

ISPE Philadelphia Classroom Training

5-8 October 2009
Hilton Philadelphia Airport
Philadelphia, Pennsylvania, USA

Gain industry-specific knowledge on GAMP, HVAC, C&Q, sterile drug manufacturing facilities, and more, at ISPE Philadelphia classroom training. Instructors provide the know-how you need for job success today and in the future.

Complete course descriptions and online registration at www.ISPE.org/philadelphiatraining.

Practical Application of Computerized Systems

Compliance (GAMP® 5)

5-6 October, 1.5 CEUs

James W. (Jim) John, Project Lead, Altus Automation, a ProPharma Group Company

Gain hands-on experience in applying practical techniques and solutions to solve computerized systems compliance challenges. Discuss and analyze case studies, and discuss your real-life challenges with other participants and an expert trainer.

Sterile Drug Manufacturing Facilities

5-6 October, 1.3 CEUs

Gordon Farquharson, BSc (Hons), CEng, Principal Consultant, Bovis Lend Lease Technology

Review sterile drug manufacturing regulatory philosophy, aseptic process and equipment considerations, aseptic clean room design and operation, differential pressure requirements, airlocks, basic utility systems, European HVAC considerations, basic C&Q issues, and a brief on barrier isolation technology. Receive a complimentary copy of the *Sterile Manufacturing Facilities Baseline® Guide*.

Pharmaceutical Water Generation

5-6 October, 1.5 CEUs

Gary V. Zoccolante, Pharmaceutical Technical Director, US Filter, a Siemens Business

Review principles of design and operation of water systems used directly in pharmaceutical manufacturing, including the fundamental concepts and principles of systems used to generate USP and non-compendial waters. Complimentary copies of the *Water and Steam Systems Baseline® Guide* and the *Good Practice Guide: C&Q of Water and Steam* provided.

HVAC for Pharmaceutical Facilities

5-7 October, 2.0 CEUs

Norman Goldschmidt is the Principal and Founder of Pharma Engineering Advisors

Gain an understanding for HVAC system fundamentals, including primary system components such as fans, coils, humidifiers, and filters. 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.

Basic Principles of Commissioning and Qualification

7-8 October, 1.3 CEUs

Timothy Howard, PE, CPIP, Commissioning Agents, Inc.

Referencing the *ISPE Commissioning and Qualification Baseline Guide*, this course covers philosophy/concepts, impact assessment, good engineering practices (GEPs), commissioning versus qualification, methods of integrating commissioning and validation activities, and includes several interactive exercises. Receive a complimentary copy of the Guide.

Oral Solid Dosage Forms

7-8 October, 1.3 CEUs

Charles F. Carney, Retired, Seraphim Life Sciences Consulting

Focus on fundamentals of each discrete processing step (unit operation) required for the manufacture and packaging of tablets and capsules — the most common of solid dosage forms.

Auditing for GMP

7-8 October, 1.3 CEUs

Jeri L. Weigand, Corporate Auditor, Medtronic

Receive the training you need to improve your role as a GMP auditor. Learn how to prepare for audits; conduct internal and vendor audits; formulate and ask good questions; properly evaluate and report audit findings; and provide recommendations for corrective actions.

Pharmaceutical Water Operation

7-8 October, 1.3 CEUs

Gary V. Zoccolante, Pharmaceutical Technical Director, US Filter, a Siemens Business

Explore fundamental concepts and principles of specification, design, installation, operation, testing, and maintenance of equipment and systems used to store and distribute water in pharmaceutical manufacturing, as well as elements of system validation. Complimentary copies of the *Water and Steam Systems Baseline Guide* and the *Good Practice Guide: C&Q of Water and Steam* provided.

ISPE Delaware Valley Chapter

ISPE partnered with the ISPE Delaware Valley Chapter to select Philadelphia Classroom Training Courses. For information about this Chapter and its events, please visit www.ISPE.org/delawarevalley.