

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

HVAC for Pharmaceutical Facilities

Level: Advanced

Type: Classroom Training Course

Location: Shanghai/Beijing

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Course Introduction

This course will provide a detailed description of HVAC system fundamentals, including a discussion of primary system components such as fans, coils, humidifiers, and filters. Participants will receive an overview of critical parameters for products and processes that can be affected by HVAC, and explore the basic concepts of controlling these parameters using properly designed HVAC control systems. Participants will discuss what HVAC can and cannot do to maintain good manufacturing practices (GMPs) as they are addressed for facilities designed to manufacture bulk pharmaceutical chemicals (BPC), oral solid dosage (OSD) products, sterile products, and bulk biopharmaceuticals. HVAC systems for production laboratories and warehouse facilities utilized for the storage of product, raw materials, and components are also covered.

On completion of facility-specific systems, the requirements for commissioning and qualification are explored with emphasis on distinguishing between critical and noncritical parameters. Other course topics include HVAC controls, monitoring of critical parameters, and system construction. Dust collection systems and laboratory fume hoods are not covered, as these systems are addressed by other sources. The course concludes with suggestions for system maintenance.

Attendees will be provided with updates to course materials if GMPs or technology related to meeting GMPs change within 12 months of attending the course (e-mail address required).

Participants should be familiar with basic pharmaceutical product forms and GMPs.

Participants will receive a complimentary copy of the *ISPE Good Practice Guide: Heating, Ventilation, and Air Conditioning*.

Course Modules

- HVAC Basics
- Air Filters
- HVAC Controls
- Air Balance
- Cleanroom Basics
- LAB HVAC
- HVAC GMPs
- API HVAC
- Oral Solids
- Sterile Products & Medical Devices
- HVAC requirements for GMP
- Design to Qualify, Economics
- Qualification and Risk
- IQ - OQ - PQ
- Wrap Up
- Air Filter References
- GMP References
- Design References
- Qualification References
- Other References
- Final Exam, Exercises

Take Back to Your Job

- Define basic HVAC system concepts
- Discuss HVAC system-critical parameters that must be controlled and monitored
- Distinguish among pharmaceutical cleanroom air classifications and explain how they are applied
- Explain the role of HVAC in protecting products
- Examine typical HVAC system designs utilized for bulk, oral solid dosage, sterile, biopharmaceutical, and packaging and warehousing operations
- Understand the basics of process laboratory HVAC
- Describe HEPA filter theory, application, monitoring, testing, and repair
- Cite HVAC maintenance requirements

Attendance Suggested For

- Project engineers, HVAC technicians and mechanics, HVAC control designers, commissioning personnel, government agency inspectors, quality assurance specialists, and manufacturing managers
- Professionals needing a thorough understanding of HVAC systems utilized in pharmaceutical operations
- Engineering professionals and other consultants who work with the pharmaceutical industry

Community of Practice (COP)

This training course is of particular interest to existing and future members of the ISPE HVAC [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.

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

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Pharmaceutical Knowledge

