Food Safety Agencies’ Use of Social Media <i>Jessica Badour, Georgia Department of Agriculture</i>
10:30 am – 12:00 pm	<b>Drugs, Devices &amp; Cosmetics Committee   Location:</b> Suite 8, 9 & 10
11:00 am – 12:00 pm	<b>Professional Development Committee   Location:</b> Suite 4 & 5 <b>Guest Speakers/Presentations:</b> Preparing for the Implementation of a Routine Inspection Program in Colorado <i>Nicole Berzins, Colorado Department of Public Health</i>
11:00 am – 12:00 pm	<b>Laboratory, Science and Technology Committee Meeting   Location:</b> Keystone Boardroom <b>Guest Speakers/Presentations:</b> Awareness of Food Safety Risks In Production of Produce on Oklahoma Farms <i>Bryan Buchwald, Oklahoma Department of Agriculture</i>

**SUNDAY, JUNE 21, 2015 (CONTINUED)**

<p>12:00 pm – 2:00 pm</p>	<p><b>Body Art Sub-Committee</b>   Location: Suite 8, 9 &amp; 10  <b>Guest Speakers/Presentations:</b>  Proposed Body Art Definitions and Standards  The Body Art Materials Sub-committee will review and discuss proposed body art material definitions and standards. A presentation on current concerns of the body art community will also be given by a member of the body art community.  <i>John Misock, Oklahoma Department of Agriculture</i></p>
<p>12:00 pm – 1:30 pm</p>	<p><b>Seafood Committee</b>   Location: Metro Suite  <b>Guest Speakers/Presentations:</b>  Surface Pathogen Elimination Practices for Ready-to-eat Fishery Products  <i>Eugene Evans, New York Department of Ag &amp; Markets</i></p>
<p>12:00 pm – 1:30 pm</p>	<p><b>Alumni Committee</b>   Location: Keystone Boardroom  <i>Dan Sowards, Retiree</i></p>
<p>12:30 pm – 2:00 pm</p>	<p><b>Administrative Committee</b>   Location: Suite 4 &amp; 5  <b>Guest Speakers/Presentations:</b>  Change Management Practices by State and Local Food Safety Regulatory Agencies  <i>Tessa Dixon, Louisiana Department of Health and Hospitals</i></p>
<p>1:30 pm – 3:30 pm</p>	<p><b>International &amp; Government Relations Committee</b>   Location: Plaza A  <b>Guest Speakers/Presentations:</b>  Barriers to Inspections of Ethnic, Women-Operated Food Establishments in Dallas, Marshall, and Polk Counties, Iowa  <i>Thao Nguyen, Iowa Department of Inspection and Appeals</i>  Overview on Mexico’s Enhanced Import and Export Policies  <i>Ricardo Cavazos Cepeda, Director, General De Estudios Economicos, COFEPRIS</i>  Overview of Health Canada’s Openness and Transparency Initiative of Posting Inspection Results and Ratings  <i>Kenneth Moore, Regional Director, Compliance &amp; Enforcement, Health Canada</i>  Update Overview on the FSMA Import Rule  <i>Joann M. Givens, Acting Food and Feed Program Director, Office of Regulatory Affairs, U.S. Food and Drug Administration</i>  Update Overview on the Canadian Import Rule  <i>Nicole Bouchard-Steeves, Director General, Atlantic Operations, Canadian Food Inspection Agency</i></p>
<p>3:00 pm – 4:30 pm</p>	<p><b>Laws &amp; Regulations Committee</b>   Location: Metro Suite  <b>Guest Speakers/Presentations:</b>  The Impact of Native Language-Based Training on Food Safety Compliance in Suffolk County, New York  <i>Lisa Potopsingh, Suffolk Department of Health Services New York</i>  Trends in State Laws Related to Food  <i>Doug Farquhar, Program Director for Environmental Health, National Conference of State Legislatures</i></p>
<p>4:30 pm – 6:00 pm</p>	<p><b>OPENING SESSION</b>   Location: Plaza A, B &amp; C  <i>Steve Stich, AFDO President and Director, New York Department of Agriculture &amp; Markets</i></p> <p><b>INVOCATION</b>  <i>Patricia R. Case, Director of Marketing &amp; Communication, St. Luke’s UMC</i></p> <p><b>WELCOME FROM NCAFDO</b>  <i>Kirsten Knopff, Training and Outreach Coordinator, Minnesota Department of Agriculture</i></p> <p><b>IFPTI: COHORT IV GRADUATION CEREMONY</b>  <i>Gerald Wojtala, Executive Director, International Food Protection Training Institute (IFPTI)</i></p> <p><b>PRESIDENT’S ADDRESS</b>  <i>Steve Stich, AFDO President and Director, New York Department of Agriculture &amp; Markets</i></p> <p><b>ENDOWMENT FOUNDATION ADDRESS</b>  <i>John Young, Chair, AFDO Endowment Foundation, and Partner, Young &amp; Associates</i></p> <p><b>GLENN W. KILPATRICK MEMORIAL ADDRESS</b>  <i>Steven Solomon, DVM, Deputy Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration</i></p>
<p>6:00 pm – 7:30 pm</p>	<p><b>WELCOME RECEPTION</b>   LOCATION: Clearwater Ballroom  Sponsored by the AFDO Associate Members and the North Central Association of Food and Drug Officials (NCAFDO) – <b>All are welcome to attend!</b></p>
<p>8:00 pm – 10:30 pm</p>	<p><b>AFDO BINGO</b>   LOCATION: Suite 16   Sponsored by General Mills and International Food Protection Training Institute.  Sponsored by AFDO Past Presidents, First Time Attendees will receive one free card. Don’t miss out on the fun!</p>

# Food Sessions

MONDAY, JUNE 22, 2015

## MORNING JOINT SESSION

**Moderator:** Stan Stromberg, Director, Food Safety Division, Oklahoma Department of Agriculture, Food & Forestry

7:30 am - 9:00 am **CONTINENTAL BREAKFAST** | LOCATION: Plaza Ballroom Foyer

8:30 am - 9:00 am **ANNOUNCEMENTS & AWARDS** | LOCATION: Plaza A, B & C  
*Steve Stich, AFDO President and Director, New York Department of Agriculture & Markets*

9:00 am - 10:00 am **U.S. FOOD AND DRUG ADMINISTRATION ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS UPDATE** | LOCATION: Plaza A, B & C  
*Melinda Plaisier, Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration*

10:00 am - 10:30 am **BREAK** | LOCATION: Plaza Ballroom Foyer

**Moderator:** Natalie Adan, Division Director, Georgia Department of Agriculture

10:30 am - 11:15 am **U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition Update** | Location: Plaza A, B & C

Dr. Mayne will reflect on her first five months as CFSAN Center Director and give an update on several important CFSAN initiatives.  
*Susan T. Mayne, Ph.D., Director, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration*

11:15 am - 12:00 pm **An Investigation into Foodborne Illness and Its Impacts** | Location: Plaza A, B & C

This presentation will describe some of the challenges facing the United States with regard to foodborne illness and will discuss the impacts that foodborne disease has on individuals and on our society. Presenter will explore food safety's status quo and suggest solutions for the future.  
*Patricia Buck, Executive Director, Center for Foodborne Illness Research and Prevention*

12:00 pm - 1:30 pm **BURDITT LUNCH** | LOCATION: Clearwater Ballroom 

**Moderator:** Pamela Miles, Program Supervisor, Virginia Department of Agriculture

1:30 pm - 2:15 pm **Menu and Vending Machine Nutrition Labeling** | Location: Plaza A, B & C

*Felicia Billingslea - Director, Food Labeling and Standards Staff, Office of Nutrition, Labeling, and Dietary Supplements (ONLDS), Center for Food Safety and Applied Nutrition (CFSAN), U.S. Food and Drug Administration*

2:15 pm - 3:30 pm **IFPTI Fellow Poster Sessions and Exhibitor Spotlight Ice Cream Social/Break**

**Fellowship Select Presentations** | Location: Plaza A, B & C

**Awareness of Food Safety Risks In Production of Produce on Oklahoma Farms**  
*Bryan Buchwald, Oklahoma Department of Agriculture*

**Factors Influencing Multi-Jurisdictional Collaboration Within State Food Emergency Rapid Response Teams (RRTs)**  
*Randy Treadwell, Washington State Department of Agriculture*

**Poster Sessions** | Location: Suite 8, 9 & 10

The poster session features the research projects carried out by the Cohort 4 IFPTI Fellows. While strolling with your sundae, 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.

**Fellowship Poster Session sponsored by:** Food Marketing Institute Foundation, Meijer, Inc. and Association of Food and Drug Officials

3:00 pm - 3:30 pm **BREAK / EXHIBITOR SHOWCASE / POSTER SESSIONS** | LOCATION: Plaza Ballroom Foyer & Suite 8, 9 & 10


## BREAKOUTS (CHOOSE 1)

3:30 pm - 5:00 pm **Gen Next - Whole Genome Sequencing of Foodborne Microbiological Pathogens** | Location: Plaza A & B

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

This session will provide an overview of an emerging new tool to identify, target and link pathogens to reduce foodborne outbreak incidents. Regulators will provide a perspective on when and how whole genome sequencing will be used to enhance and support their outbreak investigation and associated enforcement actions. For industry, this new technology could be used as a preventative tool to understand transient and/or established populations in your operations.

*Eric Brown, Director, Division of Microbiology, CFSAN, U.S. Food and Drug Administration*  
*Burton W. Blais, Ph.D., Section Head, Research and Development Section, Canadian Food Inspection Agency*  
*Jairus R. David, Ph.D., Research & Innovation - Applied Science & Technology, ConAgra Foods, Inc.*  
*Brian Saunders, New York State Department of Agriculture & Markets*

<b>3:30 pm – 5:00 pm</b>	<b>Panel Discussion on the Growing Demand for Locally Sourced Meat and Poultry – Production, Marketing/Distribution and Food Safety Opportunities and Challenges</b>   Location: Plaza C
<b>Moderator:</b> Keith Payne, Deputy Director, Outreach and Partnership Division, United States Department of Agriculture	
Panel Discussion on the Growing Demand for Locally Sourced Meat and Poultry – Production, Marketing/Distribution and Food Safety Opportunities and Challenges - This session will provide diverse perspectives from Federal and State regulators, producers and local food advocates regarding the increasing effort to build more locally based, self-reliant food economies that encompass sustainable food production, processing, distribution and consumption. The focus of this session here will be on meat and poultry, and what programs are in place to support these locally sourced products, and what obstacles exist that might hinder these self-reliant food systems. <i>David M. Bough, DVM, Director, EIAO, Indiana Board of Animal Health</i> <i>Greg Gunthorp, Owner, Gunthorp Farms</i> <i>Vanessa Zajfen, Farm to School Regional Lead, Midwest, United States Department of Agriculture</i> <i>Cindy Klug, Director, Meat Safety and Inspection Bureau, WI Department of Agriculture</i>	
<b>6:00 pm</b>	<b>MONDAY NIGHT EVENT: A NIGHT IN THE CITY</b>  Let's race on down to Downtown Indianapolis. The evening will begin at Rock Bottom Brewery with food, beer tastings and networking. Rock Bottom Brewery is located in the heart of the downtown night life and buses will be available throughout the evening until midnight for return to the hotel. Ticket includes bus transportation, buffet, 2 drinks (beer, wine and soda), and unlimited Beer Samples. Buses will start loading at 6:00pm.

<b>TUESDAY, JUNE 23, 2015</b>	
<b>MORNING JOINT SESSION</b>	
<b>Moderator:</b> Pete Salsbury, Project Manager, U.S. Food and Drug Administration	
<b>7:00 am - 9:00 am</b>	<b>CONTINENTAL BREAKFAST</b>   LOCATION: Plaza Ballroom Foyer
<b>8:00 am - 8:15 am</b>	<b>ANNOUNCEMENTS &amp; AWARDS</b>   LOCATION: Plaza A, B & C <i>Steve Stich, AFDO President and Director, New York Department of Agriculture &amp; Markets</i>
<b>8:15 am – 9:15 am</b>	<b>EBOLA OUTBREAK RESPONSE</b>   LOCATION: Plaza A, B & C <i>Doug Thoroughman, Ph.D., M.S., CAPT, U.S. Public Health Service, CDC Career Epidemiology Field Officer, KY Department for Public Health</i>
<b>9:15 am - 10:00 am</b>	<b>HEALTH FRAUD PRESENTATION</b>   LOCATION: Plaza A, B & C <i>Jason Humbert, Senior Regulatory Manager, Office of Regulatory Affairs, U.S. Food and Drug Administration</i>
<b>10:00 am – 10:30 am</b>	<b>BREAK / EXHIBITOR SHOWCASE</b>   LOCATION: Plaza Ballroom Foyer
<b>Moderator:</b> Courtney Mickiewicz, Regional Manager, Virginia Department of Agriculture and Consumer Services	
<b>10:30 am – 11:15 am</b>	<b>Food Waste and the Issue of Product Date Labeling: Looking into the Future</b>   Location: Plaza A, B & C
This presentation will address date labeling of foods and how it leads to misapplication of resources, unnecessary financial burden, and food waste. The U.S. history on this topic and current challenges surrounding date labeling of foods will be reviewed, and actions needed to move toward a solution will be provided. <i>Rosie Newsome, Director, Science and Policy Initiatives, Institute of Food Technologists (IFT)</i>	
Product date labels are gaining national attention as awareness about consumer confusion and food waste increases. The food industry is working to understand consumer needs and behaviors, label products for optimum quality, identify advances in technologies, and identify what is needed in terms of educational programs for consumers. Consumer research and industry initiatives will be discussed to put some context around this complex issue. <i>Hilary Thesmar, Ph.D., RD, CFS, Vice President, Food Safety Programs, Food Marketing Institute (FMI)</i>	
<b>11:15 am – 12:00 pm</b>	<b>FSIS Regulatory Update</b>   Location: Plaza A, B & C
DUS Almanza will discuss recent FSIS regulatory developments such as Ground beef records at retail, Listeria testing at retail, and catfish inspection strategy. He will also discuss collaboration and areas he feels the states [AFDO] and FSIS could better collaborate together in [i.e. Recalls, illness investigations, inspections, sampling]. <i>Alfred Almanza, Deputy Under Secretary for Food Safety, United States Department of Agriculture</i>	
<b>12:00 pm – 1:30 pm</b>	<b>LUNCH ON YOUR OWN</b>
<b>BREAKOUTS (CHOOSE 1)</b>	
<b>1:30 pm – 3:00 pm</b>	<b>Retail</b>   Location: Plaza A & B
<b>Moderator:</b> Laurie Farmer, Director State Cooperative Programs, SE Region, Office of Regulatory Affairs, U.S. Food and Drug Administration	
<b>1:30 pm – Strategies to Mitigate and Control Environmental Listeria Monocytogenes in Retail Delis</b>	
This seminar will be an interactive discussion of current research on Listeria monocytogenes prevalence in retail delis conducted at Purdue University. Studies tested the efficacy of changes to daily SSOPs, a novel deep clean SSOP, and food safety training programs to reduce environmental L. monocytogenes prevalence. Conclusions from this work include recommendations for mitigating environmental L. monocytogenes in retail delis and identification of opportunities for further research. <i>Susan Hammons, Ph.D. Student, Department of Science, Purdue University</i>	
<b>2:00 pm – Food Trucks are rolling into town: Are you ready?</b>	
A panel discussion consisting of industry, advocates, and regulators will review the history of food trucks as they evolved into "restaurants on wheels," as well as the wide range of regulations across the United States, including vast differences from city to city. This will be a discussion to think outside the box on how food trucks fit into the regulatory arena, looking at changes and challenges with increased numbers of food trucks and how to work towards consistent rules and regulations. Real world scenarios and examples will be discussed. <i>Robert Frommer, Attorney, Institute for Justice</i> <i>Matt Kornmeyer, Owner, Scratch Streetfood, LLC, Indy Food Truck Alliance</i>	

1:30 pm – 3:00 pm	<b>Preparing for FSMA Implementation Rules (Food, Feed &amp; Produce) – Controls Implementation   Location: Plaza C</b>
<p><b>Moderator: Ellen Buchanan, Audit Director, Office of Regulatory Affairs, U.S. Food and Drug Administration</b>  <i>Bob Ehart, Senior Policy &amp; Science Advisor, National Association of State Departments of Agriculture</i>  <i>Joann M. Givens, Acting Food and Feed Program Director, Office of Regulatory Affairs, U.S. Food and Drug Administration</i>  <i>Warren Stone, Sr. Director, Science Policy, Grocery Manufacturers Association (GMA)</i></p>	
3:00 pm – 3:30 pm	<b>BREAK / EXHIBITOR SHOWCASE   LOCATION: Plaza Ballroom Foyer</b>
3:30 pm – 5:30 pm	<b>Retail (Continued)   Location: Plaza A &amp; B</b>
<p><b>Moderator: Rick Akin, Deputy Director, Florida Department of Business and Professional Regulation, Division of Hotels and Restaurants</b></p> <p><b>3:30 pm – Enhancing Consumer Protection by Ensuring Retailers Can Trace Sources of Raw Ground Beef</b>  This presentation will cover the USDA's Food Safety and Inspection Service's proposed rule that requires all makers of raw ground beef products to keep records to protect consumers further by ensuring retailers can trace sources of ground meats. Retail establishments regularly make ground beef by mixing cuts of beef from various sources, and this proposed rule would require them to keep clear records indentifying the source, supplier and names of all materials used in the preparation of raw ground beef products. This should help in traceback investigations, and this proposed rule is part of the Agency's latest efforts to target its food safety prevention tools toward areas that will have the most significant public health impact.  <i>Dr. Daniel Engeljohn, Assistant Administrator, United States Department of Agriculture</i></p> <p><b>4:00 pm – Mapping the Mystery of Food Safety &amp; Alcohol Regulations</b>  Take a guided tour through the National Restaurant Association's new interactive regulatory maps. Learn how to use the maps to find Food Code requirements for manager, food handler and safe alcohol service in every state and county, and in some cities, coast to coast. Your tour guide will show you the easy-to-use interactive features and how to access a level of detail not available to the general public  <i>Mark Miklos, Sr. Manager Program Compliance, National Restaurant Association</i></p> <p><b>4:30 pm - Solution-Based Roundtable Chat - Factors That Influence Whether Health Inspectors Write Down Violations on Inspection Reports</b>  In this interactive session, we will explore factors that influence whether health inspectors record violations on inspection reports. Strategies/recommendations for overcoming these factors will be explored in roundtable chat sessions with peers.  <b>Facilitators:</b>  <i>Dionne Crawford, Food Safety Supervisor, US Operations, McDonald's Corporation</i>  <i>Tara Paster, President, Paster Training, Inc.</i>  <i>Alan Tart, Acting Deputy Director, Office of Partnerships, Office of Regulatory Affairs, U.S. Food and Drug Administration</i></p>	
3:30 pm – 5:30 pm	<b>Gluten Free with Industry, Government &amp; Consumers   Location: Plaza C</b>
<p><b>Moderator: Susan Parachini, Direct Implementation Programs Unit Manager, Colorado Department of Public Health and Environment</b>  <i>Felicia Billingslea – Director, Food Labeling and Standards Staff, Office of Nutrition, Labeling, and Dietary Supplements (ONLDS), Center for Food Safety and Applied Nutrition (CFSAN), U.S. Food and Drug Administration</i>  <i>Mary Schluckebier, BS, MA, Executive Director, Celiac Support Association</i></p>	
6:30 pm	<b>PRESIDENT'S RECEPTION   LOCATION: Clearwater Ballroom Foyer</b>
7:30 pm	<b>WILEY AWARD BANQUET   LOCATION: Clearwater Ballroom </b>

WEDNESDAY, JUNE 24, 2015

7:00 am - 9:00 am

CONTINENTAL BREAKFAST | LOCATION: Plaza Ballroom Foyer

BREAKOUTS (CHOOSE 1)

8:00 am – 11:30 am

Retail Breakout Sessions (Continued) | Location: Plaza A & B

Moderator: Dionne Crawford, Food Safety Supervisor, US Operations, McDonald’s Corporation

8:00 am - Grading and Scoring of Inspections at Retail - An Interactive Debate to Consider Pros and Cons...Where do YOU Fall on this Issue?

This live panel debate will put you right in the middle of the retail food establishment inspection scoring or grading controversy. Audience members will use hand held devices to cast a vote for or against the grading of food establishment inspection before the debate begins. Two distinguished panels of regulatory and industry officials will debate the pros and cons of inspection scoring or grading systems. After the debate, the audience will vote again. How will the bar be moved? Which team of distinguished debaters will persuade you? Will you leave this session convinced of your original opinion or willing to consider changing it? This promises to be an exciting, as well as informative, session that you will regret not attending.

Moderator: Alan Tart, Acting Deputy Director, Office of Partnerships, Office of Regulatory Affairs, U.S. Food and Drug Administration

- Catherine Adams Hutt, PhD, RD, CFS, President, RdR Solutions Consulting, LLC.
Rose Henderson R.N., R.E.H.S., Environmental Health Manager, Southern Nevada Health District
Janelle Kaufman, Administrator, Food and Consumer Safety Department, Marion County Public Health Department, Indianapolis, Indiana
Andre C. Pierce, MPA, REHS, Environmental Health and Safety Director, Wake County Environmental Services
David Plunkett, J.D., J.M., Food Safety Program, Center for Science in the Public Interest
Diann Worzalla, REHS, MPA, Director, Florida DBPR, Division of Hotels and Restaurants

9:00 am – Interagency Food Safety Analytics Collaboration

Established in 2011, Interagency Food Safety Analytics Collaboration (IFSAC) seeks to improve coordination of federal food safety analytic efforts and address cross-cutting priorities for food safety data collection, analysis, and use. Projects and studies aim to identify foods that are important sources of illnesses. The current focus of IFSAC’s activities is foodborne illness source attribution, defined as the process of estimating the most common food sources responsible for specific foodborne illnesses.
Michael Bazaco MS, PhD, Epidemiologist, Office of Analytics and Outreach, U.S. Food and Drug Administration

9:30 am – Break

10:00 am – Conquering the Retail Program Standards

Join us for an informative panel discussion of state and local jurisdictions that have had success in meeting the challenges associated with implementing the Voluntary National Retail Food Regulatory Program Standards. This panel of representatives will provide insight into how to effectively and efficiently use the Retail Program Standards as part of an achievable continuous improvement process.

Moderator: Janelle Kaufman, Administrator, Food and Consumer Safety Department, Marion County Public Health Department, Indianapolis, Indiana

- Lane Drager, Consumer Protection Program Coordinator, Boulder County Public Health
Ernest Julian, Ph.D., Chief, Office of Food Protection, Rhode Island Department of Health
Andre C. Pierce, MPA, REHS, Environmental Health and Safety Director, Wake County Environmental Services

8:00 am – 11:30 am

Overcoming Communication Barriers | Location: Plaza C

Regulatory professionals and federal and state regulators need to be able work well with others. When the communication process breaks down, misunderstandings occur and organizations are not productive.

During a high energy, interactive-session, Nancy Singer, former Department of Justice prosecutor, will use case studies and role-playing exercises to demonstrate techniques to improve the attendees’ ability to convey information. Participants will leave the session with actionable and practical information that they will be able to use immediately.

Topics to be discussed include:

- Factors that enhance and impair the communication process
Ways to overcome resistance to the listener receiving the message
The importance of active listening
Techniques for influencing the outcome at meetings
How to give constructive feedback in a way that will minimize a negative response
How to use questions to influence other people to adopt a particular point of view

Nancy Singer, Compliance-Alliance
Cynthia Culmo, Principal Consultant, CC Consulting

10:00 am – 10:30 am

BREAK | LOCATION: Plaza Ballroom Foyer

11:30 am – 12:00 pm

AFDO BUSINESS MEETING | LOCATION: Plaza A & B

12:00 pm – 4:00 pm

AFDO BOARD OF DIRECTORS MEETING | LOCATION: Suite 16

SEAFOOD HACCP – SEGMENT 2 TRAINING (WEDNESDAY, JUNE 24, 2015 8:00AM-5:00PM)

9:30 am – 5:00 pm

MUST BE PRE-REGISTERED TO ATTEND | LOCATION: Plaza D
Arthur Ness, Wisconsin Department of Agriculture, Trade & Consumer Protection

JUICE HACCP TRAINING (WEDNESDAY, JUNE 24, 2015 8:00AM - 5:00PM – THURSDAY, JUNE 25, 2015 8:00AM - 12:00PM)

9:30 am – 5:00 pm

MUST BE PRE-REGISTERED TO ATTEND | LOCATION: Suite 4 & 5
Byron Beerbower, Michigan Department of Agriculture & Rural Development
Leslie Bourquin, Michigan State University

# Drug & Medical Device Sessions

MONDAY, JUNE 22, 2015

## MORNING JOINT SESSION

**Moderator:** Stan Stromberg, Director, Food Safety Division, Oklahoma Department of Agriculture, Food & Forestry

7:30 am - 9:00 am **CONTINENTAL BREAKFAST** | **LOCATION:** Plaza Ballroom Foyer

8:30 am - 9:00 am **ANNOUNCEMENTS & AWARDS** | **LOCATION:** Plaza A, B & C  
*Steve Stich, AFDO President and Director, New York Department of Agriculture & Markets*

9:00 am - 10:00 am **U.S. FOOD AND DRUG ADMINISTRATION ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS UPDATE** | **LOCATION:** Plaza A, B & C  
*Melinda Plaisier, Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration (Invited)*

10:00 am - 10:30 am **BREAK** | **LOCATION:** PLAZA BALLROOM FOYER

**Moderator:** Gretchen Bowker, Chief Operating Officer, Pearl Pathways

10:30 am - 10:35 am **Welcome** | **Location:** Plaza D & E

*Art Czabaniuk, Detroit District Director, Office of Regulatory Affairs, U.S. Food and Drug Administration*

10:35 am - 11:15 am **Pharmaceutical Counterfeiting** | **Location:** Plaza D & E

The FDA's Forensic Chemistry Center (FCC) is responsible for providing rapid response and specialized analytical services for activities related to product tampering, chemical terrorism, and counterfeit products. As the primary analytical support laboratory for the FDA's Office of Criminal Investigations, the FCC processes suspected counterfeit products ranging from packaging and labeling to solid dosage forms, injectables, creams, ointments, patches and inhalers. This presentation will focus on the different techniques that are utilized to evaluate suspect pharmaceutical products, and on examples of counterfeits that have been detected

*Cheryl Flurer, Director, Forensic Chemistry Center, Organic Laboratory Branch, Office of Regulatory Affairs, U.S. Food and Drug Administration*

11:15 am - 12:00 pm **Increasing Supply Chain Reliability – Shifting Paradigms** | **Location:** Plaza D & E

As an industry, we are not focusing on areas that are proving to increase the reliability of our supply chain. Understand paradigm shifts uncovered by manufacturers and suppliers working together through the Xavier University Integrity of Supply Initiative that hold the key to the answers we are all looking for. It is through this renewed focus that our efforts can turn toward meaningful and impactful solutions.

*Marla Phillips, Director, Xavier Health*

12:00 pm - 1:30 pm **BURDITT LUNCH** | **LOCATION:** Clearwater Ballroom 

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

1:30 pm - 2:15 pm **When Does Your Software Become Regulated?** | **Location:** Plaza D & E

The explosion of medical and clinical software applications and the "Internet of Things" has created new challenges and questions for both the regulators and the regulated industry. This session will cover the important new guidance's, initiatives, and enforcement activity relating to software, with a focus on FDA and FTC initiatives.

*Marian Lee, Partner, Gibson, Dunn & Crutcher LLP*

2:15 pm - 3:00 pm **FDA Drug and Device Field Operations in 2015 - Highlights and Trends in Work Plan Development, Risk Assessment and Inspectional Outcomes** | **Location:** Plaza D & E

*Ellen Morrison, Assistant Commissioner for Operations, Office of Regulatory Affairs, U.S. Food and Drug Administration*

3:00 pm - 3:30 pm **BREAK / EXHIBITOR SHOWCASE / POSTER SESSIONS** | **LOCATION:** Plaza Ballroom Foyer & Suite 8, 9 & 10

**Moderator:** Cynthia Culmo, Principal Consultant, CC Consulting

3:30 pm - 4:15 pm **Updates from Health Canada** | **Location:** Plaza D & E

Bill C-17 represents the most significant amendment to Canada's Food and Drug Act in over 50 years, and includes expanded powers for Health Canada.

- What impact is it expected to have on manufacturers?
- How will confidential corporate information be handled when/if it is requested by Health Canada?
- How will this legislation lead to greater patient safety?

*Chad Sheehy, Senior Regulatory Advisor, Health Canada - Inspectorate*

4:15 pm - 5:00 pm **Implementing an Electronic System for CAPA and Complaints: Challenges and Opportunities** | **Location:** Plaza D & E

To achieve compliance many companies use electronic systems to help ensure that their employees complete the required documentation and that documentation is accessible to regulators during an FDA inspection. Getting the employees to use the system presents many challenges. Michael Viscido, Corporate Director Quality Systems and Services at Ikarria, Inc. will explain what the challenges are and how to overcome them.

*Michael Viscido, Corporate Director, Quality Systems and Services, Ikarria, Inc.*

6:00 pm **MONDAY NIGHT EVENT: A NIGHT IN THE CITY** 

Let's race on down to Downtown Indianapolis. The evening will begin at Rock Bottom Brewery with food, beer tastings and networking. Rock Bottom Brewery is located in the heart of the downtown night life and buses will be available throughout the evening until midnight for return to the hotel. Ticket includes bus transportation, buffet, 2 drinks (beer, wine and soda), and unlimited Beer Samples. Buses will start loading at 6:00pm.

**TUESDAY, JUNE 23, 2015**

**MORNING JOINT SESSION**

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

7:00 am - 9:00 am	<b>CONTINENTAL BREAKFAST</b>   <b>LOCATION:</b> Plaza Ballroom Foyer
8:00 am - 8:15 am	<b>ANNOUNCEMENTS &amp; AWARDS</b>   <b>LOCATION:</b> Plaza A, B & C <i>Steve Stich, AFDO President and Director, New York Department of Agriculture &amp; Markets</i>
8:15 am - 9:15 am	<b>EBOLA OUTBREAK RESPONSE</b>   <b>LOCATION:</b> Plaza A, B & C <i>Doug Thoroughman, Ph.D., M.S., CAPT, U.S. Public Health Service, CDC Career Epidemiology Field Officer, KY Department for Public Health</i>
9:15 am - 10:00 am	<b>HEALTH FRAUD PRESENTATION</b>   <b>LOCATION:</b> Plaza A, B & C <i>Jason Humbert, Senior Regulatory Manager, Office of Regulatory Affairs, U.S. Food and Drug Administration</i>
10:00 am - 10:30 am	<b>BREAK / EXHIBITOR SHOWCASE</b>   <b>LOCATION:</b> Plaza Ballroom Foyer

**DRUG & DEVICE SESSION**

**Moderator:** Thomas Brinck, Manager, Drugs & Medical Devices Group, Texas Department of State Health Services

10:30 am - 11:15 am	<b>Component Counterfeiting: Considerations in Developing a Program to Prevent</b>   <b>Location:</b> Plaza D & E <i>Donna Djinovich, Director of Regulatory Affairs, Rauland-Borg Corporation</i> <i>George Hughes, Office of Criminal Investigations, Office of Regulatory Affairs, U.S. Food and Drug Administration</i>
11:15 am - 12:00 pm	<b>Drug Shortages and Aging Facilities</b>   <b>Location:</b> Plaza D & E Drug shortages have and continue to be a focus of both the industry and regulators. The session will provide an industry perspective on the topic of Drug Shortages followed by a closer look into one of the areas linked to this issue, aging facilities. <i>Glenn E. Wright, Senior Director Project Management, Technical Services/Manufacturing Science, Eli Lilly and Company and Co-Chair, Aging Facilities Task Force</i> <i>Parenteral Drug Association</i> <i>Sandra Sifferlen, Assistant General Counsel, Regulatory Legal, Eli Lilly and Company</i>
12:00 pm - 1:30 pm	<b>Interacting with Federal and State Regulators: What to Do and How to Do It (WORKING LUNCH PRESENTATION*)</b>   <b>Location:</b> Plaza D & E During a high-energy, interactive working lunch, the attendees will be divided into teams and asked to comment on how they would respond to challenging regulatory inspection situations. Then a panel of experts consisting of Nancy Singer, ComplianceAlliance; Maridalia Torres Irizarry, FDA District Director for Puerto Rico; Evelyn Bonnin, FDA District Director for Baltimore; Julie Larsen, BioTeknica; KC Stevenson, Ceutical Labs; and Cynthia Culmo, CC Consulting will provide their guidance and advice. <p style="text-align: center;"><b>Lunch provided only for registered attendees of the Drug &amp; Device conference track</b></p> <p style="text-align: right;"><b>* Sponsored by Ceutical Laboratories, Inc.</b></p>

**Moderator:** Courtland Imel, CEO, Ceutical Laboratories, Inc.

1:30 pm - 2:15 pm	<b>Interpretation and Application of the New Device Correction Guidance</b>   <b>Location:</b> Plaza D & E This presentation will include the Food and Drug Administration's expectations and provide clarity on Distinguishing Medical Device Recalls from Medical Device Enhancements guidance document. The guidance is intended to: clarify when a change to a device constitutes a medical device recall, distinguish those instances from device enhancements and clarify reporting requirements under 21 CFR Part 806. This guidance does not address nor apply to: whether a new premarket submission is required, radiation-emitting electronic product defects or failures to comply with radiation safety performance standards contained in 21 CFR Parts 1020 to 1050 or methodologies for risk management or risk assessment. <i>Maureen Bernier, Biomedical Engineer, Center for Devices and Radiological Health, U.S. Food and Drug Administration</i>
2:15 pm - 3:00 pm	<b>Update on GDUFA Implementation and Accomplishments</b>   <b>Location:</b> Plaza D & E <i>Alonza E. Cruse, Acting Director, Office of Medical Products &amp; Tobacco Operations, Office of Regulatory Affairs, U.S. Food and Drug Administration</i>
3:00 pm - 3:30 pm	<b>BREAK / EXHIBITOR SHOWCASE</b>   <b>LOCATION:</b> Plaza Ballroom Foyer
3:30 pm - 4:15 pm	<b>EU Enforcement: Update on Unannounced Audit Program Progress and Results</b>   <b>Location:</b> Plaza D & E This session will provide a top level comparison of the EU system for regulating medical devices with the US system and review progress with EU requirements introduced in 2014 mandating that all medical device manufacturers placing devices in Europe be subject to routine additional unannounced audit visits. The discussion includes the reasons behind unannounced visits, the details of the changed EU requirements and a review of experience to date now that several hundred unannounced visits have been delivered by EU Notified Bodies at US medical device manufacturers. <i>Paul Brooks, Senior VP, Healthcare Solutions</i>
4:15 pm - 5:00 pm	<b>Compliance Questions Panel</b>   <b>Location:</b> Plaza D & E Moderator: Julie Larsen, Director, Inspection Readiness Services, BioTeknica The compliance question and answer panel is made up of four distinguished FDA representatives who will answer compliance questions from industry participants. This is an excellent opportunity for industry to ask questions about their more difficult decisions, interpretations and applications of the regulations to their products. Questions will be answered directly by those who are decision makers in interpreting what practices are considered compliant and what is considered acceptable according to the regulations. <i>Ricki Chase, Director of Investigations, Chicago District, Office of Regulatory Affairs, U.S. Food and Drug Administration</i> <i>Maureen Bernier, Biomedical Engineer, Center for Devices and Radiological Health, U.S. Food and Drug Administration</i> <i>Steven Barber, Director, Compliance Branch, Detroit District, Office of Regulatory Affairs, U.S. Food and Drug Administration</i> <i>George Hughes, Office of Criminal Investigations, Office of Regulatory Affairs, U.S. Food and Drug Administration</i>
6:30 pm	<b>PRESIDENT'S RECEPTION</b>   <b>LOCATION:</b> Clearwater Ballroom Foyer
7:30 pm	<b>WILEY AWARD BANQUET</b>   <b>LOCATION:</b> Clearwater Ballroom 