Global Education and Training Course: Mitigating the Risk of Food Fraud-Using the USP Food Fraud Tool

December 2, 2015
USP Meetings Center, Rockville, MD

PROGRAM
(As of October 28, 2015 / Subject to Change)

Wednesday, December 2, 2015

8:30 a.m.  Registration & Coffee

9:00 a.m. – 5:00 p.m.  Global Education and Training Course: Mitigating the Risk of Food Fraud-Using the USP Food Fraud Tool

Instructors:  Shaun Kennedy, Henry Chin, Ph.D.

Location:  Spalding Auditorium, USP-U.S., Rockville, MD

Course Overview
Intentional economically motivated adulteration (EMA) of food threatens the integrity of the food supply and introduces public health and other risks. EMA of food has been estimated to cost the food industry $10 to $15 billion per year. The incident of melamine adulteration of milk powder alone was estimated to have cost the affected companies up to $10 billion. But even more important than the economic cost, the impact on public health was enormous. An estimated 290,000 consumers were affected with more than 50,000 hospitalizations. There are also collateral damages caused by incidences of intentionally motivated adulteration, including the loss of public confidence in the safety of the food supply and confidence in government regulatory systems. This course will give participants information on how to assess the vulnerability of ingredients and processes to EMA and how to use the USP Food Fraud Guidance Tool to systematically evaluate vulnerabilities and begin the design of mitigation programs.

Learning Objectives
• The overall objective of the course is to provide the participants with sufficient familiarity and applications experience with the USP Food Fraud Guidance to be able to begin application of the guidance within their organization and to train others on its application.
• At the conclusion of the course, each participant will be able to:
  o Identify what contributes to an ingredient or sources overall potential food fraud vulnerability.
  o Apply each of the individual factor scoring rubrics.
  o Integrate the individual factor scores for an overall prioritization of the need for a food fraud mitigations strategy plan and develop the basic plan framework.
  o Access available information resources on food fraud history, QA method vulnerability, trade and economic anomalies, and consumption profiles, among others.
  o Return from the course with a draft assessment of an ingredient/source of interest.

Audience
• Cross-functional teams from Quality Assurance, Audit, Purchasing, Regulatory Affairs, and Risk Management who are responsible for mitigating risk from EMA will benefit from this course.
Thursday, December 3, 2015

OPENING SESSION
Spalding Auditorium
Moderator: Gabriel I. Giancaspro, Ph.D.

8:30 a.m. Registration & Coffee
9:00 a.m. Housekeeping Matters
         Brian Knaack, CMP
9:05 a.m. Welcome
         Nandakumara Sarma, Ph.D.
         Jeff Moore, Ph.D.
9:15 a.m. Opening Remarks
         Mark Blumenthal, American Botanical Council
         John Larkin, Ph.D., Food Protection and Defense Institute

PLENARY 1 – New Perspectives on Adulteration and Fraud
Spalding Auditorium
Moderator: Gabriel I. Giancaspro, Ph.D.

9:30 a.m. INTERPOL's Initiatives to Combat Fraud in Foods and Dietary Supplements
         Françoise Dorcier, Trafficking in Illicit Goods and Counterfeiting Sub-Directorate, INTERPOL

10:00 a.m. Adulteration Effects and Repercussions for the World of Sport
          Jordi Segura, Ph.D., IMIM- Hospital del Mar Medical Research Institute, Pompeu Fabra University, Spain

10:30 a.m. Break

JOINT SESSION
Spalding Auditorium

11:00 a.m. The Economics of Adulteration: Metrics, Pressures, and Prices
          Shaun Kennedy, University of Minnesota
11:30 a.m. Impact of the FDA Food Safety Modernization Act on Supply Chain Integrity (or WEMA Efforts on Food Fraud Activities)
Jennifer Thomas, Ph.D., US Food and Drug Administration

12:00 p.m. Lunch

1:00 p.m. USP’s Food Fraud Mitigation Guidance as Tool for Industry
Jeff Moore, Ph.D., USP

1:45 p.m. Breakout to Tracks 1 and 2

TRACK 1: Adulterated Supplements Challenge
Scientists and Regulators
Spalding Auditorium
Moderator: Ikhlas Khan, Ph.D.

2:00 p.m. Adulteration as a GMP Concern
Steven Casper, Ph.D., US Food and Drug Administration

2:30 p.m. Evolution of Botanical Integrity Paradigms
Guido Pauli, Pharm.D., Ph.D., University of Illinois at Chicago, Member, Member, Botanical Dietary Supplements and Herbal Medicines Expert Committee

3:00 p.m. Break

3:15 p.m. Field Investigation of DS Adulteration
Connie Gryniewicz-Ruzicka, Ph.D., US Food and Drug Administration

3:45 p.m. Analytical Challenges with Complex Matrices
Dries de Kaste, Ph.D., National Institute for Public Health and the Environment

4:15 p.m. Quickfire Poster Session (Spalding)

4:30 p.m. Reception, Corridor of the Volunteers

5:30 p.m. Adjourn for the Day

TRACK 2: Food Protection and Defense Institute Roundtable on State of Food Fraud Prevention Tools
Briggs & Parker, Marshall, Wiley Rooms
Moderator: Karen Everstine, Ph.D.

2:00 p.m. Mitigating Against Food Fraud - Introduction to the Free Tool that Helps Industry Undertake Vulnerability Assessments and Prepare Mitigation plans
Kelvin Harris, PricewaterhouseCoopers (PwC)

2:30 p.m. EMA VAT - Development of an Interactive Tool
Samantha Cooper, Grocery Manufacturers Association

3:00 p.m. Break

3:15 p.m. Testing Today and Tomorrow: Integrative Authenticity Analysis Using Clearinghouse Solutions
Bert Pöpping, M.Sc., Ph.D., Mérieux NutriSciences Corporation, Member USP Food Ingredients Expert Committee

3:45 p.m. Panel Discussion on Needs Moving Forward
Friday, December 4, 2015

8:30 a.m. Registration & Coffee

Moderator: Robin Marles, Ph.D.

8:45 a.m. Keynote Presentation: New Technologies to Detect Adulteration
James Harnly, Ph.D., US Department of Agriculture

PLENARY II: DNA-based Methods for Identification

9:30 a.m. DNA-based Identification Enables Metabolomics-Driven Detection of Botanical Adulteration
Charlotte Simmler, Pharm.D., Ph.D., University of Illinois at Chicago

10:00 a.m. Confirming Species Identity of Herbal Dietary Supplements, An Example from Devil’s Claw
Damon Little, New York Botanical Garden

10:30 a.m. Break

11:00 a.m. Meat Speciation
Geoffrey Cottenet, Nestlé Research Center

11:30 a.m. Fish Speciation
Jonathan R. Deeds, Ph.D., M.Sc., US Food and Drug Administration

12:00 p.m. Lunch

1:00 p.m. Panel Discussion: Future of DNA Methods to Detecting Adulteration
Moderator: Jonathan DeVries, Ph.D.
Panelists: Geoffrey Cottenet; Jonathan R. Deeds, Ph.D., M.Sc.; Damon Little, Ph.D.; Guido Pauli, Pharm.D., Ph.D.; Charlotte Simmler, Pharm.D., Ph.D.

1:45 p.m. Breakout to Tracks 3 and 4

TRACK 3: Analytical Tools to Detect Adulteration
Briggs & Parker, Marshall, Wiley Rooms
Moderator: Mark Blumenthal

2:00 p.m. <2251> Adulteration of Dietary Supplements with Drugs and Drug Analogs; Supplement Adulteration Database
Anton Bzhelyansky, M.S.

2:30 p.m. Crossover Analytical Technique (CAT): A Phytoforensic Technique for Reconciling Conflicting Identity Data
James Neal-Kababick, Flora Research Laboratories; Member, Non-Botanical Dietary Supplements Expert Committee

3:00 p.m. Break

TRACK 4: Food Adulteration
Spalding Auditorium
Moderator: Susan Brown, M.E.A.

2:00 p.m. Adulteration of Natural Food Coloring Materials
Mark Goldschmidt, Sensient (NCA)
Timothy Ivancic, Ph.D., Sensient

2:30 p.m. Adulteration of Food with Illegal Dyes
Thomas Tarantelli, NY State Department of Agriculture and Markets, Division of Food Laboratory

3:00 p.m. Break
3:15 p.m.  **ABC Laboratory Guidance Documents**  
  *Stefan Gafner, Ph.D.*

3:15 p.m.  **Juice Adulteration (Technical Committee on Juice and Juice Products)**  
  *Susan K. Martin, Ph.D., Director, Juice Ingredient Quality, Coca-Cola*

3:45 p.m.  **Panel Discussion**

3:45 p.m.  **Honey Adulteration**  
  *Lutz Elfein, Ph.D. Intertek*

4:15 p.m.  **Path Forward: Workshop Summary**

4:30 p.m.  **Adjourn the Workshop**  
  *Gabriel Giancaspro, Ph.D.*
Mark Blumenthal  
**USP Affiliation:** Workshop Steering Committee  

Founder & Executive Director  
American Botanical Council  
Austin, Texas  

Mark Blumenthal is the Founder and Executive Director of the American Botanical Council (ABC), the leading independent, non-profit organization dedicated to disseminating accurate, reliable, and responsible information on herbs and medicinal plants.

He is the Editor/Publisher of HerbalGram, an international, peer-reviewed quarterly journal. For six years he was an Adjunct Associate Professor of Medicinal Chemistry at the University of Texas at Austin, College of Pharmacy, teaching the course "Herbs and Phytomedicines in Today's Pharmacy." Mark is the Senior Editor of the English translation of The Complete German Commission E Monographs—Therapeutic Guide to Herbal Medicines (1998), Herbal Medicine: Expanded Commission E Monographs (2000), The ABC Clinical Guide to Herbs (2003), and co-author of Rational Phytotherapy, 5th edition (2004). He has appeared on over 400 radio and television shows and has written over 500 articles, reviews and book chapters for many major publications. In 2010 he was awarded the prestigious Tyler Prize in honor of the late Purdue Professor Varro E. Tyler from the American Society of Pharmacognosy.

In 2008 he was awarded the “Natural Legacy” award from Natural Foods Merchandiser magazine and he has also been named to Natural Health Magazine’s Hall of Fame Award for “…opening America’s eye to the healing powers of herbs.” He has been a leader in the concerns for more rational regulations of herbal and natural product manufacturing, and education on plant-based medicines for over 40 years.

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** Moderator **

Opening Remarks  
Thursday, December 3, 2015, 9:15 a.m. – 9:30 a.m.

Moderator - TRACK 3: Analytical Tools to Detect Adulteration  
Friday, December 4, 2015, 2:00 p.m. – 4:15 p.m.

The chemically complex nature of herbs and botanically-derived ingredients calls for unique quality control processes by suppliers, manufacturers, and producers of herbal products. One of the universal regulatory requirements in industrialized nations around the world is the appropriate testing for identity and authenticity of botanical materials that are to be used in consumer products. Nevertheless, there have been numerous recent cases of accidental misidentification of botanical materials due to human error, sometimes resulting from the lack of adequate quality control measures and/or lack of adequate training. In addition, there is evidence of intentional adulteration, also referred to as economically motivated adulteration (EMA), where raw materials are intentionally substituted or diluted with undisclosed lower-quality ingredients for financial gain of the seller. Another concern is the occurrence of extracts "spiked" with various exogenous compounds, including prescription pharmaceutical drugs, to create a false sense of efficacy. This reflects a significant challenge to the global botanical medicine marketplace and, in some cases, consumer safety.

Examples of adulteration are currently being compiled in a series of peer-reviewed articles and short overviews (Botanical Adulterants Bulletins) by an independent consortium of nonprofit organizations consisting of the American Botanical Council (ABC), the American Herbal Pharmacopoeia (AHP), and the National Center for Natural Product Research (NCNPR) at the University of Mississippi. The ABC-AHP-NCNPR Botanical Adulterants Program (BAP) is an
international educational program supported and endorsed by over 165 botanical industry companies, third-party analytical laboratories, manufacturers of analytical equipment, nonprofit professional organizations, trade associations, research centers, and others. Articles on specific topics, e.g., the adulteration of bilberry (Vaccinium myrtillus) fruit extracts with synthetic dyes or anthocyanin-rich materials from other plants, and the adulteration of black cohosh (Actaea racemosa) root and rhizome with Chinese herbs in the same genus, are followed by the publication of Laboratory Guidance Documents in which analytical methods on crude botanical raw materials and/or herbal extracts are reviewed and evaluated for their fitness for purpose and ability to detect the suspected adulteration. The analytical techniques discussed include macroscopic, microscopic, chemical, and genetic assays. Since most of the available methods focus on the determination of marker/active compounds, much emphasis is given to the chemical analysis. In addition, the Program publishes a quarterly newsletter, the “Botanical Adulterants Monitor”, where current issues with regard to adulteration of botanical materials are discussed. The efforts by the BAP are intended to raise the awareness of issues with regard to the authenticity of botanical materials, to provide solutions that allow manufacturers to deal with botanical adulteration, and ultimately to improve the quality of herbal dietary supplements in the marketplace. All publications of the Program are available on the Program website at http://cms.herbalgram.org/BAP/index.html.
Susan Brown, M.E.A
USP Affiliation: Workshop Steering Committee

Director Regulatory Affairs (retired)
McCormick and Co. Inc.
Forest Hill, Maryland

Susan retired from McCormick and Co. in the July 2015 as Director Regulatory Affairs. She joined McCormick in 1976 as an Analytical Chemist, focusing on methods development and product stability. She moved into Quality Assurance in the late 80’s and for a number of years was the Quality Assurance Manager at McCormick’s Spice Mill. Where she had oversight of the quality programs which included GMP compliance, HACCP, and Vendor expectations for spice items.

In her role as Director of Regulatory Affairs, she was actively engaged in the development of programs to help assure a safe, wholesome supply chain. These programs had particular emphasis on adulteration and contaminates.

Susan has been active in the American Spice Trade Association (ASTA), chairing both the Technical and Government Relations Committees. As well as serving on the Board of Directors including President from 2007-2008.

She is a member of the Institute of Food Technologists (IFT), American Chemical Society (ACS) American Society for Quality (ASQ), the Association of Food Drug Officials (AFDO) and active on multiple GMA committees including the FSMA Task Force.

Moderator
TRACK 4: Food Adulteration
Friday, December 4, 2015, 2:00 p.m. – 3:45 p.m.
Anton Bzhelyznsky, M.S.
Scientific Liaison, Dietary Supplements and Herbal Medicines
USP
Rockville, Maryland

Presentation
<2251> Adulteration of Dietary Supplements with Drugs and Drug Analogs; Supplement Adulteration Database
Friday, December 4, 2015, 2:00 p.m. – 2:30 p.m.
Steven Casper, Ph.D.
Biologist
U.S. Food and Drug Administration
College Park, Maryland

Presentation
Adulteration as a GMP Concern
Thursday, December 3, 2015, 2:00 p.m. – 2:30 p.m.
Samantha Cooper
Manager of Food Safety and Quality Assurance
Grocery Manufacturers Association (GMA)

Samantha Cooper is Manager of Food Safety and Quality Assurance within the Science and Regulatory Affairs division at the Grocery Manufacturers Association (GMA), Washington, D.C., representing the world’s leading food, beverage, and consumer products companies. Samantha holds a Bachelor of Science in Food Science and Technology from Virginia Tech where she graduated Cum Laude. At GMA, Samantha serves as the staff liaison for the Regulatory Inspections Compliance Committee and the Inspections & Enforcement Working Group. In addition, she assists in HACCP plan reviews for GMA members and is also a member of GMA’s Supplier Share Group. Prior to her role with GMA, Samantha was a Food Safety Manager at sous-vide manufacturer.

Presentation
EMA VAT - Development of an Interactive Tool
Thursday, December 3, 2015, 2:30 p.m. – 3:00 p.m.

Economically motivated adulteration (EMA) is a growing threat to industry, and is becoming difficult for companies to address the countless imaginable risks EMA could present. It is hard to conclusively know the exact number of EMA incidents as the majority go undetected – the perpetrators do not want to get caught and generally aren’t intending to cause a food safety hazard. What industry needs is a better way of prioritizing the actual risks to specific commodity supply chains, so that decision makers can best apply available resources to mitigate risk. GMA’s Economically Motivated Adulteration Vulnerability Assessment Tool (EMA VAT) will provide a secure, comprehensive, and intuitive tool that will enable users to work with relevant information to assess the potential risks posed by EMA. To be successful and remain relevant with users, the envisioned tool will encompass a user friendly input function, be hosted on a secure platform, and have continuously updated commodity-attribute data. The output will inform the user about potential EMA risks associated with a designated ingredient within their food supply chain; however, it will not provide solutions on risk mitigation as each company may have a different level of risk tolerance and different ways of handling the risk.

Understanding how a fraudster thinks, and how these choices may change due to defensive actions taken by industry, is both important and difficult to accomplish. By taking the factors involved in fraudster decisions and making them into meaningful mathematical structures for calculation and analysis, the tool will be able to be quantitative and anticipatory in nature. While it will be informed by historical events, it will be more than a historical incident database in order to perform as a forward-thinking tool.
**Geoffrey Cottenet**  
Nestlé Research Center  
Lausanne, Switzerland

Geoffrey COTTENET obtained his Master degrees in Molecular Biochemistry at the University of Burgundy (FR) and in Food Science and Technologies at the AGROSUP high school (FR). Since 2007, he has been working as a scientist at Nestlé Research Center in Lausanne, Switzerland.

He is leading the development and validation of molecular methods  
- for the detection and quantification of GMO,  
- for authenticity topics, such as meat, fish and plant species identification.

He is a member of the “Genetically modified foodstuffs” working group of the European Committee for Standardization (CEN/TC 275/WG 11) and a member of the “Meat Speciation” working group in the “Horizontal methods for molecular biomarkers analysis” committee of the International Organisation for Standardisation (ISO/TC 34/SC 16/WG 8).

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**Presentation**  
DNA-based Methods for Meat Speciation  
Friday, December 4, 2015, 11:00 a.m. – 11:30 a.m.

Europe was faced in 2013 with a case of food fraud with major coverage and loss of consumer confidence: beef adulterated with horse meat. The impact for businesses can be enormous and in some cases lead to bankruptcy. Fighting against food fraud and adulteration is an endless activity which requires the contribution from all the value chain including procurement, regulatory, specification management, analytical sciences. Vulnerability assessment of meat raw materials takes into consideration various parameters such as price variation of the commodity, previous cases of adulteration and level of processing of the raw material purchased. Meat powder is indeed more vulnerable to food fraud than real meat pieces. In order to identify meat species and detect potential meat substitution, analytical methods are needed. To overcome limitations related to heat-treated or processed products, the use of DNA-based methods and especially Polymerase Chain Reaction (PCR) techniques are preferred for both raw ingredients and processed food. However the described PCR methods still present the same limitation: the majority of them always targets the usual meat species, such as beef, pork, horse, chicken and turkey, and/or is limited to maximum 5-6 meat species. Considering also the latest Chinese cases of meat substitution where fox and rat meat were detected instead of donkey and lamb, there is a strong need to expand the range of detectable species. Although DNA sequencing is considered as a reference method to identify (meat) species, its capability to detect potential mixtures is limited. Another approach based on DNA macro-array was evaluated and allowed a simultaneous screening of 32 meat species with a detection of meat mixtures ≤ 1% (m/m) as recommended by the European legislation. Easy to use, fast, and cost efficient, this Meat LCD Array can be easily applied to monitor meat raw materials. Both DNA Barcoding and Meat LCD Array are DNA-based methods which allow the specific identification of meat species as required by food labelling regulations and maintain consumer trust.
Dries de Kaste, Ph.D.
National Institute for Public Health and the Environment

Dr. Dries de Kaste (1950) obtained his degree as pharmacist from the State University of Groningen, the Netherlands, in 1979. He studied medicinal chemistry at the University of Amsterdam and the State University of Utrecht. In 1990, he received a doctorate for the thesis: “Receptor classification with weak-selective ligands”.

During 1991-2013, he was head of the department for Quality Control and Pharmacopoeial Affairs.

Since January 2013, he acts as senior-scientific officer in the Centre of Health Protection in the National Institute for Public Health and the Environment (RIVM, Bilthoven, the Netherlands). This laboratory is an active participant in the network of the Official Medicines Control Laboratories in Europe, coordinated by the EDQM in Strasbourg. He is the contact in the Netherlands for the Official Medicines Control Laboratories (OMCL) network, since 1991.

He is member of the Dutch delegation of the European Pharmacopeia Commission and is secretary of the Dutch Pharmacopoeia Authority, since 1991. He is Chair of Expert Group P4 of the European Pharmacopoeia Commission, since 2001. He is chair of the Dutch working party on the evaluation of Monographs, since 1995.

He is team leader of the project Pharmaceutical Crime, commissioned by the Dutch Health Care Inspectorate. In this capacity, he provides analytical and forensic support to inspection services and customs authorities. He is appointed as a forensic/pharmaceutical expert in several criminal court cases. Since 2009, he is lecturer for the master class: “Forensic Pharmacy”, a five weeks training course (18 students) organised annually in co-operation with the University of Utrecht, department of Pharmacy.

He is author of more than 50 scientific papers in international scientific journals, conference proceedings and scientific RIVM reports.

Presentation
Analytical Challenges with Complex Matrices
Thursday, December 3, 2015, 3:45 p.m. – 4:15 p.m.
Dr. Jonathan Deeds currently works as a research biologist in the FDA Center for Food Safety and Applied Nutrition (CFSAN) Office of Regulatory Science where he acts as a research coordinator and subject matter expert in the areas of seafood safety and labeling. Dr. Deeds holds degrees in Biology from the University of Dayton (B.S., 1995), in Environmental Toxicology from the University of Louisiana at Lafayette (M.Sc., 1997) and in Marine Estuarine and Environmental Science from the University of Maryland (Ph.D., 2003). He began his FDA career in 2003 in the Office of Seafood researching the sources and fate of natural toxins that accumulate in commercial seafood in order to develop better management controls. He currently leads several research projects for the development of methods for the detection of marine biotoxins in various fish and shellfish products to prevent consumer illness and for the implementation of updated methods for the species identification of FDA regulated seafood products. For this educational activity, he will be discussing the development and implementation of forensic DNA-based methods now being used by the Agency to identify seafood products involved in outbreaks of illness, to develop and refine species-specific hazards controls, and to confirm product labeling to detect seafood substitution and fraud.

Presentation
The Use of Forensic DNA-Based Methods to Prevent Species-Specific Foodborne Illness and Detect Seafood Fraud
Friday, December 4, 2015, 11:30 a.m. – 12:00 p.m.

In 1914 the agency that would later become the FDA received an inquiry if dyed whitefish eggs could be labeled as caviar, leading to one of the Agency’s earliest policies on seafood labeling. The FDA has worked since its inception to provide consistent and scientifically sound recommendations about acceptable market names for seafood. Seafood labeling is required to be truthful and not misleading. Truthful labeling requires identifying seafood species using an acceptable market name. FDA provides guidance to industry on the development and use of acceptable market names for seafood sold in interstate commerce. Incorrect use of an established acceptable market name that results in the labeling being false and/or misleading can result in the product being misbranded. In addition, due to its incredible diversity, the control strategies for hazards associated with various seafood products are species-specific. Correct labeling for species is essential to the proper implementation of FDA’s Hazard Analysis Critical Control Point (HACCP) regulation. In recent years there have been numerous reports of seafood in the U.S. being labeled with an incorrect market name which has had negative impacts both on the seafood industry and on consumer confidence in seafood. In response to this issue, CFSAN initiated Project Fish SCALE (Seafood Compliance and Labeling Enforcement) which is a multi-faceted approach to address FDA issues with seafood labeling and species identification. At the heart of this project is the updating of FDA’s species identification capabilities to modern forensic techniques using DNA sequencing. Protocols, reference standards, and other training materials generated through this project are now being used in FDA Office of Regulatory Affairs Regional Field Laboratories across the country whenever the identity of a seafood product needs to be determined. In addition, these materials are being used by other domestic and international agencies as well as by private laboratories that directly service the seafood industry. The data generated has allowed FDA to respond to claims of mislabeling and fraud, take regulatory action against non-compliant seafood producers and distributors, and has enhanced our ability to rapidly respond to several illness outbreaks involving seafood.
Jonathan DeVries, Ph.D.
**USP Affiliation:** Chair, USP Food Ingredients Expert Committee; Workshop Steering Committee

CEO
DeVries & Associates
Coon Rapids, Minnesota

In his capacity as Senior Principal Scientist, Jonathan W. DeVries served as Senior Technical Manager for the Medallion Laboratories division of General Mills, Inc., providing analytical services to the food and other industries. Dr. DeVries has been active in quality-related analytical work for more than 47 years. He has been active in food safety, nutrition, and quality research, including packaging research and trace analyses, for more than 37 years. His analytical methods work includes methods for dietary fiber(s) and its components; fat and oils, and components thereof; vitamins; minerals; sugars; pesticide and fumigant residues; sulfites; lead and other heavy metal residues; natural toxins (aflatoxin, deoxynivalenol, fumonisins); and potential migrants from packaging (regular and microwave-heated) to foods. For 36 years, Dr. DeVries has been working for validation and international standardization of analytical methods through such organizations as AOAC International and American Association for Cereal Chemists International. He began his work on economic adulteration (EA) in the early 1980s in the fruit-juice purity arena, renewing his activity in EA again in 2007. Beginning in the 1990s, he also worked on food identity and quality standards through the National Academies of Science Institute of Medicine’s Food Chemicals Codex Expert Committee. Dr. DeVries served as Chair of the USP Food Ingredients Intentional Adulterants Expert Panel and member of the USP Monographs—Food Ingredients Expert Committee in the 2010-2015 cycle. He received his bachelor’s degree in Chemistry (minor in mathematics) from Augsburg College, Minneapolis, MN, and his Ph.D. in Organic Chemistry (minors in physical chemistry and biochemistry) from the University of Minnesota in Minneapolis.

**Moderator**
Panel Discussion: Future of DNA Methods to Detecting Adulteration
Friday, December 4, 2015, 1:00 p.m. – 1:45 p.m.
Francoise Dorcier
Criminal Intelligence Officer
INTERPOL
Lyon, France

After 15 years’ experience at French Customs at the legal, criminal intelligence, international cooperation and investigation department, Françoise DORCIER joined INTERPOL as a seconded Criminal Intelligence Officer in 2010. She’s been in charge of developing Capacity Building Programmes and coordinating Operations on Trafficking in Illicit Goods and Counterfeiting in Africa, Europe and Latin America. She built a new capacity building project dedicated to create a network of officers getting a specialist knowledge of trafficking in illicit goods and counterfeiting with blended training of on-line courses, lectures and workshops for Africa, Asia, Latin America, North Africa/Middle East.

She is the coordinator of transnational investigation cases involving law enforcement agencies from INTERPOL member countries.

She is in charge of Operation OPSON targeting counterfeit and/or substandard food and beverages.

As educational background, she graduated with a Masters in a of International Administration of Politics, France (International Public Law, Economics, Languages).

Languages: French, English, German, Spanish

Presentation
INTERPOL’s Initiatives to Combat Fraud in Foods and Dietary Supplements
Thursday, December 3, 2015, 9:30 a.m. – 10:00 a.m.

INTERPOL is the largest international police organization with 190 member countries. Its role is to facilitate cross-border police cooperation, support its member countries to prevent or combat international crime by providing secured channels of communication, databases, round-the-clock multilingual support, capacity building activities and coordinated operations.

Food fraud has become one of the topics INTERPOL is focusing on as it has witnessed not only the dramatic consequences that this type of criminality has on the health of consumers but also the involvement of organized crime.

INTERPOL has set up an operational platform called Operation OPSON which is jointly coordinated by INTERPOL and Europol. The objective of Operation OPSON is to seize counterfeit and/or substandard food and/or beverages and to dismantle the organized crime groups involved in this trafficking. Besides the seizures, OPSON is designed to facilitate the cooperation between law enforcement agencies (Police, Customs) and regulatory bodies, to enhance the collaboration with the private sector and to facilitate the exchange of information at an international level. Trafficking knows no boundaries, which makes the role of international police organizations key in preventing and curbing this trafficking.

The development of Operation OPSON, both in terms of participating countries and in terms of quantity of seized products, demonstrates that food fraud is now taken seriously.

Starting in 2011 with 10 countries, the fourth edition of Operation OPSON included the participation of 47 member countries and led to the seizure of 11,591 tons, 814,000 liters, 1,233,000 items of illicit food and beverage products. Operational deployments were carried out in Africa, America, Asia, Europe and in the Middle East, confirming that we are facing a global phenomenon. Operation OPSON IV unveiled cases such as the production of fake mozzarella,
a fishing facility which sold previously frozen seafood as fresh seafood after adding chemicals to make it appear fresh, a plant producing fake vodka in the UK, the illegal importation of meat in Thailand, and counterfeit beer in Rwanda, just to name a few.

Dietary supplements are also some of the products being targeted by traffickers as these types of products are increasingly being consumed. Adulteration and mislabeling can have serious consequences on the health of the consumers. This possible endangerment of public health captured the attention of law enforcement forces. Cases have been built in various regions of the world. Operation OPSON provides with a platform facilitating the exchange of information and the international cooperation. International and public-private cooperation are key to combatting this type of fraud in order to provide a safe environment to the citizens.
Lutz Elflein, Ph.D.
Intertek Food Services
Bremen, Germany

Lutz Elflein 15 years professional experience as a certified food chemist, thereof 12 years experience and particular expertise in scientific research, analytical testing, and legal assessment of bee products (honey, royal jelly, beeswax, pollen, propolis). He is currently working as site manager and scientific manager of one of the world’s most renowned independent private laboratories in this field, with currently approximately 140 employees dealing with round about 70,000 samples and issuing more than 240,000 test reports for clients of import, export, and retail business as well as food safety authorities regarding products quality and legal compliance. Lutz Elflein is Intertek’s designated contact person for expert services regarding honey.

Presentation
Honey Adulteration
Friday, December 4, 2015, 3:45 p.m. – 4:15 p.m.

Honey trade is a global business, with high import rates into the EU and USA, and high export rates from Asia, South and Middle America, South and Eastern Europe. Honey is a natural and mostly untreated food produced by bees. The industrial processing is usually minimized to liquefaction, homogenization and filtration of raw honeys prior to packaging for retail. Therefore, the consumers esteem honey as a natural, pure authentic, healthy and valuable product. There are numerous honey varieties of different botanical and geographical origins available on the international market. Additionally, there are certain specialty honeys with particular properties like Manuka honey from New Zealand with its characteristic antibacterial activity. Honey is not only sold as a mono product, e.g. as breakfast spread or as sweetener for tea, but is also of major importance for the food industry as an ingredient to substitute corn, cane or beet sugar. As consumers become more ecosensitive and health-conscious the demand for natural and organic food is growing and people are willing to pay more money for that compared to conventional food. For this reason, it is very important to control raw and finished food products labeled with such properties in order to ensure their quality and purity and protect consumers from fraud. Honey is listed as one of the top ten food items particularly prone to fraud, because the demand is high and production volumes are limited. Furthermore, legal regulations for honey and food surveillance measures are not internationally harmonized, so that there are enough chances to gain profit with adulterated honey. This presentation will give an overview of the existing and currently applied analytical methods to detect honey adulteration, e.g. isotopic screening methods (EA/LC-IRMS) or specific methods to detect marker molecules of sugar syrups in honey, e.g. by LC-MS/MS, ICP-MS, HPLC or enzymatic methods, discuss their benefits and limitations, point out the future analytical challenges (e.g. NMR) and address particular problems with the analytical assessment for international trade and official food control.
Karen Everstine, Ph.D.
Scientific Liaison, Food Standards
USP
Rockville, Maryland

Karen recently joined United States Pharmacopeia (USP) as a Scientific Liaison with the food program. Previously, she was a Research Associate with the University of Minnesota Food Protection and Defense Institute (FPDI) where she served as PI, co-Investigator, and researcher on multiple federally funded projects focused on mitigating the risk of economically motivated adulteration (EMA) of food products. While at FPDI, Karen created the EMA Incidents Database as a resource for industry and government stakeholders to support mitigation efforts. She earned both her MPH and PhD in public health at the University of Minnesota.

Moderator
Track 2: Food Protection and Defense Institute Roundtable on State of Food Fraud Prevention Tools
Thursday, December 3, 2015, 2:00 p.m. – 3:45 p.m.
Dr. Stefan Gafner received his degree in pharmacy at the School of Pharmacy, University of Berne, Switzerland. After obtaining his PhD with focus on phytochemistry from the University of Lausanne, Switzerland, he conducted postdoctoral research on cancer chemopreventive natural products at the University of Illinois – Chicago.

For more than a decade, Dr. Gafner has served as director of analytical chemistry in the R&PD department of Tom’s of Maine. His current position is Chief Science Officer of the American Botanical Council, an independent, nonprofit organization dedicated to providing reliable information on the responsible and safe use of medicinal herbs.

Presentation
The ABC-AHP-NCNPR Botanical Adulterants Program: Tools and Resources
Friday, December 4, 2015, 3:15 p.m. – 3:45 p.m.

The chemically complex nature of herbs and botanically-derived ingredients calls for unique quality control processes by suppliers, manufacturers, and producers of herbal products. One of the universal regulatory requirements in industrialized nations around the world is the appropriate testing for identity and authenticity of botanical materials that are to be used in consumer products. Nevertheless, there have been numerous recent cases of accidental misidentification of botanical materials due to human error, sometimes resulting from the lack of adequate quality control measures and/or lack of adequate training. In addition, there is evidence of intentional adulteration, also referred to as economically motivated adulteration (EMA), where raw materials are intentionally substituted or diluted with undisclosed lower-quality ingredients for financial gain of the seller. Another concern is the occurrence of extracts “spiked” with various exogenous compounds, including prescription pharmaceutical drugs, to create a false sense of efficacy. This reflects a significant challenge to the global botanical medicine marketplace and, in some cases, consumer safety.

Examples of adulteration are currently being compiled in a series of peer-reviewed articles and short overviews (Botanical Adulterants Bulletins) by an independent consortium of nonprofit organizations consisting of the American Botanical Council (ABC), the American Herbal Pharmacopoeia (AHP), and the National Center for Natural Product Research (NCNPR) at the University of Mississippi. The ABC-AHP-NCNPR Botanical Adulterants Program (BAP) is an international educational program supported and endorsed by over 165 botanical industry companies, third-party analytical laboratories, manufacturers of analytical equipment, nonprofit professional organizations, trade associations, research centers, and others. Articles on specific topics, e.g., the adulteration of bilberry (Vaccinium myrtillus) fruit extracts with synthetic dyes or anthocyanin-rich materials from other plants, and the adulteration of black cohosh (Actaea racemosa) root and rhizome with Chinese herbs in the same genus, are followed by the publication of Laboratory Guidance Documents in which analytical methods on crude botanical raw materials and/or herbal extracts are reviewed and evaluated for their fitness for purpose and ability to detect the suspected adulteration. The analytical techniques discussed include macroscopic, microscopic, chemical, and genetic assays. Since most of the available methods focus on the determination of marker/active compounds, much emphasis is given to the chemical analysis. In addition, the Program publishes a quarterly newsletter, the “Botanical Adulterants Monitor”, where current issues with regard to adulteration of botanical materials are discussed. The efforts by the BAP are intended to raise the awareness of issues with regard to the authenticity of botanical materials, to provide solutions that allow manufacturers to deal with botanical adulteration, and ultimately to improve the quality of herbal dietary supplements in the
marketplace. All publications of the Program are available on the Program website at http://cms.herbalgram.org/BAP/index.html.
Dr. Giancaspro is the Vice President, Science—Dietary Supplements, and Herbal Medicines at USP. His department provides staff support to Expert Committees responsible for setting USP's standards for dietary supplements, herbal medicines, and food ingredients.

Previously, he was the Director for Dietary Supplements in the Documentary Standards Division at USP responsible for the development of monographs and general chapters for botanical and non-botanical dietary supplements, safety evaluations, performance standards, and the publication of the USP Dietary Supplements Compendium.

Before joining USP, Dr. Giancaspro's teaching and research experience included medicinal chemistry, drug analysis, and drug stability at the Pharmacy School at the University of Buenos Aires. He also has extensive industrial experience as the former Technical Director of Rigecin, Schwabe-Argentina and Kampel-Martian, in charge of Regulatory Affairs, Analytical Research and Development, and Quality Control of parenterals, herbal medicines, and oncological medicines.

Dr. Giancaspro holds a Pharmacist degree and a Ph.D. in pharmaceutical sciences (medicinal chemistry) from the University of Buenos Aires, Argentina.
Mark Goldschmidt
Sensient Technologies
St. Louis, Missouri

Presentation
Adulteration of Natural Food Coloring Materials
Friday, December 4, 2015, 2:00 p.m. – 2:30 p.m.
Connie Gryniewicz-Ruzicka, Ph.D.
Division of Pharmaceutical Analysis
US Food and Drug Administration
Saint Louis, Missouri

Connie Gryniewicz-Ruzicka earned her bachelor’s degree in chemistry from Wayne State University in 1998 and a Ph.D. in Analytical Chemistry from the former University of Missouri-Rolla which is now known as Missouri University of Science and Technology in 2005. She joined the Food and Drug Administration in October 2005 as a chemist in the Division of Pharmaceutical Analysis (DPA), St. Louis, MO. Dr. Ruzicka is a member of DPA’s Rapid Spectroscopic Screening group where her research interests include the application of rapid screening technologies to problems in regulatory pharmaceutical analysis, in particular the application of spectroscopic and chemometric methods for the determination of stability and authentication of pharmaceutical products. Her current work focuses on the use of ion mobility spectrometry for the identification of misbranded, substandard or adulterated pharmaceutical products and dietary supplements. She has presented her work at professional conferences, taught several pharmaceutical inspectorate courses on emerging technologies for pharmaceutical surveillance and published numerous papers on the development and use of rapid spectroscopic screening methods for pharmaceutical applications in peer-reviewed journals.

Presentation
Field Investigation of DS Adulteration
Thursday, December 3, 2015, 3:15 p.m. – 3:45 p.m.

FDA, Division of Pharmaceutical Analysis, St. Louis, MO
The increased availability and use of dietary supplements among consumers has been accompanied by increased detection of synthetic pharmaceuticals in these products. The presence of these adulterated products in the marketplace is a worldwide problem and their consumption poses health risks to consumers. In response, the FDA has developed a program to evaluate rapid screening tools to be used in assessing the quality and safety of pharmaceutical products and dietary supplements. One of the techniques that the Division of Pharmaceutical Analysis (DPA) has employed in the program is ion mobility spectrometry (IMS), a rapid, reliable screening tool that requires minimal sample preparation and produces results in less than a minute. A pilot study was conducted using the IMS instruments at US ports of entry to screen weight loss and male enhancement products labeled as dietary supplements suspected of containing undeclared Active Pharmaceutical Ingredients (APIs). Samples failing IMS screening were collected and sent to FDA laboratories for confirmatory testing using liquid chromatography-tandem mass spectrometry (LC-MS/MS). This presentation will describe the development of IMS screening methods for detecting undeclared APIs in products labeled as dietary supplements as well as discuss the efforts used to deploy the instruments in the field. A comparison of the IMS field screening results to the corresponding LC-MS/MS laboratory results will be conducted in order to assess the scientific reliability of the data acquired in the field on the IMS instruments.
James Harnly, Ph.D.  
**USP Affiliation:** Member, USP Botanical Dietary Supplements and Herbal Medicines Expert Committee; Workshop Steering Committee

Research Leader  
U.S. Department of Agriculture  
Beltsville, Maryland

Dr. Harnly serves as Research Leader for Food Composition and Methods Laboratory (FCMDL), part of the Beltsville Human Nutrition Research Center of the US Department of Agriculture. He received his BA from the University of Colorado and his PhD from the University of Maryland. He joined USDA as a research scientist in 1979 and became the Research Leader in 1997. His lab is tasked with the development of new analytical methods for nutrients and bioactive compounds in foods, dietary supplements, and botanical materials in support of nutrition research at USDA. Current projects in the lab include development of new methods for vitamins, metabolomics, and spectral fingerprinting for the identification and authentication of botanical materials. Dr. Harnly has served on the board of directors on for AOAC International, the advisory board of the American Botanical Council, numerous advisory committees for US Pharmacopeia, and for 22 years as the US Editor for the Journal of Atomic spectrometry for the Royal Society of Chemistry. His current research interest is the development of chemometric methods for the identification and authentication of botanical materials.

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**Presentation**  
Keynote Presentation: New Technologies to Detect Adulteration  
Friday, December 4, 2015, 8:45 a.m. – 9:30 a.m.

Advances in hardware and software technology for analytical instrumentation has given the analyst powerful new tools for the detection of adulteration. We can now collect more data, at a faster rate, and with greater sensitivity and precision. We can analyze it for trends using very sophisticated processing methods. It is also possible to archive all this data and retrieve it at a later date for the purpose of data mining. These capabilities have brought about changes in analytical philosophy. We no longer think in terms of specific analytes and matrices, but rather in terms of the metabolome and chromatographic and spectral fingerprints of whole materials. We are shifting from targeted to non-targeted analysis. Sample preparation, separation, and detection are directed towards the potential of characterizing the whole sample and every component. Commercial and proprietary (associated with each instrument) software offer almost limitless possibilities for data manipulation and interpretation. Advances in computer power allow us to archive the data and establish databases for future reference. By identifying all the components that should be there it is easier to identify those that shouldn’t be there, the adulterants. However, we can’t forget that a key aspect of detecting adulteration is the collection of authentic samples to use as references. This critical step sets the stage for application of the new technologies now at our disposal.
Kelvin Harris
Retail and Consumer Consulting
PricewaterhouseCoopers (PwC)
Atlanta, Georgia

Presentation
Track 2: Mitigating Against Food Fraud - Introduction to the Free Tool that Helps Industry Undertake Vulnerability Assessments and Prepare Mitigation plans
Thursday, December 3, 2015, 2:00 p.m. – 2:30 p.m.
Timothy Ivancic, Ph.D.
Chemist II
Sensient Colors LLC
St. Louis, Missouri

Presentation
Track 4: Adulteration of Natural Food Coloring Materials
Friday, December 4, 2015, 2:00 p.m. – 2:30 p.m.
Shaun Kennedy
Director
The Food System Institute
Saint Paul, Minnesota

Shaun Kennedy is Director of The Food System Institute, a food and agriculture system risk management and research organization, and an adjunct Associate Professor of Food Systems in the Department of Veterinary Population Medicine at the University of Minnesota. Prior, Shaun was an Associate Professor of Food Systems in the Department of Veterinary Population Medicine at the University of Minnesota where he also served as the Director, and one of the founders, of the National Center for Food Protection and Defense, a Department of Homeland Security Center of Excellence, and Associate Director for the Center for Animal Health and Food Safety.

Shaun’s food system research focuses on food safety, food defense, food security and food system resiliency. Following the melamine contamination of wheat gluten, he was the principal investigator on the first federal grant to identify ways of anticipating economically motivated adulteration. His publications include articles in Science, Risk Analysis, Annals of the New York Academy of Sciences, Global Advances in Health and Medicine, the Journal of Food Protection, Food Protection Trends, Journal of Homeland Security and Emergency Management and the Journal of Biosecurity & Bioterrorism.

His more than 140 invited presentations include formal Congressional Testimony and presentations at leading food protection and homeland security conferences including the International Association for Food Protection, the Institute of Food Technologists, the International Symposium on Agro-Terrorism and meetings hosted by the World Health Organization, the European Food Safety Authority, the Food Standards Authority and others. His awards include the Department of Homeland Security Impact Award, the Department of Homeland Security Commendation and the Commissioner of the Food and Drug Agency Citation for Advancing Food Defense.

Presentation
The Economics of Adulteration: Metrics, Pressures, and Prices
Thursday, December 3, 2015, 11:00 a.m. – 11:30 a.m.
Ikhlas Khan, Ph.D.
**USP Affiliation:** Member, USP Botanical Dietary Supplements and Herbal Medicines Expert Committee; Workshop Steering Committee

Associate Director, NCNPR
University of Mississippi
University, Mississippi

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**Moderator**
Track 1: Adulterated Supplements Challenge Scientists and Regulators
Thursday, December 3, 2015, 2:00 p.m. – 3:45 p.m.
John Larkin, Ph.D.
Research Director
Food Protection and Defense Institute, University of Minnesota
Saint Paul, Minnesota

Dr. John W. Larkin is the Research Director at the Food Protection and Defense Institute (FPDI). Dr. Larkin manages the research program of FPDI, which includes research conducted at FPDI and projects funded by the Department of Homeland Security (DHS) through the FPDI. Research areas include agent detection, supply chain, information sharing, risk analysis, and economically motivated adulteration.

Dr. Larkin earned his B.S. and M.S. degrees in Food Science and Nutrition at the Ohio State University in 1978 and 1980, respectively, and a Ph.D. degree in Agricultural Engineering and Food Science and Technology at Michigan State University in 1984. After his Ph.D., he worked as an Assistant Professor in Food Engineering at Virginia Tech for over three years before joining the Food and Drug Administration. Dr. Larkin has been intimately involved in conducting research pertaining to the thermal processing and production of foods and has played a significant role in the regulatory science of Low Acid Food Processing systems. Dr. Larkin held the positions of Branch Chief and Acting Associate Director of Research in the Food Processing Science and Technology Division of the FDA. In 2014 Dr. Larkin moved to the University of Minnesota as the Research Director for NCFPD. Dr. Larkin is a recipient of the Institute of Thermal Processing Specialists Marvin A. Tung achievement award and the Michigan State University Biosystems & Agricultural Engineering Department Distinguished Alumni Award, and is a fellow in the Institute of Food Technologists.

Presentation
Opening Remarks
Thursday, December 3, 2015, 9:15 a.m. – 9:30 a.m.
Damon Little, Ph.D.
Associate Curator
The New York Botanical Garden
Bronx, New York

Dr. Little received a B.S. in botany from the University of Vermont in 1998. His undergraduate research, supervised by Dr. David S. Barrington, was focused on the systematics of holy ferns (Polystichum). He went on to pursue a Ph.D. in plant science at the L. H. Bailey Hortorium (Cornell University) under the supervision of Dr. Kevin C. Nixon. At Cornell, he studied the evolution and circumscription of the true cypresses (Cupressus and Calitropsis). Upon the completion of his Ph.D. in 2004, Dr. Little joined The New York Botanical Garden (NYBG) as a postdoctoral research associate under the supervision of Dr. Dennis Wm. Stevenson. As a postdoc, Dr. Little developed computational tools and molecular techniques for plant DNA barcoding. In 2007, he was appointed as an Assistant Curator of Bioinformatics at the New York Botanical Garden and in 2014 he was promoted to Associate Curator. His current research focuses on developing DNA barcoding assays with the aim of making barcoding techniques more widely accessible to non–specialists. Dr. Little also holds adjunct appointments at the City University of New York, Fordham University, and Montgomery Botanical Center.

Presentation
Confirming Species Identity of Herbal Dietary Supplements, An Example from Devil's Claw
Friday, December 4, 2015, 10:00 a.m. – 10:30 a.m.

Dried fragmentary plant materials, such as those often found in herbal dietary supplements, are difficult to identify to species using morphological characteristics alone. Although often partially degraded, plant DNA can survive many common types of processing (e.g. drying, grinding). Short portions (less than 200 bp) of plant DNA from herbal supplements can usually be PCR amplified and sequenced. When compared to the growing database of publicly available DNA barcode sequences, these sequences can be used to provide reliable species–level identification. For example, Devil’s Claw is the vernacular name for a genus of medicinal plants that occur in the Kalahari Desert and Namibia Steppes. The genus comprises only two species: *Harpagophytum procumbens* and *H. zeyheri*. Although the European pharmacopeia considers the species interchangeable, recent studies demonstrate that *H. procumbens* and *H. zeyheri* are chemically distinct and should not be treated as equal. Further, the sale of *H. zeyheri* as an herbal supplement is not legal in the United States. Various methods of quality control have been proposed for commercial manufacture of Devil’s Claw supplements, but they have either been unreliable or unable to detect mixtures of *H. procumbens* and *H. zeyheri*. A novel DNA mini–barcode assay for the authentication of *H. procumbens* in herbal dietary supplements was designed (specificity = 1.00 [95% confidence interval = 0.71–1.00]; sensitivity = 1.00 [95% confidence interval = 0.70–1.00]). The mini–barcode assay was used to estimate the frequency of mislabeled *H. procumbens* herbal supplements available on the market in the United States. PCR amplification did not succeed for four (17%) of the 23 supplements sampled. Out of the nineteen supplements for which PCR amplification succeeded, 84% contained only *H. zeyheri*, 16% contained both *H. zeyheri* and *H. procumbens*, and none contained just *H. procumbens*. We recommend this novel mini–barcode as a standard method of quality control in the manufacture of Devil’s Claw supplements.
Robin Marles, Ph.D.
USP Affiliation: Chair, USP Botanical Dietary Supplements and Herbal Medicines Expert Committee

Senior Scientific Advisor
Health Canada Food Directorate
Ottawa, Canada

Robin J. Marles has volunteered with the United States Pharmacopeial Convention since 2005, currently as Chair, Botanical Dietary Supplements and Herbal Medicines Expert Committee (2015-2020) and member, Council of Experts and USP Convention Governance Committee. He is the Senior Scientific Advisor, Nutrition Premarket Assessment Division, Bureau of Nutritional Sciences, Food Directorate, Health Canada, for safety, quality and claims regarding botanical, bioactive and nutrient food ingredients, novel foods and additives. Other roles at Health Canada since 2003 have included Manager for safety, efficacy and quality assessments of botanicals, isolates, nutrients, and probiotics for natural health product (NHP) licensing, Director for NHP clinical trial authorizations, health risk assessments and monograph development, and Science Advisor for NHP policy. He holds a BSc (U. Victoria: Biology), MSc (U. Saskatchewan: Biology), and PhD (U. Illinois at Chicago: Pharmacognosy), and had two postdoctoral fellowships (U. Ottawa: botanical pesticides; U. Ottawa / Health Canada: botanical drug standardization). At Brandon U. (1992-2002) he taught biology, botany, ethnobotany, phytochemistry, and herbal medicine Continuing Education for pharmacists and physicians. Research publications cover traditional medicines and foods of North and Latin America and West Africa, their chemistry and pharmacology, for natural health products, drug discovery, alternate crops and non-timber forest products.

Moderator
Moderator - Plenary Session II: DNA-based Methods for Identification
Friday, December 4, 2015, 8:45 a.m. – 12:00 p.m.
Susan Martin
Director, Juice Ingredient Quality
The Coca-Cola Company
Apopka, Florida

Susan Martin is the Director, Juice Ingredient Quality at The Coca-Cola Company. She is responsible for the safety, quality and authenticity of fruit/vegetable juices and other strategic ingredients for Coca-Cola products world-wide. Susan oversees four analytical laboratories staffed with over 60 chemists and state-of-the-art analytical instrumentation. She is a 33-year veteran of Coca-Cola and an internationally recognized expert on juice and juice ingredients. Susan received her BS in Biochemistry from Michigan State University and an MS in Food Science and Human Nutrition from the University of Florida. She is a Certified Food Scientist (IFSCC). She is past-chair of the Food Industry Analytical Chemist Committee of the Grocery Manufacturers Association and past-chair of the Technical Committee for Juice and Juice Products.

Presentation
Juice Adulteration (Technical Committee on Juice and Juice Products)
Friday, December 4, 2015, 3:15 p.m. – 3:45 p.m.
Jeff Moore, Ph.D.
Director, Food Standards
USP
Rockville, Maryland

Jeff Moore is the Director of Science for the Food Standards Program at US Pharmacopeial Convention (USP). Dr. Moore is a leader in the area of collaborative approaches to advance scientific solutions to challenges in food safety, quality, and sustainability. He joined USP in 2007 as a scientific liaison and served as USP’s technical leader in the development of new risk-based food fraud prevention systems including USP’s Food Fraud Database and USP’s Food Fraud Mitigation Guidance. Jeff also served as the technical lead for a multinational collaborative research effort involving more than 15 organizations and 40 scientists to investigate and develop new analytical testing technologies to detect economic adulteration in milk products. Dr. Moore serves as USP’s representative to the Codex Committee on Food Additives, and has authored more than 20 manuscripts in peer reviewed food science journals. Prior to USP, Jeff worked for Nestlé. Jeff holds a Ph.D. in Food Science from the University of Maryland.

Presentation
Welcome
Thursday, December 3, 2015, 9:05 a.m. – 9:15 a.m.

USP’s Food Fraud Mitigation Guidance as Tool for Industry
Thursday, December 3, 2015, 1:00 p.m. – 1:45 p.m.
James Neal-Kababick
USP Affiliation: Member, USP Non-botanical Dietary Supplements Expert Committee

Director
Flora Research Laboratories, LLC
Grants Pass, Oregon

James Neal-Kababick is the founder and Director of Flora Research Laboratories, LLC (FRL) an independent CRO specializing in the research, analysis, and phytoforensic investigation of botanicals, dietary supplements and related products. James trained at FDA in the 90’s in botanical microscopy and has over two decades of professional experience in pharmaceutical, forensic and botanical microscopy and more than four decades of microscopy experience overall. For several years he taught botanical drug identification by microscopy and thin layer chromatography at Bastyr University. James is a very active USP volunteer serving as vice-chair of the USP<2251> Adulteration of Dietary Supplements with Drugs and Drug Analogues Expert Committee, as a member of the USP Non-Botanical Dietary Supplement Expert Committee and the USP Joint Standards Setting Subcommittee (JS3). With over two decades of experience in the dietary supplements industry, James also serves/served on multiple expert committees for AOAC (including the Official Methods Board and as the founding chair of the Methods Committee on Dietary Supplements), at NIH as a R15/R21 grant reviewer as a phytochemistry expert, and various trade organization working groups. Currently, his work is focused on the utilization of modern analytical technologies in the investigation of dietary supplements and other agricultural products. He pioneered the field of “Phytoforensic Science.” Phytoforensic Science involves utilizing numerous technologies from microscopy to mass spectrometry to detect adulteration and contamination in the global food supply chain with a special focus on dietary supplements. In 2010 James was named “Fellow of AOAC,” awarded to scientists for meritorious service to the scientific organization and for contributions in their field of science. It is the second highest honor the organization bestows upon scientists. He is also a collaborating researcher with numerous scientific equipment manufacturers developing applications and educational resources for the industries he serves. James is also a renowned expert in the detection of clandestine adulteration in dietary supplements as well as sophisticated adulteration schemes for spices, agricultural crops and herbal products and has been involved in various newspaper, magazine and television programs in this area. He has served as an expert for various state and federal agencies.

Presentation
Crossover Analytical Technique (CAT): A Phytoforensic Technique for Reconciling Conflicting Identity Data
Friday, December 4, 2015, 2:30 p.m. – 3:00 p.m.
Guido Pauli, Ph.D.
USP Affiliation: Member USP DS EC

Professor
University of Illinois at Chicago
Chicago, Illinois

Guido F. Pauli is a pharmacist by training and holds a doctoral degree in natural products chemistry and pharmacognosy. As Professor and University Scholar at UIC, Chicago (IL), he is principal investigator and collaborator in interdisciplinary natural product-centered research projects, and director of the NAPRA ALERT database. Main interests are in the metabolome analysis of complex natural products, bioactive principles, herbal dietary supplements, anti-TB drug discovery, and dental applications of natural agents. Scholarly activities include international collaborations and guest professorships, the education of the next generation of pharmacognosist, as well as service on funding agency panels, pharmacopoeial expert committees, and in professional societies. His portfolio comprises 150+ peer-reviewed journal articles, international seminars and conference presentations, four book chapters, patents, as well as journal editorial and board functions.

Presentation
Evolution of Botanical Integrity Paradigms; Panelist - Future of DNA Methods to Detecting Adulteration
Thursday, December 3, 2015; Friday, December 4, 2015, 2:30 p.m. – 3:00 p.m.

The recently coined term Botanical Integrity (BI) encompasses a broad, multifactorial definition of parameters that define a botanical material collectively. BI is essential to the reproducibility of research and clinical and/or dietary use of botanicals, and involves information about adulteration. The accuracy of any protocol for the detection of botanical adulteration depends on the precision of the definition of two terms: botanical (or taxonomical) identity and botanical authenticity. Both terms form the basis of defining reference (plant) materials for adulteration analysis.

Botanical or taxonomical identity has its roots in the plant genome and the anatomic and morphologic characteristics of plant materials. In contrast, botanical authenticity considers several factors: botanical identity (genomic and morphologic descriptions), traceability (geographic origins and cultivation conditions), and metabolomic description of a given herbal material. As botanical authenticity includes, and goes beyond, the determination of botanical identity, authentication requires the combination of various fields of expertise that include but are not limited to botany and phytochemistry. Notably, neither field of expertise prevails over the other in the quality control of botanical dietary supplements (BDSs). Accordingly, Botanical Integrity (BI) represents the overarching integration level: it encompasses botanical identity, authenticity, pharmacologic efficacy as well as safety of plant-derived materials designated for human consumption. As such, the achievement of successful authentication and valid detection of adulteration will depend on how taxonomic identification is performed, what methods are used, and how they are combined with phytochemical and chemotaxonomical tools.

Diagnostic morphological features of plant species on which the traditional taxonomic system is based do not always guarantee the botanical identity of powdered or otherwise processed BDSs. Genomic-based identification methods such as DNA barcoding can provide additional assurance of identity as the DNA molecule is stable and found in all parts of the plant, even when they are crushed to a powder. However, DNA-based identification methods cannot target and certify the chemical (metabolomic) profiles of a given plant material, and, thus, cannot guarantee botanical authenticity. The determination of authenticity requires documentation of...
the traceability of the taxonomically verified, genetically identified crude materials, any extraction processes involved, and the results obtained from phytochemical analyses.

This explains the multifactorial nature of BI, its role in the definition of botanical authenticity, identity, and adulteration, and the need for careful design and assembly of assays. On one hand, DNA barcoding methods can support the detection of biologically unrelated plant material and/or other botanical adulterants. On the other hand, metabolomic fingerprinting/profiling methods are capable of detecting unusual chemical profiles and, thereby, promote the identification of the contaminant species as well as the type of chemical adulterants. Therefore, in order to enhance the definition of BI, genomic-based identification methods need to go hand in glove with other suitable analytical chemistry tools, ideally metabolomic methods, in order to successfully define botanical authenticity and standards for the detection of adulteration.
Dr. Bert Popping holds the position of Chief Scientific Officer at Mérieux NutriSciences. He has more than 20 years experience in the food industry and authored over 50 publications on topics of food analysis, validation and regulatory assessments. He also edited one book in this field. Dr Popping is member of the editorial board of J.AOAC, J. Food additives and Contaminants, J. Food Analytical Methods and Quality Assurance and Safety of Crops & Foods. He is active member of numerous national and international organisations, including USP, AOAC, ISO, CEN, BSI and several German method working groups.

Presentation
Testing Today and Tomorrow: Integrative Authenticity Analysis Using Clearinghouse Solutions
Thursday, December 3, 2015, 3:15 p.m. – 3:45 p.m.

The food testing market is predicted to reach 16.1 Billion USD by 2020. This equates to an incredible number of analysis performed on all kinds of food. The majority of the analytical result data will remain with the company submitting the samples to the third party laboratory.

If such data would be anonymized by an independent third party provider and entered into a database they could be analyzed using appropriate algorithms and used in a number of ways that benefit all contributors of the database.

In the future, we are likely to see more and more non-targeted screening applications rather than specific tests for a few analytes. Therefore, such databases have a high potential of detecting even yet unknown adulterants and other types of undesirable substances by identifying communalities within a matrix groups as well as deviations.

This presentation will provide an idea for a data clearing house solution and discuss the advantages and challenges.
Nandu Sarma, Ph.D.
Director, Dietary Supplements
USP
Rockville, Maryland

Dr. Nandakumara (Nandu) Sarma is the Director for the Dietary Supplements program at U.S. Pharmacopeia (USP) responsible for the development of quality standards (monographs and general chapters) for dietary supplements, including admission evaluations, performance standards, and the publication of the USP Dietary Supplements Compendium (www.usp.org/dietary-supplements/overview). Before joining USP 2006, he was a post-doctoral fellow at National Cancer Institute, Bethesda, and Thomas Jefferson University, Philadelphia and was a Senior Scientific Officer at The Himalaya Drug Company, India. His research experience in the field of dietary supplements includes isolation and analysis of active components of plant materials and their biologic activity. He published more than 25 scientific articles in peer-reviewed journals. Dr. Sarma holds a Pharmacist degree and a Ph.D. in pharmaceutical sciences (pharmacognosy) from Banaras Hindu University, India.

Presentation
Welcome
Thursday, December 3, 2015, 9:05 a.m. – 9:15 a.m.
Adulteration and Fraud in Food Ingredients and Dietary Supplements
December 2 – 4, 2015, Rockville, Maryland

Jordi Segura
Researcher
IMIM- Hospital del Mar Medical Research Institute, Pompeu Fabra University
Barcelona, Spain

Jordi Segura (1949, Barcelona) is Scientist at the Bioanalysis and Analytical Services Research Group at IMIM-Hospital del Mar Research Institute in Barcelona, and Past-Director of its WADA-Accredited Antidoping Laboratory.

He is part of the IOC Medical Commission Games Group and the FINA Doping Control Review Board, and recent member of some WADA expert groups. At present he is the Past-President of the World Association of Antidoping Scientists (WAADS). He is Professor of Chemistry at the Pompeu Fabra University. His main expertise is in Chromatography, Mass Spectrometry, Doping, Drugs of Abuse and Drug Metabolism, having published around 350 research articles on these topics.

Presentation
Adulteration Effects and Repercussions for the World of Sport
Thursday, December 3, 2015, 10:00 a.m. – 10:30 a.m.

The consumption of nutritional supplements is widely extended among the recreational and, especially, the elite athletes. Athletes hope compensation for poor food choices or search for vital nutrients supposed to be underrepresented in their diets. Expectations of better performance and health benefits are expected outcomes.

Different investigations have revealed that a significative percentage of supplements contain substances prohibited by the World Anti-Doping Agency. Sometimes these substances are indicated on the label, but very often this is not the case and the false advertising may lead to inadvertent doping. Unfortunately for the athlete taking contaminated products, strict liability applies. It means that every athlete is responsible for the substances found in their bodily specimen during a doping control analysis. For an athlete confronted with an anti-doping rule violation, no sanction or a reduced sanction may apply only if he or she can demonstrate respectively no fault or no significant fault. This requires, however, to demonstrate clearly that every reasonable precaution was taken to avoid ingestion of a prohibited substance.

WADA Accredited anti-doping laboratories are not allowed to perform investigations allowing to claim that a given supplement is doping-clean. It is presupposed that good manufacturing practices are the logical mechanism for such a warranty in the hands of manufacturers. According to the UNESCO Convention against Doping in Sport, governments must encourage producers to include accurate labeling, quality assurance and avoidance of false marketing. A few non-WADA laboratories are specialized in these kind of analysis. However, given the wide variety of prohibited substances in sport and the low doses potentially originating an adverse finding, these sources cannot guarantee that dietary supplements are free of risk, but offer risk minimization.

Among the substances present in contaminated nutritional supplements, stimulants (ephedrines, sibutramine, oxilofrine, methylhexaneamine) are prominent. The use of different names (Ma Huang or Ephedra Sinica for ephedrines; dimethylamilamine, dimethylpentyamine, geranamine, 2-amino-4-methylhexane,... for methylhexaneamine) contribute to the confusion even in labelled products. Contamination by anabolic steroids is of even higher prevalence. Surveys in 2001-2002 amounted up to about 15% of supplements containing anabolics not declared in the label. More recent data seems to point towards an important reduction of such a percentage, but not to the elimination of the problem. Designer steroids previously unknown
have added complexity to the situation. A non-steroidal anabolic agent particularly prevalent is clenbuterol, although its origin can be usually traced more specifically to tainted meat than to dietary supplementation. More recently, a shift towards other kind of products in supplements is apparent. Some of them are growth hormone releasing factors, selective androgen receptor modulators or gene modulators, found as contaminants even before that the active principle is authorized for the clinical market.

Athletes should consider the risks and benefits of dietary supplements. The products must be purchased only from low risk sources from companies whose products undergo frequent quality control regarding the presence of doping agents. Dietary supplements produced by pharmaceutical companies may appear as a safer alternative.
Charlotte Simmler is a licensed pharmacist (University of Strasbourg, France) and obtained a doctoral degree in pharmacognosy from the same university. In 2011, she joined the UIC/NIH Center for Botanical Dietary Supplements Research at the University of Illinois at Chicago (UIC), as Postdoctoral Associate. Her research involves metabolomic analysis of botanical dietary supplements, with a focus on licorice (Glycyrrhiza), development of innovative phytochemical methods including countercurrent separation and qNMR, as well as plant DNA analysis. Dr. Simmler is now a Research Assistant Professor, also serving as a key investigator in the newly founded UIC/NIH Center for Natural Product Technologies, which is devoted to the coordination and dissemination of knowledge and innovation that can address challenges and drive future developments in the field of natural product research.

Presentation
DNA-based Identification Enables Metabolomics-Driven Detection of Botanical Adulteration
Friday, December 4, 2015, 9:30 a.m. – 10:00 a.m.

The determination of botanical authenticity and, thus, the detection of adulteration both rely on the strategically sound combination of efficient, modern analytical tools. Their assembly must be capable of differentiating closely related species, detecting unexpected biological and chemical adulterants, and should also consider the inherent phytochemical variations of a plant material for the detection of typical vs. unusual phytochemical profiles.

In recent years, DNA barcoding methods have been demonstrated to serve in two main roles: (i) confirmation of the identity of commercial raw plant material, and (ii) potential identification of botanically or other biologically unrelated adulterants. While DNA barcoding alone is insufficient for botanical quality control, it can play a fundamental role in the selection of genetically verified and identical plant materials that are devoid of DNA detectable adulterant and, thus, are suitable reference materials for establishing authenticity through phytochemical analyses.

Phytochemical profiles of taxonomically verified and genetically identical plant material are inevitably subject to variation, as plant metabolomes reflect phenotypes and other effects such as from environmental stresses, cultivation conditions, time of harvest, and mode of extraction to cite a few. Therefore, efficient detection of adulteration requires a comprehensive definition of botanical authenticity. Ideally, such a definition should embrace the natural phytochemical variations of genetically identical plants, rather than serving as an absolute genetic reference point. Integration of the chemical variations into the definition of the authenticity of genetically identical plant materials requires metabolomic and chemometric analyses, such as principal component analysis and other statistical comparison of multiple phytochemical fingerprints.

Metabolomic analyses have been shown to offer a comprehensive determination of botanical authenticity, thereby facilitating the detection of both chemical and botanical adulterations. In such an integrative approach, DNA barcoding methods enable the selection of unambiguously identified material, with which metabolomics are performed and statistical models are built for the determination of authenticity. As such, the integrative approach combining DNA barcoding with metabolomics can potentially solve the overly complex problem of botanical adulteration. This presentation will illustrate the methods, strengths, and challenges of the approach, exemplified by results obtained from the research on for authentication methods for licorice (Glycyrrhiza sp.) botanicals.
Thomas Tarantelli  
Senior Food Chemist  
NYS Dept. Agriculture and Markets  
Albany, New York

Tom was born in Columbus, Ohio and grew up in Schenectady, New York with the exception of 2 years his family lived in Milan, Italy. Tom graduated from The State University of New York at Albany with a B.S. in Chemistry and spent over 20 years working in PVC manufacturing before joining the New York State Food Laboratory where he has been analyzing food, animal feed and fertilizers for more than 10 years.

During his professional career with the lab, Tom inherited the color analysis, which now consumes approximately half of his time. A subject matter expert in color analysis, Tom has been analyzing food for color for more than four years and has conducted well over 2000 samples in that time period.

Tom is passionate about his profession, always on the lookout for a good sample, no one was surprised when his family took a vacation in the Philippines and he came back with a suitcase full of food samples to analyze!

Presentation  
Adulteration of Food with Illegal Dyes  
Friday, December 4, 2015, 2:30 p.m. – 3:00 p.m.

The New York State Department of Agriculture and Markets Food Laboratory has been analyzing food products for both allowed and unallowed dyes for decades. Historically, a paper chromatography method was used to determine food dyes, classified as acid dyes. This method works well for two reasons: the dyes have unique color characteristics both in white and ultraviolet light and the method is a non-targeted method so it will determine not only dyes that are being considered but any acid type dyes in the food product.

In early 2011 the Food Lab received an imported pink candy coated fennel seed product. No acid dye was found in the sample but the bright pink color did not appear to be natural. After researching news articles and scientific papers on colors in food, Rhodamine B, a basic industrial dye stood out as a potential adulterant to look for in the pink candy coated seeds. The lab purchased a Rhodamine B standard and developed an HPLC/MS/MS method to detect Rhodamine B, which was subsequently identified in the candy sample using the new method.

Additional research has expanded the HPLC/MS/MS method to screen for 36 industrial colorants, none of which are allowed in food anywhere in the world. To date approximately 15 different industrial colorants have been found.
Jennifer Thomas, Ph.D.
U.S. Food and Drug Administration
College Park, Maryland

Presentation
Impact of the FDA Food Safety Modernization Act on Supply Chain Integrity (or WEMA Efforts on Food Fraud Activities)
Thursday, December 3, 2015, 11:30 a.m. – 12:00 p.m.
Poster Presenters

(in last name order of presenting author)
Yu-Pei Huang, M.S.
Associate Technical Specialist
Taiwan, China Food and Drug Administration

Ms. Yu-Pei, Huang, is the Associate Technical Specialist of Division of Research and Analysis in Taiwan, China Food and Drug Administration (TFDA). She obtained MS degree from National Taiwan University in Taiwan, China and joined in TFDA since 2015. Now she is participating in the research group of food adulteration and primary responsible for animal adulteration in vegetarian food and species identification of unknown plants or fish by molecular biology method.

Poster Presentation
Development of Real-time PCR Approach for Rapid Detection of Dory fish (Zeus faber) and Catfish (Pangasianodon hypophthalmus) in Foods
Co-Authors: Jung Kuan, Hsiu-Wei Tsuei, Che-Yang Lin, Hsu-Yang Lin, Yueh-Jong Chung-Wang, Hsiu-Kuan Chou, Hwei-Fang Cheng

Increased worldwide trade and processing of seafood has increased the potential for seafood mislabeling and species substitution on the commercial market. To detect and prevent fish substitution, fish products purchased from markets were investigated and the substitution of catfish (Pangasianodon hypophthalmus) for Dory fish (Zeus faber) was found. Dory fish is a saltwater and high economic value fish. Catfish is a freshwater and low economic value fish that cultivate in Mekong river delta in Vietnam mainly. In order to avoid fraudulent mislabeling, a reliable real-time PCR method for the identification of Z. faber and P. hypophthalmus has been developed respectively. Specific primers and TaqMan probe based on barcode marker cytochrome c oxidase subunit I (COI) of mitochondria DNA were designed. The specificity of the method was confirmed by analyzing 100 fish species samples collected in Taiwan, China and no cross-reaction was observed with any of the tested samples. Sensitivity tests revealed the method was sensitive in detecting the low level of 0.001% wt/wt (1pgDNA). Subsequently, the method was applied to 12 commercial fish fillet samples from retailer in Taiwan, China all of them were low economic value catfish. It was demonstrated that the method is useful in verifying food labeling regulations. In conclusion, the real-time PCR detection method developed herein is a rapid, sensitive and applicable detection tool for accurate identification of Z. faber and P. hypophthalmus ingredients in foods.
Huzefa Raja, Ph.D.
Mycologist
University of North Carolina at Greensboro

Huzefa Raja received his Ph.D. in Plant Biology (Mycology) from the University of Illinois at Urbana-Champaign in 2007. Currently, Huzefa is a mycologist working in the Department of Chemistry and Biochemistry at the University of North Carolina at Greensboro. At UNCG, he researches fungal diversity and biology. He works on isolating and describing fungi, thus contributing to the origins and diversity of the fungal kingdom. His research findings have important implications in studies of biodiversity, phylogenetics, and taxonomic studies of the kingdom fungi. Cultures generated from his studies are being used for comparative genetic, chemical, and biological studies. In the past few years, he has been actively involved with fungal barcoding projects, and is a working member of the fungal barcoding consortium, where he has published multicollaborative manuscripts on various aspects of fungal barcoding using the Internal Transcribed Region (ITS) of the ribosomal RNA gene. More recently, he has been involved with New Chapter P&G and has been working on fungal barcoding of medicinal mushrooms used in the production of dietary supplements. His research on fungal barcoding is thus focused on testing the utility of fungal ITS DNA barcoding towards the identification of mushrooms sold for medicinal value or as commercial edible species to address the following two questions: 1. Is it feasible to extract high quality DNA and sequence the ITS region from processed mushroom powders used in medicinal mushroom dietary supplements? 2. What are the pros and cons of fungal ITS barcoding as it pertains to fungal based dietary supplements?

Timothy Baker, Ph.D.
Research Fellow
Proctor and Gable

Tim received his B.S. in Chemistry from Canisius College (1979) in Buffalo. After working several years at an contract lab using GC/MS to quantitate environmental pollutants he returned to school and obtained a Ph.D. in Analytical Chemistry, specializing in mass spectrometry, with Paul Vouros at Northeastern University in Boston (1990). Tim then joined P&G’s Health & Personal Care Technology Division, in Cincinnati, Ohio. After several years in that division and then Over-The-Counter products research, he joined the pharmaceutical discovery effort in P&G Pharmaceuticals, in 1995. During over a decade working in P&G’s pharmaceutical business, Tim acquired expertise supporting pharmacokinetic and in vitro studies using HPLC/MS/MS. He also supported metabolite identification studies and introduced high resolution mass spectrometry to that and similar efforts, within P&G. With the formation of a core facility supporting all of P&G’s R&D efforts, Tim led the Quantitative HPLC/MS Lab. In 2009 Tim formed the Qualitative MS Lab and this group continues to support all of P&G with identifications of metabolites, impurities, degradation products, contaminants, adulterants, color-change agents, as well as characterization of oligomeric mixtures and natural products. Tim’s group has a great deal of experience characterizing complex mixtures using a variety of chromatographic approaches (UHPLC, SFC, GC, 2D-GC) coupled with high resolution mass spectrometry.

Jason Little, Ph.D.
Vice President Product Safety and Regulatory Affairs
New Chapter / Proctor and Gamble

Jason Little is the VP of Product Safety and Regulatory Affairs at New Chapter and a Senior Toxicologist in Proctor and Gamble Personal Health Care for Dietary Supplements. He has a PhD in Pharmacology and Toxicology from the University of Utah, where he performed original research and published several manuscripts and book chapters related to the cardiac effects of epilepsy. After graduate school Jason pursued a career in the dietary supplement industry,
Nicholas H. Oberlies, Ph.D.
Professor
University of North Carolina at Greensboro

Nick received his B.S. in Chemistry from Miami University (1992) and his Ph.D. in Medicinal Chemistry and Pharmacognosy from Purdue University (1997), where he studied under Professor Jerry L. McLaughlin. He then spent a year as a postdoctoral chemist at American Cyanamid, where he investigated leads with insecticidal, herbicidal, and fungicidal properties from natural sources. In 1998, he joined Research Triangle Institute, specifically to be mentored by Dr. Mansukh Wani and the now late, Dr. Monroe Wall, who are the co-discoverers of taxol and camptothecin. He rose through the ranks of RTI and eventually directed the Natural Products Laboratory. In 2009, he moved his group to the Department of Chemistry & Biochemistry at the University of North Carolina at Greensboro, who has a relatively new Ph.D. program in Medicinal Biochemistry that has an emphasis in natural products chemistry. There he leads a multidisciplinary effort to characterize and develop new chemical entities from natural sources. Over the past ten years, his lab has worked to profile fungi for leads in diverse areas, including herbicidal, antitumor, and anthelmintic. His lab also has a wealth of experience in the characterization of dietary supplements, including the verification of species identities of fungi using DNA barcoding techniques.

Poster Presentation
DNA barcoding for identification of species in mushrooms: A component of product certification
Co-Authors: TR Baker, JG Little, NH Oberlies

One challenge in the botanical industry is the confirmation of species identification, and this can be compounded by the processing of the materials before reaching the vendor, such as milling or drying. This can be particularly difficult for samples that contain fungal mycelia, where morphological characteristics do not present sufficient variation to differentiate species. However, monitoring the safety and quality of such products is a requirement for the protection of consumer health. DNA barcoding, a genetic-based species identification system, has become popular in the past decade, and it shows great promise for species level identification of fungi. By using DNA barcoding of nuclear ribosomal internal transcribed spacer (ITS) of the rRNA gene with fungal specific ITS primers, we generated ITS barcodes for 33 representative mushroom fungi, which are being used by consumers for food and dietary supplement purposes. After generating ITS barcodes utilizing standard procedures accepted by the Consortium for the Barcode of Life, we tested the utility of the ITS by performing a BLAST search against both curated and non-curated public databases. Results demonstrated that the ITS region was able to identify the mushrooms used in the present study to species-level. We anticipate that this presentation will motivate a discussion on DNA barcoding based species identification, particularly as it applies to the verification/certification of mushrooms containing products.
Charlotte Simmler

Poster Presentation
The Utility of DNA Authentication for the Metabolomic Classification and Quality Control Of Licorice Botanicals
Co-Authors: Jeffrey R. Anderson, Laura Gauthier, Shao-Nong Chen, Guido F. Pauli

Licorice sold as Botanical Dietary Supplements (BDSs) can be obtained from mainly three Glycyrrhiza species: G. glabra, G. uralensis, and G. inflata.1 Hence, commercial licorice BDSs can potentially be composed of either one single Glycyrrhiza species, mixtures of G. species, or even G. hybrids. A DNA barcoding method2 was optimized and applied for the authentication of 51 licorice BDSs. As expected, DNA authentication enabled the classification of all acquired licorice samples into the three major groups: single species (37 samples), hybrids (6 samples), and mixtures (8 samples) of Glycyrrhiza species. Interestingly, the DNA analyses also revealed that 11 samples were mislabeled, containing either hybrids or another Glycyrrhiza species than the one initially claimed. Parallel 1H NMR and UHPLC-UV-based metabolomic analyses performed with the corresponding crude extracts enabled building of accurate chemometric models, using only DNA verified samples of single G. species. Two types of classification models were developed: SIMCA was performed with the 1H NMR spectra, and CDA was carried out using the UHPLC-UV data. The models enabled the chemical classification/identification of the official Glycyrrhiza species as well as the overall metabolomic characterization of licorice mixtures. Together with DNA barcoding, both models were utilized for the identification of Glycyrrhiza hybrids and species outliers. The presentation addresses the congruence and complementarity between DNA analysis and metabolomics for the quality control of licorice botanicals.3

**Chia-Fen Tsai, Ph.D.**
Section Chief  
Taiwan, China Food and Drug Administration

Many in the governmental and business labs regard Dr. Chia-Fen Tsai as a leading authority and experienced expert in food chemistry analysis. Chia-Fen has about thirty years of experience in food chemistry analysis and extends the majority of experience to illegal medicine analysis recently. Now as the Section Chief of Section of Adulterant and Illegal Drugs, stuffs respect and admire her enthusiasm and professionalism.

**Poster Presentation**

Co-Authors: Ya-Tze Lin, Shih-Shan Huang, Fen-Ling Lu, Pei-Yi Chen, Hwei-Fang Chen

Chinese herbs are the raw material of Chinese herbal medicines which are the basic resources of Chinese medicine and the pharmaceutical industry. Moreover the authenticity and quality of the herbs play key rule on the influence and effectiveness to the medical results. Misuse and adulteration of Chinese herb may happen when the resource of the herb is misjudged or different products have the same name as well as multiple names for the same product. The adulteration of the Chinese herbs will also put peoples’ health on risk. In 2000, our department began to focus on the examination of prototype of herbs in check and registration. Check and registration were the required processes for the pharmaceutical companies when applying for a medicine checked and registered. During this process, any herbs involved within the medicine should be sent to our department and examined. In this study, we had found 21 misuse cases in check and registration during 2014~2015 Aug. The misuse types were misuse of botanical origin, wrong process methods, misuse of wrong parts on herbs, and interference. In order to protect health and safety of people as well as to provide references standard for modern Chinese herbs, we had made comparisons between the authentic and misused herbs.
Betsy Jean Yakes, Ph.D.
USP Affiliation: Member, USP Skim Milk Advisory Group

Research Chemist
U.S. Food and Drug Administration (CFSAN)
College Park, Maryland

Dr. Betsy Jean Yakes has been with the FDA since July 2007 as a spectroscopy and immunoassay expert. She currently develops and validates methods for rapid, sensitive detection of foodborne pathogens and adulterants through the use of surface plamson resonance biosensors and Raman spectroscopy. Her initial research at FDA on prototype instrumentation has led to the establishment of a spectroscopy laboratory with five instruments totaling approx. 1 million in equipment. This instrumentation has been used for the improved detection of seafood toxins, viruses, bacteria, small-molecule contaminants, and additives/adulterants in food commodities. Her laboratory supports not only CFSAN but is also involved in multi-FDA laboratory collaborations (e.g., CVM on Raman spectroscopy of crystals in tissues) and international collaborations (e.g., development of seafood toxin assays with the U.K. and Czech Republic). Prior to joining FDA, Dr. Yakes designed a detection platform for bacteria using surface-enhanced Raman scattering which led to multiple publications and a licensed patent. Her current projects focus on improving authentication/adulteration screening methods using portable spectroscopy instrumentation. In addition, she is currently serving as a U.S. FDA Liaison to the USP Skim Milk Powder Advisory Group as well as a co-chair of the FDA Portable Devices Technical Advisory Group.

Poster Presentation
Development of a Non-targeted, Raman Detection Method for Authentication of Milk Powders
Co-Authors: Sanjeewa R. Karunathilaka, Tara Jade Michael, Magdi Mossoba

Recently, there has been a push to develop screening methods that employ portable, rapid, high-throughput instrumentation for the proactive detection of adulteration in foodstuffs. One commodity that is vulnerable to attack and that is consumed by some of the most vulnerable populations (e.g., infants and persons on restricted diets) is milk powder (MP). The recent economic adulteration of MP with melamine in 2008 highlights the needs for innovative methods to prevent contamination. As a first step, a collection of MPs are being used to establish libraries of authentic Raman spectra that include the natural variations in this product (e.g., origin, processing temperature, fat and protein content, etc.). Initial research has shown that advanced data processing methods (i.e., chemometrics) are necessary to fully fingerprint a sample/contaminant and create successful models for verifying authenticity. In order to evaluate the universal models and determine the ability to screen out potential contamination, melamine was chosen as the initial contaminant of interest. The chemometric models have shown success at identifying melamine-contaminated MP as not being authentic MP samples, thus allowing for a potential rapid, first-line of defense that could be used to screen a large number of MP samples. Work is underway to assess the false-positive/-negative rates of identification as well as the benefits/drawbacks to each method. Future studies to expand the testing to other potential adulterants are underway. As the methods and instrumentation are further developed, we envision a system where these analytical tools can be employed by non-experts to proactively protect the food supply and consumers.