

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

Process Validation in Biotechnology Manufacturing

[Register Now](#)

Level: Advanced

Location: Shanghai / Beijing

Type: Classroom Training Course

Course Introduction

The inherent complexity and uncertainty of biotechnology makes developing and validating bioprocesses for manufacturing proteins and biopharmaceuticals very difficult. Understanding and using FDA's new Process Validation Guideline is critical to establishing and maintaining control of complex processes, as well as achieving regulatory approval of new products.

This course is designed to provide a clear understanding of the regulatory, scientific, and engineering tools required to successfully develop and validate bioprocesses. In addition, the course identifies the long list of activities required to validate biopharmaceutical processes.

Topics include a comprehensive strategy to process validation; a review of important biotechnology manufacturing processes, and the regulatory requirements for their validation.

In addition to classroom lectures, participants will take part in several interactive exercises, solve group problems, and participate in class discussions to understand the underlying principles behind Process Validation.

This is an advanced course. Participants should have a basic understanding of commissioning, qualification and validation and basic familiarity with biotechnology manufacturing processes and unit operations.

Course Modules

- Introduction
 - The evolving definition of Process Validation
 - Quality of Information and its significance
 - Good Manufacturing Practices
- Q8 Pharmaceutical Development
 - Definition of Design Space
 - Attributes and parameters
- USFDA's New Process Validation Guidelines
 - The new validation paradigm
 - Quality by Design (QbD) concepts and their application
- Manufacturing Sciences - Validation tools
 - Design Space concepts
 - Experimental models
 - Overview of DOE Methods
 - Mathematical models
 - PAT - Process & Product Control
 - Risk Analysis - ICH Q9
- Product Definition - CQA
- Activities required for Process Validation
 - Process Master Plan elements
 - Cell Bank validation
 - Viral clearance validation
 - Conformance lots
- Process Verification
 - SPC tools for verification
- Legacy products
- Validation of Bioprocess Unit Operations
 - Fermentation & Cell Culture
 - Harvest & Recovery
 - Tangential Flow Filtration (TFF)
 - Chromatography
- Course Quiz

Take Back to Your Job

- Develop and execute validation master plans and validation protocols
- Understand and use FDA's current process validation guidelines
- Successfully run conformance lots for process qualification
- Define key validation activities for biopharmaceutical process development and manufacturing
- Apply strategies and fundamental approaches for process validation of upstream and downstream processes for clinical and commercial manufacturing
- Discuss validation documentation requirements

Attendance Suggested For

- Process development engineers, validation personnel, manufacturing supervisors and managers, quality assurance specialists, and management personnel.
- Senior manufacturing and engineering managers who want to understand the regulatory and scientific requirements associated with process validation.
- Other professionals with commissioning, qualification, and validation responsibilities who need an understanding of process validation for biotechnology manufacturing.

Community of Practice (COP)

This training course is of particular interest to existing and future members of the ISPE Biotechnology and Process/Product Development [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

