

# ISPE PROFESSIONAL DEVELOPMENT TRAINING

**China Training**  
*2012*

## Enhance Your Career with ISPE Professional Development Training

Our courses are a recognized opportunity for in-depth, topic-specific learning. ISPE uses the expertise of its global members to develop courses that address the current need to meet industry requirements, especially design a curriculum to meet the needs of the Chinese pharmaceutical industry. You will be able to enhance your career development by acquiring and applying new skills and practical knowledge as well as providing you with valuable solutions to daily work problems.

- Lower Production Costs
- Increase Production Quality
- Improve Process Efficiency
- Meet Regulatory Requirements

### GMP Auditing for the Pharmaceutical Industry

**Level:** Fundamental

**Type:** Classroom Training Course

**Location:** Shanghai / Beijing

[Register Now](#)

### Course Introduction

Auditing is a critical function within a pharmaceutical company. It provides management with information about how effectively the company controls the quality of their processes and products. Auditors must perform their jobs competently to ensure their company's compliance with pharmaceutical USFDA GMP regulations and other quality standards like ICH Q10. Auditing for GMP is specifically designed to address the challenges of GMP auditing for the pharmaceutical industry and present the basic competencies required to effectively perform the auditor's assigned responsibilities and contribute to the improvement of auditor performance within a regulated industry.

Note: This course is not designed to prepare companies to be audited and does not contain content for medical device auditing.

### Course Modules

- Background Information
- Auditing Department Basics
- Traits/Skills of a Good Auditor
- GMP Background Information for Auditors
- Pre-Audit Information
- Conducting the Audit
- Post Audit
- Resources
- Worksheet

### Take Back to Your Job

- Prepare and conduct audits using an audit trail and checklists
- Effectively evaluate audit and report findings
- Identify critical components for a good audit report

- Conduct an audit using an audit trail and checklist
- Understand the concepts behind compliance auditing
- Increased knowledge of cGMP concepts and regulatory requirements related to auditing
- Identify the critical competencies needed to be a conscientious auditor

### Attendance Suggested For

- This course is recommended for individuals with two to three years of direct experience working with the USFDA and PIC/S GMP guidelines who want to develop additional expertise in GMP Auditing
- New auditors or individuals wanting to become auditors
- Professionals who are responsible for conducting internal or vendor GMP audits
- Suppliers and others who are audited, such as quality assurance and quality control specialists, validation scientists, manufacturing supervisors, technical support personnel, engineers, and all levels of management

### Community of Practice (COP)

This training course is of particular interest to existing and future members of the [ISPE Process/Product Development \(COP\)](#).

### Curriculum for ISPE Training Courses 2012

	Course name
<b>Biotechnology</b>	<ul style="list-style-type: none"> <li>• <a href="#">Process Validation in Biotechnology Manufacturing</a></li> <li>• <a href="#">Applying the Biopharmaceutical Manufacturing Facilities Baseline® Guide Principles</a></li> <li>• <a href="#">GMP fundamentals for the Biotechnology Industry</a></li> </ul>
<b>Cleaning</b>	<ul style="list-style-type: none"> <li>• <a href="#">Cleaning Validation</a></li> </ul>
<b>Commissioning and Qualification</b>	<ul style="list-style-type: none"> <li>• <a href="#">Application of Commissioning and Qualification: Applying the Commissioning and Qualification Baseline Guide Principles</a></li> </ul>
<b>Facilities</b>	<ul style="list-style-type: none"> <li>• <a href="#">Sterile Drug Manufacturing Facilities: Applying ISPE Baseline® Guide and FDA Guidance Principles to Design and Operation</a></li> </ul>
<b>GAMP</b>	<ul style="list-style-type: none"> <li>• <a href="#">Practical Application of Computerized Systems Compliance: Applying the GAMP5® Guide: A Risk-based Approach to Compliant GxP Computerized Systems</a></li> </ul>
<b>GMPs</b>	<ul style="list-style-type: none"> <li>• <a href="#">GMP Auditing for the Pharmaceutical Industry</a></li> </ul>
<b>HVAC</b>	<ul style="list-style-type: none"> <li>• <a href="#">HVAC for Pharmaceutical Facilities</a></li> </ul>
<b>Manufacturing</b>	<ul style="list-style-type: none"> <li>• <a href="#">Managing the Risk of Cross Contamination: Applying the Risk-MaPP Baseline® Guide</a></li> </ul>

For more training course information please visit: [www.ISPE-EVENT.org.cn](http://www.ISPE-EVENT.org.cn)



#### Registration

Visit [www.ISPE-EVENT.org.cn](http://www.ISPE-EVENT.org.cn) for more course description and register online.

E-mail: [chinaevent@ispe.org](mailto:chinaevent@ispe.org) Tel: +86-21-5108-1511



#### Sponsorship

Contact us for sponsorship opportunities:

E-mail: [nliu@ispe.org](mailto:nliu@ispe.org) Tel: +86-10-5206-1082 +86-21-5108-1563