



# Final GMP Regulation for Dietary Supplements

**Understanding, Implementing and  
Advancing Quality & Safety**

**1-1/2 day seminar**  
covering all aspects  
of the final GMP  
regulation and interim  
final rule on 100%  
identity testing

Co-sponsored by  
Capsugel®



**Sept. 12-13, 2007**  
Marriott Salt Lake City Center  
Salt Lake City, UT



# DAY ONE PROGRAM

<i>Time</i>	<i>Presentation</i>	<i>Presenter</i>
10:00 am – 1:00 pm	<b>REGISTRATION</b>	
1:00 – 1:15 pm	<p><b>WELCOME and Review of the Seminar</b></p> <p><b>Welcome from Capsugel:</b> Seminar Co-Sponsor</p>	<p><b>Loren Israelsen</b>, Executive Director <i>United Natural Products Alliance (UNPA)</i></p> <p><b>Brian Frisby</b>, Manager of Business Development Dietary Supplements / <i>Capsugel Americas</i></p>
1:15 – 2:00 pm	<b>Overview of the Final Regulation and Interim Final Rule on 100% Identity Testing</b>	<b>Loren Israelsen</b> , Executive Director <i>United Natural Products Alliance (UNPA)</i>
2:00 – 2:30 pm	<b>Congressional News:</b> Global Food Safety, FDA Oversight and Impact on DSHEA & GMPs	<b>Peter Reinecke</b> , Senior Advisor, <i>UNPA</i> President, <i>Reinecke Strategic Solutions</i> Former Chief of Staff, <i>Senator Tom Harkin</i>
2:30 – 3:00 pm	<b>Botanical Identity and Quality:</b> The Role of AHP and Quality Management	<b>Roy Upton</b> , Executive Director <i>American Herbal Pharmacopeia</i>
3:00 – 3:15 pm	<b>BREAK and Cell Phone Fix</b>	
3:15 – 4:00 pm	<b>The Office of Dietary Supplements:</b> Current Programs and Funding of Dietary Supplement Quality Initiatives	<b>Joseph M. Betz, Ph.D.</b> , Director <i>Dietary Supplement Methods &amp; Reference Materials Program, Office of Dietary Supplements National Institutes of Health (NIH)</i>
4:00 – 4:45 pm	<b>The Role of Certified Reference Materials in Implementing GMP Requirements</b>	<b>Katherine E. Sharpless, Ph.D.</b> , Research Chemist <i>Analytical Chemistry Division, National Institute of Standards and Technology (NIST)</i>
4:45 – 5:30 pm	<b>Good Agricultural Practices:</b> The First Step in Botanical Quality	<b>Edward Croom, Ph.D.</b> , Senior Scientific Advisor <i>Indena USA, Inc.</i>
5:30 – 7:00 pm	<p><b>RECEPTION</b></p> <p>Warm and Cold Appetizers Selected Beverages (Quality Guaranteed)</p>	



# DAY TWO PROGRAM

<i>Time</i>	<i>Presentation</i>	<i>Presenter</i>
8:00 – 8:30 am	<b>REGISTRATION and Continental Breakfast</b>	
8:30 – 8:45 am	<b>Review of Day 1 and Overview of Day 2</b>	<b>Loren Israelsen</b> , Executive Director <i>United Natural Products Alliance (UNPA)</i>
8:45 – 10:45 am	<b>Analytical Methods: Validated or Scientifically Valid?</b> Creating, Selecting and Using Appropriate Methods	<b>Darryl Sullivan</b> , AOAC INTERNATIONAL <b>Eike Reiche, Ph.D.</b> , CAMAG Scientific, Inc. <b>Paula Brown, M.Sc.</b> , Analytical Research Collective <b>Jana Hildreth</b> , Blaze Science Industries
10:45 – 11:00 am	<b>BREAK</b>	
11:00 am – 12:30 pm	<b>Certificates of Analysis: The Bridge Between Suppliers and Manufacturers</b>	Panel Q & A Discussion
12:30 – 1:30 pm	<b>LUNCH</b>	
1:30 – 2:30 pm	<b>Third Party Certification and Auditing Engaging the Industry</b>	<b>Srini Srinivasan, Ph.D.</b> , USP <b>David Abney</b> , NSF International
2:30 – 3:30 pm	<b>Guidance on Appropriate Microbial Limits for Herbal Dietary Supplement Products and Available Technologies for Microbial Reduction</b>	<b>Josef Brinckmann</b> , Vice President of Research and Development, <i>Traditional Medicinals</i>
3:30 – 3:45 pm	<b>BREAK</b>	
3:45 – 4:30 pm	<b>Documentation and Record Keeping: The New Mandate</b>	<b>Glen Putnam</b> , Executive Director of Quality <i>USANA Health Sciences</i>
4:30 – 5:00 pm	<b>100% Identity Testing Exemption: Interim Final Rule Breakthrough of Bust?</b>	<b>Loren Israelsen</b> , Executive Director <i>United Natural Products Alliance (UNPA)</i>
4:00 – 5:00 pm	<b>Q &amp; A / Summary of the Conference</b>	



# M A T E R I A L S   O R D E R   F O R M

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### About UNPA:

**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.

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