



UNPA®

Co-Sponsored by:

The National Center for Natural Products Research,
School of Pharmacy, University of Mississippi

United Natural Products Alliance (UNPA)

GMP V: Inspections, Enforcement, Compliance in 2010 and Beyond

Two day seminar covering the most recent news regarding:

- GMP implementation
- Inspection 483 reports: What does it mean?
- The rising risks of adverse event reporting as they relate to GMPs
- Thinking about the unthinkable: Recalls and what triggers them, and how to avoid them
- Bane of spiking: How do you test for “ghost ingredients” that are not supposed to be there?
- What are FDA’s expectations on in-bound raw material identification?



Feb. 11-12, 2010

**Salt Lake City, Utah
Marriott City Center**



SEMINAR PROGRAM / DAY ONE / THURSDAY, FEBRUARY 11, 2010

8:15 AM	REGISTRATION
9:00 AM	Introduction of Faculty by Loren Israelsen, United Natural Products Alliance (UNPA) <ul style="list-style-type: none">• Carl C. Reynolds, Senior Advisor, Division of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, U.S. Food & Drug Administration• Bradford W. Williams, Manager, Division of Dietary Supplement Programs, Office of Nutrition, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, U.S. Food & Drug Administration• Dr. Ikhlas Khan, Director of the FDA Center of Excellence, Research Professor, as well as Professor in the Department of Pharmacognosy at the National Center for Natural Products Research at the University of Mississippi
9:30 AM	I. Historical Perspectives and Current Status <ul style="list-style-type: none">• Review of Dietary Supplement GMP Regulations and Implementation• Other Regulatory Authorities for Dietary Supplements, Beverages and Foods
10:00 AM	II. Who • What • Where • When • Why <ul style="list-style-type: none">• Subpart A – General Provisions / Definitions Exercise• Subpart B – Personnel• Subpart C – Physical Plant and Grounds• Subpart D – Equipment and Utensils
11:00 AM	BREAK
11:15 AM	III. Production and Process Controls <ul style="list-style-type: none">• Subpart E – Production and Process Control System• Subpart F – Quality Control• Subpart G – Components, Packaging and Labeling
12:30 PM	LUNCH
1:30 PM	Review of Section III 483's by Loren Israelsen, United Natural Products Alliance (UNPA) <ul style="list-style-type: none">• What are the “Hot Spots?”• What are Inspectors Looking for?
3:15 PM	BREAK
3:30 PM	<ul style="list-style-type: none">• Botanical Authentication and Common Adulterants• Certificates of Analysis and Vendor Qualification• Analysis of Adulterants in Supplements: What's Working? What's Cost Effective?
4:45 pm	Review/Questions
5:00 pm	Reception for Faculty and Attendees

SEMINAR PROGRAM / DAY TWO / FRIDAY, FEBRUARY 12, 2010

9:00 AM **Congressional Update**
by Congressman Jim Matheson, Utah's 2nd District
(congressional schedule permitting)

9:20 AM **Overview of Day 1**
by Loren Israelsen, United Natural Products Alliance (UNPA)

- 9:30 AM
- Subpart H – Master Manufacturing Record
 - Subpart I – Batch Production Record
 - Subpart J – Laboratory Operations
 - Subpart K – Manufacturing Operations
 - Subpart L – Packaging and Labeling Operations

11:00 AM **BREAK**

- 11:15 AM
- Subpart M – Holding and Distribution
 - Subpart N – Returned Dietary Supplements
 - Subpart O – Product Complaints
 - Subpart P – Recordkeeping

12:30 PM **LUNCH**

1:30 PM **Q & A with All Faculty**

3:30 PM **BREAK**

- 3:45 PM **Other Key Issues Affecting GMP Planning**
by Loren Israelsen, United Natural Products Alliance (UNPA)
- Adverse Event Reporting
 - Recalls
 - Traceability

4:45 pm **Review of Key Learnings and Adjournment**



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REGISTRATION

GMP V: Inspections, Enforcement, Compliance in 2010 and Beyond

Registration Info:

Attn: Kira Olsen, United Natural Products Alliance (UNPA)
1075 Hollywood Avenue, Salt Lake City, UT 84105
Tel: (801) 474-2572 / Fax: (801) 474-2571 / e-mail: kira@unpa.com

February 11-12, 2010
Salt Lake City, Utah

Marriott City Center

220 South State Street

Salt Lake City, UT 84111

\$169/night UNPA room rate

Reservations: 1-877-905-4491

[Click here for reservations](#)

UNITED NATURAL PRODUCTS

ALLIANCE (UNPA) is an international association representing leading dietary supplement companies in the state of Utah and throughout the world. Utah is a global manufacturing center for dietary supplements—with annual sales exceeding \$4.1 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.

Registration Fees:

	# of Attendees	Fees
\$995 per person	1 x \$995 =	\$995
\$795 per additional person from same company	_____ x \$795 =	_____
	Total Fees	_____

Registration Form: (No On-Site Registrations Accepted)

NAME (LAST, FIRST)

POSITION

ORGANIZATION

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CITY

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Payment Method:

Check: Payable to UNPA. Note "GMP V Seminar" on the check and send the to UNPA address listed above.

Credit Card: Visa MasterCard American Express

CREDIT CARD NUMBER

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SIGNATURE OF CARDHOLDER



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