

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

Managing the Risk of Cross Contamination: Applying the Risk-MaPP Baseline® Guide

Level: Intermediate

Type: Classroom Training Course

Location: Shanghai / Beijing

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Course Introduction

As manufacturers are looking to reduce cost and increase efficiency, more multi-product facilities are being utilized either directly by the manufacturers or through partnerships with contract manufacturing organizations (CMO's). With the use of multi-product facilities, the risk of cross contamination increases. By properly managing the risk of cross contamination, manufacturers can reap the benefits of lower cost and higher efficiency while maintaining product quality and patient safety.

The key is to understand your risk of cross contamination and be able to present scientific justification for the methods used for risk assessment as well as risk control strategies to regulators and auditors worldwide. ISPE's Baseline® Guide: Risk-MaPP, helps companies manage their risk of cross contamination by outlining a scientific, risk-based methodology based on ICH Q9 that can be used to lead teams through the process to satisfy auditors as well as global regulators. This introductory session will focus on use of the logic diagram, how health based limits are developed, setting cleaning validation limits, risk assessments for cross contamination and formulating a Quality Risk Management Plan as part of a Quality System.

Immediately apply the course objectives using the complimentary copy of the [ISPE Baseline Guide: Volume 7 Risk-Based Manufacture of Pharmaceutical Products \(Risk-MaPP\)](#).

Course Modules

- Overview of ICH Q9 and how Risk-MaPP fits in
- Introduce the Logic Diagram
- Risk Assessment
 - Risk Identification and setting limits
 - Risk Analysis – gathering data
 - Risk Evaluation – comparing identified and analyzed risk against risk criteria

- Risk Control
 - Risk Reduction
 - Risk Acceptance
- Risk Management Tools
- Regulations
- Governance documents and ICH Q10
- Pulling it all Together
- Risk Review
- Risk Communication

Take Back to Your Job

At the conclusion of this session, participants will be able to:

- Determine when multi-product facilities can be used
- Use the logic diagram to guide a team through the process of determining how to manage the risk of cross contamination
- Understand where to get health-based data for use in risk assessments
- Develop scientific risk-based cleaning validation limits
- Prepare a Quality Risk Management Plan for Cross Contamination

Attendance Suggested For

Anyone dealing with multi-product facilities especially QA, Toxicologists, EH&S professionals, Engineers, Operations, Cleaning Validation, Project Managers, Regulators/ Inspectors

NOTE: This course will expand upon some basic concepts in the following areas so attendees should be familiar with the basics prior to attending this session.

- Containment basics and the use of operator exposure limits.
- Setting cleaning limits (note this session will not discuss cleaning procedures, processes, etc).

Community of Practice (COP)

This training course is of particular interest to existing and future members of the following ISPE [Communities of Practice \(COP\)](#).

- [Containment](#)
- Oral Solid Dosage
- [Active Pharmaceutical Ingredients](#)
- [Biotechnology](#)
- Sterile Products Processing
- [Process/Product Development](#)
- [Project Management](#)
- HVAC
- [Commissioning and Qualification](#)

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.

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Sponsorship

Contact us for sponsorship opportunities:

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Pharmaceutical Knowledge

