

# 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

### **Sterile Drug Manufacturing Facilities: Applying ISPE Baseline® Guide and FDA Guidance Principles to Design and Operation**

**Level:** Intermediate

**Type:** Classroom Training Course

**Location:** Shanghai / Beijing

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#### **Course Introduction**

This course references ISPE's *Sterile Manufacturing Facilities Baseline® Guide* and the FDA's newly published *Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice*. Both of these documents help provide an understanding of the key requirements and GMPs for sterile manufacturing facilities. The Baseline® Guide provides valuable information on design, construction, and commissioning/qualification while the FDA's new Guidance helps professionals understand the regulatory context and expectations for sterile drug manufacturing.

Using the referenced documents, this course will cover regulatory philosophy, aseptic process and equipment considerations, aseptic clean room design and operation, differential pressure requirements, airlocks, basic utility systems, European HVAC considerations, basic commissioning and qualification issues, and a brief introduction to barrier isolation technology. (Note: parts of *Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice* that do not focus on facilities and equipment will not be discussed in detail.)

In addition, the course will include an exercise in the layout of an aseptic filling facility. In many cases, when a new facility is required within an existing or new building, the designer will begin by sketching a floor plan. This exercise will demonstrate how to use process flow diagrams and an accommodation schedule to thoroughly define facility requirements before advancing to the floor plan layout stage.

#### **Course Modules**

- Concepts and Regulatory Philosophy
- Process and Equipment Considerations
- Architecture and Layout

- HVAC
- Utility Systems
- Electrical services
- Control & Instrumentation
- Cleaning: Engineering Issues
- Barrier-Isolator Technology
- General Considerations
- Commissioning and Qualification
- Exercises
- Supplemental Materials

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

- Identify sources of contamination in aseptic operations
- Explain methods for contamination control
- Describe the major requirements for design, renovation, and operation of a sterile manufacturing facility
- Discuss the fundamentals of aseptic clean room design
- Understand the importance of monitoring critical parameters: temperature, humidity, air velocity, differential pressure, airflow patterns, non-viable particle counts, and microbial counts
- Design a systematic process for aseptic facility layout
- Apply ISO 14644, *Clean Rooms and Associated Controlled Environments - Part 1: Classification of Air Cleanliness to Aseptic Processing Clean Rooms*
- Discuss the difference between U.S. and European clean room HVAC standards
- Distinguish between the 2004 and 1987 versions of the FDA's *Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice* as applied to the design, operation, maintenance, and modification of facilities

### **Attendance Suggested For**

- Engineers, validation scientists, quality assurance specialists, and manufacturing managers
- Professionals who want a fundamental understanding of sterile manufacturing facilities and their design, renovation, and operation
- Engineering firm professionals and other consultants who work with the pharmaceutical industry

## 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.

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