

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: Advanced- Application
Type: Classroom Training Course

Location: Shanghai / Beijing

[Register Now](#)

Course Introduction

Through interactive workshops, this course will apply the principles of the *Commissioning and Qualification Baseline® Guide* for a project consisting of process equipment components, classified area, critical utilities, and an associated automation platform. Activities begin with formation of a project team; development of critical requirements for projects based on current good manufacturing practices (cGMPs) and the basis of design; performance of an impact assessment including system impact and component criticality assessments; and performance of enhanced design review. Participants will then develop an outline for the contents of a commissioning plan and validation master plan; develop a test plan to implement the integration of commissioning and qualification; and develop an outline for the contents of the *Commissioning and Qualification Baseline® Guide* including installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) protocols for one system.

Course Modules

- Formation of the Project Team
- Development of User Requirements
- Performing System Impact Assessment
- Developing the Validation Master Plan
- Developing the Commissioning Plan
- Development of the Project Test Plan
- Identification of Deliverables
- Performing Component Criticality Assessments
- Performance of Enhanced Design Review

- Development of the Commissioning Protocol
- Development of IQ and OQ Protocols
- Development of the PQ Protocol
- Background Info

Take Back to Your Job

- Assemble an effective project team including assignment of roles, responsibilities, and authority
- Examine the critical requirements for a project based on cGMPs, basis-of-design, and design documents
- Perform impact assessments including system impact assessment and component criticality assessment based on provided design documents
- Execute an effective enhanced design review to verify that the critical requirements are incorporated into design
- Formulate an integrated commissioning and qualification strategy using test plans
- Develop a content outline of the commissioning and validation master plans
- Construct test plans for each system to specify how commissioning and qualification will be implemented and use the plans in the development of qualification protocols
- Prepare an outline of the qualification protocol contents for provided systems and equipment based on actual design

Attendance Suggested For

- Individuals who have previously attended the Introduction to Commissioning and Qualification training course or those who have basic knowledge and understanding of the *Commissioning and Qualification Baseline*[®] Guide.

Community of Practice (COP)

This training course is of particular interest to existing and future members of the [ISPE Commissioning and Qualification \(COP\)](#).

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