

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

Biopharmaceutical Manufacturing Facilities

[Register Now](#)

Level: Advanced

Location: Shanghai / Beijing

Type: Classroom Training Course

Course Introduction

Using case studies and exercises this course in facility design provides an overview of the concepts utilized in the development and renovation of sound designs for facilities that manufacture biopharmaceutical products. The course includes a review of facility design and regulatory issues important in the US and Europe that involve industry trends and changing regulatory policy. Participants will discuss current case studies on a wide array of facility topics, and complete class exercises that involve developing facility scope of work and deliverables to meet corporate economic goals and regulatory requirements.

Participants will receive a complimentary copy of the [Biopharmaceutical Manufacturing Facilities Baseline® Guide](#).

Course Modules

- BOD
- Block Flow Diagrams
- Equipment List
- Slide Presentation
- Class Exercises
- Appendix

Take Back to Your Job

- Discuss facility design concepts related to current Good Manufacturing Practices (cGMPs)
- Describe the regulatory review process
- Apply engineering design principles related to biotechnology product manufacturing
- Understand biotechnology process attributes that impact equipment and facility design
- Utilize current industry guidance documents that impact facility design
- Describe impact of critical utilities on facility design

- Understand project economics and their impact on facility design
- Discuss current industry trends impacting facility design and construction

Attendance Suggested For

- Individuals who want to improve their working knowledge of biotechnology manufacturing facility design concepts
- Professionals who need a focused understanding of the issues a biotechnology manufacturing company must address in order to develop a facility design that meets current regulatory requirements and corporate economic goals
- Individuals who provide services and/or assistance to biotechnology manufacturing companies to design, construct, validate, and finance facilities

Community of Practice (COP)

This training course is of particular interest to existing and future members of the ISPE Biotechnology Community of Practice (COP).

Curriculum for ISPE Training Courses 2012

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

For more training course information please visit: www.ISPE-EVENT.org.cn



Registration

Visit www.ISPE-EVENT.org.cn for more course description and register online.

E-mail: chinaevent@ispe.org Tel: +86-21-5108-1511



Sponsorship

Contact us for sponsorship opportunities:

E-mail: nliu@ispe.org Tel: +86-10-5206-1082 +86-21-5108-1563