

S E M I N A R P R O G R A M

Analytical Methods  
are the "GPS System"  
that guide GMPs and  
quality management for  
dietary supplements

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# Analytical Methods

for Dietary Supplements:

**The Critical Link for GMPs & Analytical Standards**



**April 22, 2005**  
Huntsman Cancer Institute  
Salt Lake City



# Analytical Methods for Dietary Supplements:

## The Critical Link for GMP Compliance

**S**ection 9 of DSHEA states: “...The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and **may not impose standards for which there is no current and generally available analytical methodology.** No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation...”

The linch pin to full and effective GMP regulations and quality management for dietary supplements is analytical methods. Yet few standardized, validated analytical methods exist for dietary supplements, whether for raw materials or finished goods. The FDA will soon publish a final regulation for dietary supplements, yet absent generally available analytical methods these regulations cannot be fully implemented. Difficult issues face dietary supplement companies who must answer questions such as:

- Do we build a lab at great cost or contract out analytical services, also at great cost?
- Will all in-house methods be replaced by official ones?
- Will we be required to do continuous finished product testing?

### This one-day seminar will:

- Introduce AOAC INTERNATIONAL and its Official Methods<sup>SM</sup> Program for dietary supplements.
- Review key elements of GMPs for dietary supplements and the role of analytical methods.

- Explain Section 9 of DSHEA and why analytical methods are the centerpiece of quality management with GMPs.
- Examine costs and personnel needs.
- Introduce the latest analytical technology for dietary supplements.
- Introduce you to key players in the analytical methods world.

### Who should attend?

- Manufacturers and/or marketers of dietary supplement ingredients or products
- Analytical laboratory managers and technicians
- Production, quality assurance, purchasing and analytical testing managers
- Marketing, sales and legal staff who need to understand labeling issues and claims based on analytical data
- Finance managers who need to understand the investment and costs to run an analytical lab



# P R O G R A M

<i>Time</i>	<i>Presentation</i>	<i>Presenter</i>
8:00 – 8:30 am	<b>Registration / Morning Coffee &amp; Tea</b>	
8:30 – 8:45 am	<b>DSHEA &amp; Final GMPs for Dietary Supplements:</b> <i>Why Analytical Methods are the Key</i>	<b>Loren Israelsen</b> , Executive Director <i>UNPA (Utah Natural Products Alliance)</i>
8:45 – 9:00 pm	<b>An Overview of AOAC INTERNATIONAL</b>	<b>James Bradford</b> , Executive Director <i>AOAC INTERNATIONAL</i>
9:00 – 9:30 pm	<b>Analytical Methods for Dietary Supplements:</b> <i>An Update on Public and Private Initiatives</i>	<b>Leila Saldanha, Ph.D.</b> , Scientific Consultant <i>National Institutes of Health</i>
9:30 – 10:00 pm	<b>The Office of Dietary Supplements Analytical Methods Program: A Top Priority for Industry</b>	<b>Joseph Betz, Ph.D.</b> , Director, Dietary Supplements <i>Office of Dietary Supplements, NIH</i>
10:00 – 10:30 pm	<b>What are Validated Methods:</b> <i>Why are they so Important?</i>	<b>Mark Roman, Ph.D.</b> , Director, Research & Development, <i>CHROMADEX</i> ; Co-Chair: AOAC Methods Committee on Dietary Supplements <i>AOAC INTERNATIONAL</i>
10:30 – 10:45 am	<b>BREAK</b>	
10:45 – 11:15 am	<b>The Challenge of Botanicals and Analytical Methods</b>	<b>William R. Obermeyer, Ph.D.</b> , Vice President for Research and Development; <i>ConsumerLab.com</i>
11:15 – 11:45 am	<b>Conflicted Results Among Contract Analytical Labs: What's going on?</b>	<b>Paula Brown, Ph.D.</b> , School of Health Sciences <i>BC Institute of Technology</i> ; AOAC General Referee for Botanicals & Dietary Supplements <i>AOAC INTERNATIONAL</i>
11:45 – 12:15 pm	<b>Summary of Morning Session / Q &amp; A</b>	
12:15 – 1:15 pm	<b>LUNCH</b>	
1:15 – 1:45 pm	<b>Budgeting for Testing:</b> <i>What does it Cost to Run a Well-Equipped Lab?</i>	<b>Matt Arveseth</b> , Laboratory Director <i>Cornerstone Research &amp; Development</i>
1:45 – 2:15 pm	<b>Case Study—The Omega-3 Working Group:</b> <i>The Role of Management in Supporting Quality Standards and Analytical Methods</i>	<b>Robert Orr</b> , President <i>Ocean Nutrition Canada</i>
2:15 – 2:45 am	<b>Finished Product Testing for Dietary Supplements:</b> <i>What is Feasible?</i>	<b>Aaron Secrist</b> , Associate Director of Quality <i>Nature's Way Products, Inc.</i>
2:45 – 3:00 pm	<b>BREAK</b>	
3:00 – 3:30 pm	<b>Vendor Certification Checklist: How to Qualify Vendors and Agree on Methods for Raw Materials</b>	<b>Glen Putnam</b> , Director of Quality Assurance and Regulatory Affairs: <i>USANA Health Sciences</i>
3:30 – 4:00 pm	<b>In-House versus Official Methods:</b> <i>Is there Room for Both?</i>	<b>Jana Hildreth, Ph.D.</b> , Scientific Liaison <i>AOAC INTERNATIONAL</i>
4:00 – 5:00 pm	<b>Summary of the Seminar / Q &amp; A with all presenters</b>	
6:00 pm	<b>Reception for all attendees and faculty at UNPA offices</b> 1075 E. Hollywood Avenue (1975 South 1075 East), Salt Lake City	

# Analytical Methods for Dietary Supplements:

## The Critical Link for GMP Compliance

### Registration Info:

Attention: **Lindsay Wright**, Utah Natural Products Alliance (UNPA)  
 1075 Hollywood Avenue, Salt Lake City, UT 84105  
 Phone: (801) 474-2572 / Fax: (801) 474-2571 / e-mail: lindsay@unpa.us

### Registration Fees:

	# of Attendees	Fees
<b>UNPA or Paid AOAC Members:</b>		
\$395 first person	1	x \$395 = _____
\$195 each additional from same company	_____	x \$195 = _____
<b>Non-UNPA or Non-Paid AOAC Members:</b>		
\$595 first person	1	x \$595 = _____
\$295 each additional from same company	_____	x \$295 = _____
<b>Academic or Non-profit Organizations:</b>		
\$195 each person	_____	x \$195 = _____
		<b>Total Fees</b> _____

### Registration Form: (No On-Site Registrations Accepted)

NAME (LAST, FIRST) \_\_\_\_\_

POSITION \_\_\_\_\_

ORGANIZATION \_\_\_\_\_

ADDRESS \_\_\_\_\_

CITY \_\_\_\_\_

STATE \_\_\_\_\_

ZIP \_\_\_\_\_

PHONE \_\_\_\_\_

FAX \_\_\_\_\_

E-MAIL \_\_\_\_\_

Will you be attending the post seminar reception at our offices?  Yes  No

### Payment Method:

Check:  Payable to "UNPA". Please note "April 22 Seminar" on the check. Send payment to the UNPA address listed above.

Credit Card:  Visa  MasterCard  AMEX

CREDIT CARD NUMBER \_\_\_\_\_

EXPIRATION DATE \_\_\_\_\_

SIGNATURE OF CARDHOLDER \_\_\_\_\_

**April 22, 2005**

**Huntsman Cancer Institute**

2000 East Circle of Hope

6th Floor

Salt Lake City

### About the Sponsors

**AOAC INTERNATIONAL** is an independent, third-party, non-governmental, scientific association committed to worldwide confidence in analytical results. AOAC has 120 years of experience in validating analytical and proficiency testing. The AOAC® Official Methods<sup>SM</sup> is the "gold standard" accepted worldwide by regulatory agencies and organizations, and is used to facilitate trade. In fact, many AOAC methods are required in the enforcement of some state, provincial, municipal, and local laws and many federal food standards worldwide, including the FDA and Codex.

### UTAH NATURAL PRODUCTS

**ALLIANCE (UNPA)** is a national association that represents many of the leading dietary supplement companies in the state of Utah and elsewhere. Utah is one of the largest manufacturing centers of dietary supplements in the world—with annual sales exceeding \$3.5 billion. World class production and quality control systems are a basic requirement of UNPA membership, as are rigorous raw materials specifications, in-process controls and analytical testing methods.