



The Natural Products Association Presents:

**What You Need to Know: How the FDA GMP Rule
[21 CFR 111] for Dietary Supplements Applies to You**
(This is a one and a half day course)

The WHO WHAT WHERE WHEN WHY & HOW of Dietary Supplement cGMPs

It's now more important than ever to understand the cGMP requirements as they apply to your company. FDA inspections under 21 CFR 111 are in full swing and it's no longer a matter of if – it's when your company will be inspected. **In FY 2011, FDA conducted over 150 inspections of dietary supplement companies. Unfortunately, more than 70 percent of these inspections resulted in either voluntary action indicated (VAI) or official action indicated (OAI) outcomes and the FDA issued more than 30 warning letters.**

NPA offers a comprehensive training course with expert presenters who cover the complex GMP issues and provide practical tips for compliance. NPA and our seminar presenters have many years of experience working with dietary supplement GMPs, and evaluating warning letters and compliance plans to determine the FDA's expectations. The NPA seminar will assist your company to address cGMP requirements and prepare for when the FDA knocks on your door. Additionally, you will leave the seminar understanding what to expect during an inspection, how to respond to interactions with FDA officials, and how to avoid having Form 483 observations turn into warning letters.

NPA is the leader in dietary supplement GMPs, launching the industry's first GMP third-party certification program in 1999 and providing the first and best dietary supplement GMP education to more than 1,000 attendees in 13 years. The 2012 Program features an agenda that covers the FDA GMP requirements that are proving to be the most complex and challenging, including examples and case studies throughout to illustrate the concepts.

Seminar presenters include: Cindy Beehner, president of QSD Consulting; Aaron Secrist, quality and regulatory manager at NOW Foods; and Natural Products Association staff. Beehner and Secrist are industry experts who have worked with hundreds of industry firms of all sizes to help them develop and implement effective quality systems. Between the two of them, they have more than 40 years combined experience working in and consulting with the industry to address FDA regulations, especially in the area of good manufacturing practices and dietary supplements.

This course is relevant and valuable for anyone whose job requires an understanding of the FDA GMP rule for dietary supplements, including senior management and regulatory affairs, QA/QC, production, and laboratory personnel.

The seminar agenda will include:

- **New for 2012!** Overview of industry business models and their respective GMP responsibilities
- **New for 2012!** Revised format that focuses on application of the concepts and includes topics related to issues identified in recent FDA inspections and warning letters
- **New for 2012!** Incorporates examples and case studies illustrating real-life GMP issues and scenarios
- **FDA Hot Topic** – Developing compliant master manufacturing and batch production records
- **FDA Hot Topic** - Qualifying your suppliers and other vendors to ensure quality and consistency in meeting GMP compliance and qualifying COAs to allow for reduced testing of components
- **FDA Hot Topic** - Conducting material reviews and appropriate handling of customer complaints, and adequate documentation of related investigations and resulting corrective action outcomes
- Comprehensive discussion of specific FDA GMP requirements and hot button issues, including establishing and confirming specifications, QC personnel responsibilities, laboratory operations, scientifically valid analytical methods, raw materials and finished product testing requirements, and change control
- Tips on addressing compliance with FDA GMP requirements and strengthening your company's current GMP systems, and developing GMP-compliant SOPs
- How to handle FDA visits and discussion of FDA expectations based on recent inspections and warning letters
- Opportunity for technical Q&A discussion with industry GMP experts

2012 Seminars Will Be Presented in Conjunction with the Following Trade Shows:

<p>Expo West – Anaheim, CA: March 8, 8 a.m. – 5 p.m. & March 9, 8 a.m. – noon NPA MarketPlace 2012 – Las Vegas, NV: June 13, 8 a.m. – 5 p.m. & June 14, 8 a.m. – noon Expo East – Baltimore, MD: September 19, 8 a.m. – 5 p.m. & September 20, 8 a.m. – noon Located Close to an Industry Supply Show – Las Vegas, NV: November 5, 8 a.m. – 5 p.m. & November 6, 8 a.m. – noon</p>
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**REGISTRATION FORM:
Final FDA GMP Rule for Dietary Supplements Seminar**

Name(s) & Title(s) _____

Company _____

Address _____

City/State/Zip _____

Phone _____ Ext. _____ Fax: _____

Email (confirmation sent by email) _____

Registrations must be accompanied by check or credit card information.

- Registration substitutions may be made at any time.
- All requests for refunds are subject to a \$100 processing fee. Refunds will be issued if notification is postmarked, emailed or faxed five (5) business days prior to the day of the seminar.
- Natural Products Association reserve the right to make program changes as necessary or to cancel the program if minimum enrollment has not been reached or events occur beyond the reasonable control of the Natural Products Association.

Please send completed registration form with payment to: Natural Products Association, P.O. Box 347136, Pittsburgh, PA 15251-4136.

If paying by credit card, please fax your registration to (202) 223-0250.

All registrants will receive a confirmation notice five (5) business days before the seminar.

Credit Card # _____

CID Number (usually on back of card) _____ Expiration Date _____

Authorized Signature _____

Credit Card Billing Address _____

FEES (10% discount for multiple registrants from the same company)

NATURAL PRODUCTS ASSOCIATION Member:
\$745 for one attendee or \$670.50 per attendee for multiple registrants per company \$ _____

Non-NATURAL PRODUCTS ASSOCIATION Member:
\$995 for one attendee or \$895.50 per attendee for multiple registrants per company \$ _____

TOTAL AMOUNT \$ _____

Please mark seminar you will attend:

- Expo West – Anaheim, CA.: March 8-9
- NPA MarketPlace 2012 – Las Vegas, NV: June 13-14
- Expo East – Baltimore, MD: September 19-20
- Close to Industry Supply Show – Las Vegas, NV: November 5-6

Call Vicki Whitsitt at (202) 503-1961 for more information.

Pre-registration deadline is five business days prior to the day of the seminar. Those who do not pre-register can register onsite, space permitting, for an additional fee of \$100 per attendee.