

USP Workshops and Courses

→ **DNA Standards for Botanical Identification
Workshop and Botanical ID Methodology
Test Course**

August 21-22, 2018



Speaker Biographies and Abstracts



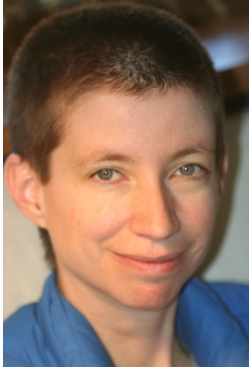
Michael Ambrose, Ph.D.
US Pharmacopeia (USP)
Maryland, USA

BIO

Michael Ambrose is an experienced leader with over 25 years of industrial experience. This experience includes working with small biotech start-ups to established biopharmaceuticals companies ranging from R&D to strategy and development. Michael has been at USP over 12 years first as the Director of the Biologics and Biotechnology Laboratory in the Rockville, responsible for the build out and opening of the laboratory in Rockville Maryland. Michael was also part of the design teams for the Biology laboratories at our India and China sites as well as the Microbiology laboratory in Ghana. In 2016, Michael transitioned to a newly established group at USP and is currently the Director, Research and Innovation. Responsibilities in R&I include leading forward-looking, inter-departmental laboratory projects such as the application of qNMR methods for advanced Reference Standard characterization and development of DNA methods for Botanical Identification. As part of the R&I group, Michael is also involved in the evaluation of novel technologies for potential compendial applications. Michael also leads the Innovation Infrastructure team exploring novel tools and mechanisms to integrate and expand staff empowerment for opportunity identification and problem solving.

Panel Discussion – Application of Standards

Wednesday, 8/22/2018, 10:30am



Wendy Applequist, Ph.D.
Missouri Botanical Garden
Missouri, USA

BIO

Wendy L. Applequist is a native of Illinois who received a Ph.D. in plant systematics from Iowa State University. She is an associate curator in the Missouri Botanical Garden's William L. Brown Center, where she has worked since 2000, and currently serves as acting director of the Brown Center and editor-in-chief of the Garden's journal *Novon*. She is the author of a book on morphological authentication of botanicals in commerce; her research interests include the taxonomy, authentication, and quality control of medicinal plants, natural products discovery, plant nomenclature, and taxonomy of flora of Madagascar.

Presentation

Globally Recognized Definition of Voucher Specimen

Tuesday, 8/21/2018, 3:00pm

Abstract

A traditional botanical voucher specimen is a permanently preserved specimen that represents and documents a single observation of, or collection of material from, a single population. Such vouchers should contain all the necessary plant parts to allow botanical identification and should be deposited in institutions where they will be accessible to other researchers. Sometimes the only available voucher material is not botanically identifiable; for example, if partially processed commercial material is purchased for research use, a sample of that material must be preserved as the only possible voucher, which may be identifiable by validated proxy methods if not by traditional botany. At other times, an identifiable herbarium voucher can be obtained but not on the date when material is harvested or research samples collected; if there is no doubt that it represents the same individual or population, a specimen collected at a different time does serve as evidence of taxonomic identity.



Joseph Betz, Ph.D.

Member: USP Non-Botanical Dietary Supplements Expert Committee

BIO

Joseph M. Betz, Ph.D., was appointed Acting Director of the Office of Dietary Supplements (ODS) in June 2018. Dr. Betz directs an office whose purpose and responsibilities were defined in the Dietary Supplement Health and Education Act (DSHEA) of 1994:

- a. to explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care;
- b. to promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions;
- c. to conduct and coordinate scientific research within NIH relating to dietary supplements;
- d. to collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources; and
- e. to serve as the principal advisor to the Secretary and to the Assistant Secretary for Health and provide advice to the Director of NIH, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the Food and Drug Administration on issues relating to dietary supplements.

Dr. Betz joined ODS in 2002 as the first director of the [Analytical Methods and Reference Materials](#) (AMRM) program. As AMRM director, he oversaw several large intra- and extra-governmental initiatives with the goal of providing stakeholders with rugged, validated analytical methods and reference materials for measuring natural products in research, industrial, and regulatory settings.

Prior to joining ODS, Dr. Betz was vice president for scientific and technical affairs at the American Herbal Products Association (AHPA). Before serving at AHPA, Dr. Betz worked for many years at the U.S. Food and Drug Administration (FDA) beginning when he joined the Division of Natural Products at FDA's Center for Food Safety and Applied Nutrition for his postdoctoral work. Later he accepted a fulltime job as a research chemist at FDA, where he remained for 12 years.

Dr. Betz is an adjunct associate professor in the Department of Pharmacology and Physiology at the Georgetown University School of Medicine and in the Department of Cell Biology and Biotechnology at his alma mater, the Philadelphia College of Pharmacy and Science, now called the University of the Sciences (USciences). He is a member of the Board of Visitors of the Misher College of Arts and Sciences in the University of the Sciences. He is a member of the American Society of Pharmacognosy and a fellow of AOAC International. He also is chair of the Editorial Board for the Journal of AOAC International, a member of the United States Pharmacopeia's Expert Committee on Dietary Supplements, and serves on expert scientific advisory committees for the governments of Canada and Hong Kong.

The author or co-author of over 100 peer-reviewed publications and book chapters, Dr. Betz is the recipient of the American Botanical Council's first Norman R. Farnsworth Award for excellence in Botanical Research, the American Herbal Product Association's Herbal Insight Award for contributions to the Botanical Sciences, AOAC International's Technical Division on Reference Materials (TDRM) Reference Material Achievement Award, and the American Society of Pharmacognosy's Varro E. Tyler Prize for outstanding scientific contributions to the broad field of dietary supplements, with special emphasis on botanicals. He was recognized by the NIH Office of the Director with an Honor Award for his contributions to the establishment and development of the ODS Vitamin D Standardization Program.

A native of Philadelphia Dr. Betz earned a B.Sc. degree in Biology at USciences and a M.Sc. in Marine and Environmental Science at C.W. Post/Long Island University. Dr. Betz earned a Ph.D. in Pharmacognosy at USciences.

Discussion: Q&A / Summary

Tuesday, 8/21/2018, 4:30pm



Karen Clark, Ph.D.

National Center for Biotechnology Information,
National Library of Medicine, National Institutes of Health
Maryland, USA

BIO

Dr. Karen Clark studied signal transduction in yeast before joining NCBI as a GenBank indexer. For the past 10 years she has headed the GenBank indexing team that processes prokaryotic and eukaryotic genomes that are submitted to GenBank. Her team has worked to make the submission process simple for submitters, while also including validations to ensure that the genomes that are accepted into GenBank are a useful resource for researchers.

Presentation

Database of Molecular Sequences: GenBank and RefSeq

Tuesday, 8/21/2018, 3:00pm

Abstract

GenBank is the NIH DNA database of public sequences submitted by researchers across the globe. In addition, GenBank is part of the International Nucleotide Sequence Database Collaboration, with the DNA DataBank of Japan (DDBJ), and the European Nucleotide Archive (ENA). Each organization is responsible for vetting the accuracy of the data submitted to it, and the three organizations exchange their public data daily. Sequences submitted to GenBank undergo an array of basic validations, and sequences that fail those validations are not accepted into the database. GenBank is an archival database, containing data that was submitted more than 30 years ago and GenBank has worked to improve its validations over the years, so there are problematic sequences present. We will discuss GenBank's work to identify contamination in and misidentification of submitted genomes. Another resource at NCBI is the Reference Sequence (RefSeq) collection; it provides a comprehensive, integrated, non-redundant, well-annotated set of sequences and other resources for researchers. We will discuss the RefSeq Fungi resources, including the Targeted Loci Project of ribosomal RNAs and Internal Transcribed Sequences (ITS).



Tyler Daniels, MS
Scientist, Biotechnology
Thorne Research
Idaho, USA

BIO

Tyler Daniels is a Research & Development Scientist at Thorne Research, focusing on the botanical dietary ingredient portfolio, developing the company's quality system, and integrating human -omics data into preventative healthcare. Of his ongoing projects, he is perhaps most passionate about thoughtfully managing the commercialization of novel botanical extracts and fractions, including the practice of DNA testing to unify supply chain. Tyler's experience leading DNA testing has made him extremely familiar with the advantages and challenges of next-generation-sequencing technology for the dietary supplements industry. He completed a Master's of Animal Sciences at Washington State University in 2009.

Presentation

Steps Needed for Actionable DNA Data: Method Specificity & Certificates of Analysis
Wednesday, 8/22/2018, 8:45am

Abstract

Despite being subject of widespread industry attention, DNA testing is not yet a typical part of the Dietary Supplement Quality Control landscape. While this lag is largely due to the scientific challenges surrounding the use of genetic data to assign taxonomic identity, there is opportunity for the players in the space to do more with what is currently available. The primary advantage of DNA data is granularity, consistency, and objectivity, which make it uniquely suitable to connect participants in the supply chain. Unfortunately, DNA technology has not yet been able to foster that connection, as the capabilities of the methods in the business context are oftentimes not well understood between those that can benefit from it. Furthermore, experimental design parameters such as technology platform, exclusion panels, and reference databases each dictate the capabilities and limitations of the system and until these are better controlled the data will continue to create more questions than answers. By standardizing the appropriate fit-for-purpose use criteria of these and other parameters, the industry context will more quickly emerge, and the benefits of using genetic methods will as well.



David Erickson, Ph.D.

Founder & CEO
DNA4 Technologies
Maryland, USA

BIO

David Erickson received his PhD in Botany from the University of Georgia where he studied population and evolutionary genetics while supported by a NSF Research Training Grant. David then completed postdoctoral training at the University of Maryland and the Smithsonian Institution studying quantitative and evolutionary genetics respectively. David subsequently helped establish and run the plant DNA barcode program at the Smithsonian Institution's National Museum of Natural History. After having published widely in genetics, ecology and evolution, in 2015 David founded the biotechnology company DNA4 Technologies (www.dna4tech.com). At DNA4 they offer fee for testing services while also developing cloud-based bioinformatics software for the analysis of genomic DNA sequence data to resolve the taxonomic identity and purity of natural products in commercial use.

Presentation

Quantification of Type I and Type II Errors in Genomic Assessment of Botanical Authentication
Tuesday, 8/21/2018, 1:00pm

Abstract

Identifying and mitigating errors is a critical step to implementation of DNA based testing in commercial quality control programs. This presentation reviews basic elements of hypothesis testing, with emphasis on how it relates to authentication and validation of natural products. We review several examples of the literature that provide a framework for understanding how best to utilize DNA data in testing programs, and how to recognize and avoid pitfalls in its use. We conclude with a set of recommendations that are most likely to allow for implementation of DNA tests that are accurate, quantitative and reproducible.



Gabriel Giancaspro, Ph.D.
US Pharmacopeia (USP)
Maryland, USA

BIO

Dr. Giancaspro is the Vice President, Science—Dietary Supplements and Herbal Medicines, for 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 Rigeicin, 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.

Presentation

Welcome and Introduction of Keynote Speakers
Tuesday, 8/21/2018, 8:30am

Welcome
Wednesday, 8/22/2018, 8:30am

**Sara Handy, Ph.D.**

Research Biologist
U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition
Office of Regulatory Science
Maryland, USA

BIO

Sara Handy obtained her Ph.D. in Oceanography at the University of Delaware in 2007, working under the direction of Dr. David Hutchins. During her Ph.D. she focused on DNA based identification of harmful algal species. In 2007, she started a postdoctoral position the University of Maryland with Dr. Charles Delwiche in the department of Cell Biology and Molecular Genetics on the evolution of dinoflagellates. In 2009, she began her work at the U.S. Food and Drug Administration in the Center for Food Safety and Applied Nutrition, where she could combine her DNA background with her understanding of phylogenetic tools. As a Research Biologist in the Office of Regulatory Science, she now works to develop and evaluate genomic methods to identify plant and animal species in foods and dietary supplements. She has authored or coauthored 38 manuscripts primarily focused on DNA based identification methods.

Session Chair

Session II - Methodologies
Tuesday, 8/21/2018, 1:00pm

Presentation

Genomic Approaches used by FDA to Investigate Botanicals
Tuesday, 8/21/2018, 10:30am

Abstract

DNA based analyses that target genome differences have become a powerful and sometimes controversial tool in identifying species in raw and finished food products and dietary supplements. Due to the ever-increasing variety of plant and animal species being traded in commerce around the world, proper species identification is proving to be a critical component of the FDA's mission of assuring US consumers that the food they eat is both safe and accurately labeled. These data can be used directly to aid in FDA trace-backs during investigations into product adulteration or can be combined with additional chemical, or microbiological data during outbreak investigations. Advances in DNA sequencing and other technologies have made this once complicated and expensive process more affordable and amenable to standardization and validation and therefore useful in the regulatory arena, but this is not without caveats. Since questions have been raised about traditional DNA barcoding especially for processed products and closely related species, developing methods targeting smaller diagnostic regions and reference libraries for rapid species identification of plants in foods and dietary supplements would be useful and complementary to chemical methods. Here, case studies will be presented to highlight the pros and cons of some DNA based identification methods.



Robert Hanner, Ph.D.

Associate Professor
Biodiversity Institute of Ontario
Centre for Biodiversity Genomics
Department of Integrative Biology
University of Guelph
Canada

BIO

Dr. Robert (Bob) Hanner is an Associate Professor at the Biodiversity Institute of Ontario & Centre for Biodiversity Genomics at the University of Guelph. He earned a B.S. in Biology from Eastern Michigan University in 1992 and a Ph.D. in Biological Sciences from the University of Oregon in 1997. He held a Kalbfleisch Postdoctoral Fellowship at the American Museum of Natural History (AMNH) from 1998 to 1999 and then served as Curatorial Associate for the Ambrose Monell Collection for Molecular and Microbial Research at the AMNH, where he spearheaded development of the Museum's genomic resource collections (2000-2003). He then joined the faculty of the Coriell Institute for Medical Research, where he served as Scientific Program Director of the Coriell Cell Repositories from 2003-2005. He also served as President of the International Society for Biological and Environmental Repositories (ISBER) from 2003-2004. He is an Associate Editor of Mitochondrial DNA and also serves on the editorial board of Biopreservation and Biobanking. His research interests are at the intersection of biodiversity and food security. He has authored over 80 scientific publications and exposed widespread seafood fraud and adulteration of ground meats using molecular techniques. His work has been featured in the New York Times and CBC Marketplace, among many other media outlets.

Presentation

Multitude of Methods: Guidelines to Compare Methods
Wednesday, 8/22/2018, 8:45am

Abstract

NOT AVAILABLE AT THE TIME OF PRINTING



Caroline Howard, BSc, Ph.D., PGCertHE, HEA Fellow

Principal Scientist BP-NIBSC Herbal Laboratory
National Institute for Biological Standards and Control
United Kingdom

BIO

Caroline Howard began her studies at De Montfort University, Leicester UK, attaining a 1st class (Hons) degree in Biology, on the Biotechnology stream. After 2 years in industry, Caroline returned to academia to study for a PhD in 'DNA authentication of Herbal Medicines' in 2007 working with Professor Slater, this was completed in three years. Caroline continued to work in the Biomolecular technology group as a post-doc, engineering a portfolio position including lecturing and research supervision, grant funded research, and leading negotiations with private companies for contract-based research. This industry collaboration led to a large funding application under the EU Marie Curie Industry-Academia partnership pathway which Caroline co-authored, project managed and worked on as a Research Fellow. In 2014 Caroline was recruited by the Medicines and Healthcare products Regulatory Agency (MHRA) to work for the British Pharmacopoeia and investigate the use of DNA methods for identification of Herbal Drugs. In this role Dr Howard has designed and implemented the methodology and approach of DNA barcoding to identify the materials used for monograph elaboration, and further developed this into an Appendix and Supplementary Chapter of the British Pharmacopoeia. To accompany this, she also designed and produced the BPNARM reference material. Following the success of this work, the scope of the group was expanded, and Caroline is now the Principal Scientist of the BP Herbal Laboratory, managing a team which is responsible for the analysis of herbal drugs for the purpose of monograph publication, including DNA identification, HPTLC and physical testing. Caroline remains research active, currently co-supervising PhD students with collaborators from De Montfort University, the Botanic Gardens Kew, the University of Copenhagen and others.

Presentation

Keynote

British Pharmacopoeia Herbals Team: Approach to DNA methods

Tuesday, 8/21/2018, 8:45am

Abstract

The advent of DNA barcoding for species identification was heralded as a step change for numerous applications, including the identification of plants used for medicinal purposes. The picture became less clear as global consortia came to the conclusion that one barcode would not be sufficient to resolve all plant species. The power of DNA-based identification methods when applied to herbal medicines was shown in numerous publications, with pharmacopoeias then required to address whether to include this new technology, and if so how. The approach of the British Pharmacopoeia (BP) to this opportunity is described, and how the Herbals Laboratory uses these methods. The Appendix Method, published in the BP 2015, is described and the rationale underpinning it and the development of 'reference sequences' for each monograph target. The BP Nucleic Acid Reference Material is also introduced, and examples given of how it is used in practice. The future prospects of DNA-barcoding for herbal drugs are outlined, with the application of more advanced methodologies discussed.

DNA-based identification methods for herbal drugs have made a considerable contribution to the quality of monographs by yielding previously unavailable information about the purity of specimens. The complementarity of these methods with HPTLC and physical testing can provide quality assurance.



Holly Johnson, Ph.D.
Chief Science Officer
American Herbal Products Association
Maryland, USA

BIO

Holly E. Johnson Ph.D., is the Chief Science Officer for the American Herbal Products Association (AHPA). She previously served for three years as Laboratory Director for Alkemist Labs, an ISO 17025 accredited natural products testing lab specializing in botanical dietary supplements. Dr. Johnson took her Ph.D. in Pharmacognosy at the College of Pharmacy, University of Illinois – Chicago (UIC), under renowned Pharmacognosist and researcher Dr. Norman Farnsworth. Holly was awarded a National Institutes for Health (NIH) Fellowship and trained at the UIC/NIH Center for Botanical Dietary Supplements. She was a Postdoctoral Research Fellow at the Institute for EthnoMedicine studying the etiology of neurodegenerative disease, and also worked for Waters Corporation conducting technical training and regulatory consulting for pharmaceutical and supplements companies. She is currently a Research Associate with the National Tropical Botanical Garden and serves on AOAC working groups, stakeholders panels and expert review panels for Foods and Dietary Supplements. She is a member of the United States Pharmacopeia's (USP) Medical Cannabis Expert Panel, the Editorial Board of the Journal of AOAC International, and she serves on the Advisory Boards of the American Botanical Council and the American Herbal Pharmacopeia. Holly has over 20 years experience working with natural products & botanicals and spent many happy years conducting research on medicinal plants and giving courses at the University of Hawaii.

Session Chair:

Session 1 - Industry Experiences and Regulatory Approaches
Tuesday, 8/21/2018, 10:30am

Presentation

Botanical Authenticity Interlaboratory Studies
Wednesday, 8/22/2018, 8:45am

Abstract

In the Fall of 2018, NIST and AHPA initiated an interlaboratory study to investigate how fit for purpose different techniques are for the determination of authenticity of botanical products. A series of authentic materials were collected by AHPA and then gravimetrically adulterated with *Sophora japonica* fruit extract. Ground *Ginkgo biloba* leaf materials with different preparations were selected and extracts prepared with different solvents were used. The authentic samples were sent without adulteration and adulterated at 3 %, 5 %, and 7 % *Sophora japonica* fruit extract and sent to a series of laboratories. Twenty eight sets of results were sent back and the samples were analyzed by genomic methods, chromatographic methods, and microscopy. In this presentation we will discuss the study design and the current data interpretation.

**Damon Little, Ph.D.**

Associate Curator of Bioinformatics
Cullman Program for Molecular Systematics
The New York Botanical Garden
New York, USA

BIO

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 *Callitropsis*). 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

Keynote

Tuesday, 8/21/2018, 8:45am

Abstract

NOT AVAILABLE AT THE TIME OF PRINTING



Stefano LoPriore
Managing Director
Hyris, Ltd.
Italy

BIO

NOT AVAILABLE AT THE TIME OF PRINTING

Presentation

New Approaches in Genetic Testing and Data Management for Botanicals: A roadmap for viable genomic identification tests for QC applications

Tuesday, 8/21/2018, 1:00pm

Abstract

In the past years, the use of traditional medicine has increased globally, leading to a booming herbal medicine and dietary supplement industry. The increased popularity of herbal products has led to a rise in demand for botanical raw materials. Accurate identification of medicinal herbs is a legal requirement and prerequisite for delivering a quality product that meets consumer expectations. Identification methods include botanical taxonomy, macroscopic and microscopic examination, and chemical methods. Advances in the identification of biological species using DNA-based techniques have led to the development of a DNA marker based platform for authentication of plant materials providing additional tools for the authentication of herbs. DNA barcoding has been proposed as a means to identify herbal ingredients and to detect adulteration. However, general barcoding techniques have been shown to provide mixed results with regard to data accuracy. Newer technologies, such as mini-barcoding, or next-generation sequencing (NGS) have been proposed to overcome some of the issues observed in traditional barcoding. However, at the end of the day, each of these methods will have to be evaluated for its fitness to provide the correct result for the application in the quality control laboratories.

We are presenting the features of the Hyris platform (bCUBE), which offers the unique capability to perform genetic analysis of biological samples in any kind of setting. It incorporates all the needed hardware, software and reagents (bKITS) that can be used as a fully portable testing laboratory to provide highly accurate results, reducing the time and costs associated with traditional methods. Moreover, it can be controlled by bAPP, a dedicated mobile app that provides a complete, intuitive, user-friendly interface. This mobile embodiment of mainstream DNA analysis technology allows to perform genetic analysis in a standard quality control laboratory with simple protocols. Based on this technology Indena, Hyris and NHP Research Alliance have signed a Strategic Cooperation agreement for the joint development of DNA authentication test kits for Botanicals and related Natural Health Products.

Description of the Hyris platform and details of the cooperation will be discussed in the presentation along with some case studies. bCUBE® is a miniaturized, state-of-the-art device for the analysis of nucleic acids. It allows user to run both temperature cycles and isothermal analysis, enabling a wide array of DNA and RNA detection methods such as qPCR, isothermal amplifications etc. Multiwavelength signal acquisition, fast processing and wireless connectivity with its smartphone based control panel are all integrated. Hyris employs customized cartridges that can be used to analyze multiple sample at once. bKITS are reagent sets used to analyze a specific genetic sequence. They can be used e.g. for the detection of a pathogen in a biological sample, the correct identification of the nature of the sample and a large number of other purposes.



Zhengfei Lu, Ph.D.

Analytical Scientist II
Herbalife
California, USA

BIO

Dr. Zhengfei Lu is an Analytical Scientist in the Center of Excellence (COE) Quality Control Laboratory at Herbalife Nutrition. With his efforts, the Herbalife Nutrition COE Laboratory has developed and validated various DNA methods for the authentication of both raw botanical components and processed botanical extracts. His work using adapter-ligation and PCR amplification to characterize and visualize small fragments of DNA in processed botanical materials was published in Food Chemistry. In July 2018, the two-tiered DNA barcoding method for raw botanical identification developed and validated by his team became ISO 17025 accredited. In an effort to promote the application of DNA-based test methods in dietary supplement industry, Zhengfei is also representing Herbalife by co-chairing the United States Pharmacopeia (USP) DNA methods for botanical identification project team. Prior to joining Herbalife, Zhengfei launched his career as a clinical genomic scientist at Vantari Genetics. Zhengfei has published over 10 articles in prestigious peer-reviewed journals including Food Chemistry, Blood, and DNA Repair. Zhengfei holds a Ph.D. in Experimental Pathology from the University of Southern California and received a Medical degree from Peking University.

Presentation

Methods to Characterize Highly Processed Materials

Tuesday, 8/21/2018, 10:30am

Abstract

DNA-based methods have been gaining recognition as a tool for botanical authentication in herbal medicine; however, their application in processed botanical materials is challenging due to the low quality and quantity of DNA left after extensive manufacturing processes. The low amount of DNA recovered from processed materials, especially extracts, is “invisible” by current technology, which has casted doubt on the presence of amplifiable botanical DNA. A method using adapter-ligation and PCR amplification was successfully applied to visualize the “invisible” DNA in botanical extracts. The size of the “invisible” DNA fragments in botanical extracts was around 20-220 bp compared to fragments of around 600 bp for the more easily visualized DNA in botanical powders. This technique is the first to allow characterization and visualization of small fragments of DNA in processed botanical materials and will provide key information to guide the development of appropriate DNA-based botanical authentication methods in the future.



Robin Marles, Ph.D.

Chair: USP Botanical Dietary Supplements and Herbal Medicines Expert Committee

BIO

Robin J. Marles PhD volunteers as Chair of the USP Botanical Dietary Supplements and Herbal Medicines Expert Committee. His paid job is as the Senior Scientific Advisor, Bureau of Nutritional Sciences, Food Directorate, in Canada's Department of Health. Dr. Marles advises on safety, quality and claims for botanical, bioactive and nutrient ingredients of foods including novel, fortified, and supplemented foods and additives. Previously, at Health Canada's Natural Health Products Directorate (2003–2013), he was a regulator of natural health products (botanicals, isolates, vitamins, minerals, amino acids, fatty acids, and probiotics). He served as Director of Research and Science; Manager for safety, efficacy and quality assessment for product licensing; Director of NHP clinical trial authorizations, health risk assessments and monograph development; and Senior Science Advisor for NHP regulatory development and policy. At Brandon University, Manitoba (1992–2002) he was a tenured Associate Professor teaching biology, botany, ethnobotany, phytochemistry, and Continuing Education courses on herbal medicines. He served eight years as an Associate Editor of the journal *Pharmaceutical Biology*. His research and scientific publications deal with: safety of nutrient supplements; food health claims; botanical ingredient quality, safety, and efficacy as antidiabetic, antiviral and antimigraine bioactives; quantitative structure-activity relationship analyses and plant-derived drug discovery; indigenous people's traditional foods and medicines, and sustainable development of alternate crops and non-timber forest products. He did two postdoctoral fellowships: on plant-derived photodynamic pesticides (U. Ottawa 1988–1990) and on migraine prophylactic herbal drug standardization (U. Ottawa and Health & Welfare Canada's Bureau of Drug Research 1990–1992). His PhD in pharmacognosy (U. Illinois at Chicago, 1988) involved field research on Amazonian ethnopharmacology and laboratory research on isolation and structure elucidation of bioactives, anticancer bioassays, coumarin adulteration of vanilla extracts, and plasticizer contamination of herbal extracts. His MSc in biology (U. Saskatchewan, 1984) involved research on Canadian boreal ethnobotany. His BSc in biology (U. Victoria, 1977) included research on ethnopharmacology. During and after his undergraduate studies he worked as a wildlife biologist, forestry technician and park nature interpreter.

Session Chair:

Session III – Potential Solutions

Tuesday, 8/21/2018, 3:00pm



Jesse Miller, Ph.D.
Director, Applied Research Center
NSF AuthenTechnologies
Michigan, USA

BIO

Jesse Miller is the Director of Applied Research at NSF International. He manages global R+D for the organization with specializations in Front End Innovation, Genomics, Clinical HAI Reduction, Toxicological Risk Assessments and Bioanalytical Method Development.

Presentation

Next-Generation Sequencing as a QA Tool
Tuesday, 8/21/2018, 1:00pm

Abstract

Next Generation Sequencing (NGS) is taking center stage in the biological sciences as a discovery and analysis technique. It may also be used to validate and verify your supply chain inputs. In this talk, we discuss the use of NGS for sample identification and adulteration detection, examine the quality controls that are necessary for creation of sound data and discuss some of the gaps in our current knowledge base that need to be built upon



Steve Newmaster, Ph.D.
Director, NHP Research Alliance
University of Guelph
Canada

BIO

Dr Newmaster is a botany and genetics professor specializing in genomics, plant diversity and molecular diagnostic identification systems with more than 120 publications including botanical field guides, book chapters and numerous Journal articles on botany including: new species discovery, ethnobotany, plant classification, medicinal plants, DNA barcoding, and advanced DNA-based plant identification biotechnology. His research program has generated over \$20 million dollars in research. Currently he is conducting leading international research on molecular diagnostic tools for NHP authentication, genomic diversity in plants, medicinal plants and natural health products. His R&D has resulted in the development of policy on biodiversity, and International trade of herbal products including product authentication certification within the food and natural product industry within Canada, USA, Europe and Asia. He advises on the authentication of herbal products to regulators and is developing new QA/QC industry standards for testing natural ingredient authenticity. He is has developed biotechnology for rapid plant identification and is one of the founders for the world's first international certification program (TRU-ID) of natural ingredients registered in Canada, USA and the E.U. Including 28 countries.

Presentation

Guidelines for Assembling Biological Reference Materials (RM) and Validation of Methods for Molecular Diagnostic Identification of Botanicals

Tuesday, 8/21/2018, 1:00pm

Abstract

NOT AVAILABLE AT THE TIME OF PRINTING



Roberto Pace, Ph.D.
Indena QC Corporate Director
Indena
Italy

BIO

Roberto Pace has been dealing with analytical research in pharmaceutical industries since 1990. In this environment, he gained considerable experience in the identification and analysis of natural products, herbal remedies and food supplements, being involved from early discovery to the market of a number of drugs, health foods and cosmetics. He is involved in the analytical study of several major classes of bioactive natural products, especially polyphenols, taxoids and cochicine derivatives along with the identification and analysis of active principles derived from plants for pharmaceuticals, health foods and cosmetics. He is coordinator of inter-laboratories trials with European Pharmacopoeia and AOAC International organisations and assistant in the monographs editing. He is a collaborator of United States Pharmacopeia for monograph revision and for definition and qualification of reference materials. He is currently involved, as responsible of Quality Control Laboratories of the Indena Groups, located in Italy, France and India, in the organisation and harmonisation of the analytical activities of the Indena SpA, an Italian Company leader in the manufacturing of herbal products and preparations.

Presentation

New Approaches in Genetic Testing and Data Management for Botanicals: A roadmap for viable genomic identification tests for QC applications
Tuesday, 8/21/2018, 1:00pm

Abstract

In the past years, the use of traditional medicine has increased globally, leading to a booming herbal medicine and dietary supplement industry. The increased popularity of herbal products has led to a rise in demand for botanical raw materials. Accurate identification of medicinal herbs is a legal requirement and prerequisite for delivering a quality product that meets consumer expectations. Identification methods include botanical taxonomy, macroscopic and microscopic examination, and chemical methods. Advances in the identification of biological species using DNA-based techniques have led to the development of a DNA marker based platform for authentication of plant materials providing additional tools for the authentication of herbs. DNA barcoding has been proposed as a means to identify herbal ingredients and to detect adulteration. However, general barcoding techniques have been shown to provide mixed results with regard to data accuracy. Newer technologies, such as mini-barcoding, or next-generation sequencing (NGS) have been proposed to overcome some of the issues observed in traditional barcoding. However, at the end of the day, each of these methods will have to be evaluated for its fitness to provide the correct result for the application in the quality control laboratories.

We are presenting the features of the Hyris platform (bCUBE), which offers the unique capability to perform genetic analysis of biological samples in any kind of setting. It incorporates all the needed hardware, software and reagents (bKITS) that can be used as a fully portable testing laboratory to provide highly accurate results, reducing the time and costs associated with traditional methods. Moreover, it can be controlled by bAPP, a dedicated mobile app that provides a complete, intuitive, user-friendly interface. This mobile embodiment of mainstream DNA analysis technology allows to perform genetic analysis in a standard quality control laboratory with simple protocols. Based on this technology Indena, Hyris and NHP Research Alliance have signed a Strategic Cooperation agreement for the joint development of DNA authentication test kits for Botanicals and related Natural Health Products. Description of the Hyris platform and details of the cooperation will be discussed in the presentation along with some case studies. bCUBE® is a miniaturized, state-of-the-art device for the analysis of nucleic acids. It allows user to run both temperature cycles and isothermal analysis, enabling a wide array of DNA and RNA detection methods such as qPCR, isothermal amplifications etc. Multiwavelength signal acquisition, fast processing and wireless connectivity with its smartphone based control panel are all integrated. Hyris employs customized cartridges that can be used to analyze multiple sample at once. bKITS are reagent sets used to analyze a specific genetic sequence. They can be used e.g. for the detection of a pathogen in a biological sample, the correct identification of the nature of the sample and a large number of other purposes.



Caroline Puente-Lelievre, Ph.D.
ORISE postdoctoral fellow
U.S. Food and Drug Administration
Silver Spring, MD

BIO

NOT AVAILABLE AT THE TIME OF PRINTING

Presentation

Development and Validation of Real-time PCR Assays for Allergen Detection: Examples in Peanut and Tree Nuts
Tuesday, 8/21/2018, 10:30am

Abstract

NOT AVAILABLE AT THE TIME OF PRINTING



Catherine (Kate) Rimmer, Ph.D.

Dietary Supplement Reference Material Program Manager and One of the founding members of the NIST/NIH-ODS Health Assessment Quality Assurance Program
National Institute of Standards and Technology
Maryland, USA

BIO

Kate Rimmer received her Ph.D. in analytical chemistry from Florida State University and completed a National Research Council postdoctoral fellowship at the National Institute of Standards and Technology (NIST). She is currently the dietary supplement reference material program manager and one of the founding members of the NIST/NIH-ODS Health Assessment Quality Assurance Program. In addition she has contributed to the certification measurements of many food and supplement Standard Reference Materials.

Presentation

Botanical Authenticity Interlaboratory Studies

Wednesday, 8/22/2018, 8:45am

Abstract

In the Fall of 2018, NIST and AHPA initiated an interlaboratory study to investigate how fit for purpose different techniques are for the determination of authenticity of botanical products. A series of authentic materials were collected by AHPA and then gravimetrically adulterated with *Sophora japonica* fruit extract. Ground *Ginkgo biloba* leaf materials with different preparations were selected and extracts prepared with different solvents were used. The authentic samples were sent without adulteration and adulterated at 3 %, 5 %, and 7 % *Sophora japonica* fruit extract and sent to a series of laboratories. Twenty eight sets of results were sent back and the samples were analyzed by genomic methods, chromatographic methods, and microscopy. In this presentation we will discuss the study design and the current data interpretation.



Barbara Robbertse, Ph.D.

National Center for Biotechnology Information,
National Library of Medicine, National Institutes of Health
Maryland, USA

BIO

Dr. Barbara Robbertse has 15 years of experience in fungal research related to plant pathology, fungal genetics and genomics. In 2009 she joined NCBI and has been doing value-added biocuration involving fungal genomes, proteins and barcoding genes with the focus on verifying sequence-name associations.

Presentation

Database of Molecular Sequences: GenBank and RefSeq

Tuesday, 8/21/2018, 3:00pm

Abstract

GenBank is the NIH DNA database of public sequences submitted by researchers across the globe. In addition, GenBank is part of the International Nucleotide Sequence Database Collaboration, with the DNA DataBank of Japan (DDBJ), and the European Nucleotide Archive (ENA). Each organization is responsible for vetting the accuracy of the data submitted to it, and the three organizations exchange their public data daily. Sequences submitted to GenBank undergo an array of basic validations, and sequences that fail those validations are not accepted into the database. GenBank is an archival database, containing data that was submitted more than 30 years ago and GenBank has worked to improve its validations over the years, so there are problematic sequences present. We will discuss GenBank's work to identify contamination in and misidentification of submitted genomes. Another resource at NCBI is the Reference Sequence (RefSeq) collection; it provides a comprehensive, integrated, non-redundant, well-annotated set of sequences and other resources for researchers. We will discuss the RefSeq Fungi resources, including the Targeted Loci Project of ribosomal RNAs and Internal Transcribed Sequences (ITS).



Pawel Rudzinski, MS
Vice President - Quality
The Nature's Bounty Co.
New York, USA

BIO

Pawel joined The Nature's Bounty Company in 2014, promoted in 2017 to the role of Vice President of Global Quality. In this role, he is responsible for end to end Global Quality, starting from specifications creation through quality in operations, compliance, method development, corporate systems to vendor and CMO management worldwide.

Prior to joining The Nature's Bounty Company, he was leading Quality for Reckitt Benckiser's in Europe and North America. During his career with Reckitt, he worked on various product categories such as food, OTC and medical devices. He also held several positions in Quality, R&D, packaging development and operations at Reckitt Benckiser. Pawel developed several systems and processes for global vendor qualification and assurance, consumer feedback, specifications management and R&D technical transfer.

He started his career with Danone in Europe (Dannon) over 18 years ago, where he had the opportunity to execute multiple technical roles in manufacturing and regional Quality.

Pawel holds a Master's Degree in physical and inorganic chemistry from Warsaw University. He is certified ISO 9001, 14001, 17025, 14385, HARPC and cGMP auditor. Proud holder of Black Belts in Six Sigma and Engineering Statistics. He has strong background in Quality Systems and Quality Engineering.

Pawel is a Quality Professional with diverse experience in Quality, Regulatory, and R&D across FMCG, food, OTC and dietary supplements industries. Expert in Quality Assurance and laboratory operations management.

Presentation

Industry Perspectives

Tuesday, 8/21/2018, 10:30am

Abstract

This presentation provides Industry – end user perspective, on the use of DNA techniques for botanical identification purpose. Current Good Manufacturing Practice (cGMP) for Dietary Supplements calls for Raw Material, In-Process, and Finished Product Specifications to address all of the categories of identity, purity, strength, composition, and potential contaminants (CFR 111.70). Applicable regulations require manufacturers to conduct at least one appropriate test to confirm identity of each incoming dietary ingredient before being used. Testing performed on ingredients or finished product must be scientifically valid. FDA does not use DNA sequencing by itself to analyze herbal extract for phytochemicals. Any out of specification result related to identification testing, whether generated by chemical method or DNA technique, must be investigated. For that purpose, appropriate and documented, out of specification investigation process must be established. While such process for chemical methods is broadly discussed and published in the industry, there is still much to do, to established OOS investigation standards for DNA techniques. DNA technique must be validated prior to use for identification of botanical ingredient purpose. Specificity is the characteristic that at minimum must be evaluated for the purpose of validation. While DNA techniques cannot identify targeted phytonutrient and quantify it, they can help in identification of herbal species. Both, chemical and DNA testing, are equally important in the war against adulteration.



Nandakumara (Nandu) Sarma, Ph.D.

US Pharmacopeia (USP)
Maryland, USA

BIO

Dr. Nandakumara (Nandu) Sarma is the Director for the Dietary Supplements and Herbal Medicines program at US Pharmacopeia (USP) responsible for strategy and external stakeholder engagement for new and innovative projects, working with global stakeholders and expert volunteers in the development of quality standards (monographs and general chapters) for dietary supplements and herbal medicines that are published in the USP *Dietary Supplements Compendium* (<http://www.usp.org/dietary-supplements/overview>) and the *Herbal Medicine Compendium* (<http://hmc.usp.org/>).

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 includes isolation and analysis of active components of botanicals 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

Learning from the USP Project Team on Botanical Library for DNA-based Identification: Use of Orthogonal Test Methods

Wednesday, 8/22/2018, 8:45am

Abstract

Quality control for botanicals requires manufacturers to use scientifically-valid methods to establish specifications for the identity. The inherent complexities with botanicals demand use of orthogonal methods that are fit for purpose and can discriminate closely related species. Suitability of analytical test methods varies depending on the matrix of the analyte, the analytical procedure used and the intent for the analysis. The sensitivity and specificity of detection are major attributes of DNA-based methods that can distinguish closely related or morphologically similar species. The presentation will discuss the current compendial *United States Pharmacopeia* (USP) botanical identification methods based on chromatographic (HPTLC / HPLC) and botanical (morphological / microscopy) methods, and the ongoing collaboration with a Project Team to investigate the species-specific DNA-based methods. Pilot studies on species-specific test methods using authenticated and commercial samples of *Panax ginseng*, *P. quinquefolius*, and *P. notoginseng* demonstrate discriminatory capability of the methods. Use of multiple identification methods have also called for out-of-specification investigation protocols in order to address false negative tests due to matrix (such as red ginseng or extracts) which impact DNA extraction or false positives due to contamination. The studies have shown the value of orthogonal methods for cross validation of the identification methods, and demonstrate that orthogonal tests increase confidence on identity based on unique attributes.



P.C. Shaw, Ph.D.

The Chinese University of Hong Kong
Hong Kong

BIO

I am now Professor and Director of Biochemistry Programme of School of Life Sciences of the Chinese University, Cabinet Member of the Chung Chi College and Master of the Postgraduate Halls. I have associated with this university for more than 30 years, first as a student at the Biology Department and then as an academic staff at the Biochemistry Department, with a few years off in between to pursue my Ph.D degree and postdoctoral training at the Imperial College, London, UK.

My training is in molecular biology and biotechnology. I have been teaching topics in these areas for several years. I have broad interest in scientific research, its applications and ethical issues and aim at promoting the advancement of science and technology in Hong Kong and China. At present, I also serve as Chairman of the Hong Kong Bioethics Association.

During my limited spare time, I still keep the hobbies of collecting stamps, growing orchids, reading, playing tennis and hiking. Life is busy!

Presentation

Application of Molecular Techniques to Authenticate Herbal Medicine Granules
Tuesday, 8/21/2018, 3:00pm

Abstract

NOT AVAILABLE AT THE TIME OF PRINTING



Jeremy Stewart, Ph.D.

VP Scientific Affairs
Gaia Herbs, Inc
North Carolina

BIO

Jeremy Stewart received a B.S. in chemistry from North Carolina State University in 1999 and a Ph.D. in Pharmacognosy from the University of Mississippi in 2005. He has experience working in the chemical industry (BASF 1998-1999), academia as a post-doctorate chemist (2005, University of Mississippi), in government (Environmental Protection Agency 2008-2010), and in the dietary supplement industry (Gaia Herbs 2005-2008, 2010-present). His current position is Chief Scientist and Vice President of Scientific Affairs.

Session Chair

Session IV – Need for Standards
Wednesday, 8/22/2018, 8:45am



Natascha Techen, Ph.D.

University of Mississippi
Mississippi, USA

BIO

A native of Hamburg, Germany, Dr. Natascha Techen received her BS, MS and Ph.D in Plant Molecular Biology at the University of Hamburg, Germany. Dr. Natascha Techen joined Dr. Ikhlas A Khan's team in 2002, where she is working on the identification of genomic markers, also known as DNA-barcoding, that can help with the authentication of plant material/dietary supplements and its adulterations by using various molecular methods. In addition her research has helped with the genetic improvement of crops, medicinal or ornamental plants for higher yield and nutrient value, disease and pest tolerance, non-invasiveness, and ornamental traits.

Presentation

Selection of Molecular Markers to Distinguish Closely-related Species

Tuesday, 8/21/2018, 3:00pm

Abstract

Some members of a plant family may be used as medicinal plants in dietary supplements and homeopathic medicines or as spices. Other members may be dangerous and can be an irritant or even poisonous. It is therefore very important to correctly identify the species present in any plant material samples to ensure product safety. Species identification can be done relatively easy with universal oligonucleotides when single-species plant material is present. One disadvantage of universal primers is that they may not be very helpful to detect low amounts of adulterating material. Using species-specific primers, aiming to detect a specific adulterating plant material, requires some knowledge about what adulterating plant may be present. Consequently, unexpected adulterants may go undetected. An approach is presented using primers that were designed to amplify from a broader variety of plant material than just from single-species, but at the same time are not totally universal for all Angiosperms. The presented primers were helpful for species identification of single species plant material representing ten genera, and were also useful to detect Ranunculaceae DNA present in a mix of eleven non-Ranunculaceae DNAs.

The size of these generated PCR products is approximately 150-200 bp, which is a desired mini-barcode size to be used for damaged/fragmented DNA often found in dietary supplements. The designed primers were helpful for detecting Ranunculaceae DNA present in a variety of dietary supplements (raw plant material, watery solutions, oil, capsules) and homeopathic medicines (pellets).



Ning Zhang, Ph.D.
US Pharmacopeia (USP)
Maryland, USA

BIO

Dr. Ning Zhang got his Ph.D degree in 2009 in the Chinese Academy of Sciences, Beijing. Then he started his postdoctoral position in the Fudan University, Shanghai, to study the phylogeny of flowering plant using low-copy nuclear genes. In 2012, he moved to the Penn State University to continue the phylogenomic project using transcriptomic data. In 2013, he was awarded the Peter Buck Fellowship by the Smithsonian Institution, and studied the molecular mechanisms of the origin and evolution of tendril in the grape family. In October, 2015, he worked with FDA as an ORISE fellow, he assembled chloroplast genomes using whole genome sequencing data, for > 100 plant founded in foods, dietary supplements, toxin producers, common contaminants, and adulterants, and their close relatives. From May 2018, he works with the USP in the Research and Innovation department, and aims to develop species-specific primers to identify species for commonly used botanical dietary supplements, like ginseng, black cohosh, Echinacea, Ginkgo et al.

Presentation

Learning from the USP Project Team on Botanical Library for DNA-based Identification: Use of Orthogonal Test Methods

Wednesday, 8/22/2018, 8:45am

Abstract

Quality control for botanicals requires manufacturers to use scientifically-valid methods to establish specifications for the identity. The inherent complexities with botanicals demand use of orthogonal methods that are fit for purpose and can discriminate closely related species. Suitability of analytical test methods varies depending on the matrix of the analyte, the analytical procedure used and the intent for the analysis. The sensitivity and specificity of detection are major attributes of DNA-based methods that can distinguish closely related or morphologically similar species. The presentation will discuss the current compendial *United States Pharmacopeia* (USP) botanical identification methods based on chromatographic (HPTLC / HPLC) and botanical (morphological / microscopy) methods, and the ongoing collaboration with a Project Team to investigate the species-specific DNA-based methods. Pilot studies on species-specific test methods using authenticated and commercial samples of *Panax ginseng*, *P. quinquefolius*, and *P. notoginseng* demonstrate discriminatory capability of the methods. Use of multiple identification methods have also called for out-of-specification investigation protocols in order to address false negative tests due to matrix (such as red ginseng or extracts) which impact DNA extraction or false positives due to contamination. The studies have shown the value of orthogonal methods for cross validation of the identification methods, and demonstrate that orthogonal tests increase confidence on identity based on unique attributes.