

# Training Courses

## Intensive Training on

Auditing

Biotechnology Process Validation

Cleaning Validation

Clinical Trial Materials

Facility Project Management

*GAMP*® 5

OSD

QbD

QRM

Risk-MaPP

Science and Risk-Based C&Q

Sterile Facilities



ISPE 2013  
Training Series

22 - 24 May  
Brussels, Belgium

7-9 October  
Prague, Czech Republic



# Save the Date for Future ISPE Events!

## Europe

### March 2013

Critical Utilities EU Conference,  
12–13 March, Copenhagen, Denmark

Regulatory Compliance EU Conference,  
Spring 2013, Brussels, Belgium

### May 2013

Brussels Training Courses, 22–24 May,  
Brussels, Belgium

### June 2013

Supply Chain EU Conference, Prague,  
Czech Republic

### September 2013

Biotechnology EU Conference, France

### October 2013

Prague Training Courses, 7–9 October,  
Prague, Czech Republic  
Lean Manufacturing EU Conference,  
Berlin, Germany

## Training Schedule

### 22 – 24 May Brussels, Belgium Training Courses

Wednesday – Thursday

T43: Turning QbD into a  
Practical Reality

T40: Science and Risk-Based  
Commissioning & Qualification

T10: Oral Solid Dosage Forms

T13: Clinical Trial Materials

T42: Applying Quality Risk Management

T26: Facility Project Management

Wednesday – Friday

T45: Basic Principles of Computerised  
Systems Compliance using  
GAMP<sup>®</sup> 5, Including Revised Annex  
11 and Part 11 Update

### 7–9 October Prague, Czech Republic Training Courses

T17: Cleaning Validation Principles

TBD: QbD

T32: Process Validation in  
Biotechnology Manufacturing

T41: Managing the Risk of Cross  
Contamination: Applying the Risk  
MaPP Baseline<sup>®</sup> Guide

T21: A Risk-Based Approach to  
GxP Process Control Systems  
Applying the GAMP<sup>®</sup> Good  
Practice Guide: A Risk-Based  
Approach to GxP Process  
Control Systems (2<sup>nd</sup> Edition)

G07: GMP Auditing for the  
Pharmaceutical Industry

T12: Sterile Drug Manufacturing Facility

For more information visit

[www.ISPE.org/events](http://www.ISPE.org/events)

# Overview

Our training courses leverage the expertise of our global membership and use ISPE Guidance documents to provide the practical, “real world” solutions to help you improve product quality, reduce risk, lower production costs and increase process efficiency while understanding regulatory requirements.

Our topic-specific courses will help you increase your knowledge and master skills through lecture, team-based exercises and case studies so you can immediately apply the learning objectives on the job. With three levels of courses we provide fundamental knowledge to help you develop a new skill set and intermediate knowledge for developing an expertise in a specific area, and advanced workshop intensive courses to develop practical techniques.

## General Information

Some courses include a pre-recorded course primer. Access information will be provided via email one week prior to the start of the training event.



**ISPE Online Learning** provides 24/7 access to an extensive library of on-demand webinars and courses. Visit [www.ISPE.org/OnlineLearning](http://www.ISPE.org/OnlineLearning)

**ISPE On-site training** can help you meet your regulatory requirements for training with cost-effective, customisable and convenient delivery. Contact [training@ispe.org](mailto:training@ispe.org), or call ISPE Member Services at tel: +1-813-960-2105.

**Group Discounts** are available for three or more individuals.

**ISPE CEUs** are awarded four weeks after the event and are based upon verification of attendance and receipt of a completed course evaluation.

**ISPE COPs** connect like-minded pharmaceutical industry professionals. Visit [www.ISPE.org/COPs](http://www.ISPE.org/COPs).



Courses contain knowledge related to the **Certified Pharmaceutical Industry Professional™ (CPIP™)** Technical Knowledge and Competency Elements. Visit [www.ISPE.org/CPIP-PCC](http://www.ISPE.org/CPIP-PCC) to find out how to advance your career.

## Sponsorship Opportunities



Choose from a variety of sponsorship packages designed to build brand awareness and increase your exhibition traffic. Many sponsorship opportunities include: exposure via web and electronic communication before, during and after the event; onsite exposure through value-added exhibition opportunities, signage and mentions in print materials.

For more information or to secure your sponsorships, please contact **John Phillips** at [jphillips@ispe.org](mailto:jphillips@ispe.org), +1-813-739-2292

## Turning QbD into a Practical Reality (T43)

### Course Level:



### ISPE CEUs: 1.5

Substantial business benefits are emerging from industry when Quality by Design (QbD) principles are used for new and existing drug products yielding reduced operating costs, enabling significantly more efficient manufacturing processes and better positioning companies to meet increasing regulatory expectations.

For example, the completion of ICH Guidelines, Q8 (R2): Pharmaceutical Development, Q9: Quality Risk Management and Q10: Pharmaceutical Quality System and the recent US FDA guidance on Process Validation contain recommendations for building and capturing process knowledge and understanding and establishing a strategy for process control during Stage 1, process design. There is evidence from 483s and warning letters that FDA is citing unacceptable levels of process understanding, like unidentified or lack of control of factors that cause variability in process. Additionally, FDA appears to be accelerating the QbD push, suggesting that ANDAs for generic drugs should have QbD elements from 2013 onward.

This interactive training course utilises the *ISPE PQLI Guide Series: Part 1 - Product Realization using Quality by Design, Concepts and Principles* and *Part 2 - Product Realization using Quality by Design, Illustrative Example* as the basis for explaining and providing examples of how products and processes can be developed, using QbD, with special emphasis on the considerations for implementing these processes in manufacturing.

Through group exercises the course will delve into implementation and operation of an effective and efficient control strategy in manufacturing which is a key element of process performance and product quality monitoring and continual improvement. The link to control of attributes and parameters to relevant critical quality attributes of the product and application and implementation of enhanced, QbD approaches and US FDA Process Validation Guidance will also be explored.

**Note:** This course will not cover the regulatory submission processes or detailed engineering designs.

Immediately apply the course learning objectives through group exercises using the complimentary

copies of the *ISPE PQLI Guide Series: Part 1 – Product Realization using Quality by Design (QbD): Concepts and Principles* and *Part 2 – Product Realization using Quality by Design (QbD): Illustrative Example*. Mini-regulation handbooks for ICH Q8 (R2), Q9 and Q10 and Q11 will be provided.

### At the conclusion of the Webinar, participants will be able to:

Understand the background for the origins of the ICH guidelines, Q8 (R2), Q9, Q10 and Q11: Development and manufacture of drug substances (chemical entities and biotechnological/biological entities) and understand the link between these and other relevant regulatory guidelines and the ISPE PQLI Guides.

### Take Back to Your Job

Within the manufacturing environment:

- Understand and apply QbD terminology including the principles of a science- and risk-based approach, the importance of product and process understanding and patient requirements
- Use tools and techniques provided to understand the application of Quality Risk Management (QRM)
- Understand the implications of relevant ICH, EMA, and FDA Guidelines
- Learn about the QbD process
- Review QRM tools (FMEA, risk ranking) and apply FMEA to Control Strategy selection
- Know the relationship between PQS and GMP and how they link to Control Strategy
- Understand the considerations when implementing a control strategy derived from enhanced QbD approaches
- Review the scope of the US FDA Process Validation including equipment qualification, ASTM E-2500 and the ISPE Commissioning and Qualification Guides and the links to science- and risk-based approaches
- Examine opportunities for continual improvement arising from application of statistical techniques

### Attendance Suggested For

Manufacturing, engineering, quality and validation professionals with intermediate level experience in manufacturing, engineering, validation, quality control and assurance, technology transfer and those that are new to Quality by Design principles.

**Instructor:** Line Lundsberg-Nielsen, Ph.D., Senior Consultant, NNE Pharmaplan

## Science and Risk-Based Commissioning & Qualification (T40)

### Course Level:



### ISPE CEUs: 1.5

Through interactive workshops, this course will explain and apply the science and risk-based approach to verification of systems, equipment and facilities in accordance with the ICH documents Q8, Q9, and Q10 and ASTM E-2500. Topics covered include the principles and activities that constitute an efficient and acceptable approach to demonstrating facility and equipment fitness for use as required by major global regulatory authorities; improving the ability to meet documented process requirements; controlling risks within the manufacturing process; producing high-quality products and consistent operation to meet product user requirements. Guidance on the transition of an organisation's approach to Commissioning and Qualification to one that incorporates a science and risk-based approach will be discussed.

**Note:** It is strongly recommended that participants should be familiar with basic concepts of commissioning and qualification prior to attending this course.

Immediately apply the course objectives using the complimentary copy of the *ISPE Good Practice Guide: Applied Risk Management for Commissioning and Qualification*.

### At the conclusion of the Webinar, participants will be able to:

- Relate the ASTM Standard to GMP regulations and guidance documents
- Explain the regulatory foundation for the risk-based approach
- Understand the 2001 *ISPE Baseline® Guide: Commissioning and Qualification* and how it links to new concepts in the *ISPE Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment*
- Differentiate qualification versus verification
- Differentiate between the new risk assessment approach versus the old one
- Understand how the new draft US FDA Process Validation Guidance links to ASTM E-2500
- Understand the details on verification process flow

- Implement verification through the C&Q process (FAT, SAT, IV, FV, PT)
- Understand the ways GEP can be used as a foundation for verification

### Take Back to Your Job

- Explain the relationship between *ICH Q9*, *ASTM E-2500*, *ISPE Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment* and the *ISPE Good Practice Guide: Applied Risk Management for Commissioning and Qualification*
- Discuss the information necessary to develop Requirements Documents that will support a science and risk-based approach to qualification. Given the necessary information and a list of requirements, identify those that are necessary for product quality and those that are business / safety related
- Apply risk management methodologies throughout design and verification phases
- Explain the link between risk assessments, design review, and quality risk management
- Understand and examine the development of a Verification Strategy that incorporates use of vendor testing, construction quality assurance, site acceptance testing, installation checks, and functional testing
- Know what is involved in a system Acceptance and Release report given requirements, critical aspects, and verification test results in compliance with a verification strategy
- Outline the use of GAMP® 5 principles in support of system delivery of a packaged system inclusive of mechanical and control system elements
- Summarise US / EU / SFDA / and WHO regulatory requirements and expectations that may influence application of a science and risk-based approach

### Attendance Suggested For

- Intermediate practitioners of commissioning and qualification who want to understand and use the Science and Risk-based approach
- Project engineers, project managers, commissioning and validation professionals, engineering service providers, and quality assurance personnel involved in qualification and validation and regulatory

**Instructor:** Robert Adamson, Consultant, RBQ Services Limited

## Oral Solid Dosage Forms (T10)

### Course Level:



### ISPE CEUs: 1.3

Oral solid dosage forms (Tablets and Capsules) are some of the most popular and convenient methods of drug delivery. They can be produced in a non-sterile environment and the process, equipment and technology is well defined and known, after more than 100 years of development.

With the high volume of products produced in these dosage forms, it is important that the unit operations for their production be thoroughly understood. This course focuses on the fundamentals of each discrete processing step (unit operation) required for the manufacture and packaging of tablets and capsules.

The course will begin with a description of the three main OSD processing methods: Direct Compression, Wet Granulation and Dry Granulation. It will continue with a detailed review of all the major unit operations associated with OSD manufacturing processes. This includes: Ingredient Dispensing/Formulation; Blending; Granulation; Drying; Compression/Encapsulation; Coating; Packaging and Miscellaneous Operations.

The course will focus on the process, equipment and technology associated with the unit operation, giving the attendee a general understanding of the OSD process and many of the issues, considerations and related concerns. The specific types of equipment and technology used in today's modern manufacturing processes will be discussed and attendees will gain an appreciation for the selection and evaluation of such criteria. For example, a discussion of granulation will include information on different types of granulators (low shear, high shear, top drive, bottom drive, integrated processing trains) and typical challenges encountered during operation and scale-up.

A variety of process monitoring techniques will also be discussed. The course will review many known techniques for process monitoring with particular emphasis on their utilisation in scale-up and technology transfer, final dosage unit and analyse the necessary steps in the packaging operation to get from the finished tablet or capsule to the final filled and sealed container. Introduction to packaging equipment for tablet/capsule counting,

capping, security seals and bands, labelling, cartooning, and blister packaging will also occur. The course will conclude with a discussion on technology transfer, how to get the product from the R&D laboratory to full-scale manufacturing, and how to transfer a marketed product from one facility to another. A competency test will be administered upon course completion.

Immediately apply the course learning objectives with the complimentary copy of the *ISPE Baseline® Guide: Oral Solid Dosage Forms*.

### Take Back to Your Job

- Discuss the theory behind basic unit operations
- Explain different methods for performing a unit operation
- Describe how product characteristics dictate the unit operations method
- Identify the types of equipment utilised to perform unit operations
- State how good manufacturing practice (cGMP) influences unit operations and subsequent equipment design, production suites design, control and monitoring requirements
- Utilise process monitoring techniques during the scale-up and technology transfer exercises

### Attendance Suggested For

- New pharmaceutical solid dosage unit professionals
- Individuals with significant expertise from another industry who need to learn about solid dosage unit operations
- Those with significant pharmaceutical industry experience who now have solid dosage responsibilities and want to gain a fundamental understanding of unit operations and equipment used to manufacture, package, and test solid dosage products

**Instructor: Robert Walker**, Director, Rob Walker GMP Consultancy Ltd

## Clinical Trial Materials (T13)

### Course Level:



### ISPE CEUs: 1.3

CTM Managers continue to play a critical role in a company's ability to efficiently bring life-saving products to market. Unfortunately in today's high-pressure and time sensitive research environment, CTM Managers frequently learn while focusing on the specific requirements of an assigned trial, with less priority being given to the critical need for solid training in all aspects of CTM management.

In this course, you will receive a thorough overview of the clinical supply chain from beginning to end, including: designing appropriate packaging and labelling to match the study design, creating a plan of action to prepare the CTM and how to implement the plan and troubleshoot. The course will also cover the logistics of distribution of the CTM to the clinical sites globally. Important tools, such as outsourcing vendors for packaging and labelling and Interactive Response Technology, will be covered to ensure familiarity with all the necessary concepts.

Participants will discuss the different roles of the Clinical Team and how they interact with the CTM group. We will also cover current Good Manufacturing Practices (cGMPs) and how they are implemented in the packaging process. The course will also provide a dictionary of terms used in the CTM industry and how they apply to our daily business. After taking this course, you'll be better prepared to manage every aspect of CTM for your clinical trials!

Participants will receive a complimentary copy of the *Comprehensive Guide to Clinical Materials: A Handbook for Training Clinical Materials Professionals*.

### Take Back to Your Job

- Translating a clinical study protocol to define CTM supply requirements
- Understand and apply documentation, cGMPs, and regulatory considerations specifically affecting CTM
- Know how to prepare a project plan for all major steps in CTM production – manufacturing, packaging, labelling and distribution
- Identify the roles of the project team and how CTM interacts with each one
- Ability to apply real-life case studies to your own projects

### Attendance Suggested For

- Pharmaceutical professionals new to the CTM area who are involved in the manufacture, review, packaging and labelling of clinical trial materials
- Note to Clinical Supply Chain Managers and Supervisors: This is an excellent way to document general training for employees in the areas of cGMPs and CTM operations

**Instructor:** **Antonia Daniel**, Director, Airmid Consulting Limited

# Applying Quality Risk Management (T42)

## Course Level:



## ISPE CEUs: 1.5

Regulators expect that Quality Risk Management (QRM) is inherently built into the backbone of the Quality Management System (QMS) by using both formal and informal risk tools based on ICHQ9. However, the application and the complexity of the tools need to be appropriate to the timing of the risk event, the level of risk and the elements of the QMS under scrutiny. The criteria for risk ratings and mitigation requirements should be clearly defined in advance of commencing the risk assessment. With the necessity to track and monitor the outputs of risk assessments and use them for the purposes of trending and the development of the site risk management file and risk dashboard, risk communication is key in the overall QRM process.

QRM principles require that the evaluation of risk to quality is based on scientific knowledge and the protection of the patient. In so doing, the level of effort, formality and documentation of the QRM process is commensurate with the level of risk and the overall approach should be defined in a formal Risk Management Plan (RMP) for the site. To date the application of ICHQ9 is evident in risk-based approaches to C&Q but to a lesser extent holistically throughout the product lifecycle.

Through interactive workshops, this course will explain and apply the key principles of QRM programmes that need to include Quality Systems elements (ICH Q10) within the product/system lifecycle, including but not limited to:

- All processes, tests, systems, equipment and facilities related to the clinical and commercial manufacturing of products
- New product and process development and transfer
- Change control
- Vendor selection and qualification
- Supplier management
- Corrective and preventative actions

- Complaint handling
- Deviations
- Inspections both internal and external
- Training
- New regulatory requirement
- Trends from quality indicators, periodic quality and product reviews
- New business strategies that may have a critical impact on the quality system
- Stability monitoring
- Validation approach

**Note:** It is strongly recommended that participants should be familiar with basic concepts of ICHQ8 R2, ICH Q9 and ICH Q10 and a fundamental understanding of risk-based C&Q prior to attending this course. The course will not focus on the detail of the tools but the overall risk management process. However, worked examples of different tools will be given to enhance learning and understanding.

## At the conclusion of the Webinar, participants will be able to:

Understand the background for the origins of the ICH guidelines, Q8 (R2), Q9, Q10 and the basic concepts of risk-based C&Q to provide a foundation to the QRM process.

Immediately apply the course objectives using the complimentary copy of the *ISPE Good Practice Guide: Applied Risk Management for Commissioning and Qualification* and the ICH Q8R2, ICH Q9 and ICH Q10 booklets.

## Take Back to Your Job

- Understand the philosophy and application of a holistic QRM process through the development of a Quality Risk Management Plan
- Know how to develop and implement a risk decision tree and the appropriate use of risk assessment tools
- Know the risk-based approach for the delivery of facilities, systems, and equipment and the *ISPE Good Practice Guide: Applied Risk Management for Commissioning and Qualification* and how this

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aligns with the overall implementation of a robust QRM system that is applicable for the product lifecycle

- The ability to apply risk management methodologies throughout design and verification phases
- Explain the link between risk assessments, design review, and quality risk management
- Understand the expected format of the risk management plan and file inclusive of risk ranking
- Understand the importance, format and maintenance of a Risk Dashboard
- Summarise US / EU / SFDA / and WHO regulatory requirements, citations and expectations that may influence the implementation of a holistic QRM process

**Attendance Suggested For**

- Intermediate and management level Quality and Compliance Managers
- Intermediate practitioners of Commissioning and Qualification who want to understand and use QRM
- Project engineers, project managers, commissioning and validation professionals, engineering service providers, and quality assurance personnel involved in qualification and validation and regulatory

**Instructor:** Alice Redmond, Ph.D.,  
Commissioning Agents Inc

**Invest in your organisation's success by attending one of the upcoming ISPE Training Courses in 2013**

**Brussels Training Courses**

22-24 May  
Brussels, Belgium

Visit [www.ISPE.org/2013-brussels-may-training](http://www.ISPE.org/2013-brussels-may-training) for more information

**Prague Training Courses**

7-9 October  
Prague, Czech Republic

Visit [www.ISPE.org/2013-prague-october-training](http://www.ISPE.org/2013-prague-october-training) for more information

Bring your colleague and benefit from discounted group rates!  
Also obtain your complimentary copy of the ISPE Guidance documents related to the Training Courses with your registration!

## Facility Project Management (T26)

### Course Level:



ISPE CEUs: 1.3



ISPE has been reviewed and approved as a provider of project management training by the Project Management Institute (PMI®)

This course aims to deliver more than the usual project basics and will develop the concept of the project lifecycle from initiation through to delivery of business benefits and provide tools to manage all project resources. It is specifically targeted to the needs of facility projects within the regulated pharmaceutical industry and demonstrates the value inherent in the use of “good practice” project management in the regulated pharmaceutical environment. Trends in regulatory compliance, environmental, health and safety legislation, project delivery methodologies and product speed to market expectations all impact how pharmaceutical facility are managed. Each course module introduces key generic project management concepts and tools as well as methodologies which specifically support successful project delivery within the regulated pharmaceutical industry. This course is structured around a typical facility project lifecycle of Project Initiation, Delivery Planning, Design Planning and Delivery, Procurement, Construction, Commissioning and Qualification and Project Close-Out & Review and uses case study examples throughout to illustrate key points.

**Note:** Attendees should have a basic sound understanding of GMP and the pharmaceutical industry as well as the basic concepts of project delivery i.e. cost, schedule and scope planning and control.

Immediately apply the course learning objectives with the complimentary copy of the *ISPE Good Practice Guide: Project Management for the Pharmaceutical Industry*.

### Take Back to Your Job

- Define a common language within the pharmaceutical Project Management community
- Define the relationship between project management and the technical aspects of delivering a project: validation, design, procurement, construction, commissioning and qualification
- Identify the key areas where compliance to cGMP can be positively impacted by the use of “good practice” project management and appropriately manage risk at all stages in the project lifecycle
- Articulate the key project management concepts, methodologies and tools applicable to each stage in the lifecycle of a typical pharmaceutical facility project
- Understand the role of risk management within the regulated pharmaceutical environment and how it should be integrated into each aspect of a project
- Effectively integrate “hard” project management skills such as cost, change and schedule controls; with “soft” project management skills such as project team building, management of sponsors and customers, etc, in order to ensure that project objectives are achieved and business benefits delivered
- Apply the principles of “good practice” project management within the regulated pharmaceutical environment appreciating the similarities and the differences between facility projects and other project types
- Understanding of the Project Management delivery system

### Attendance Suggested For

Personnel entering facility project management coming from another discipline within the pharmaceutical industry; those with two-three years experience within a project that are looking to improve their project delivery capability; engineers, project engineers, quality and IT professionals likely to support or deliver projects and managers who are likely to sponsor projects.

**Instructor:** Patricia Melton, Ph.D. Managing Director, MIME Solutions Ltd

## Basic Principles of Computerised Systems Compliance using GAMP® 5, Including Revised Annex 11 and Part 11 Update (T45)

### Course Level:



### ISPE CEUs: 2.0

This course has been updated to include the new revised EU GMP Annex 11, and an update on 21 CFR Part 11.

This three-day fundamental course introduces participants to regulatory requirements for computerised systems in the pharmaceutical industry and explores tried, tested, and internationally recognised methods of meeting those requirements. GAMP® guidance provides a pragmatic and effective framework for achieving computerised systems that are fit for intended use and meet current regulatory requirements.

The course does not aim to cover detailed and highly technical aspects of software and hardware engineering, but rather gives the principles and an overview of the overall computer systems compliance process, including a scalable and efficient system lifecycle, Quality Risk Management, updated GAMP® categories, the role of the supplier, and the selection of appropriate specification and verification activities.

### Course Topics Include:

- What are the FDA and EU regulatory requirements for GxP computerised systems?
- How do investigators approach a computer systems inspection?
- Overview of *GAMP® 5 Guide: A Risk-based Approach to Compliant GxP Computerized Systems*
- The GAMP® system lifecycle and specifications
- Quality Risk Management for computerised systems
- Practical Risk Assessment methods
- Scalable specification and verification based on risk
- Updated GAMP® Categories
- Role of users and suppliers - assessment and cooperation and leveraging supplier activities and documentation
- Testing in GAMP® - principles and practical approaches

- Pragmatic and efficient practices - cost effective compliance
- Revised EU Annex 11 Computerised Systems, including the official GAMP® interpretation of key aspects
- FDA 21 CFR Part 11 Update, including the current FDA interpretation and Part 11 “add on” inspections
- A Risk-Based approach to Electronic Records and Signatures to meet both FDA and EU expectations

Immediately apply the course learning objectives with the complimentary copy of the *GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems Guide* and the *GAMP Good Practice Guide: A Risk-Based Approach to Compliant Electronic Records and Signatures*.

### Take Back to Your Job

- Explain the regulatory requirements and expectations for computerised systems used in pharmaceutical manufacturing
- Apply GAMP® principles to specific systems and cases
- Describe the GAMP® approach to computerised system compliance
- Apply these ideas to systems within your own organisation

### Attendance Suggested for

- Quality assurance and quality control specialists, validation specialists, manufacturing supervisors, technical support personnel, engineers, MIS professionals and all levels of management who need a fundamental understanding of computerised system compliance and regulations
- Computer system vendors or consultants, engineering contractors, and validation service companies

**Instructor:** Sion Wyn, Director, Conformity Ltd.

### Advance your career with ISPE Training Courses!

ISPE offers a wide variety of professional development courses in Europe to boost your expertise and further enhance your technical knowledge.

Our training programmes are delivered by high-level industry professionals who are experts in their own disciplines, in order to provide you with the latest trends, best practices and regulatory standards.

Visit [www.ISPE.org/Training](http://www.ISPE.org/Training) for more information on our training offer.

### Prague Training Courses, 7-9 October 2013

#### T17: Cleaning Validation Principles

This course will cover elements of a cleaning validation programme from start to finish, exploring such concepts as the determination of residues to be targeted, selection of analytical and sampling methods, determination of appropriate limits in various pharmaceutical and biotechnology processes and establishment of scientific rationales acceptable to regulatory inspectors.

#### TBD: QbD

#### T32: Process Validation in Biotechnology Manufacturing

This course is designed to provide a clear understanding of the regulatory, scientific, and engineering tools required to successfully develop and validate bioprocesses. In addition, the course identifies the long list of activities required to validate biopharmaceutical processes.

#### T41: Managing the Risk of Cross Contamination: Applying the Risk MaPP Baseline® Guide

This course will focus on using 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.

#### T21: A Risk-Based Approach to GxP Process Control Systems Applying the GAMP® Good Practice Guide: A Risk-Based Approach to GxP Process Control Systems (2nd Edition)

The course covers recommended good practice based on a lifecycle approach for the development and management of process control systems and shows how the principles and concepts of GAMP® 5 may be practically applied to process control systems.

#### G07: GMP Auditing for the Pharmaceutical Industry

This course is specifically designed to address the challenges of GMP auditing for the pharmaceutical industry and present the basic competencies required to effectively perform the auditor's assigned responsibilities and contribute to the improvement of auditor performance within a regulated industry.

#### T12: Sterile Drug Manufacturing Facility

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.

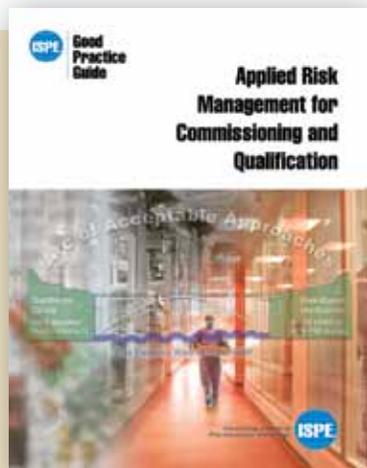
Visit [www.ISPE.org/2013-prague-october-training](http://www.ISPE.org/2013-prague-october-training) for more information coming soon.

### FREE copy of ISPE Good Practice Guide complimentary to your registration!

Obtain a free copy of the ISPE Guidance documents related to the Training Courses with your registration.

Register for Brussels 'Applying Quality Risk Management' Training Course and get your complimentary copy of the *ISPE Good Practice Guide: Applied Risk Management for Commissioning and Qualification!*

For more information on ISPE Guidance documents visit [www.ISPE.org/guidance-documents](http://www.ISPE.org/guidance-documents)



## How to Register

**Online:** Visit the website specific to you and register online under the 'Fees and Registration' Tab or 'Attend the Trainings' Tab.

**Via Fax:** Complete the registration form online and fax it to: +32 2 743 15 84

**Via Mail:** Complete the Registration Form online and mail it to: [ISPERegistrations@associationhq.com](mailto:ISPERegistrations@associationhq.com)

ISPE Registration Services

Avenue de Tervueren, 300 – B-1150 Brussels, Belgium

Tel: +32 2 743 44 22

## Questions?

Call ISPE Member Services at

Tel: + 32 2 743 44 22 or email: [ISPERegistrations@associationhq.com](mailto:ISPERegistrations@associationhq.com)

## Registration Fees

Include training materials, refreshment breaks listed in the programme, lunches, exhibition networking receptions and exhibition access. Registration is confirmed only when payment is received. Visit the Training Event website for more details.

## Discounted Student and Group Rates

Discounted student and group rates are available upon request. For more information contact ISPE Registration Services by telephone: +32 2 743 44 22 or by email [ISPERegistrations@associationhq.com](mailto:ISPERegistrations@associationhq.com).

## Hotel Information

Check the Training Event website for information on the hotel. When making your reservation, mention ISPE for a discounted group rate. Discounted rates are only good for a limited time.

## Early Bird Prices

Prices mentioned above reflect discounted rates if you register before 22 April for Brussels Training Courses. Visit the Training Event website for more details.

Information on fees and early bird prices for Prague Training Courses will be available soon on the Training Event website.

## Brussels Training Courses, 22-24 May

Fees	Member	New Member	Non Member
T43: Turning QbD into a Practical Reality	€1.650	€1.869	€1.965
T40: Science and Risk-Based Commissioning & Qualification	€1.650	€1.869	€1.965
T10: Oral Solid Dosage Forms	€1.550	€1.769	€1.860
T13: Clinical Trial Materials	€1.550	€1.769	€1.860
T42: Applying Quality Risk Management	€1.650	€1.869	€1.965
T26: Facility Project Management	€1.550	€1.769	€1.860
T45: Basic Principles of Computerised Systems Compliance using GAMP® 5, Including Revised Annex 11 and Part 11 Update	€1.975	€2.194	€2.305

## Save the Date for Future ISPE Events!

### Europe

#### March 2013

Critical Utilities EU Conference, 12–13 March, Copenhagen, Denmark

Regulatory Compliance EU Conference, Spring 2013, Brussels, Belgium

#### May 2013

Brussels Training Courses, 22–24 May, Brussels, Belgium

#### June 2013

Supply Chain EU Conference, Prague, Czech Republic

#### September 2013

Biotechnology EU Conference, France

#### October 2013

Prague Training Courses, 7-9 October, Prague, Czech Republic  
Lean Manufacturing EU Conference, Berlin, Germany

### North America

#### 13 – 14 May

Supply Management Summit  
Indianapolis, Indiana

#### 11 – 13 June

CGMP Conference  
Baltimore, Maryland USA

#### 27 – 28 August

Biotechnology Conference  
Raleigh, North Carolina USA

#### September

San Francisco Area (Burlingame)  
California Training Event

#### 14 – 15 October

Proactive Compliance Conference  
Philadelphia, Pennsylvania

#### 16 – 17 October

Process Validation Conference  
Philadelphia, Pennsylvania

#### 3 – 6 November

ISPE 2013 Annual Meeting  
Washington, DC

#### 9 – 12 December

Tampa, Florida Training Event

For more information visit [www.ISPE.org/events](http://www.ISPE.org/events)