

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

Practical Application of Computerized Systems Compliance: Applying the GAMP5® Guide: A Risk-based Approach to Compliant GxP Computerized Systems

Level: Advanced - Application
Type: Classroom Training Course

Location: Shanghai / Beijing

[Register Now](#)

Course Introduction

This highly interactive workshop gives participants hands-on experience in applying practical techniques and solutions to solve computerized systems compliance challenges. Participants will discuss and analyze case studies, apply newly acquired knowledge to hypothetical case-study systems, and have the opportunity to discuss their own real-life challenges with other participants and an expert trainer. Participants should come prepared to work in groups to devise workable and creative solutions to realistic problems and case study scenarios, facilitated by the instructor.

Immediately apply the course learning objectives using the complimentary copy of the [GAMP® 5 Guide: A Risk-based Approach to Compliant GxP Computerized Systems](#).

Highlights of the course include:

- Overview of key themes and concepts in GAMP® 5
- Understanding the process and overall GxP Risk
- Effective planning for compliance
- Supplier assessment and leveraging supplier knowledge and documentation
- The key role of clear and complete user requirement specifications
- Choosing a suitable specification and verification approach
- GAMP® 5 Quality Risk Management approach (based on ICH Q9)
- Specific risk assessment tools for computerized systems

- Selecting a suitable life cycle and scaling the lifecycle based on risk, complexity, and novelty
- Developing a strategy and writing a computerized system validation plan
- Writing high-quality test scripts
- Maintaining the control in operation - a scalable approach
- Regulatory hot topics

This course was developed by members of the ISPE GAMP® Community of Practice. GAMP was established by industry leaders to interpret and improve the understanding of regulations governing the use of computerized systems in pharmaceutical manufacturing.

Participants will receive a complimentary copy of the [GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems](#)

Take Back to Your Job

- Build upon and expand understanding of the regulatory requirements and expectations for the compliance of computerized systems used in pharmaceutical manufacturing
- Apply this understanding to example systems and case studies
- Analyze case studies and apply the GAMP® 5 process for achieving compliance and fitness for intended use
- Apply quality risk management and risk assessment concepts

Attendance Suggested For

- Quality assurance and quality control specialists, validation specialists, manufacturing supervisors, technical support personnel, engineers, MIS professionals and all levels of management who need a practical understanding of computerized system compliance
- Computer system vendors or consultants, engineering contractors, and validation service companies
- Those who have previously attended a GAMP® Basic Principles training course or those whose practical experience has provided the equivalent level of knowledge

Community of Practice (COP)

This Training course is of particular interest to existing and future members of the [ISPE GAMP® 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.

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Sponsorship

Contact us for sponsorship opportunities:

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Pharmaceutical Knowledge

