

# 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

### **Application of Commissioning and Qualification: Applying the Commissioning and Qualification Baseline® Guide Principles**

**Level:** Fundamental  
**Type:** Classroom Training Course

**Location:** Shanghai / Beijing

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#### **Course Introduction**

The principles and approaches of this course apply to both bulk and secondary biotechnology manufacturing operations. Participants can expect open class discussions, sample problems, and an analysis of case studies. Throughout the course, the GMPs will be positioned as an essential tool for developing manufacturing control strategies that integrate product quality, regulatory compliance, and product performance. The course will help participants apply GMPs to their specific job responsibilities and acquire the comfort level required to interact with fellow employees concerning GMP issues.

Current good manufacturing practices (cGMPs) define acceptable standards for all aspects of biopharmaceuticals manufacture - and their proper interpretation and application is critical for meeting customer as well as regulatory expectations. This hands-on course gives participants the opportunity to stay on top of current issues and trends in the biotechnology industry, and to learn the basic requirements of the U.S. Food and Drug Administration (FDA).

With a focus on biotechnology products, the course will emphasize the rationale behind cGMPs. Participants will learn the history of the GMP regulations, the regulatory process, and the concept of operating in a state-of-control environment. The course will review GMPs as they relate to the industry and why simple statements in the GMP regulation may result in extensive control mechanisms for compliance.

In addition, the course will present information about the FDA, including how the agency enforces GMP regulations and what to expect during a routine GMP inspection. Participants will gain valuable insight into compliance and auditing processes, and the importance of science in supporting regulatory decisions. They will also be exposed to the people side of the GMPs, the challenge of defending products against contamination, how to consistently build quality into products, and how

Important it is to personally audit for GMP compliance and performance. The lecture part of the course will conclude with a discussion on how to provide proof, through validation, that processes are operating properly, that the workplace is adequately designed to fit the application, and that GMPs are successfully maintained.

Case study discussions will help verify participants' understanding of the learned concepts.

### **Course Modules**

- Overview: Law, Regulations, cGMPs
- cGMP Regulations
- Quality Systems and Associated Issues
- Preparing for Inspections
- General Facility/Equipment Issues
- Appendix
- Case Studies
- 21 CFR Part 600
- Glossary

### **Take Back to Your Job**

- Develop a basic understanding of:
  - cGMP regulations that apply to biopharmaceuticals
  - Worldwide regulations as well as the differences between pharmaceutical and biotechnology regulations
  - Inspectional approaches and inspection groups for the biotechnology industry
- GMP fundamentals applied to biotechnology operations
- How regulatory authorities review the production of biotechnology products
- GMP problem areas and how to proactively address them before they surface as issues
- Key control areas associated with biotechnology operations required for compliance: operational and relational
- The basic GMP requirements for laboratory operations

### **Attendance Suggested For**

- Quality assurance, quality control, validation, manufacturing, technical support, IT, supply chain, and engineering professionals who have worked in the pharmaceutical industry but need a fundamental understanding of the GMPs related to biotechnology operations
- All levels of management who require exposure to GMP regulations related to biotechnology operations
- Service organizations, suppliers, and vendors who serve biotechnology industry clients

## 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.

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### Sponsorship

Contact us for sponsorship opportunities:

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