

# 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

### **Cleaning Validation Principles**

**Level:** Intermediate to Advanced  
**Type:** Classroom Training Course

**Location:** Shanghai / Beijing

### **Course Introduction**

As cleaning technology and detection methodology advance, so do the challenges associated with establishing, managing, and maintaining a scientifically sound cleaning validation program. FDA's risk-based regulatory initiatives focus new attention on the risks of cross-contamination. The solution is to understand life cycle management techniques for an effective cleaning validation program.

This course will cover elements of a cleaning validation program from start to finish, exploring such concepts as the determination of residues to be targeted, selection of analytical and sampling methods, determination of appropriate limits in various pharmaceutical and biotechnology processes, and establishment of scientific rationales acceptable to regulatory inspectors. For mature cleaning validation programs, concepts such as understanding process control, capability, learning to effectively self-audit a cleaning validation program, and documentation will be essential takeaways.

### **Course Modules**

- Developing, Deploying and Maintaining
- Regulatory Requirements
- Fundamentals of Cleaning Validation
- Master Plans
- Equipment Characterization
- SOP Development
- Selecting Residues, Developing and Maintaining Limits
- Methods Validation and Recovery Studies
- Engineering Studies and Cycle Development
- Creating Cleaning Validation Protocols
- Collecting and Testing Validation Samples

- Validation Reports

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

- Identify and characterize potential residues including product, processing aids, cleaning agents, and adventitious agents
- Apply appropriate analytical methodology for selected residues
- Determine suitable sampling techniques and the selection of sampling locations that present a challenge for the cleaning process
- Calculate residue limits that meet all necessary regulatory requirements
- Create scientifically sound rationales, validation protocols, and reports
- Manage the challenges of multi-product facilities in the establishment of limits, determination of validation strategies, and maintaining the validated state
- Understand campaign-based production strategies for effective and scientifically sound validation
- Differentiate the requirements for cleaning validation when using manual, semi-automatic, and automatic cleaning technologies
- Determine scientific grouping or bracketing approaches
- Comprehend the pitfalls inherent in cleaning after the production of biopharmaceutical and pharmaceutical products
- Accomplish analytical method validation and recovery study requirements in cost-effective studies that provide the necessary assurance of an analytical system
- Evaluate cleaning practices, limit calculations, scientific rationales, and validation documents through internal self-audits to ensure compliance with ever-changing regulatory needs
- Practice hands-on exercises designed to reinforce core competencies and job-focused skills

### **Attendance Suggested For**

- Professionals responsible for all aspects of cleaning validation programs, including development, deployment, and maintenance
- Quality assurance specialists, quality control technicians, regulatory affairs professionals, pharmacologists and toxicologists, validation scientists, and validation service personnel
- Manufacturing supervisors, technical support personnel, and engineers responsible for evaluating cleaning systems, reviewing equipment, and supporting the cleaning validation program on the plant floor
- All levels of management who need to understand the science of cleaning and cleaning validation including the aspects of residue selection, sampling method and analytical detection method validation, limits determination, and strategies for managing multi-product facilities

## 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.

E-mail: [chinaevent@ispe.org](mailto:chinaevent@ispe.org) Tel: +86-21-5108-1511



### Sponsorship

Contact us for sponsorship opportunities:

E-mail: [nliu@ispe.org](mailto:nliu@ispe.org) Tel: +86-10-5206-1082 +86-21-5108-1563

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