SATURDAY, JUNE 21, 2014	
5:30 pm	**AFDO COMMITTEE CHAIRS AND CO-CHAIRS MEETING**
SUNDAY, JUNE 22, 2014	
7:00 am – 9:00 am	**CONTINENTAL BREAKFAST** | **Location**: Imperial Ballroom Foyer
8:00 am – 4:00 pm	**AFDO COMMITTEE MEETINGS**
8:00 am – 9:00 am	**Endowment Foundation** | **Location**: Grays Peak
8:00 am – 9:30 am	**Food Protection & Defense Committee** | **Location:** Mt. Evans **Guest Speakers/Presentations:** *Amy Kircher, Associate Director, National Center for Food Protection and Defense*
9:00 am – 10:00 am	**Associate Membership Committee** | **Location:** Grays Peak
9:30 am – 11:00 am	**Foodborne Outbreak & Emergency Response Committee** | **Location:** Mt. Evans **Guest Speakers/Presentations:** *Priscilla Neves, Consumer Safety Officer, U.S. Food and Drug Administration* *Mark Sestak, Director, Food and Lodging Program, Alabama Department of Public Health*
9:30 am – 11:00 am	**Laws & Regulations Committee** | **Location:** Mt. Elbert A **Guest Speakers/Presentations:** Trends in State Laws Related to Food *Doug Farquhar, Program Director for Environmental Health, National Conference of State Legislatures* GMO Labeling Regulations *Lisa Drake, U.S. State and Local Government Affairs Lead, Monsanto Company*
10:30 am – 12:00 pm	**Drugs, Devices & Cosmetics Committee** | **Location:** Mt. Elbert B
11:00 am – 12:30 pm	**Administration Committee (includes Awards, Media & Public Relations, Membership, Nominations, and Resolutions Sub-Committees)** | **Location:** Grays Peak **Guest Speakers/Presentations:** *Discussion on the formation of a "Fellowship Alumni" and possible activities for this group*
11:00 am – 12:00 pm	**Laboratory, Science and Technology Committee Meeting**| **Location:** Pikes Peak **Guest Speakers/Presentations:** Chemical rinses for surface pathogen elimination for seafood: *Rita Johnson, Co-Chair, Seafood Committee and Rapid Response Coordination, Florida Department of Agriculture and Consumer Services*
12:00 pm – 1:00 pm	**Body Art Sub-committee** | **Location:** Mt. Elbert B Body Art has become a common feature of American culture in recent decades. Once isolated to specific groups of people, body art can now be found across all sectors of American society. There is an urgent need for manufacturing GMP guidelines and also for standards for the materials themselves. There is an opportunity for AFDO to serve as a focal point for development of national safety standards for body art materials. By forming coalitions with the body art industry, state and local health departments, academia and federal agencies, significant improvements in the safety of body art could be made.
1:00 pm – 2:30 pm	**Food Committee (includes Field, Meat & Poultry, and Retail Food sub-committees)** | **Location:** Mt. Evans **Guest Speakers/Presentations:** *Roberta Wagner, Deputy Director for Regulatory Affairs, U.S. Food and Drug Administration/Center for Food Safety and Applied Nutrition* FSMA Field Operations Team Work Groups Update: *Stephen Stich, Director, New York Department of Agriculture & Markets* *Byron Beerbower, Compliance Manager, Food & Dairy Division, Michigan Department of Agriculture and Rural Development* *Ernest Julian, Chief, Office of Food Protection, Rhode Island Department of Health* Retail Food – CFP Update *Alan Tart, Retail Food Program Specialist, U.S. Food and Drug Administration* Meat and Poultry Update *Stan Stromberg, Director, Food Safety Division, Oklahoma Department of Agriculture, Food and Forestry*
2:00 pm – 4:15 pm	**International & Government Relations Committee** | **Location:** Mt. Elbert A **Guest Speakers/Presentations:** *Cathleen McInerney Barnes, International Policy Analyst, U.S. Food and Drug Administration* *Ricardo Cavazos Cepeda, Director General De Estudios Economicos, COFEPRIS* *Stephen Baker, Vice President, CFIA Operations*
2:30 pm – 4:00 pm	**Seafood Committee** | **Location:** Mt. Columbia **Guest Speakers/Presentations:** Transporting Live Shellfish Under the FSMA Proposed Rule on Sanitary Transportation of Human and Animal Foods *Kevin Smith, Director, Retail Food and Cooperative Programs Coordination, U.S. Food and Drug Administration* Seafood HACCP Alliance and Technology Update *Steve Otwell, PhD. Emeritus Professor, University of Florida*

Ticket required

SUNDAY, JUNE 22, 2014 (CONTINUED)

4:30 pm – 6:00 pm	**OPENING SESSION** | **Location:** Imperial Ballroom *David Read, AFDO President and Assistant Director, Minnesota Department of Agriculture* **INVOCATION** *Pastor Brad Meuli, President/CEO, Denver Rescue Mission, and Chaplain, House of Representatives, Denver, CO* **WELCOME FROM DENVER** *Dr. Larry Wolk, Executive Director and Chief Medical Officer, Colorado Department of Public Health and Environment* **WELCOME FROM WAFDO** *Lorinda Lhotka, WAFDO President and Section Manager, State of Alaska Department of Environmental Conservation* **PRESIDENT'S ADDRESS** *David Read, AFDO President and Assistant Director, Minnesota Department of Agriculture* **ENDOWMENT FOUNDATION ADDRESS** *John Young, Chair, AFDO Endowment Foundation, and Partner, Young & Associates* **GLENN W. KILPATRICK MEMORIAL ADDRESS** *Howard Sklamberg, Deputy Commissioner for Global Regulatory Operations and Policy, U.S. Food and Drug Administration*
6:00 pm – 7:30 pm	**WELCOME RECEPTION |** LOCATION: GRAND BALLROOM *Sponsored by the AFDO Associate Members and the Western Association of Food and Drug Officials (WAFDO) –* ***All are welcome to attend!***
8:00 pm – 10:30 pm	**AFDO BINGO |** LOCATION: MT. SOPRIS *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!*

MONDAY, JUNE 23, 2014

MORNING JOINT SESSION

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

7:30 am - 9:00 am	**CONTINENTAL BREAKFAST** | LOCATION: IMPERIAL BALLROOM FOYER
8:30 am - 9:00 am	**ANNOUNCEMENTS & AWARDS** | LOCATION: IMPERIAL BALLROOM *David Read, AFDO President and Assistant Director, Minnesota Department of Agriculture*
9:00 am – 10:00 am	**INSIGHTS AND GLOBAL TRENDS IMPACTING FOOD AND MEDICAL PRODUCTS** | LOCATION: IMPERIAL BALLROOM *Dr. David Acheson, M.D., President and CEO, The Acheson Group LLC.*
10:00 am - 10:30 am	**BREAK** | LOCATION: IMPERIAL BALLROOM FOYER

FOOD SESSION

Moderator: Dawn Smith, Food Program Manager, Oregon Department of Agriculture

10:30 am - 11:00 am	**Integrated Food Safety System and FDA's Office of Partnerships** | Location: Imperial Ballroom
Barbara Cassens, Senior Advisor/Acting Director, Office of Partnerships, U.S. Food and Drug Administration	
11:00 am – 12:00 pm	**The Emerging Risks of a Global Food System** | Location: Imperial Ballroom
Today's presentation will provide an overview of some of the identified non-traditional risk issues that will have a significant impact on a global food supply system. • Seven Industry Risk Profile Change Drivers • Regulatory Challenges and The Impact of the Food Safety Modernization Act • Food Defense and Foreseeable Risk • Reputation Risk, Brand Protection and Crisis Management • Changing Industry Risk Profiles – Now What? *Richard L. Shanks, ARM, National Managing Director, Aon Risk Solutions*	

DRUG & DEVICE SESSION

Moderator: Dennis Baker, Southwest Regional Food and Drug Director, FDA

10:30 am - 10:45 am	**Welcome** | Location: Grand Ballroom
Tom Brinck, Manager, Drugs and Medical Devices Group, Texas Department of State Health Services *Dennis Baker, Regional Food and Drug Director, U.S. Food and Drug Administration* *LaTonya Mitchell, Denver District Director, U.S. Food and Drug Administration*	
10:45 am – 11:15 am	**UDI Implementation** | Location: Grand Ballroom
The presentation will address issues related to the implementation of the Food and Drug Administration (FDA) Unique Device Identification (UDI) Regulation and its impact on regulated industry. The FDA UDI Regulation establishes a single device identification system that is standardized and globally harmonized. All manufacturers of medical devices, both domestic and foreign will be required to comply with the new UDI requirements. *Cornelia B. Rooks, Senior Compliance Specialist, Registrar Corp.*	
11:15 am – 12:00 pm	**Contract Manufacturing Arrangements for Drugs: Quality Agreements** | Location: Grand Ballroom
This session will review key elements of the FDA's Draft Guidance for Industry on Quality Agreements and address some recent trends and actions in contract manufacturing of human drugs. *Paula Katz, Acting Branch Chief, Regulatory Policy & Collaboration, Office of Manufacturing & Product Quality (Remote)*	

12:00 pm - 1:30 pm	**LUNCH (ON YOUR OWN)**

Ticket required

Food Session Breakouts (Choose 1)

1:30 pm – 3:00 pm | **Risk-Based Environmental Monitoring and Decision Making** | Location: Imperial Ballroom

Moderator: Warren Stone, Sr. Director of Science Policy, Compliance & Inspection, Grocery Manufacturers Association

This session will focus on how environmental data generated by industry and regulatory agencies are used for decision making. There will be time for the audience and panelist to exchange views and answer questions.

Role of Environmental Monitoring and Industry Data Review and Decision Making Criteria & Actions

Carrie Rigdon, Rapid Response Team Supervisor, Minnesota Department of Agriculture
Dr. Scott Hood, Director of Food Safety, General Mills
Leslie Hintz, Consumer Safety Officer, U.S. Food and Drug Administration
Nancy Schmidt, Compliance Officer, U.S. Food and Drug Administration

1:30 pm – 3:00 pm | **Enhancing your Organizational Effectiveness – Change Management Principles & Practices** | Location: Mt. Evans

Moderator: Courtney Mickiewicz, Regional Manager, VA Department of Agriculture

Change Management is often referred to as that "soft and squishy stuff" that HR people do, but has limited value in real science and engineering applications. In reality, changing behaviors is the really hard stuff! In this hands-on session, we'll explore practical application of basic change management. Through examples from an environment with hard rocks, hard data, hard heads in hard hats – we can demonstrate the value of the soft stuff that can help crack even the toughest nuts. Participants will then be guided through a change assessment where they can apply newly created knowledge to a personal or professional change that they are currently facing.

Richard A. Versen, Team Lead, Lean Program, Encana Oil & Gas

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

3:30 pm – 5:00 pm | **Understanding and Managing Mycotoxins in Food and Feed** | Location: Imperial Ballroom

Moderator: Warren Stone, Sr. Director of Science Policy, Compliance & Inspection, Grocery Manufacturers Association

This session will provide a brief overview of mycotoxins and why they need to be managed in food and feed. Speakers will provide data, insights and implications from their surveillance programs.

Dr. Michael Henry, Animal Scientist, U.S. Food and Drug Administration Center for Veterinary Medicine (CVM), Division of Animal Feeds
Dr. Tim Herrman, State Chemist and Director of the Office of the Texas State Chemist, Texas A & M University System

3:30 pm – 5:00 pm | **Consumer Perspectives – Key Insights and Areas of Interest** | Location: Mt. Evans

Moderator: Courtney Mickiewicz, Regional Manager, VA Department of Agriculture

Food Allergen Policy Issues

Nicole Smith, Vice President of Government Relations, FAACT – Food Allergy & Anaphylaxis Connections Team

Consumer Expectations About FSMA Implementation and Impact

Sandra Eskin, Director, Food Safety, The Pew Charitable Trusts

Antibiotics in Agriculture and the Campaign on Human Health and Industrial Farming

Gail Hansen, Senior Officer, Human Health and Industrial Farming, The Pew Charitable Trusts

Drug & Device Session

Moderator: Andrew Bonanno, Divisional VP, Global Compliance, Abbott Laboratories

1:30 pm – 2:15 pm | **Compliance Question Panel** | Location: Grand Ballroom

Moderator: Julie Larsen, Director, Inspection Readiness Services, BioTeknica

The compliance question and answer panel is made up of three 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.

Ricky Rodriguez, Dallas District Director, U.S. Food and Drug Administration
Howard Manresa, Director, Denver District Compliance Branch, U.S. Food and Drug Administration
Ricki Chase, Director of Investigations, U.S. Food and Drug Administration

2:15 pm –3:00 pm | **Medical Devices: Reports of Corrections and Removals** | Location: Grand Ballroom

This session will provide an overview of requirements for reports and removals and some of the common pitfalls and omissions from the perspective of FDA and Industry.

Caroline Le, PharmD, Recall and Emergency Coordinator, Denver District Office, U.S. Food and Drug Administration

Zena Kaufman, Senior Vice President, Global Quality, Hospira

3:30 pm – 5:00 pm | **Compounding Pharmacies** | Location: Grand Ballroom

Moderator: Andrew Bonanno, Divisional VP, Global Compliance, Abbott Laboratories

This session will focus on contemporary and critical issues surrounding Compounding Pharmacies. Presentations will highlight the specialized profession and practice of pharmacy compounding, the challenges and needs of this expanding industry, and the current, existing as well as new laws and regulations applicable to compounding pharmacies.

Susan Laska, Acting Deputy Director, Office of Medical Products and Tobacco Operations

Erika Butler, Drug Specialist, U.S. Food and Drug Administration

Shan Chikhale, Professor of Pharmaceutics and Pharmaceutical Sciences, School of Pharmacy, South College

6:00 pm - 9:30 pm | **Monday Night Event: Taste of Denver - A Picnic in the Park!**

Your Mile High culinary adventure awaits! AFDO's Denver Monday Night Event will be your one-stop passport to a true foodie journey! Enjoy a relaxing evening of music, friends and beautiful scenery while sipping and sampling offerings from some of Denver's finest chefs, brewers and distillers. Enjoy the serene expanse of the Denver City Park Pavilion, Lake Ferril and the nearby rose gardens.

Before the event, enjoy the crown jewel Denver Museum of Nature and Science, the Denver Zoo, or simply the tranquil view of the Rocky Mountains. Come and enjoy reconnecting with friends, old and new and enjoy a proper Denver welcome! Space is limited so secure your passport to this Monday night event!

Ticket required

Tuesday, June 24, 2014

Morning Joint Session

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

7:00 am - 9:00 am	**Continental Breakfast** | Location: Imperial Ballroom foyer
8:00 am – 8:30 am	**Macro Trends and Consideration** | Location: Imperial Ballroom *Clayton Smith, Senior Manager, Deloitte*
8:30 am – 9:30 am	**FDA – Progress, Trends and Compliance** | Location: Imperial Ballroom *Ellen Morrison, Assistant Commissioner for Operations, U.S. Food and Drug Administration/Office of Regulatory Affairs* *Roberta Wagner, Deputy Director for Regulatory Affairs, U.S. Food and Drug Administration/Center for Food Safety and Applied Nutrition*
9:30 am - 10:00 am	**Health Canada – Progress, Trends and Compliance** | Location: Imperial Ballroom *Ward Chickoski, Regional Director General, Health Canada, Prairie Region (Invited)*
10:00 am – 10:30 am	**Break / Exhibitor showcase** | **Location: Imperial Foyer**

Food Session

Moderator: Mark Reed, Manager, Kentucky DPH Food Safety Branch

10:30 am – 11:00 am	**CFIA – Progress, Trends and Compliance** | Location: Imperial Ballroom

Stephen Baker, Vice President, CFIA Operations

11:00 am – 11:30 am	**USDA – Progress, Trends and Compliance** | Location: Imperial Ballroom

Controlling Listeria monocytogenes (Lm) in Retail Delicatessens - This presentation provides specific recommendations that retailers can take in the delicatessen (deli) area to control Listeria monocytogenes (Lm) contamination of ready-to-eat (RTE) meat and poultry products. FSIS posted new guidance for controlling Listeria monocytogenes (Lm) in retail delicatessens (delis) which advices retailers of specific actions they can take to decrease the potential for Lm growth or cross-contamination in the deli area.

Jerry L. Elliott DVM, Director – Compliance and Investigations Division, USDA

11:30 am – 12:00 pm	**Funding Opportunities for State, Local, Tribal, and Territorial Retail Food Regulatory Programs** | Location: Imperial Ballroom

This session will highlight efforts by FDA to provide funding opportunities for state, local, tribal, and territorial retail food regulatory programs. Grants and cooperative agreements provide Agencies with the opportunity to enhance or develop new and existing programs intended to aid in safeguarding products intended for human or animal consumption. The discussion will include an update on recent funding to help regulatory agencies overcome barriers to achieving conformance with national standards including the Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards). This funding will help regulatory programs achieve success through continuous quality improvement and demonstrate their value to their community while taking steps to reduce the occurrence of foodborne illness.

Pete Salsbury, Project Manager, U.S. Food and Drug Administration
Cathy Hosman, Grant Project Office, Office of Partnerships, U.S. Food and Drug Administration

12:00 pm – 1:30 pm	***Wafdo/Burditt Luncheon***  ***Location: Mt. Sopris***

Drug & Device Session

Moderator: JoAnn Pittman, Regional Public Affairs Specialist, FDA

10:30 am - 11:15 am	**Comparing the U.S. and European System for Regulating Medical Devices** | Location: Grand Ballroom

This session will provide a brief comparison of the EU system for regulating medical devices and the details of EU approach of CE Marking works in practice today. There will also be updates on the proposals being considered to update the EU regulatory following recent problems with medical devices that were cleared for the EU Market and overview of the new EU requirements for routine unannounced audit visits to medical device manufacturers

Paul C. Brooks, Senior Vice President, Healthcare Solutions, BSI Americas

11:15 am - 12:00 pm	**Case for Quality Initiative Update** | Location: Grand Ballroom

Hear directly from FDA Leadership on the impact of the number one strategic priority for the Center for Devices and Radiological Health. How will this initiative impact you, what are the anticipated changes, and what is the implementation plan?

Ricky Rodriguez, Dallas District Director, U.S. Food and Drug Administration

Steve Silverman, Director, Office of Compliance, U.S. Food and Drug Administration (Remote)

12:00 pm - 1:30 pm	**Interactive Session: Response to Challenging Regulatory Inspection Situations (Working Lunch Presentation*)** | Location: Grand Ballroom

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, Compliance-Alliance, Julie Larsen, BioTeknica, and representatives from FDA, state governments, and industry will provide their insights and advice.

Lunch provided only for registered attendees of the Drug & Device conference track

**** Sponsored by BioTeknica***

Revised 5/28/14

 *Ticket required*

TUESDAY, JUNE 24, 2014 (CONTINUED)

FOOD SESSION BREAKOUTS (CHOOSE 1)

1:30 pm – 3:00 pm | **Food Safety at Retail: Perspectives on Policy Setting, Changing Food Worker Behavior, and Assessing Performance and Active Managerial Control** | Location: Imperial Ballroom

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

"Establishing Retail Food Safety Policy"- The Federal, State & Local perspective, including the outcomes from the 2014 Conference for Food Protection (CFP).
Kevin Smith, Director, Retail Food & Cooperative Programs Coordination Staff U.S. Food and Drug Administration
Therese Pilonetti, Delegated Programs Unit Manager, Division of Environmental Health and Sustainability, Colorado Dept. of Public Health and Environment
Monique Mull, Environmental Health Specialist, Mesa County Health Department

"Are things getting better?" Overview of FDA's Retail Risk Factor Study and the Promotion of Active Managerial Control
Mario Seminara, R.S., Regional Retail Food Specialist, U.S. Food and Drug Administration/Office of Regulatory Affairs
Lane Drager, Consumer Protection Coordinator, Boulder County Public Health, Environmental Health Division

"Improving Behaviors on the Front Line" - FDA's Partnership with Google to Test the Effectiveness of Oral Culture Learner Project Materials
Alan Tart, Retail Food Program Specialist, U.S. Food and Drug Administration
Chuck Catlin, Global Food Program Quality Assurance and Risk Manager, Google

1:30 pm – 3:00 pm | **Data for Decision-Making: Laboratory Analysis, Methods Development and Using Results** | Location: Mt. Evans

Moderator: Adam Inman, Assistant Program Manager, Kansas Department of Agriculture

Methods Development - Case studies on method development, validation and use for regulatory action with and without established FDA tolerance limits
Robert Sheridan, Chemistry Program Manager, NY State Department of Agriculture and Markets
Quality Laboratory Results
Kristen Durie, Chemistry Quality Assurance Officer, NY State Department of Agriculture and Markets
Update on Sampling agreements between State Laboratories and State Food Safety Programs
Michelle Motsinger, Consumer Safety Office, U.S. Food and Drug Administration

3:00 pm – 3:30 pm | **BREAK / EXHIBITOR SHOWCASE** | LOCATION: IMPERIAL FOYER

3:30 pm – 5:00 pm | **Sanitation & GMP's – Understanding the Impact of Sanitation on Food Safety Performance** | Location: Imperial Ballroom

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

The session will provide a high level overview of key principles for developing and managing a robust food manufacturing sanitation plan. Industry & a state agency will present common minor & major deficiencies and suggestions on remediation. The session will benefit individuals involved in developing & auditing programs & practices.

Data and Decisions/Actions based on Common Deficiencies from State Agencies
Natalie Adan, Division Director, Georgia Dept of Agriculture
Wet & Dry Principles & Practices
Warren Stone, Sr. Director of Science Policy, Compliance & Inspection, Grocery Manufacturers Association
Industry Examples of Common Challenges & Deficiencies
Karl Thorson, Manager, Sanitation Center of Excellence, General Mills

DRUG & DEVICE SESSION
Moderator: CYNTHIA T. CULMO, R.PH.

1:30 pm - 2:15 pm | **Medical Device Single Audit Program Pilot** | Location: Grand Ballroom

In November 2012 CDRH joined an international coalition of regulatory authorities, including Australia's Therapeutic Goods Administration (TGA), Brazil's Agência Nacional de Vigilância Sanitária (ANVISA), and Canada's Health Canada/Santé Canada to establish a Medical Device Single Audit Program (MDSAP) Pilot. The MDSAP Pilot will allow a single regulatory audit of a medical device manufacturer to satisfy the needs of multiple regulatory jurisdictions. The Pilot began January 2014 – this presentation will provide up to date information on the Pilot program.

Kimberly Trautman, Medical Device Int'l Quality Systems Expert, Center for Devices and Radiological Health (Pre-Recorded)

Paul C. Brooks, Senior Vice President, Healthcare Solutions, BSI Americas (Answering Questions)

2:15 pm - 3:00 pm | **Metric, Data & Analysis, & Biometrics** | Location: Grand Ballroom

Discussion of the ORA field work plan in medical devices and drugs will cover the use of risk assessment in determining the frequency of inspection, inspectional coverage and resource allocation. Specifically, the tools used by the Centers and the Districts will be discussed as well as an overview of inspectional outcomes on a national level.

Ricki Chase, Director of Investigations, U.S. Food and Drug Administration

3:30 pm - 4:15 pm | **Pharmaceutical Inspection Co-Operation Scheme** | Location: Grand Ballroom

Pharmaceutical Inspection Co-operation Scheme update on the strengthening and cooperation efforts for sharing, training and leveraging of resources.

Susan Laska, Acting Deputy Director, Office of Medical Products and Tobacco Operations

Ticket required

3:30 pm – 5:00 pm	**Elevating Public Health Globally through Purposeful Engagements** | Location: Mt. Evans

Moderator: Adam Inman, Assistant Program Manager, Kansas Department of Agriculture

Understanding the tapestry of global collaborations used to drive proactive and positive public health outcome in-country is critical. Investment and actions by governments can directly impact a countries and/or industries ability to understand and meet food safety and regulatory requirements facilitating trade.

FDA International Programs – Objectives, areas of focus, key organizations and outcomes.
Cathleen McInerney Barnes, International Policy Analyst, U.S. Food and Drug Administration

Customs and Border Protection – Objective and interfaces with other agencies to prevent the illegal entry of agricultural and food products while facilitating trade.
Brenda Smith, Executive Director, Office of International Trade, US Customs and Border Protection

Global Regulatory Competencies, Curricula, and Capacity Building
Jerry Wojtala, Executive Director, International Food Protection Training Institute

4:15 pm - 5:00 pm	**Biosimilars Regulations** | Location: Grand Ballroom

The Patient Protection and Affordable Care Act (Affordable Care Act), signed into law by President Obama on March 23, 2010, amends the Public Health Service Act (PHS Act) to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to an FDA-licensed biological product. This presentation will discuss the history and status of biosimilar products and their unique regulatory issues to include interchangeability.

Thomas Berry, Denver District Senior Compliance Officer, U.S. Food and Drug Administration

6:30 pm	**President's Reception** | Location: Mt. Sopris
7:30 pm	**Wiley Award Banquet** | Grand Ballroom

Wednesday, June 25, 2014

7:00 am - 9:00 am	**Continental Breakfast** | Location: Imperial Ballroom foyer
8:00 am – 8:30 am	**AFDO Business Meeting** | Location: Imperial Ballroom

Food Session Breakouts (Choose 1)

8:30 am – 12:00 pm	**Training and Assessment in the 21st Century Workplace: Demonstrating the Ability to do** |Location: Imperial Ballroom

Moderator: Jerry Wojtala, Executive Director, International Food Protection Training Institute

Demystifying the scientific approach to assuring workforce competence. Learn how all the training and certification pieces fit together in developing a National Curriculum Standard for food protection professionals. This workshop will help participants understand the steps in developing training and certification programs using practical case studies of familiar examples from around the home. The session will include an update on the status of the Partnership for Food Protection Training and Certification Workgroup charges.

Dr. Will Dardick, Professor and Psychometrician, George Washington University
Dr. Allan Bateson, Psychometrician, U.S. Food and Drug Administration – DHRD
Dr. Craig Kaml, Vice President of Curriculum, International Food Protection Training Institute

8:30 am – 12:00 pm	**Defensible Food Safety Decisions in an Uncertain World: The role of Sampling in Food Safety Decision-Making** |Location: Grays Peak

Moderator: Nancy Thiex, AAFCO Sampling and Sample Handling Working Group Chair and Principal, Thiex Laboratory Solutions LLC.

The significance of the impact of sampling on the defensibility of data has historically been overlooked in the food world. Sampling generally has a greater impact on data quality than most other variables. This seminar addresses the integration of sampling objectives into development of sampling protocols which will help you generate data of known quality to support food borne illness prevention, response, and compliance programs.

Charles Ramsey, President, EnviroStat, Inc.

Laboratory Session

8:30 am – 11:30	**Mentoring Training** |Location: Mt. Evans

APHL will be hosting a workshop as part of AFDO's Annual Meeting that will bring together mentors and mentees to develop a Toolkit. The purpose of the Toolkit will be to make the relationship more productive and efficient and will cover expectations, roles, etc.

Cathy Johnson, Manager, NCPHLL Leadership and Management Curriculum, Association of Public Health Laboratories

11:30 am – 12:00 pm	**Lunch (Invitation Only)*** | Location: Mt. Evans **** Ticket Required***
12:00 pm – 3:00 pm	**Focus Group-Curriculum Framework** |Location: Mt. Evans

A chance to discuss and learn more about the Curriculum Framework being developed by the International Food Protection Training Institute and AFDO to help guide laboratories on working towards standardized training for their staff in response to FSMA. Training is being mapped to the sections identified in the framework, and competencies are also being developed. This activity will help with short and long-term training planning.

Dr. Craig Kaml, Vice President of Curriculum, International Food Protection Training Institute

10:00 am – 10:15 am	**Break** | Location: Imperial Foyer
12:00 pm – 4:00 pm	**AFDO Board of Directors Meeting** | Location: Mt. Columbia

Seafood HACCP – Segment 2 Training

8:30 am – 5:00 pm	**Must be Pre-Registered to Attend** | Location: Mt. Sopris B *Laura Van Wagenen-Birdsill, Wholesale Food Program Coordinator, Colorado Dept. of Public Health and Environment* *Ken Boyer, Food Safety/QA Manager, Seattle Fish Company*

Ticket required