



Mock FDA GMP Inspection for Dietary Supplements

Learn What to Do and How to Pass

This **one-day seminar** is conducted as a true mock inspection where each part of the process will be broken down, role-played, discussed and analyzed. Attendees will receive a template SOP for FDA inspections.

Two former FDA inspectors with nearly 50 years of combined experience will lead the seminar. And meet current FDA inspectors for a Q&A opportunity.



May 28, 2009

Salt Lake Marriott City Center
Salt Lake City, UT



SEMINAR PROGRAM

<i>Time</i>	<i>Presentation</i>
8:00 – 8:30 am	Registration / Continental Breakfast
8:30 – 8:45 am	Welcome / Review of the Day / Introduction of Speakers Loren Israelsen, Executive Director, <i>United Natural Products Alliance (UNPA)</i>
8:45 – 9:45 am	SESSION I: The Inspection Begins Shelly Maifarth, <i>Retired FDA Compliance Officer</i> Martina LaGrange, <i>Former FDA Consumer Safety Officer</i> <ul style="list-style-type: none">• The 482 form• Initial meeting• Into the factory
9:45 – 10:45 am	SESSION II: The Walk-Through Shelly Maifarth / Martina LaGrange <ul style="list-style-type: none">• Quarantined to finished goods inspection• Visiting the lab• Inspecting records
10:45 – 11:00 am	BREAK
11:00 am – 12:15 pm	SESSION III: Inspectional Observations — Form 483 Loren Israelsen <ul style="list-style-type: none">• What do you do now?• A review of 483's of DS manufacturing facilities, including NBTY and others
12:15 – 1:15 pm	LUNCH BREAK
1:15 – 2:15 pm	SESSION IV: Meet the Inspectors Before You are Inspected FDA Representatives Invited
2:15 – 3:00 pm	SESSION V: Q & A with Past and Present FDA Shelly Maifarth / Martina LaGrange and FDA Representatives
3:00 – 3:30 pm	SESSION VI: Inspection Hot Spots Loren Israelsen <ul style="list-style-type: none">• Sterilization, total plate count and irradiation• Record keeping; SOPs• Analytical testing validation and challenge tests by FDA• Access to sensitive records — when to say no• When, if ever, do you bring in the lawyers?
3:30 – 4:00 pm	BREAK
4:00 – 4:45 pm	SESSION VII: Food Safety Legislation — Will Congress Really Overhaul FDA and the Food Safety System? A Look at the New HHS, FDA and USDA Loren Israelsen
4:45 – 5:00 pm	Summary and Conclusions of Seminar



