



ISPE-CCPIE

China Training 2009

Pharmaceutical Water Systems: Regulation, Purification, Distribution and Validation

Instructor: Gordon Farquharson, BSc (Hons), CEng

Review the principles of design and operation of water systems used directly in pharmaceutical manufacturing, including the regulatory requirements, fundamental concepts, and principles for systems used to generate, store and distribute both compendial and non-compendial waters. These concepts include specification, design, installation, operation, testing, validation and maintenance of components and systems. Examine methods for proper water quality selection and receive detailed guidance regarding the choice and use of appropriate construction materials and instrumentation. The course covers both US and European regulatory requirements (compendia, current good manufacturing practices and regulatory guides) and explores typical concerns of the regulator.

Participants will receive a complimentary copy of the *Water and Steam Systems Baseline[®] Guide* and the *Good Practice Guide: C&Q of Water and Steam*.

Who Should Attend

Pharmaceutical professionals new to water treatment systems or with engineering expertise from another industry who need pharmaceutical water treatment systems knowledge

Those with industry experience in other capacities now with water generation system engineering and/or maintenance responsibilities and need fundamentals for designing, building, operating, testing, and maintaining these systems

Water treatment systems QA/QC specialists, validation professionals, manufacturing supervisors, technical support personnel, and all levels of management needing fundamentals of pharmaceutical water generation systems

Those with responsibility for design, specification, procurement, commissioning and qualification of water systems.

Managers who need to ensure currency in Pharma Water regulations and best practice.

Learning Objectives

- Understand the impact of water quality requirements (compendial and non-compendial) on water system operations
- Differentiate regulatory requirements from myths relative to water generation, distribution and storage systems
- Understand the essential purification processes, their strengths and weaknesses.
- Identify alternative system designs and their advantages and disadvantages
- Understand the importance of microbiological control techniques and system sanitization.
- Identify the principles behind water system testing and qualification.
- Define the basic requirements for water distribution system component installation and overall system construction
- Integrate and streamline commissioning and validation activities
- Understand how to develop the PQ validation phase to the unique requirements of water systems.
- Learn how to monitor and improve operational reliability of systems.
- Develop your knowledge to improve the interface between designers, users, and suppliers.

ISPE and CCPIE

The China Centre for Pharmaceutical International Exchange (CCPIE) and ISPE have developed a curriculum to deliver a series of training courses specifically designed to meet needs of the Chinese pharmaceutical industry.



ISPE-CCPIE

China Training 2009

Sterile Drug Manufacturing Facilities: Applying ISPE Baseline® Guide, FDA, EU/PICS and WHO Principles to Design and Operation

Through review of ISPE's *Sterile Manufacturing Facilities Baseline Guide*, US FDA's 2004 *Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice*, and the new March 2009 implementation of *Annex 1 of the EU GMP*, gain an understanding of the key requirements and GMPs for sterile products manufacturing facilities. Additional information will be reviewed from the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and from the World Health Organization (WHO). Learn about 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 basic barrier isolation technology.

Participants will receive a complimentary copy of the *ISPE Baseline Guide: Sterile Manufacturing Facilities*.

Who Should Attend

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; and engineering firm professionals and other consultants who work with the pharmaceutical industry.

This course contains knowledge related to the CPIP™ technical knowledge competency element Facilities and Equipment and Production Systems. For complete information about the CPIP Credential, please visit www.ISPE-PCC.org.

Instructor



Gordon Farquharson, Sc (Hons), CEng is a Chartered Consulting Engineer with more than 30 years of experience in quality and safety critical processes and facilities used by industries like healthcare, life science, and micro-electronics. He is Principal Consultant with Bovis Lend Lease Technology Division's global operation.

Learning Objectives

- 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
- Apply a systematic process for aseptic facility layout, and consider advantages and disadvantages of different options.
- 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
- Understand how to integrate the requirements of the 2004 US FDA Guidance *Sterile Drug Products Produced by Aseptic Processing, EU/PIC-S GMP Annex 1* as applied to the design, operation, maintenance, and modification of facilities

ISPE and CCPIE

The China Centre for Pharmaceutical International Exchange (CCPIE) and ISPE have developed a curriculum to deliver a series of training courses specifically designed to meet needs of the Chinese pharmaceutical industry.

Shanghai Courses Add location of the training event <i>Please select course you will attend.</i>	Member	Nonmember *
<input type="checkbox"/> Sterile Drug Manufacturing Facilities, 1-2 June Includes the <i>ISPE Baseline Guide: Sterile Manufacturing Facilities.</i>	RMB2,900/ USD430	RMB3,200/ USD470
<input type="checkbox"/> Pharmaceutical Water Systems, 4-5 June Includes the <i>ISPE Water and Steam Systems Baseline Guide</i> and the <i>Good Practice Guide: C&Q of Water and Steam.</i>	RMB2,900/ USD430	RMB3,200/ USD470
Beijing Courses Add location of the training event <i>Please select course you will attend.</i>	Member	Nonmember *
<input type="checkbox"/> Sterile Drug Manufacturing Facilities, 8-9 June Includes the <i>ISPE Baseline Guide: Sterile Manufacturing Facilities.</i>	RMB2,900/ USD430	RMB3,200/ USD470
<input type="checkbox"/> Pharmaceutical Water Systems, 11-12 June Includes the <i>ISPE Water and Steam Systems Baseline Guide</i> and the <i>Good Practice Guide: C&Q of Water and Steam.</i>	RMB2,900/ USD430	RMB3,200/ USD470

ISPE China Office

Suite 2302, Wise Logic International Centre
66 North Shan Xi Road, Shanghai, China 200041
Tel: +86 21-5116-0265
Fax: +86 21-5116-0260
Email china@ispe.org