# **USP Workshops and Courses**

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

August 21-22, 2018



## ~FINAL AGENDA~



Day One: Tuesday, August 21, 2018

8:00 AM Registration & Coffee

8:30 AM USP Welcome and Introduction of Keynote Speakers

Gabriel Giancaspro, PhD., VP, Science-DS & Herbal Medicines, USP

8:45 AM Keynotes

Damon Little, PhD., New York Botanical Gardens

Caroline Howard, PhD., British Pharmacopeia - National Institute for Biological Standards and Control

10:00 AM Networking Morning Break

10:30 AM Session I – Industry Experiences and Regulatory Approaches

Session Chair: Holly Johnson, PhD., American Herbal Products Association

**Industry Perspectives** 

Pawel Rudzinski, Nature's Bounty

**Methods to Characterize Highly Processed Materials** 

Zhengfei Lu, PhD., Herbalife

Genomic Approaches Used by FDA to Investigate Botanicals

Sara Handy, PhD., FDA

**Development and Validation of Real-time PCR Assays for Allergen Detection:** 

**Examples in Peanut and Tree Nuts** 

Caroline Puente-Lelievre. PhD., FDA

12:00 PM Networking Lunch

1:00 PM Session II – Methodologies

Session Chair: Sara Handy, PhD., FDA

Guidelines for Assembling Biological Reference Materials (RM) and Validation of Methods

for Molecular Diagnostic Identification of Botanicals

Steven Newmaster, PhD., University of Guelph

Quantification of Type I and Type II Errors in Genomic Assessment of Botanical Authentication

David Erickson, PhD., DNA4Technologies

Next-Generation Sequencing as a QA Tool

Jesse Miller, PhD., NSF Authen Technologies

New Approaches in Genetic Testing and Data Management for Botanicals:

A roadmap for viable genomic identification tests for QC applications.

Roberto Pace, PhD., Indena and Stefano LoPriore, PhD., Hyris

2:30 PM Networking Afternoon Break

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#### 3:00 PM Session III – Potential Solutions

Session Chair: Robin Marles, PhD., Chair, USP Botanical Dietary Supplements & Herbal Medicines Expert Committee

# Globally Recognized Definition of Voucher Specimen

Wendy Applequist, PhD., Missouri Botanical Garden

#### Database of Molecular Sequences: GenBank and RefSeq

Karen Clark, PhD. and Barbara Robbertse, PhD, NCBI/NLM/National Institutes of Health

# Selection of Molecular Markers to Distinguish Closely-related Species

Natascha Techen, PhD., University of Mississippi

## Application of Molecular Techniques to Authenticate Herbal Medicine Granules

P-C. Shaw, PhD., The Chinese University of Hong Kong

# 4:30 PM Discussion, Q&A / Summary

Session Chair: Joseph Betz, PhD., Member, USP Non-Botanical Dietary Supplements Expert Committee

5:00 PM Adjourn

# Day Two: Wednesday, August 22, 2018

8:00 AM Registration & Coffee

#### 8:30 AM USP Welcome

Gabriel Giancaspro, PhD., VP, Science-DS & Herbal Medicines, USP

# 8:45 AM Session IV – Need for Standards

Session Chair: Jeremy Stewart, PhD., Chair, USP Botanical Library Project Team

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

Nandu Sarma, PhD., and Ning Zhang, PhD., USP

#### **Botanical Authenticity Interlaboratory Studies**

Catherine (Kate) Rimmer, PhD., NIST and Holly Johnson, PhD., AHPA

## **Multitude of Methods: Guidelines to Compare Methods**

Robert Hanner, PhD., University of Guelph

#### Steps Needed for Actionable DNA Data: Method Specificity & Certificates of Analysis

Tyler Daniels, Thorne Research

# 10:00 AM Networking Morning Break

# 10:30 AM Panel Discussion – Application of Standards

Moderator: Michael Ambrose, PhD., USP

## 12:00 PM Workshop Wrap-up & Boxed Lunch