

FDA has stated that a suitably qualified Third Party Auditing Program can be an integral component of an effective supplier qualification program.

IPEA has been a third party excipient audit provider serving the pharmaceutical, chemical, and nutraceutical industries worldwide since 2001. IPEA assesses excipient manufacturers and distributors against current good manufacturing practices (cGMP) standards as set forth in current IPEC-PQG, WHO, and USP/NF publications.

EXCIPIENT SERVICES

● Excipient GMP Certification

With encouragement from the FDA, IPEA pursued and received accreditation of its excipient certification program from the American National Standards Institute (ANSI) in April 2010. Accreditation of the program, officially called the IPEA Excipient GMP Conformance Certification Program, by ANSI signifies our conformance to (ISO)/IEC Guide 65, general requirements for bodies operating product certification systems.



ANSI Accredited Program
PRODUCT CERTIFICATION
#0857

● Excipient GMP Audits

IPEA offers manufacturer and distributor GMP audits through our worldwide pool of IPEA trained and qualified auditors. IPEA's trained auditors are experienced and seasoned professionals who are familiar with the practices and methodologies of both excipient and pharmaceutical manufacturers. Our audits are designed to be a direct substitute for pharmaceutical supplier audits and provide a means to share the expense of these audits.

● Audit Program Reports

IPEA audit reports afford excipient purchasers the opportunity to verify supplier excipient GMP conformance without the time and expense of an on-site

visit to each and every supplier manufacturing site. The audit report provides the pharmaceutical company a basis for supplier qualification decisions. For the excipient manufacturer, IPEA audit reports demonstrate to potential customers that excipient manufacturing facilities meet applicable GMP standards.

● Sampling Program

IPEA has established a blinded sampling program so excipient manufacturers can develop objective evidence of the presence of substandard excipient in the marketplace. IPEA has a protocol and relationship with regulatory authorities to facilitate review of the evidence. In a recent study, published data from this program initiated an official investigation that led to an Import Alert. (<http://www.fda.gov/Drugs/DrugSafety/ucm230492.htm>)

● Training in Excipient GMPs

IPEA offers workshops to train auditors in assessing conformance to excipient GMP and quality professionals in appropriate GMP requirements. Workshops are also available to meet GMP training requirements and conform to various IPEC guides. General or customized workshops can also be arranged by contacting us at ipeainc@aol.com.

BENEFITS OF CERTIFICATION AND AUDIT SERVICES

- All reports are reviewed by the audited facility for redaction of proprietary information and undergo a final IPEA quality review.
- Certification is granted after approval by our Certification Board of experienced industry executives and quality leaders.
- Certification and audit program reports are valid for a period of 2 years.

For excipient maker:

- Fewer site visits
- Auditors trained in GMPs appropriate to excipients
- Opportunity to review draft reports for factual accuracy and confidential details
- Opportunity to provide a corrective action plan that accompanies the report.

For a pharmaceutical customer:

- Certification may substitute for an audit in a supplier qualification program
- Audit reports of excipient manufacturing facilities provide details that establish conformance to GMP
- Convenient prompt assessment of excipient manufacturers through available audit program reports
- Savings in company manpower and time; in addition to minimization of travel costs

Confidentiality:

- Audit reports do not contain any company or product proprietary information and are treated as confidential documents.
- Pharmaceutical customers only disclosed to the audited excipient maker, never to other customers or other excipient manufacturers

GET STARTED NOW!

- Contact IPEA
- Complete an application
- Set a date



IPEA, Inc.

1655 N. Fort Myer Drive, Suite 700
Arlington, VA 22209
703-351-5266
ipeainc@aol.com
www.ipeainc.com



IPEA Inc. is a wholly owned subsidiary of IPEC-Americas, International Pharmaceutical Excipients Council of the Americas.
www.ipecamerica.org

International Pharmaceutical Excipients Auditing, Inc.



Introducing the
first ANSI accredited
Product Certification
Program for
Conformance to
Excipient GMP