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**International Pharmaceutical
Excipients Auditing, Inc.**

Excipient GMP Auditing Workshop

March 2, 2005

**Key Bridge Marriott
1401 Lee Highway
Arlington, Virginia 22209
Tel: 703-524-6400 Fax: 703-524-8964**

A full-day comprehensive workshop devoted to excipient GMP auditing techniques. It is intended for pharmaceutical & chemical company auditors who assess practices followed by excipient manufacturers.

FULL-DAY WORKSHOP PROGRAM

- ❖ **Uniqueness of Excipient Ingredients**
- ❖ **Excipient GMP Compliance**
 - IPEC Excipient GMPs
 - Comparison of Applicable Excipient cGMP Requirements to ISO 9001
 - Comparison of Excipient cGMP to Q7a and CFR211
 - Application of Excipient cGMP to Distribution Practices
- ❖ **Assessing GMP Compliance**
 - Audits
 - Questionnaires
 - Assessing a Manufacturer Compliant with Applicable Food GMP Regulations
- ❖ **GMP Auditing Considerations**
 - Full Excipient Audit
 - Risk Based Excipient Audit
- ❖ **Excipient Audit Expectations**
 - Common deficiencies
 - Qualification/Validation
 - Change Management & Significant Change Notification
- ❖ **Compliance Consideration**
 - Top Ten GMP Compliance List
 - Risk of Contamination
 - Excipient COA
 - Alternate Assessment Methods
- ❖ **IPEA Audit Program**

Wednesday, March 2, 2005

8:00 am – 8:30 am Check in and Registration
8:30 am – 4:30 **WORKSHOP SESSION**

Irwin B. Silverstein, Ph.D.

IPEA Chief Operating Officer – Workshop Leader

This interactive workshop explores the USP excipient GMP requirements and reviews the various methods of ensuring conformance, emphasizing site audit. The USP excipient GMPs were developed from the IPEC *Good Manufacturing Practices Guide for Bulk Pharmaceutical Excipients* which is the basis for this workshop. At the completion of the workshop, the participant will be able to focus on the compliance issues important to the manufacture of excipients as opposed to those of API or dosage form manufacture.

***** Register early - workshop space limited *****

Register on-line at www.ipeainc.com or call 703-351-5266

