



ISPE

Strasbourg Conference

Managing Knowledge Through Science and Risk Assessment

▶ 28 - 29 September 2009

- Commissioning and Qualification: Practical Applications of Science and Risk-based Approaches to Validation
- Disposables and Containment Technology in Biomanufacturing: Managing Risk, Reducing Cost
- GAMP® 5 Operational Aspects

▶ 30 September - 1 October 2009

- Barrier Isolation Forum, Innovation Updates and New Case Studies
- Investigational Medicinal Product (IP) Innovation in a Regulated Environment
- PQLI® - Global Realisation and Implementation of the ICH Quality Vision

▶ Training Courses

- Basic Principles of Computerised Systems Compliance (GAMP® 5) (T07)
- Cleaning Validation Principles (T17)

ISPE 2009 Strasbourg Conference-At-A-Glance

Table of Contents

Strasbourg Conference Schedule	2
About ISPE Training	2
Join ISPE	2
Exhibition Networking	2
CPIP™	3
Conference Seminars	4-15
Training Courses	16-17
Sponsorship and Exhibition	18-19
Technical Documents Advertisement	20
ISPE Membership has its Benefits	21
Registration Form	22
General Terms and Conditions	23
Mark Your Calendars	24

Exhibition Networking Receptions

Monday 28 September 17.30 – 18.30
 Wednesday 30 September 17.30 – 18.30

Exhibition networking receptions offer you a chance to engage with fellow seminar delegates and vendors. Engage with colleagues, meet like-minded professionals, make new business contacts and relax after the first day's seminar sessions.

Join ISPE - Experience the Benefits

ISPE is the Society of choice for 25,000 pharmaceutical science and manufacturing professionals from 90 countries. ISPE provides Members with opportunities to:

- Develop technical knowledge and resources to make your day-to-day job easier
- Exchange practical experience and collaborate with global regulatory agencies
- Develop professionally, with tools developed to support your professional advancement.

Nonmembers registering for this conference will receive one-year membership of ISPE. Find out more about ISPE membership, and this opportunity, by visiting www.ISPE.org.

ISPE 2009 Strasbourg Conference and Training Schedule

28 September – 1 October 2009
 Palais des Congrès

Date	Conference Seminars			Training Courses	Network Events	
Monday, 28 September	Commissioning and Qualification	Disposables and Containment	GAMP®5: Operational Aspects		Exhibition Networking	
Tuesday, 29 September						
Wednesday, 30 September	Barrier Isolation Forum	Investigational Product (IP)	PQLI®	Basic Principles of Computerised Systems Compliance (GAMP® 5) (T07)	Cleaning Validation Principles (T17)	Exhibition Networking
Thursday, 1 October						

About ISPE Training Courses

ISPE's classroom training courses address your knowledge needs with technical courses focused on the skills and knowledge you need for your job today and your future career. Gain solutions to your company's immediate goals to lower production costs, improve process efficiency, increase production quality, and meet regulatory requirements.

Find out more about ISPE training – visit www.ISPE.org/training.

ISPE Communities of Practice (COPs)

Many ISPE courses and seminars are developed by ISPE COPs. These interactive online communities provide access to specific bodies of knowledge, and allow like-minded professionals around the world to engage in electronic discussions on topics of interest; to collaborate on documents, important resources, and content relevant to the discipline; and to solve everyday problems with pragmatic approaches. Learn more about the current COPs and join groups of interest at www.ISPE.org/COPs.

Current COPs with Abbreviations:

- Active Pharmaceutical Ingredients (API)
- Biotechnology (Biotech)
- Commissioning and Qualification (C&Q)
- Containment
- Critical Utilities (CU)
- Disposables
- Engineering Standards Benchmarking (ESB)
- Good Automated Manufacturing Practice (GAMP)
- Good Control Laboratory Practices (GCLP)
- Heating, Ventilation, and Air Conditioning (HVAC)
- Investigational Products (IP)
- Oral Solid Dosage (OSD)
- Packaging
- Process Analytical Technology (PAT)
- Process/Product Development (PPD)
- Project Management (PM)
- Sterile Products Processing (SPP)
- Sustainable Facilities

Certified Pharmaceutical Industry Professional™ Certification Programme Knowledge Elements



Strasbourg Conference seminars and training courses contain knowledge related to the seven technical knowledge competency areas for the Certified Pharmaceutical Industry Professional™ (CPIP™) certification programme, an international credential made available through the ISPE Professional Certification Commission. Completion of any of these seminars does not guarantee successful completion of the CPIP Certification Programme certification exam. Visit www.ISPE.org/CPIP to find out more about CPIP.

CPIP™ Certification Programme Technical Knowledge Competency Areas	1	Product Development	A	Formulation, clinical phases, and manufacture
			B	Technology transfer
			C	Production scale-up and optimisation
	2	Facilities and Equipment	A	Design and construction/installation
			B	Commissioning and qualification as a risk management strategy
			C	Operation and maintenance
			D	Controls and automation
3	Information Systems			
4	Supply Chain Management	A	Materials management	
		B	Operational economics	
		C	Warehouse and distribution management	
5	Production Systems	A	Production unit operations – drug (small molecule) and biologics	
		B	Production management	
		C	Production control	
6	Regulatory Compliance (Drugs, Env, Health, Safety)	A	Government regulations	
		B	Standards, practices, and guides	
7	Quality Systems	A	Risk management and Quality Management System (QMS)	
		B	Systems validation	

Technical Knowledge Competency Areas

2009 Strasbourg Conference Seminars	1			2				3	4			5			6		7	
	A	B	C	A	B	C	D	A	A	B	C	A	B	C	A	B	A	B
Commissioning and Qualification: Practical Applications of Science and Risk-based Approaches to Validation				X	X	X	X								X	X	X	X
Disposables and Containment Technology in Biomanufacturing: Managing Risk, Reducing Cost			X	X	X	X	X											
GAMP® 5 Operational Aspects						X	X	X		X		X			X	X	X	X
Barrier Isolation Forum, Innovation Updates and New Case Studies				X	X	X	X											
Investigational Medicinal Product (IP) Innovation in a Regulated Environment	X	X	X					X	X	X	X				X	X	X	X
PQLI® - Global Realisation and Implementation of the ICH Quality Vision	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Basic Principles of Computerised Systems Compliance								X										X
Cleaning Validation Principles														X				

CPIP™ Certification Programme “How-to” Workshops

Tuesday 29 September 12.45 - 13.30

Wednesday 30 September 12.45 - 13.30

Interested in becoming a Certified Pharmaceutical Industry Professional™? Anders Brummerstedt, CPIP and member of the ISPE Professional Certification Commission, will lead these complimentary one-hour workshops, and provide guidance on “how-to” submit a CPIP™ certification programme eligibility application and prepare for the CPIP™ certification programme examination. Topics include: obtaining a University transcript, completing the professional experience forms, utilising the CPIP™ certification programme Study Guide resources CD-ROM, and organising CPIP™ certification programme study groups.

Visit www.ISPE.org/CPIP for more information.

Seminar Leaders:

Nuala Calnan, PM Group (Ireland);

Jörg Block, Bayer Healthcare (Germany)

The course will provide insight into the current industry imperatives for change and review the impacts and opportunities of the recent Verification Approach initiatives such as *ISPE's Baseline Guide Volume 12* and the ASTM E2500-07 Standard. It will also capture the challenges presented in transitioning from past practices to science and risk-based methodologies as described in ICH Q9 and introduce the proposed *ISPE Good Practice Guidance on Commissioning and Qualification*.

The session will concentrate on actual project case studies and practical interactive workshops presented and facilitated by practitioners currently engaged in implementing revised approaches. The course will also correlate the USA FDA's revised Guidance on Process Validation to the changes in commissioning and qualification.

In addition, the seminar will include a European Regulatory view on the importance of applying science and risk based approaches and the alignment between Europe and the USA on the requirements for Process Validation (PV).

Take Back to Your Job:

- Understand the key principles of the new *Baseline® Pharmaceutical Engineering Guide for New and Renovated Facilities, Volume 12*
- Utilise the recommendations proposed for the *Good Practice Guide for Commissioning and Qualification*
- Identify a clear pathway for transitioning from Good Practice based Commissioning and Qualification practices towards the desired state of a "fully implemented" risk-based verification approach
- Examine recent examples of pharmaceutical projects applying aspects of risk based approaches and how they transitioned from traditional approaches to "leaner" CQ approaches
- Engage in interactive workshops with user-friendly tools to develop the skills required to address the challenges facing those transitioning and discuss the variety of solutions undertaken
- Understand the philosophies and explore key tools required in the application of "Lean" principles across the lifecycle to impact successful CQ outcomes
- Awareness of the recent changes in the FDA's thinking on lifecycle based process validation and the role that verification / CQ plays in supporting these outcomes

Who Should Attend:

All those involved in or having responsibility for the specification, design, and verification of Pharmaceutical and Biopharmaceutical manufacturing systems and equipment.

- Process, Project and Plant Engineering disciplines
- Manufacturing Operations
- QA/ Validation
- Process Development and Technology Transfer personnel
- Project Managers

Related Technical Documents:

- ASTM E2500-07 Standard for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment.
- *ISPE Baseline® Pharmaceutical Engineering Guide for New and Renovated Facilities, Volume 12*
- *ISPE Baseline Guide Volume 6 and 5 and Proposed Good Practice Guide on Commissioning and Qualification*
- *ISPE Good Practice Guide on Good Engineering Practice (GEP)*

Regulatory Issues:

- ICH Q8 and Q9
- Eudralex Volume 4 Annex 20
- FDA Draft guidance on Process Validation



Technical Knowledge and Competency Elements:

A chart of the CPIP™ certification programme categories addressed by this seminar is shown on page 3.

Seminar Content Level:



Day 1

- 09.30 – 10.00** **Baseline Guide® 12 Overview**
This introduction will include the overall content of the final draft of the new *Baseline Guide* and provide an introduction to the guide covering the Regulatory Basis and Key Principles. In addition the Guide Philosophy and Key Concepts will also be introduced.
Nuala Calnan, PM Group (Ireland)
- 10.00 – 10.45** **Risk-Based Approaches to Commissioning & Qualification - A Regulatory View**
EU Regulator, invited
- 10.45 – 11.30** **Critical Support Practices for Implementing a Science & Risk Based Approach**
The session will capture the critical engineering and project practices required to support a successful risk based verification approach and to demonstrate that systems and processes are "fit for their intended use" (*Baseline Guide 12 Implementation*). Current methodologies and practical project applications will be presented, including:
 - Recommended Good Engineering Practices (GEP)
 - Essentials for Executing Quality Risk Assessments
 - Efficient Design Review
 - Effective Change Management*Bob Adamson, Foster Wheeler (UK)*
- 11.30 – 12.15** **Pfizer Case Study Implementation of an ASTM E 2500-based Verification Approach on an Aseptic Filling Line Project**
Jan Slock, Pfizer (Belgium); Graham Wrigley, Pfizer (USA)
- 12.15 – 13.30** **Lunch and Networking Break**
- 13.30 – 14.15** **FDA's new Draft Process Validation Guidance Overview and Implications for C&Q programmes**
Nuala Calnan, PM Group (Ireland)
- 14.15 – 15.00** **Changing the Culture to Prepare for Science and Risk Based Methodologies - Case Study**
Peter Werner Christensen, NINE Pharmaplan (Denmark)
- 15.00 – 15.30** **Coffee and Networking Break**
- 15.30 – 16.00** **J&J Case Study: Application and Benefits of Assessing Risks for OSD Processes**
Mike O' Neal, J&J (USA); Machteld Deconinck, J&J (Belgium)
- 16.00 – 17.00** **Linking Risk Assessments Outputs to Final Acceptance and Release**
Practical Workshop which the delegates will work with a Risk Assessment and followed through on how the RA drives the design review & verification process to achieve quality "acceptance and release"
Mike O' Neal, J&J (USA); Machteld Deconinck, J&J (Belgium)
- 17.00 – 17.30** **Questions and Answers**
Nuala Calnan, PM Group (Ireland); Jörg Block, Bayer Healthcare (Germany)
- 17.30 – 18.30** **Exhibition Networking Reception**

Day 2

- 09.00 – 09.45** **C&Q Good Practice Guide Update**
This forthcoming Guide is being designed to update the approaches first presented in the groundbreaking 2001 *Baseline Guide 5* to better reflect the subsequent developments in risk based GMP reflected in the ICH documents and the ASTM E 2500-07. Participants will get an early look at the structure and transitional approaches described in the guide. This session is lead by the European co-leader of the C&Q COP team that is drafting the Guide will preview its contents and provide a status update.
Jörg Block, Bayer Healthcare (Germany)
- 09.45 – 10.30** **Case Study 1:**
Combination Approach of Volume 5 and Volume 12 - The challenges and benefits of applying a Science and Risk-based C&Q approach within a Contract Manufacturing Organisation
Frank van der Steen, SynCo Bio Partners (The Netherlands)
- 10.30 – 11.00** **Coffee and Networking Break**
- 11.00 – 12.00** **Case Study 2:**
Combination Approach of Volume 5 and Volume 12
- 12.00 – 13.30** **Lunch and Networking Break**
- 13.30 – 15.00** **Preparing User Requirements: Identifying Critical Quality Attributes (CQA) and Critical Process Parameters (CPP) Workshop**
This workshop will focus on the critical stage of defining the key User Requirements for the project and the importance of distinguishing between user and technical requirements. It will deal with the establishing the 'Scientific' basis, understanding acceptance criteria and documentation traceability and change control.
Steve Wisniewski, IPS (USA)
- 15.00 – 16.15** **Lean Principles Workshop - Delivery the Expected Gains from a Risk-based Verification Approach**
A brief introductory presentation will provide an overview of the Lean Verification Workshop outlining the application of some key lean tools beneficial at particular project phases across the life-cycle. The Workshop will then provide participants an opportunity (in three groups) to work through the application of lean tools for real-life project challenges. In the second half of the workshop the three teams will come together and review deliverables from each team and determine success and identify issues with the process
Carlton Monkhouse, PM Group (Ireland)
- 16.15 – 16.30** **Questions and Answers, Close of Seminar**
Nuala Calnan, PM Group (Ireland); Jörg Block, Bayer Healthcare (Germany)

Seminar Leaders:

Miriam Monge, Biopharm Services, Ltd., (France);

Berthold DÜthorn, Robert Bosch GmbH, (Germany)

Attendees will learn about the use of containment and disposable technologies to ensure sterile conditions in a wide variety of applications. The seminar will also address how effective selection and implementation of disposables can drive out costs from biomanufacturing.

The seminar will highlight the value this technology can bring along with the inherent challenges, risks and regulatory requirements for implementation of the technology through a series of end-user case studies.

This seminar will feature two hands-on half-day workshop sessions focusing on containment technology in aseptic manufacturing operations and Bioprocess economic analysis tools for disposables selection.

Communities of Practice (COP):

Biotech • Containment • Disposables • Product Process Development • Sterile Products Processing

Take Back to Your Job:

- Learn how to evaluate lifecycle costs and use
- Cost modelling tools to select when and where it makes sense to implement disposable technologies
- Development of Procurement strategies for disposables to reduce supply chain risk
- Rapid build: factors to consider with disposables
- Understand the manufacturing, quality, and regulatory standards with which disposable suppliers working in this field need to comply
- Achieving contained closed processing with disposables
- Implications of lean manufacturing for disposables

Who Should Attend:

- Process development, manufacturing, engineering, procurement, and validation personnel



Technical Knowledge and Competency Elements:

A chart of the CPIP™ certification programme categories addressed by this seminar is shown on page 3.

Seminar Content Level:



Day 1

- 10.00 – 10.15 **Welcome and Introduction**
*Miriam Monge, Biopharm Services Ltd (France);
Berthold DÜthorn, Robert Bosch GmbH (Germany)*
- 10.15 – 11.00 **Biological Products Manufacturing Challenges - Now and in the Future**
Miriam Monge, Biopharm Services Ltd (France)
 - Pressure to reduce cost of goods
 - The impact of high titers
 - The role of disposables
 - Towards the flexible pipeless facility of the future?
- 11.00 – 11.45 **Occupational and Patient Exposure Issues with Large and Small Molecules**
Bob Sussman as co-ordinator, Safebridge (USA/ UK)
 - Originally thought to be reasonably safe to handle Large Molecules and Large and Small molecule conjugations have significant risks these risks are reviewed.
 - What are the routes of exposure?
 - Does conjugation take away the risk?
- 11.45 – 12.30 **Leachates and Extractables**
Speaker tbc
 - Contamination by leachates and extractables and particulates is a major issue in the disposables and containment worlds. Their impact can be significant.
 - How can they be reduced or controlled
 - What works, what does not
- 12.30 – 13.45 **Lunch and Networking Break**
- 13.45 – 15.15 **Workshops 1 and 2 (running in parallel)**
Workshop 1 Driving Out Cost in Biomanufacturing
Andrew Sinclair, Biopharm Services (UK)
Introduction to process and cost modelling techniques:
 - Evaluating lifecycle costs
 - Cost modelling methodologies CoG, ROI, NPV
 - Evaluating cost benefits options important factors to consider
 - What is the environmental contribution**Case study and exercise led by**
Guillaume de Viron, Artelis (Belgium)
 - Use of process cost and COG models to analyse the best fit of disposables versus stainless steel in end-user processes**Workshop 2 Mechanisms by which Exposure Occurs**
Julian Wilkins, Pharmaconsult US (USA)
 - Delegates will be provided with a range of tools and PPE so that they can gown, manipulate a harmless substance and assess their performance. This is a real hands on demonstration of how materials behave in the real world and how exposures occur.
 - Delegates will: write a SOP, execute the SOP, review the routes of exposure, assess performance, present the lessons learnt
- 15.15 – 15.45 **Coffee and Networking Break**
- 15.45 – 16.15 **Workshops 1 and 2 Feedback**
In groups as above
- 16.15 – 17.00 **A Risk Management Approach to Disposables Selection and Implementation**
Stephen Brown, Vivalis (France)
 - Selection, prototyping and evaluation procedure, for scalable disposable bioreactors: case study
 - Evaluation of waste management legislation for disposable technologies
- 17.00. – 17.30 **Questions & Answers, Close of Day 1**
*Miriam Monge, Biopharm Services Ltd (France);
Berthold DÜthorn, Robert Bosch GmbH (Germany)*
- 17.30 – 18.30 **Exhibition Networking Reception**

Day 2

- 09.00 – 09.15 **Review of Day 1, Introduction of Day 2**
*Miriam Monge, Biopharm Services Ltd (France);
Berthold DÜthorn, Robert Bosch GmbH (Germany)*
- 09.15 – 10.00 **Disposables Risk Management - Facilities**
Klaus Hermansen, NNE Pharmaplan (Denmark)
 - Disposable system implementation in new facilities: case studies
 - Achieving contained closed processing with disposables
 - Rapid build, factors to consider with disposables
 - Bavarian Nordic high containment facility case study
- 10.00 – 10.45 **Disposables and Lean Manufacturing Concepts**
Emmet Cronin, élan biologics (USA)
 - The seven wastes
 - Manufacturing simplification
 - Flexible technology proof facilities
 - Impact on costs
 - Case study
- 10.45 – 11.15 **Coffee and Networking Break**
- 11.15 – 12.00 **The Disposables Flexfactory - Rapid Deployment Facilities, Flexible and Cost Effective**
Geoff Hodge, Xcellerex (USA)
 - Combining disposables, controlled environment modules and process automation
 - Achieving flexible multi-product manufacture
 - Rapid response facilities building capacity quickly
- 12.00 – 12.45 **Containment Technologies**
Didier Meyer as co-ordinator, La Calhene (France)
 - A case study of a flexible film/ disposable parenteral facility
 - How it was conceived, executed and how it has performed
- 12.45 – 14.00 **Lunch and Networking Break**
- 14.00 – 14.45 **Disposable Technologies Dramatically Increasing Flexibility of a Downstream Process: a Retrofit Case Study**
Jean-Claude Muller, Schlüssler & Cramer AG (Switzerland)
 - Rapid implementation of disposables into an existing operation
 - Req't for multiple process configurations and aseptic connection methods
 - Validation challenges
- 14.45 – 15.30 **Case Study Biotech Factory of the Future**
Speaker tbc
 - Dramatic changes in the yield of fermentation processes and the need to cut costs and minimise the carbon footprint have lead to new ways to look at processing
 - The presentation looks at one companies approach to the factory of the future
- 15.30 – 16.00 **Questions & Answers, Close of Seminar**
*Miriam Monge, Biopharm Services Ltd (France);
Berthold DÜthorn, Robert Bosch GmbH (Germany)*

Seminar Leaders:

Yves Samson, Kereon AG, (Switzerland);

Kate Samways, KAS Associates (UK)

How to plan, to manage and to monitor effectively operation of computerised systems?

The GAMP seminar will feature the launch of the *GAMP Good Practice Guide on "Maintaining Control in Operation"*.

Objectives are to present the Guide (structure and content) as well as to propose examples showing how operation good practices are already in place in the daily industry life.

This seminar will also provide to the attendees various experience reports (case studies) presented by industry practitioners.

Communities of Practice (COP):

GAMP

Take Back to Your Job:

- Review operational processes
- Investigate and assess such processes
- Improve operational controls in order to maintain GxP systems under control during operation until retirement

Who Should Attend:

- Practitioners operating computerised systems e.g. automated systems, laboratory computerised systems, information systems, and IT infrastructure
- Site engineer, system supporters, IT department (especially, and operational QA members)



Technical Knowledge and Competency Elements:

A chart of the CPIIP™ certification programme categories addressed by this seminar is shown on page 3.

Seminar Content Level:



Day 1

- 10.00 – 10.15 **Welcome and Introduction**
Yves Samson, Kereon AG (Switzerland);
Kate Samways, KAS Associates (UK)
- 10.15 – 11.00 **Overview of GPG Maintaining Control in Operation**
Kate Samways, KAS Associates (UK)
 - Why maintain control in operation
 - Scope of the Guide
 - The interactions between operational processes
- 11.00 – 11.45 **Change Management and Systems Administration - the Cornerstone**
Rob Stephenson, Pfizer (UK)
 - What is the scope of change management (Planned, Unplanned, Repair, and Sys Admin)
 - Why is it so difficult?
 - Scalability of the process (including system administration tasks)
 - Role of the change management board
- 11.45 – 12.30 **Support Services and Supplier Management**
Chris Reid, Integrity Solutions (UK)
 - What services are required?
 - Selecting the service provider
 - Monitoring the service provider
 - Exit strategies
- 12.30 – 14.00 **Lunch and Networking Break**
- 14.00 – 14.45 **Incident Management, CAPA and System Performance Monitoring**
Charlie Wakeham, PALL (UK)
 - What is an incident?
 - The relationship between the processes and process nesting
 - What metrics make sense for which systems?
- 14.45 – 15.30 **Business Continuity**
Yves Samson, Kereon AG (Switzerland)
 - When is it required?
 - What is the scope?
 - How to prepare?
- 15.30 – 16.00 **Coffee and Networking Break**
- 16.00 – 16.45 **System Retirement and Data Migration**
Pam Lawrence, Perceptive Informatics (UK)
 - Stepping through the process
 - What to do with the data
 - Co-ordination with system implementations
- 16.45 – 17.30 **Questions and Answers, Close of Day 1**
Yves Samson, Kereon AG (Switzerland);
Kate Samways, KAS Associates (UK)
- 17.30 – 18.30 **Exhibition Networking Reception**

Day 2

- 09.00 – 09.15 **Recap Day 1, Introduction to Day 2**
Yves Samson, Kereon AG (Switzerland);
Kate Samways, KAS Associates (UK)
- 09.15 – 09.45 **How Good are Your Operational Processes? (benchmarking workshop)**
Kate Samways, KAS Associates (UK)
 - Review of each operational process with delegates scoring themselves
 - Results collated with feedback session later in the day
- 09.45 – 10.45 **Case Study: Maintaining Compliance within a Laboratory Environment**
Mélanie Koch, Novartis Pharma AG (Switzerland)
 - Inventory, more than a list: a compliance management tool
 - Planning and monitoring compliance activities
 - How to trace incident, problem, and deviation
- 10.45 – 11.15 **Coffee and Networking Break**
- 11.15 – 12.30 **Operation: the Inspector's Point of View**
EU Regulator, invited
 - Regulatory requirements to operation
 - How to consider the operational phase during an inspection?
 - Typical pitfalls
- 12.30 – 14.00 **Lunch and Networking Break**
- 14.00 – 14.45 **Case Study: Prospective Planning of the Operational Phase for a Crossfunctional and Multisite System**
Evelyne Lemaire, PWC (UK)
 - How to realise a successful transition?
 - How to consider efficiently operational aspects and constraints during the project phase?
 - How to consolidate the system design for improving future system operation?
 - How to plan the compliance reviews?
- 14.45 – 15.15 **Feedback from Benchmarking**
Kate Samways, KAS Associates (UK)
 - Review with delegates the results to show strengths and weaknesses in operational controls
- 15.15 – 16.00 **Case Study: Records Management**
Eberhard Kwiatkowski, Bayer Schering Pharma (Germany)
 - Record content, responsibilities
 - Record retention and handling
 - Verify archiving activities
 - Monitor on-going availability
 - CAPA and operational change
 - Records availability for audit
 - Record destruction
- 16.00 – 16.30 **GAMP Forum Discussion**
All speakers
 - Plenary Q&A session
- 16.30 – 16.45 **Close of Seminar**
Yves Samson, Kereon AG (Switzerland);
Kate Samways, KAS Associates (UK)

Seminar Leaders:

Charlotte Enghave, NNE Pharmaplan, (Denmark);
Jack Lysfjord, Lysfjord Consulting LLC (USA)

This two-day session will keep you and your company on the cutting-edge of the newest developments and provide insights from new case studies.

This seminar teaches advanced aseptic processing using RABS and isolator technology and “what to do as well as what not to do,” from those with experience. Content includes background information but focuses on technology updates, and new case studies. An interactive workshop gives you access to discussion topics of global importance.

Communities of Practice (COP):

API • Containment • PPD • SPP

Take Back to Your Job:

- Hear from speakers from Europe, North America and Japan
- Participate in a Regulators' question and answer period
- The latest Technology updates and case studies for RABS and Isolators
- Gain insight on updated technologies applicable to advanced aseptic processing
- Learn from the experience of others in our industry
- Gain regulatory insight that will help streamline regulatory submissions and approvals
- Participate in a discussion group and answer your questions

Who Should Attend:

- Life Sciences professionals from development, quality assurance, quality control, regulatory affairs, design and project engineers
- Professionals interested in the design and operation of RABS and isolators

Technical Documents:

- *Sterile Facilities Baseline® Guide*



Technical Knowledge and Competency Elements:

A chart of the CPIP™ certification programme categories addressed by this seminar is shown on page 3.

Seminar Content Level:



Day 1

10.00 – 10.10

Welcome and Introduction

Charlotte Enghave, NNE Pharmaplan, (Denmark);
Jack Lysfjord, Lysfjord Consulting LLC (USA)

10.10 – 10.45

RABS History and Trends 2009 Preliminary Data

Jack Lysfjord, Lysfjord Consulting LLC (USA)

- 2009 summation of preliminary data on global use of RABS for aseptic processing
- Comparison and trend analysis to prior RABS surveys
- Regional breakouts of data allows for pharma companies to benchmark with others in their region and globally

10.45 – 11.30

Vision-Guided Isolated Robotic Technology; Digitally Adaptable Aseptic Processing

Chris Procyshyn, VanRx Pharmaceuticals (Canada)

- Risk-based design of an adaptable aseptic workcell
- Key adaptations of technology for isolator applications and decontamination
- Lessons from other industries
- Rethinking conventional approaches

11.30 – 12.15

Factors, Facts and Figures in Regard to the Performance of a Reproducible H₂O₂ Bio-decontamination of a Leaktight Enclosure

Didier Meyer, LaCalhene (France)

- H₂O₂ vapour as a bio-decontamination process for isolators is always an equilibrium between dry and wet status. Factors to consider to reach the most efficient equilibrium are temperature/rH of surrounding room
- Comparative sizes of surfaces of rigid and flexible materials of construction. Surprising results emphasize the need of dedicated cycle developments

12.15 – 13.15

Lunch and Networking Break

13.15 – 14.00

New Parenteral Production Facility for Hoffmann La Roche Kaiseraugst, Switzerland

Hartmut Shatz, NNE Pharmaplan (Germany);
Rainer Schmidt, Hoffmann La Roche (Switzerland)

- See the advantages of a modular layout design
- See the latest equipment features for liquid vial, freeze dried vial and pre-filled liquid syringe fill and finish equipment
- Learn the rationale behind the decision to go in RABS or isolator technology for the individual filling lines
- Review lessons learned as well as project challenges of a 170 Mio. US \$ fill and finish facility

14.00 – 14.45

Low Energy E-Beam Qualification in Aseptic Processing - A Case Study

Dr Dieter Bachmann, Cilag AG (Switzerland)

- E-Beam processing of PFS
- E-Beam qualification
- Decontamination of PFS tubs
- First experiences with E-Beam use in aseptic manufacturing

14.45 – 15.15

Coffee and Networking Break

15.15 – 16.00

Architectural Design Concepts for Isolator Based Aseptic Facilities

Dr Dieter Bachmann, Cilag AG (Switzerland)

- Study six different isolator based aseptic suite designs
- Review impact of EU Annex 1 to isolator based aseptic suite design
- Discuss EU and FDA harmonisation issues in isolator suite room classifications
- Learn practical design details for aseptic suites
- Review design examples from large pharma, generics, small biopharm, and contract manufacturers

16.00 – 16.45

Japanese Perspective on Using Isolators and RABS for Aseptic Processing

Koji Kawasaki, Airex (Japan)

- Case studies using Isolators or RABS for processing lines of ophthalmic solutions
- Application of robotics for gaseous hydrogen peroxide decontamination systems
- Implementation of the hydrogen peroxide gas distribution system to inside of RABS
- Multiple distribution system of the hydrogen peroxide gas from his generating chamber to rooms and to inside of RABS

16.45 – 17.00

Questions & Answers, Close of Day 1

Charlotte Enghave, NNE Pharmaplan, (Denmark);
Jack Lysfjord, Lysfjord Consulting LLC (USA)

17.30 – 18.30

Exhibitor Networking Reception

Day 2

09.00 – 09.10

Review of Day 1, Introduction of Day 2

Charlotte Enghave, NNE Pharmaplan, (Denmark);
Jack Lysfjord, Lysfjord Consulting LLC (USA)

09.10 – 09.55

Aseptic Blow /Fill/ Seal Technology with Isolator Supplied Sterile Insert Parts

Tim Kram, Rommelag (USA)

- Fundamental information on blow/ fill/ seal advanced aseptic technology
- Insert technology - using BFS with isolator supplied sterile parts
- SVP applications using insert technology
- Benefits and limitations of BFS insert technology

09.55 – 10.25

Coffee and Networking Break

10.25 – 11.10

In-Line Electron Beam Sterilisation Tunnels in the Pharmaceutical and Medical Device Industries

Philippe Fontcuberta, Linac Technology (France);
Martial Fouache, Sanofi Pasteur (France)

- In-line sterilisation tunnels using medium energy e-beam for core sterilisation
- Advantages of in-line sterilisation tunnels for the healthcare industry
- Economies thanks to installation of in-line e-beam sterilisation tunnels
- Validation process of a low energy e-beam unit

11.10 – 12.10

Discussion Groups

12.10 – 13.30

Lunch and Networking Break

13.30 – 14.15

Placebo to Potent: Experiences of a Clinical Barrier Isolator Facility

Sarah Doshna, Bristol Myers Squibb (USA)

- Learn how clinical trial demands differ from full scale production
- Debunk the myth that isolators are too rigid for clinical supply manufacturing needs
- See true case-studies of clinical product manufacture including highly potent and solvent-containing formulations
- Review lessons learned across design, fabrication, validation, and 24 months of GMP operations

14.15 – 14.45

Discussion Group Presentations

14.45 – 15.15

Agency Comments

EU Regulator invited

15.15 – 16.00

Questions & Answers, Close of Seminar

Charlotte Enghave, NNE Pharmaplan, (Denmark);
Jack Lysfjord, Lysfjord Consulting LLC (USA)

Seminar Leaders:

Petra Bielmeier, F. Hoffmann-La Roche AG (Switzerland);

Esther Sadler-Williams, Aptuit (UK)

This seminar is suitable for those working in Investigational Products / Clinical Trials who want to understand and develop better and innovative ways of working in line with the clinical trials regulations within Europe. It provides an ideal opportunity for delegates to meet other members of the IP Community of Practice.

Using case studies and real examples the focus will be on sharing experiences from the wide range of companies involved in the manufacture and packaging of investigational medicinal products.

Through networking events, interactive workshops and seminar presentations lead by key opinion leaders within our industry it provides a valuable forum to challenge existing preconceptions, explore alternative approaches and to share “best practice” ideas.

The following topics will be amongst many covered during this highly interactive two-day seminar:

- Practical example of how to remove the need for expiry date from labels
- How to hurdle the legislative framework when undertaking global studies with controlled substances
- Management of non IMPs
- Challenges of supplying IMPs in Japan
- Keynote presentation on implementing personalised healthcare strategies

Delegates can also attend an exclusive Networking Dinner.

Communities of Practice (COP):

IP

Take Back to Your Job:

- Shared and developed experiences through workshops, networking and development of best practice solutions to real problems
- State of the art knowledge and understanding of issues facing IPs

Who Should Attend:

Personnel working within clinical supplies (IMP) including those with an operational focus or those in project management. This is a unique conference as it is the only one focussed on needs of IP professionals, which is designed by IP professionals encompassing topics suggested by delegates. We will be using voting technology which promotes delegate engagement and provides a great opportunity throughout our seminars to obtain instant benchmarking.



Technical Knowledge and Competency Elements:

A chart of the CPIP™ certification programme categories addressed by this seminar is shown on page 3.

Seminar Content Level:



Day 1

- 08.30 – 08.45 **Welcome and Introduction**
Petra Bielmeier, Roche (Switzerland); Esther Sadler Williams, Aptuit (UK)
- 08.45 – 09.30 **Challenges to Supplying Investigational Products in Japan**
Mina Horibe, Eli Lilly (Japan)
 - Introduction
 - Regulatory environment and development strategies
 - Supply strategies
 - Supply challenges and barriers
 - Conclusion
- 09.30 – 10.15 **Regulatory Presentation - tbc**
EU regulator invited
- 10.15 – 10.45 **Coffee and Networking Break**
- 10.45 – 11.30 **The Challenges of Integrating a Clinical Trials Supply Chain**
Steve Day, GlaxoSmithKline (UK)
 - Understanding factors that drive volume in clinical trial supply chains
 - Evaluating and managing risk versus cost
 - Challenging the door to door supply paradigms
 - Linking key partners to maximise the benefit of integration
- 11.30 – 12.15 **Hurdling the International Legislative Framework for Controlled Substance IMPs – a Case Study**
Anu Davies, Shire (UK); Nick Evans Aptuit (UK)
 - Working through the DEA legislation on export of controlled substances
 - Processing of complex blinded treatment arms on two continents
 - Establishing EU distribution strategy in partnership with qualified depots
 - Pulling together multiple stakeholder inputs to agree expectations and assure delivery of critical milestones
- 12.15 – 13.30 **Lunch and Networking Break**
- 13.30 – 13.45 **Introduction to Workshops**
Petra Bielmeier, Roche (Switzerland); Esther Sadler-Williams, Aptuit (UK)
- 13.45 – 15.00 **Workshops: Group 1 (delegates choose only 1 workshop out of 3)**
Discussions on Current Regulatory Topics
Robert Smith, Genzyme (UK); Sarbari Roy, Astra Zeneca (Sweden)
Management of Non IMPs
Stefano Gregoriani, PPD (Italy)
Discussion on Optimal Structure and Supply Strategies for Clinical Supply Organisations
Evelyn Ego, Bayer Schering (Germany)
- 15.00 – 15.30 **Coffee and Networking Break**
- 15.30 – 16.45 **Workshops: Group 2 (delegates choose only 1 workshop out of 3)**
Discussion on a Current Distribution Topic
Massimo Eli, Schering Plough (Italy)
Approaches to Medication Pooling - tba
Use of IVR for Early Phase Studies
Karen Gram, Novo Nordisk (Denmark)
- 16.45 – 17.15 **Investigational Products – Communities of Practice**
Chris Bland, Chair of EU IP COP, Novartis (Switzerland)
 - Role of IP COP and what can it do for me?
 - Steering committee
 - How do I join?
- 17.15 – 17.30 **Audience Selection of Workshop Topics for Day 2**
Petra Bielmeier, Roche (Switzerland); Esther Sadler-Williams, Aptuit (UK)
- 17.30 – 18.30 **Exhibition Networking Reception**
- 19.30 **IP COP Networking Gala Dinner**

Day 2

- 08.30 – 08.40 **Introduction to Day 2**
Petra Bielmeier, Roche (Switzerland); Esther Sadler Williams, Aptuit (UK)
- 08.40 – 09.30 **Keynote Presentation - Fitting the Treatment to the Patients: Implementing Personalised Healthcare Strategies in Oncology**
Dr. Christian Meisel, Clinical Research and Exploratory Development, Roche (Germany)
 - Understanding abnormalities driving the growth of cancer
 - Identifying predictive biomarkers
 - Using translational medicine approaches for finding to the right dose and schedule
 - Companion diagnostics test development
- 09.30 – 10.15 **The 'Flying Pharmacist': Extemporaneous Dose Preparation – a Fast and Flexible Approach to Phase I Clinical Trial Supply**
Claire Newcomb, Pfizer (UK)
 - Formulating for extemporaneous preparation
 - Technologies used in the clinical trials pharmacy
 - The benefits; API sparing, trial design flexibility, improved speed of drug development
 - The GMP/ GCP interface; the regulatory considerations of extemporaneous preparation
- 10.15 – 10.45 **Coffee and Networking Break**
- 10.45 – 11.45 **Workshops: Group 3 (3 only, delegates choose 1 only)**
Three options for this workshop will be decided by seminar delegates during the previous afternoon - the most popular choices will be offered during this session.
- 11.45 – 12.30 **Case Study: How Use-by-Date Labelling was Successfully Omitted in a Global, Double Blinded Phase III Trial**
Erik Meyer, Merck Serono (Germany)
 - Obtaining buy-in from all parties - Close cooperation between CTS, QP, Development-QA, Regulatory Affairs, ClinOPs and CRO
 - Considerations around IVRS design: release and shelf life extension procedures
 - Considerations around label design
 - Communication with health authorities
 - Preparation and outcome of sponsor inspection by Health Authorities
 - Lessons learned
- 12.30 – 13.15 **Best Practices to Develop and Maintain Successful Sponsor/Service Provider Relationships**
Anja van Strien, Schering Plough (The Netherlands)
 - Vendor selection and management strategies
 - Clarifying your needs prior to vendor search
 - Identifying tools and procedures
 - Establishing clear agreements to avoid pitfalls
 - Conducting pre-qualification visits
 - Implementing effective communication strategies
 - Establishing a personal relationship
- 13.15 – 14.15 **Lunch and Networking Break**
- 14.15 – 14.45 **Wildcard Session: Interactive Voting**
- 14.45 – 15.15 **Voting Session on Themes for 2010**
Petra Bielmeier, Roche (Switzerland); Esther Sadler-Williams, Aptuit (UK)
- 15.15 – 15.30 **Questions and Answers, Close of Seminar**

Seminar Leaders:

Bruce Davis, Global Consulting (UK);
Georges France, Wyeth Europa Ltd (UK)
What is in Product Quality Lifecycle Implementation (PQLI®) for you? How does Quality by Design (QbD) impact on development, manufacturing, and the business bottom line?

In these challenging times you can both benefit from and contribute to the global implementation of QbD. PQLI brings together the regulatory and industry disciplines in the development of technical approaches and tools that you can use on a daily basis to improve the scientific and business performance of all your business sectors, whether you are from an R&D based multinational, a generic company, contract organisation or start-up company.

ISPE launched its PQLI initiative in June 2007 to help industry find practical approaches to the global implementation of recent ICH guidelines. Through PQLI, ISPE is spearheading approaches to partnership in the implementation of, in particular, Q8 (pharmaceutical development), Q9 (quality risk assessment), and Q10 (pharmaceutical quality systems). Key goals include the provision of the technical framework required for the implementation of quality by design in pharmaceutical development and manufacturing environments.

Starting with highly interactive fact-gathering sessions held in the three ICH regions, topics have thus far included:

- Criticality
- Design Space
- Control Strategy

Following comments from Industry, these three topics are being further extended and integrated into an overall "QbD flow" and, additionally, an illustrative example is being developed. More information will be available at the conference. And this year, at the request of delegates from previous meetings, we will be presenting the highly acclaimed mixture of podium presentations on the latest developments in these topics together with interactive workshops on these and new topics.

Communities of Practice (COP):

API • Biotechnology • Good Control Laboratory Practices • Investigational Products • Packaging • PAT • Product Process Development • Project Management • Sterile Products Processing

Take Back to Your Job:

- Put the latest thinking on implementation of recent ICH guidelines to work to improve business performance
- Contribute to the industry implementation of ICH guidance
- Better understand regulators' perspectives
- Meet professionals both in your own and in other disciplines
- Volunteer to join a PQLI team to develop further practical tools in support of implementation of Quality by Design

Who Should Attend:

- Any professional in a quality discipline
- There will be something for scientists and engineers involved in chemical process development and analysis, formulation and packaging development and analysis, technology transfer, validation, CMC regulatory, compliance, manufacturing, quality control, quality assurance, process control, engineering, biotechnology process development and analysis

Related Technical Documents:

Articles from June 2008 JPI provide a useful background: however, the purpose of our meeting is to further develop the concepts described.

Regulatory Issues:

ICH Q8, Q9 and Q10



Technical Knowledge and Competency Elements:

A chart of the CPIP™ certification programme categories addressed by this seminar is shown on page 3.

Seminar Content Level:



Day 1

- 10.00 – 10.15 **Introduction to Day 1**
Bruce Davis, Global Consulting (UK)
- Morning Sessions Chair**
Susanne Keitel, EDQM (France)
- 10.15 – 10.45 **Keynote Speech: Influence of New Concept (QbD) on European Pharmacopoeias**
Susanne Keitel, EDQM (France)
- 10.45 – 12.15 **IWG Update**
 - Regulators and industry representatives from the three ICH regions
 - First opportunity for feedback from the ICH meeting in Yokohama*Jean Louis Robert, Laboratoires National de Sante (Luxembourg); Jacques Morénas, AFSSAPS (France); Bob Baum, Pfizer (USA); Georges France, Wyeth Europea Ltd (UK); Regulators from USA and Japan invited*
- 12.15 – 13.15 **Lunch and Exhibition**
- Afternoon Sessions Chair**
Jacques Morénas, AFSSAPS (France)
- 13.15 – 13.55 **PQLI**
 - Update
 - Illustrative example*Bruce Davis, Global Consulting (UK)*
- 13.55 – 14.20 **EFPIA Example**
 - Mock S2*Graham Cook, Wyeth Pharmaceuticals (UK)*
- 14.20 – 14.30 **Introduction to Workshops**
Georges France, Wyeth Europa Ltd (UK)
- 14.30 – 15.45 **Break out Workshops A, B and C (part 1) (Participants stay in same workshop for both parts)**
- 15.45 – 16.15 **Coffee Break and Exhibition**
- 16.15 – 17.30 **Workshops A, B and C (part 2)**
- Workshop A**
Pharmaceutical Quality System from Development to Manufacturing Supporting an “Enhanced” Submission (e.g. QbD)
Nigel Hamilton, Sanofi Aventis (UK); Jacques Morénas, AFSSAPS (France)
- Workshop B**
QbD in the Manufacturing Environment : Control Strategy Determined from Development to Manufacturing and Batch Release
Line Lundsberg, NNE Pharmaplan (UK) ; Regulator from EU, USA or Japan tbc
- Workshop C**
RTR Testing : What is Needed for Quality Control (e.g. Specification, Sampling Size)
Graham Cook, Wyeth Pharmaceuticals (UK); Susanne Keitel, EDQM (France)
- 17.30 – 18.30 **Exhibition Networking Reception**

Day 2

- 08.45 – 08.50 **Welcome and Opening**
Georges France, Wyeth Europa Ltd (UK)
- Morning Sessions Chair**
tbc
- 08.50 – 09.20 **EFPIA and PAT Team Training Initiative Based on a Real QbD Example**
Jean Louis Robert, Laboratoires National de Sante (Luxembourg); Georges France, Wyeth Europa Ltd (UK)
- 09.20 – 09.30 **Introduction to Workshops**
Bruce Davis, Global Consulting (UK)
- 09.30 – 10.45 **Break out Workshops D, E & F (part 1) (Participants stay in same workshop for both parts)**
- 10.45 – 11.15 **Coffee Break and Exhibition**
- 11.15 – 12.30 **Workshops D,E & F (part 2)**
- Workshop D**
Biotech topics including development of CQAs and CPPs
Ranjit Deshmukh, Wyeth (USA); Regulator from EU, USA or Japan - tbc
- Workshop E**
Knowledge Management along the Life Cycle (Dispatch of Relevant Information : Onsite, on File, for Inspection, for Submission)
Mike James, GlaxoSmithKline (UK) ; Regulator from EU, USA or Japan - tbc
- Workshop F**
Pharmaceutical Quality System and Supply Chain: Auditing Process
Workshop leaders from industry and regulator from EU, USA or Japan - tbc
- 12.30 – 13.30 **Lunch & Exhibition**
- Afternoon Sessions Chair**
Jean Louis Robert, Laboratoires National de Sante (Luxembourg)
- 13.30 – 14.30 **Feedback from Workshops A – F**
Workshop Leaders
- 14.30 – 15.10 **International Challenge Outside ICH Region the View of EMEA**
Emer Cooke, EMEA (UK)
- 15.10 – 15.50 **Panel Discussion Questions and Answers**
Regulators from EU, USA and Japan - tbc
- 15.50 – 16.00 **Close of seminar**
Bruce Davis, Global Consulting (UK); Georges France, Wyeth Europa Ltd (UK)

Basic Principles of Computerised Systems Compliance (T07) –

Applying the GAMP®5 Guide: A Risk-based Approach to Compliant GxP Computerised Systems

▶ 30 September – 1 October • CEUs: 1.3

When dealing with computerised systems in pharmaceutical manufacturing, the real-life situations are as varied as the challenges they present – with complex factors such as GxP risk, company policy, and regulatory requirements playing key roles. By offering a flexible framework for companies to apply well-established principles to meet their unique requirements, GAMP guidance has become a widely adopted industry resource. The latest revision of the main *GAMP®5 Guide: A Risk-based Approach to Compliant GxP Computerised Systems* is now available.

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

Who Should Attend

- 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

Course Topics

- 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 Computerised Systems*
- GAMP system life cycle and specifications - URS, FS, and design
- Key themes and concepts
- Quality Risk Management for computerised systems

- Computerised system validation framework - plans and reports
- Risk Assessment method
- 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
- Verification approaches and qualification terminology and concepts
- Policies, procedures, and plans required for effective governance
- Pragmatic and efficient practices - cost effective compliance
- New Special interest topics, including control of spreadsheets and end-user databases
- Operation, control, and maintenance of systems
- Participants will receive a complimentary copy of GAMP 5
- This course was developed by members of the ISPE GAMP Community of Practice. GAMP was established by industry leaders to interpret and improve the understanding of regulations governing the use of computerised systems in pharmaceutical manufacturing.

Instructor Biography

Sion Wyn, Director, Conformity Ltd., is an acknowledged expert in computer system validation and compliance and international regulations. He has extensive experience in all aspects of computer systems validation and compliance, including managing validation projects, validation planning, specification and testing of systems, performing site and system compliance audits, writing SOPs, performing 21 CFR Part 11 assessments, and supplier audits. Wyn's expertise as a specialised computer validation consultant covers all stages of the lifecycle approach to validation of computerised systems and most system types including MRPII, manufacturing execution, electronic document management, EBRS, process control and monitoring, environmental monitoring, manufacturing equipment, and laboratory systems. At Conformity Ltd., Wyn provides computer validation and compliance consultancy to the pharmaceutical and other regulated healthcare industries.

Important Course Notes

- Participants will receive a complimentary copy of *GAMP®5 Guide: A Risk-based Approach to Compliant GxP Computerised Systems*
- Topics tied to the GAMP Community of Practice (COP)
- This course was developed by members of the GAMP COP
- CPIP™ Certification Programme Technical Knowledge Competency Elements – see explanation of CPIP on pages 3 and 9 along with a chart of the categories addressed by this course.



Course Level



As cleaning technology and detection methodology advance, so do the challenges associated with establishing, managing, and maintaining a scientifically sound cleaning validation programme. FDA's risk-based regulatory initiatives focus new attention on the risks of cross-contamination. The solution is to understand life cycle management techniques for an effective cleaning validation programme.

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. For mature cleaning validation programmes, concepts such as understanding process control, capability, learning to effectively self-audit a cleaning validation program, and documentation will be essential takeaways.

Take Back to Your Job

- Identify and characterise potential residues including product, processing aids, cleaning agents, and adventitious agents
- Apply appropriate analytical methodology for selected residues
- Determine suitable sampling techniques and the selection of sampling locations that present a challenge for the cleaning process
- Calculate residue limits that meet all necessary regulatory requirements
- Create scientifically sound rationales, validation protocols, and reports
- Manage the challenges of multi-product facilities in the establishment of limits, determination of validation strategies, and maintaining the validated state
- Understand campaign-based production strategies for effective and scientifically sound validation
- Differentiate the requirements for cleaning validation when using manual, semi-automatic, or automatic cleaning technologies

- Determine scientific grouping or bracketing approaches
- Comprehend the pitfalls inherent in cleaning after the production of biopharmaceutical and pharmaceutical products
- Accomplish analytical method validation and recovery study requirements in cost-effective studies that provide the necessary assurance of an analytical system
- Evaluate cleaning practices, limit calculations, scientific rationales, and validation documents through internal self-audits to ensure compliance with ever-changing regulatory needs
- Practice hands-on exercises designed to reinforce core competencies and job-focused skill

Who Should Attend

- Professionals responsible for all aspects of cleaning validation programmes, including development, deployment, and maintenance; quality assurance and control, regulatory affairs, validation; manufacturing, and engineering
- All levels of management who need to understand the science of cleaning and cleaning validation including the aspects of residue selection, sampling method and analytical detection method validation, limits determination, and strategies for managing multi-product facilities would benefit from attending this course

Instructor Biography

Rob Walker is a chartered chemist and a fellow of the Royal Society of Chemistry with degrees in applied chemistry and instrumental analytical chemistry. He has more than 30 years of experience in the pharmaceutical industry including 25 years as a qualified person. After 16 years in senior management at CP Pharmaceuticals, the last seven as quality director, he is now a director of his own GMP consultancy company. Walker has comprehensive GMP manufacturing and quality experience covering a wide range of dosage forms and has successfully managed GMP inspections by MHRA and FDA. Walker has extensive experience delivering presentations to industry forums including ISPE, the Parenteral Society and PDA in both the EU and the USA.

Important Course Notes

- Topics tied to the Process/Product Development (PPD) Community of Practice (COP)
- CPIP™ Certification Programme Technical Knowledge Competency Elements – see explanation of CPIP on pages 3 and 9 along with a chart of the categories addressed by this course.



Course Level



Sponsorship and Table Top Exhibition Opportunities

Do you want to engage with existing customers, target new audiences and develop business contacts? Reinforce your brand profile and position your products and services.

Discover our new packages

Customise your own Sponsorship Package by combining our selection of products and services to reinforce your marketing and communication strategy.

ISPE 2009 EUROPEAN TOP TIER SPONSORSHIPS					
	HOST	PLATINUM	GOLD	SILVER	BRONZE
	€ 12.000	€ 7.200	€ 5.400	€ 4.500	€ 3.300
COMMON BENEFITS					
Recognition as "HOST Sponsor" in title of event (e.g., "ISPE's XXX Event. Co-Hosted by _____") in all pre-event, onsite, and post-event marketing promotion and communications					
Recognition of "Sponsorship Category" in all pre-event, onsite and post-event marketing promotions and communications					
Company name/ logo/ ad prominently displayed on signage with "Sponsorship category"					
Logo prominently displayed in Final Programme (Subject to contract signature date)					
Company Description and contacts in the Exhibitor Directory					
Use of literature display table near ISPE registration/ welcome area					
Prominent recognition (Thank you page) in applicable issue of Pharmaceutical Engineering					
Company prominently mentioned in ISPE electronic communications prior to event					
Sponsor ribbons on badges for all company personnel attending event					
Three (3) complimentary Conference registrations including admission to all networking and social events and meals (Conference Only)					
Two (2) complimentary Conference registrations including admission to all networking and social events and meals (Conference Only)					
One (1) complimentary Conference registrations including admission to all networking and social events and meals (Conference Only)					
Table Top exhibition space and Table Top registration for two (2) staff personnel					
CHOOSE 2 CUSTOMISABLE BENEFITS					
1 - A Three Months Button Ad on either					
Strasbourg Conference Web site - www.ISPE.org/strasbourgconference					
Facility Of the Year Awards webpage – www.facilityoftheyearawards.org					
2 - Advertisement Pages in any 2009 issue of PE or JPI					
1/2 Page					
1/3 Page					
1/4 Page					
1/6 Page					
3 - Sponsor an ISPE electronic Newsletter					
ISPEAK – bi-monthly newsletter					
European Informer – monthly newsletter					
4 - Exclusive Sponsorship at one of our newly developed international webinars					
5 - A 30 mintue Vendor Session during the Strasbourg Conference					
6 - A one day exhibition visitor pass					
OR					
One Day Sponsorship at each European Events:					
- Managing Knowledge Through Science and Risk Assessment – Strasbourg, 28 September – 1 October 2009					
- ISPE Facility of the Year: Innovation Showcase – Case Studies and Plant Tours – Ulm, Germany, 2 – 3 November 2009					

Find out more about Sponsorships in Europe - Contact Christine Sainvil, European Sales Manager
 • Tel: + 32 2 740 2251 • Fax: + 32 2 743 1578 • Email: christine.sainvil@associationhq.com

Target your specific audience by sponsoring the IP COP Networking Dinner

IP COP Sponsors



Learn more on ISPE Top Tier Sponsorship Packages on: www.ispe.org/strasbourg/sponsorshipopportunities
ISPE Strasbourg Conference Exhibition is sponsored by:



Are you looking to enhance your company image, showcase products and services, and improve the perception of your company to a targeted audience? ISPE's European Table Top Exhibition provides you with an appropriate platform to accomplish your strategic goals.

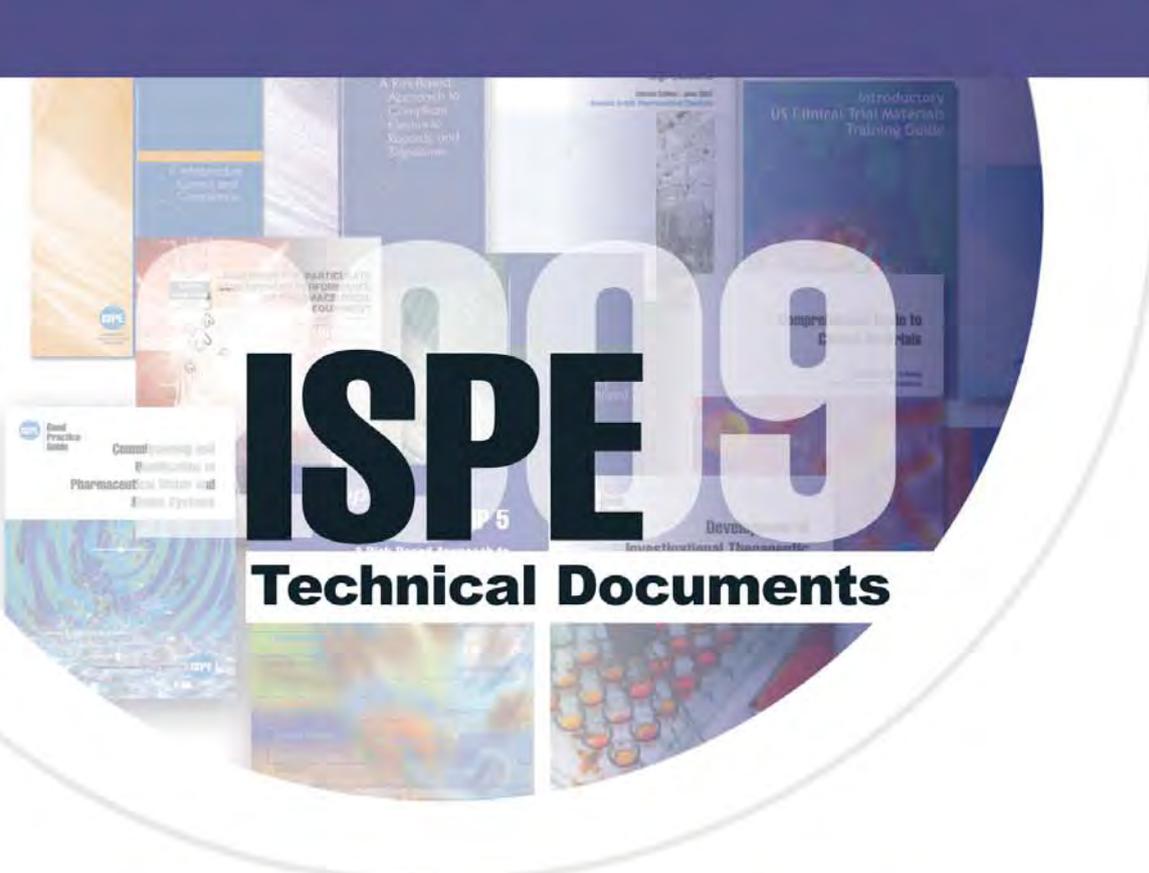
Exhibition Packages Include:

- Delegate access to three coffee breaks, two standing lunches and a networking reception in the exhibition hall.
- Your company name featured on the conference page on the ISPE Web site.
- Your company description and information in the delegates course binder.
- A complimentary one-day VIP exhibition pass.
- Pre-scheduled face-to-face meetings
- One banquet table (180cm x 80cm) to display your literature, products and services.

Maximise your face-to-face interaction by organising a half-hour Vendor Session to showcase products and services.



Find out more about Table Top Exhibits in Europe - Contact Christine Sainvil, European Sales Manager
• Tel: + 32 2 740 2251 • Fax: + 32 2 743 1578 • Email: christine.sainvil@associationhq.com



ISPE

Technical Documents

Stay on the Cutting Edge with ISPE Technical Documents and Publications

ISPE offers the tools and resources necessary to keep you up-to-date with industry changes, while keeping your production costs low.



Gamp

Reflecting current regulatory expectations and good practices, the *GAMP*[®] 5 Guide and *GAMP*[®] Good Practice Guide series help narrow the interpretation of regulatory standards for improved compliance, quality, efficiency, and cost reductions.



Good Practice Guide

ISPE Good Practice Guides (GPGs) provide information on a particular topic area while explaining underlying technical principles and suggest multiple solutions where several outcomes may be possible.



Baseline
PHARMACEUTICAL
ENGINEERING GUIDE

ISPE's *Baseline*[®] Guides offer practical answers to challenges

facing facility designers while providing an understanding of products and processes.



GM
Institute

GMP products and publications make good business sense and help meet regulatory requirements.

Electronic licenses are now available.

Contact Gloria Hall at ghall@ispe.org for more information.

ENGINEERING PHARMACEUTICAL INNOVATION



For more information on these or other ISPE technical documents and publications, visit www.ISPE.org/publications today!

ISPE Membership Has its Benefits!

Knowledge – resources to make your day-to-day job easier

- Global regulatory resources including news and access to critical information
- *Pharmaceutical Engineering* magazine subscription for the latest on design, construction, supervision, and maintenance of process equipment, plant systems, instrumentation, and facilities
- Information on new technologies, methods, products, philosophies and the associated regulatory issues through the *Journal of Pharmaceutical Innovation*
- Technical documents including *GAMP® 5*, ISPE's *Baseline® Guide series*, and much more

Community – connect with local and global experts and regulators

- Grow your local professional network by joining education, networking, and news offerings
- Collaborate with peers in your area of expertise through ISPE's discipline-specific Communities of Practice for online discussions, news, resources, and E-Letters
- Search the Membership Directory to find ISPE Members by name, title, company, location, or email address

Profession – tools to assist with professional advancement

- Education and training - face-to-face, at your location or online - to stay abreast of industry and regulatory changes, technological advancements, and best practices
- Gain professional credibility and recognition with the Certified Pharmaceutical Industry Professional™ (CPIP™) credential

Meet and Greet: Network with Your Peers!

Social Networking Event: 28 September

All conference delegates are cordially invited to attend the social and networking event. Meet and network with your peers - including regulators, speakers, fellow delegates, ISPE staff and volunteers from Europe and the United States. Catch up with your colleagues whilst enjoying a walking-tour of Strasbourg's historical city followed by a typical Alsatian dinner in a local restaurant.

ISPE France Affiliate Meeting and Reception: 29 September

ISPE France Affiliate Members are cordially invited to join an extraordinary general meeting to revise ISPE France by-laws. This meeting will be followed by a two-hour conference catering for our colleagues living in the North East of France. The session will include a presentation of the French translation of *GAMP® 5* to be released in the Autumn.

Registration Form

Please return to: ISPE Registration Services
 Avenue de Tervueren, 300 • B-1150 Brussels, Belgium
 Tel: + 32 2 743 44 22 Fax: + 32 2 743 1584
 Email: europeregistrations@ispe.org

SAVE TIME – REGISTER ONLINE: www.ISPE.org/strasbourgconference

I. Delegate Information

ISPE Member: Yes, membership number _____ No Company VAT number (mandatory): _____
 Prefix: _____ First Name: _____ Last Name: _____
 Job Title: _____ Company: _____
 Address: _____
 City: _____ Postal Code: _____ Country: _____
 Telephone: _____ Fax: _____
 Mobile: _____ Email: _____
 I wish to keep my data confidential (only for use by ISPE and its local Affiliates and Chapters)
 I do not wish for my details to be printed in ISPE's Membership Directory or on Conference Attendance Listings

II. Conference Registration

Prices below do not include VAT – 19,6% French VAT is applicable

	Payment received on or before 14 August 2009		Payment received after 14 August 2009		Academia and Emerging Economy Members		Government	Student Member
	Member	Non member*	Member	Non member*	Before 14 August Member	After 14 August Member	One Price	One Price
Full Conference								
<input type="checkbox"/> Book 2 Seminars - one per two-day series - and save 20% on the second seminar.	€1.935	€2.475	€2.475	€3.015	€972	€1.242	€1.242	€270
Seminars: 28 - 29 September								
<input type="checkbox"/> Commissioning & Qualification	€1.075	€1.465	€1.375	€1.765	€540	€690	€690	€150
<input type="checkbox"/> Disposables and Containment Technology	€1.075	€1.465	€1.375	€1.765	€540	€690	€690	€150
<input type="checkbox"/> GAMP [®] 5 Operational Aspects	€1.075	€1.465	€1.375	€1.765	€540	€690	€690	€150
Seminars: 30 September - 1 October								
<input type="checkbox"/> Barrier Isolation Forum	€1.075	€1.465	€1.375	€1.765	€540	€690	€690	€150
<input type="checkbox"/> Investigational Product (IP) Innovation	€1.075	€1.465	€1.375	€1.765	€540	€690	€690	€150
<input type="checkbox"/> PQLI [®]	€1.075	€1.465	€1.375	€1.765	€540	€690	€690	€150
Training courses: 30 September - 1 October								
<input type="checkbox"/> Basic Principles of Computerised Systems Compliance (GAMP [®] 5)	€1.510	€1.710	€1.810	€2.010	€755	€905	€755	€755 early €905 late
<input type="checkbox"/> Cleaning Validation Principles	€1.410	€1.610	€1.710	€1.910	€705	€855	€705	€705 early €855 late
Networking Evening: 28 September	€65 / person. Accompanying partners are welcome to attend this event (same fee applies).							

ISPE Members from Emerging Economy Countries benefit from a 50% discount on the regular registration fee.

Visit www.ISPE.org/EmergingEconomyList to review the full list of eligible countries.

- *Tick this box if you wish to become a Member of ISPE at no additional charge.
 Offer available to nonmember conference delegates paying full nonmember fees.
 Tick here if you are a first time ISPE Conference Attendee.

PLEASE NOTE: Multiple attendees from a company who register at the same time qualify for a discount. The following savings are taken from fees: 3-5 delegates 10%, 6-10 delegates 15%, and 11+ delegates 20%.

GROUP REGISTRATION FORM AVAILABLE ONLINE:
www.ISPE.org/strasbourgconference

III. Method of Payment – Conference

19,6% French VAT should be included in the total payment

Seminar Fees € _____
 Networking Evening (Places __X €65) € _____
 Subtotal € _____
 19,6% VAT € _____
Total Due: € _____

- Credit Card AMEX Visa Mastercard

Credit Card Number: _____ Expiry Date: _____

Cardholder's Name: _____

Signature:

IV. Special Needs (dietary or other): _____

V. Hotel Reservation

Please make the following reservation for me at

Holiday Inn Strasbourg City Centre, 20 Place de Bordeaux, 67000 Strasbourg, France

- Single Room (€180) Double Room (€190)
 Smoking Non Smoking (subject to availability)

Or at Hilton Strasbourg, Avenue Herrenchmidt, 67000 Strasbourg, France

- Single Room (€190) Double Room (€208)
 Smoking Non Smoking (subject to availability)

(Prices include VAT and breakfast)

Arrival date : ___ / ___ /2009 Departure date : ___ / ___ /2009

Please guarantee my reservation with the following credit card (mandatory):

- AMEX VISA Mastercard

Credit Card Number: _____

Expiry Date: _____

Cardholder's Name _____

Signature:

VI. Signature By signing I agree with the ISPE Registration and Cancellation Policies (see www.ISPE.org/strasbourgconference)

Date: _____ Signature:

General Information

Registration: Fees include conference or training materials, refreshment breaks listed in the programme, lunches, exhibition networking receptions and exhibition access.

If you register as a nonmember, you are entitled to a one-year ISPE membership. To receive an application form, please tick the box on the registration form. Your application must be returned within 30 days in order to activate your membership.

ISPE membership is individual, and must be paid in full to qualify for the Member fee. If you have questions regarding your membership status, please contact ISPE by telephone: +32 2 743 44 22 or by fax: +32 2 743 1584.

Payment: Payment must accompany the registration form. Registration will not be processed nor confirmed without payment in Euro (€). All registrations sent by fax must include the necessary payment information – please complete the relevant spaces and sign the registration form. American Express, Visa and MasterCard are accepted.

Early Registration Deadline: To benefit from the early registration fee, payment must be received on or before 14 August 2009. After this date the standard registration fee will be applied.

Confirmation: Upon receipt of payment, a proof of payment will be sent to you, along with your confirmation letter (time permitting). Hotel accommodation is not included in the registration fee. You will need to present your registration confirmation letter at the ISPE Registration Desk at the Palais des Congrès, Strasbourg. You will receive your conference name badge at that point.

If you do not receive a registration confirmation letter, please contact: ISPE Registration Services, Avenue de Tervueren, 300, B-1150 Brussels, Belgium. Email: europeregistrations@ISPE.org Fax: +322743 1584

In order to be listed in the official delegate roster, you must have registered for the conference and paid by 11 September 2009.

Cancellation Policies: Full refunds, less a handling fee of €100 per registrant, will be granted to requests received in writing before or on 11 September 2009. No refunds will be granted for requests received after 11 September 2009. Telephone cancellations are not accepted.

Liability: ISPE reserves the right to cancel or reschedule any conference and/or to change speakers or instructors. Please be

advised that ISPE is not responsible for any airfare/hotel penalties or other travel charges you incur. In case of government intervention or regulation, military activity, strikes or other circumstances that make it impossible for the conference to go ahead at the time and place provided, the participant shall waive any claim for damages or compensation except the amount paid for registration after deduction of actual expenses incurred in connection with the conference. There shall be no future liability on the part of either party.

Substitutions: If a delegate is unable to attend, substitutions will be accepted; however nonmembers substituting for Members must pay the difference if fees prior to the start of the event. ISPE cannot be held responsible for loss of airfare or other travel costs due to cancellation.

ISPE Speakers: The speakers invited to present ISPE programmes are leading professionals within their respective fields. Should it be necessary, we will make substitutions. Every precaution is taken to ensure accuracy, but ISPE cannot accept responsibility for the accuracy of information distributed or contained in these programmes, or for any other opinion expressed.

Group Discounts: Group discounts apply; see the registration form for details. Discounts cannot be combined and Member and nonmember pricing applies. Group registrations must be submitted at the same time. Substitutions will be accepted. To benefit from a group discount, please fill in a group registration form, available from www.ISPE.org/strasbourgconference.

Emerging Economy Countries Discount: ISPE offers a 50% discount on the normal early/late registration fees to Members from Emerging Economy countries. Visit www.ISPE.org/EmergingEconomyList to find out more. The discount will automatically apply when your registration is processed.

Student Discount: To qualify for the student registration rate, you must be a Student Member of ISPE. This rate applies to individuals enrolled full-time at a college, university or other educational institution.

Special Requirements: If you need any additional support or assistance to be able to participate in an ISPE conference or training event – from wheelchair accessible rooms to special dietary considerations – please attach a written description of your needs with your registration form. If you have any questions email: europeregistrations@ISPE.org.

About the Conference Venues and the Conference Hotels

Conference Venue

Palais des Congrès

Place de Bordeaux - 67082 Strasbourg - France

Holiday Inn Strasbourg City Centre

20 Place de Bordeaux - 67000 Strasbourg - France

Web: www.holidayinn.com

Single room rate: € 180

Double room rate: € 190

Rates include VAT - Breakfast

Directions: Visit www.ISPE.org/strasbourgconference for details on how to find the conference hotels.

For the hotel cancellation and reservation policies please visit the Web site: www.ISPE.org/strasbourgconference

Hilton Strasbourg

Avenue Herrenchmidt - 6700 Strasbourg - France

Web: www.Hilton-Strasbourg.com

Single room rate: € 190

Double room rate: € 208

PROGRAMME at a GLANCE

Date	Conference Seminars			Training Courses		Network Events
Monday, 28 September	Commissioning and Qualification	Disposables and Containment	GAMP®5: Operational Aspects			Exhibition Networking
Tuesday, 29 September						
Wednesday, 30 September	Barrier Isolation Forum	Investigational Product (IP)	PQLI®	Basic Principles of Computerised Systems Compliance (GAMP® 5) (T07)	Cleaning Validation Principles (T17)	Exhibition Networking
Thursday, 1 October						

▶ **Mark your Calendars for 2009**

2009 Washington Conference
 1 - 4 June • Washington, D.C., • USA

Philadelphia Training
 5 - 8 October • Philadelphia • USA

ISPE Facility of the Year: Innovation Showcase
 2 - 3 November • Ulm • Germany

2009 Annual Meeting
 8 - 11 November • San Diego • California • USA