



# 13<sup>th</sup> Annual Oxford International Conference On the Science and Regulation of Botanicals

## DAY 1 – TUESDAY, APRIL 15

8:00 – 9:00 a.m. Open onsite registration – Oxford Conference Center (OCC) Lobby

9:00 – 10:00 a.m. Welcome and introductory remarks (OCC) Auditorium

- **Larry A. Walker, PhD**, Director, NCNPR
- **David D. Allen, RPh, PhD**, Dean of the School of Pharmacy, Executive Director of the Research Institute of Pharmaceutical Sciences and Professor of Pharmacology
- **Alice M. Clark, PhD**, Vice-Chancellor for Research and Sponsored Programs, Frederick A.P. Barnard Distinguished Professor
- **Ikhlas Khan, PhD**, Director UM-FDA Center of Excellence

## INAUGURAL ADDRESS

- **Daniel Fabricant, PhD**, Director, Division of Dietary Supplement Programs, ONLDS/CFSAN/FDA

10:00 – 10:30 a.m. **BREAK**

10:30 a.m. – 12:00 p.m. **SESSION 1: *Two Perspectives on the Safety, Science & Quality of Botanicals 20 Years after DSHEA***  
**Moderator and Session Chair: Mark Blumenthal**

- **Loren D. Israelsen**, President, United Natural Products Alliance
- **Daniel Fabricant, PhD**, Director, Division of Dietary Supplement Programs, ONLDS/CFSAN/FDA

12:00 – 12:15 p.m. **CONFERENCE PHOTOGRAPH**  
Meet at OCC side patio across from Cedar Room Dining Hall

12:15 – 1:00 p.m. **LUNCH** – OCC Cedar Room Dining Hall

1:00 – 2:30 p.m. **SESSION 2: *Update and Future Perspectives from the Regulator***  
**Moderator and Session Chair: Daniel Fabricant, PhD**

- **Angela F. Pope, PhD**, Consumer Safety Officer, GMP Team, FDA  
“Top GMP Inspection Observations and Concerns: Why Do These Problems Persist?”
- **Cara Welch, PhD**, Regulatory Special Assistant, Division of Dietary Supplement Programs, ONLDS/CFSAN/FDA  
“AERs, Ingredient Safety, and Labeling: An Update”
- **Charles Wu, PhD**, Pharmacologist, FDA  
“Development of botanical new drugs - US FDA's regulatory perspectives”



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## DAY 1 (cont'd)

2:30 – 3:00 p.m.

**Panel Discussion**

3:00 – 3:30 p.m.

**BREAK**

3:30 – 5:00 p.m.

**SESSION 3: *Standards, Methods and Key Priorities***  
**Moderator and Session Chair: De-an Guo, PhD**

- **Joseph M. Betz, PhD**, Director, Dietary Supplement Methods and Reference Materials Program, Office of Dietary Supplements, National Institutes of Health  
“The NIH Office of Dietary Supplements: A Twenty-year retrospective”
- **Hai-nan Wang, MD**, Director, Division of Traditional Chinese Medicine, Department of Drug and Cosmetic Registration, China Food and Drug Administration.  
“Current Regulatory Status of TCM and Natural Medicinal Products of China”
- **Zhong-zhi Qian, PhD**, Department of Administrative Affairs, Chinese Pharmacopoeia Commission  
“Development of Pharmacopoeial standards in China”

5:30 p.m.

**RECEPTION / DINNER FOR FACULTY & ALL ATTENDEES**

## DAY 2 – WEDNESDAY, APRIL 16

8:30 – 10:00 a.m.

**SESSION 4: *Creating a Corporate Culture of Compliance***  
**Moderator and Session Chair: Rick Kingston, PharmD.**

- **Dan Marsman, DVM, PhD**, Section Head, Product Safety and Regulatory Affairs, Procter & Gamble Company  
“Dietary Supplement Product Stewardship and Regulatory Compliance – a Corporate View”
- **Frank Jaksch**, CEO, ChromaDex, Inc., Irvine, CA, USA  
“Testing to a Standard: How to Stop Lab Shopping”
- **Jay Udani, MD**, CEO and Medical Director, Medicus Research  
“How Will New FDA Guidelines Regarding INDs for Research Studies on Functional Foods and Dietary Supplements Affect Claims Substantiation, for the Natural Products Industry?”



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## **DAY 2 (cont'd)**

10:00 – 10:30 a.m.

**BREAK**

10:30 a.m. – 12:00 p.m.

**SESSION 5: *Collaborations for Safety, Postmarket Surveillance and Regulatory Reporting***

**Moderator and Session Chair: Rick Kingston, PharmD.**

- **Rick Kingston, PharmD**, President, Regulatory and Scientific Affairs, Safety Call International, and Clinical Professor of Pharmacy, University of Minnesota  
“Postmarket Surveillance: Integrating the Needs of Industry, Academia, Government and Consumers”
- **Victor Navarro, MD**, Chairman, Division of Hepatology; Medical Director, Liver Transplantation, Einstein Medical Center, Philadelphia  
“Challenges in Investigating Potential Cases of Botanical Induced Liver Damage: A Clinician’s View”
- **Pieter Cohen, MD**, General Internist, Cambridge Health Alliance; Assistant Professor of Medicine, Harvard Medical School  
“Detecting dangerous supplements: is Med Watch enough?”

12:00 – 1:00 p.m.

**LUNCH – OCC Cedar Room Dining Hall**

1:00 – 2:30 p.m.

**SESSION 6: *Communicating Safety to Consumers***

**Moderator and Session Chair: Bill Gurley, PhD**

- **Andrew Shao, PhD**, VP, Global Product Science & Safety, Herbalife  
“Communications to the end-user: Informing decisions for notice, advisory and warning statements on dietary supplements”
- **Mark Blumenthal**, Executive Director, American Botanical Council  
“Quality Considerations in the Global Herb Market: Accidental and Intentional Adulteration of Botanical Raw Materials & Extracts”
- **Chris Xing, PhD**, Associate Professor, Department of Medicinal Chemistry, College of Pharmacy, University of Minnesota  
“Kava’s cancer prevention potential and hepatotoxic risk – what do we know and what shall we do?”

2:30 – 3:30 p.m.

**BREAK**

3:30 – 5:00 p.m.

**Lawn Games and BBQ**



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## DAY 3, THURSDAY, APRIL 17

8:30 – 10:10 a.m.

### **SESSION 7: International Perspective on the Development of Botanicals**

**Moderator and Session Chair: Larry Walker, PhD**

- **De-an Guo, PhD**, Shanghai Research Center for TCM Modernization, Shanghai Institute of Materia Medica, Chinese Academy of Sciences, Shanghai 201203, P.R. China  
“Progress made in development of Chinese traditional Medicine”
- **Yuan Shiun Chang, PhD**, Professor, China Medical University, Taiwan, Republic of China  
“Regulation and Quality Control of Chinese Medicines in Taiwan”
- **Ed Fletcher**, Chief Operating Officer, Strategic Sourcing, Inc.  
“Looking at the Industry DSHEA Built”
- **Ghulam Nabi Qazi, PhD**, Vice Chancellor, Jamia Hamdard (Hamdard University)  
“Current Status of Indian Systems of Medicine”

10:10 – 10:30 a.m.

**BREAK**

10:30 a.m. – 12:10 p.m.

### **SESSION 8: *Modern Analytical Techniques***

**Moderator and Session Chair: Joseph M. Betz, PhD**

- **Fabien Scorza**, Sales & Marketing Manager, CAMAG Scientific Inc.
- **Kate Yu**, Senior Manager of Business Operations, QC & Manufacture, Pharmaceutical Life Science, Waters Corporation
- **Steven M. Royce**, Americas Food Segment Manager, Agilent Technologies, Life Sciences & Chemical Analysis.

12:10 – 1:00 p.m.

**LUNCH – OCC Cedar Room Dining Hall**



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## **DAY 3 (cont'd)**

1:00 – 2:30 p.m.

**SESSION 9: *The Media's Role in Educating Industry and the Public***

**Moderator and Session Chair: Frank Lampe**

- **Malcom Spicer**, Managing Editor, The Tan Sheet
- **Marc Brush**, Editor in Chief, Nutrition Business Journal
- **Mike O'Keefe**, New York Daily News

2:30 – 3:00 p.m.

**BREAK**

3:00 – 4:00 p.m.

**INDUSTRY REACTION PANEL**

**Moderator and Session Chair: Loren D. Israelsen, JD**

- **Maged Sharaf**, Chief Science Officer, American Herbal Products Association
- **Steve Mister**, President and CEO, Council for Responsible Nutrition
- **Andrew T. O'Hare (Andy)**, CAE, Sr. VP Government Affairs/COO, Natural Products Association

4:00 p.m. –5:00 p.m.

**Afternoon tour of NCNPR facilities**

6:00 p.m.

**Banquet for all faculty and attendees**