

Delivering **Cost Effective** GMP Solutions

6 Vital
Seminars
to Help Save
Time, Money
and **Resources**

- Advances in **Barrier Isolation Technology** That Will Drive Costs Down and Quality UP
- Implement Efficiently and Deliver Beyond Expectation: Use the **GAMP Guidance** and its **Practical Solutions for Computerised Systems**
- Practical Applications of **Quality by Design and Quality Systems** to Improve Cost Efficiency and Regulatory Compliance
- Evaluate Your **Containment Systems** and Achieve **Efficient Quality And Safety Compliance** Without Additional Cost
- Understand, Develop and Create Opportunities and Strategies for **Investigational Medicinal Products**
- New Developments in **Commissioning and Qualification** That Will Save Time, Money and Resources

2 Intensive
Training
Courses

- Modern Approaches to Risk-Based Commissioning and Qualification – Applying the *ISPE Good Practice Guide: Applied Risk Management for Commissioning and Qualification*
- Managing the Risk of Cross Contamination: Applying the *Risk-MaPP Baseline® Guide*

BRUSSELS CONFERENCE
19-22 September 2011
Sheraton, Brussels
www.ISPE.org/2011BrusselsConference



Gold Sponsor



Agilent Technologies

Connecting a World of
Pharmaceutical Knowledge



ISPE 2011 Brussels Conference At-A-Glance

ISPE 2011 Brussels Conference and Training Schedule

19 - 22 September 2011
Sheraton Hotel • Brussels, Belgium

| DATE | CONFERENCE SEMINARS | | | NETWORKING EVENTS |
|---|---|--|---|-----------------------|
| Monday 19 September Tuesday 20 September | Barrier Isolation Technology Forum: Innovation, Updates and New Case Studies | GAMP® : Cost-Effective Compliance - Practical Solutions for Computerised Systems | QbD and Quality Systems – Practical Applications for Cost Effectiveness and Regulatory Compliance | Exhibition Networking |
| Wednesday 21 September Thursday 22 September | Potent Compounds – A Risk-Based Approach to Reach Quality and Safety Compliance | Creating Opportunities and Strategies for the Regulated Clinical Supply Chain | Commissioning and Qualification: Science and Risk-Based Approaches – Current Industry Experiences and New Guidances | Exhibition Networking |
| TRAINING COURSES | | | | |
| Monday 19 September Tuesday 20 September | Modern Approaches to Risk-Based Commissioning and Qualification – <i>New Training Course!</i> | | | |
| | Managing the Risk of Cross Contamination: Applying the <i>Risk-MaPP Baseline® Guide</i> – <i>New Training Course!</i> | | | |

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 COPs and join at www.ISPE.org/COPs.

- 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)
- Operations Management
- Oral Solid Dosage (OSD)
- Packaging
- Process Analytical Technology (PAT)
- Process/Product Development (PPD)
- Project Management (PM)
- Sterile Products Processing (SPP)
- Sustainable Facilities

Investigational Products (IP) COP Dinner & Networking Event:

Date: 21 September 2011

Time: 19.30

Location: Brussels Area (Restaurant to be confirmed shortly - Updates available on www.ISPE.org/2011BrusselsConference)

Cost: Free for IP Education Delegates (Only registered delegates for IP Education Seminar may attend).

Included: Dinner, Drinks and Networking activities.

Exhibition Networking Receptions

Monday, 19 September 17.30 – 18.30

Wednesday, 21 September 17.30 – 18.30

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

Certified Pharmaceutical Industry Professional™ Knowledge Elements Reference Chart



Brussels 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 exam, they would be an excellent part of your preparation. Visit www.ISPE-PCC.org 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 | A | 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 | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2011 Brussels 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 |
| Barrier Isolation Technology Forum: Innovation, Updates and New Case Studies | X | | | X | | X | | | | | | X | | | | | | |
| GAMP: Cost-Effective Compliance – Practical Solutions for Computerised Systems | | | | | | | | X | | | | | | | X | X | X | X |
| QbD and Quality Systems – Practical Applications for Cost Effectiveness and Regulatory Compliance | X | X | X | X | | | X | | | | | X | X | X | X | X | X | X |
| Potent Compounds – A Risk-Based Approach to Reach Quality and Safety Compliance | X | | | X | X | X | | | | | | X | X | X | X | | X | |
| Creating Opportunities and Strategies for the Regulated Clinical Supply Chain | X | | | | | | | X | X | X | X | | | | X | X | | |
| Commissioning and Qualification: Science and Risk-Based Approaches – Current Industry Experiences and New Guidances | | | | X | X | X | X | | | | | | | | | X | X | |

ISPE Membership has its Benefits

Whether you are new to the industry or a seasoned professional, a long-time Member or new to the Society, ISPE has something for **You**.

Knowledge - Increase your understanding, keep yourself current, and make yourself marketable.

Community - Meet like-minded professionals, share ideas about real world problems, and build a network upon which you can rely

Profession - Advance your career, become part of changing the industry, and help others grow professionally.

Now, more than ever, we look forward to showing you why ISPE should be **Your** Society of Choice!

Seminar Leaders: Jack Lysfjord, Lysfjord Consulting, LLC (USA)
Charlotte Enghave-Fruergaard, NNE Pharmaplan (Denmark)

For 20 years and counting, ISPE's Barrier Isolator Seminar has been one of the key sources of information regarding today's best practices and latest technology in Aseptic Processing. Whether you are operating, retrofitting, supporting, or designing Restricted Access Barrier Systems (RABS) or Barrier Isolator Production Lines, this seminar is tailored to ensure attendees can leverage the wealth of experience and industry know-how for the benefit of both project and operational excellence.

Regardless of experience, this Seminar promises to provide all attendees with new insights in Barrier systems' application and operations as the regulatory and technology landscape changes. Conquer the 'learning curve' with the tools, knowledge and experience from industry leaders and subject matter experts. Increase effectiveness and:

- Share and learn global best practices working in RABS and Isolator based filling operations
- Discuss and understand the 'whys' behind industry practices
- Learn how to set you, your team, and your organisation up for success in designing, qualifying and operating Barrier systems
- Dedicate time to plan, understand, and consider opportunities to improve your project or operations for increased effectiveness
- Train and develop team members (reward and recognition or subject matter expertise building)
- Collect ideas and solve existing aseptic processing challenges
- Network with industry peers going through similar challenges as well as meeting vendors providing equipment and services all in one conference and location

Communities of Practice (COPs):

Biotechnology, Commissioning and Qualification (C&Q), Containment, Disposables, Engineering Standards Benchmarking (ESB), Good Automated Manufacturing Practice (GAMP®), Heating, Ventilation and Air Conditioning (HVAC), Investigational Products (IP), Process Analytical Technology (PAT), Process/Product Development (PPD), Project Management (PM), Sterile Products Processing (SPP).

Take Back to Your Job:

- Better understand technologies applicable to advanced aseptic processing using RABS and Barrier Isolation
- Describe how robotics can improve manufacturing in Barriers
- Understand measurement of hydrogen peroxide related to protein sensitivity to residuals
- Interpret Regulatory Agency perspectives to help streamline your regulatory submission and approval process
- Better understand costs related to the decision for use of RABS or Isolators for new and renovated facilities
- Understand what to do and what not to do from those who have done it before
- Apply best practices from case studies with both RABS and Isolators

Who Should Attend?

- Aseptic Processing Professionals wishing to stay at the forefront of Barrier Isolation Technologies.

Related Guidance Documents, Articles, and Publications:

- *ISPE Baseline® Guide: Sterile Manufacturing Facilities*
- *ISPE Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment*
- *ISPE Knowledge Brief: Risk-Based Approaches to Cross Contamination*

Seminar Content Level:



Monday 19 September 2011

| | |
|---------------|---|
| 10:00 - 10:10 | <p>Welcome and Introduction <i>Jack Lysfjord, Lysfjord Consulting LLC (USA); Charlotte Enghave-Fruergaard, NNE Pharmaplan (Denmark)</i></p> |
| 10:10 - 10:50 | <p>2011 Preliminary RABS Survey <i>Jack Lysfjord, Lysfjord Consulting LLC (USA)</i></p> |
| 10:50 - 11:30 | <p>Achieving Operational Flexibility With Isolator-Barrier Integrated Robotics <i>Josh Russell, Automated Systems of Tacoma (USA)</i></p> <ul style="list-style-type: none"> • Discuss the benefits of flexible automation vs. hard automation for aseptic processes within isolator barrier systems, and when flexible automation is advantageous • Safety and design considerations when selecting a robot system to be integrated within an isolator or RABS application • Utilising robot flexibility to eliminate ergonomic challenges and improve the operators ability to aseptically assemble the machinery prior to fill operation within a RABS deployed system • RABS robot cell design strategies that eliminate traditional interventions and product contamination risks • Utilising single use products and technologies in robot end of arm tooling design to increase system flexibility and mitigate contamination risks |
| 11:30 - 12:10 | <p>Enhanced Sterility Assurance in Stopper Processing and Unloading: A Unique Process and Aseptic Transfer System <i>Carole Langlois, Sartorius Stedim (France)</i></p> |
| 12:10 - 13:45 | <p>Lunch and Networking Break</p> |
| 13:45 - 14:25 | <p>Unprecedented Accuracy, Precision and Ease-of-use for low H₂O₂ Concentrations using Cavity Ring-Down Spectroscopy <i>Matt Sweeney, Picarro (USA)</i></p> <ul style="list-style-type: none"> • CRDS theoretical background • Precision at low concentration • Achieving high accuracy with infrequent calibration • Ease of use as an engineering requirement • Industrial integration options |
| 14:25 - 15:10 | <p>High Speed Filling Line for Pre-Sterilised Syringes <i>Jörg Zimmermann, Vetter (Germany)</i></p> <p>In this case study, a high-speed filling line for pre-sterilised syringes is presented. Several innovative concepts are integrated into this 50,000 syringes/hour line: a spray-tunnel for the introduction of the tubs, a bale-compactor for waste, vision systems for process-controls etc. The current status of the line will be discussed as well as the lessons learned so far.</p> |
| 15:10 - 15:40 | <p>Networking Break</p> |
| 15:40 - 16:25 | <p>Confirmation of the Effectiveness of Hydrogen Peroxide Gas Decontamination System <i>Koji Kawasaki, Airex Co. Ltd. (Japan)</i></p> <ul style="list-style-type: none"> • Applications scales of the bio-decontamination using Hydrogen peroxide gas in Japan • Issues and challenges for the bio-decontamination using Hydrogen peroxide gas • Existence of the Dead Leg and how to understand and deal with it • Decontamination method inside the packed syringe • Effectiveness of Hydrogen peroxide gas against insects, eggs and moulds |

| | |
|---------------|--|
| 16:25 - 17:15 | <p>FOYA Case <i>Simone Dahlmanns, Hamelin (Germany)</i></p> |
| 17:15 - 17:20 | <p>Summation and Close of Day 1 <i>Jack Lysfjord, Lysfjord Consulting LLC (USA); Charlotte Enghave-Fruergaard, NNE Pharmaplan (Denmark)</i></p> |
| 17:30 - 18:30 | <p>Exhibition Networking Reception</p> |

Tuesday 20 September 2011

| | |
|---------------|--|
| 9:00 - 9:10 | <p>Review Day 1, Introduction of Day 2 <i>Jack Lysfjord, Lysfjord Consulting LLC (USA); Charlotte Enghave-Fruergaard, NNE Pharmaplan (Denmark)</i></p> |
| 9:10 - 10:15 | <p>3 Discussion Groups</p> |
| 10:15 - 10:45 | <p>Networking Break</p> |
| 10:45 - 11:15 | <p>3 Discussion Group Summaries</p> |
| 11:15 - 12:45 | <p>Cost Analysis Comparison of Conventional, RABS and Isolator Applications for Aseptic Processing 75 Minutes <i>Sterling Kline, IPS (USA)</i></p> |
| 12:45 - 13:45 | <p>Lunch and Networking Break</p> |
| 13:45 - 15:00 | <p>Formulation Process Under Isolator, an Enhancement of the Isolated Process Chain <i>Patrick Vanhecke, GSK Biologicals (Belgium); Volker Sigwarth, Skan AG (Switzerland)</i></p> <p>GSK Bio Presentation:</p> <ul style="list-style-type: none"> • When and why GSK Bio has decided to move to isolators technology? • What are the Processes covered by this Technology? • Our Approach in the Conceptual Design for an Isolator dedicated to Formulation • The Process to define the equipment to build • The Challenges of the Project (MAL VHP cycle, cycle time, cold loads, potential impact on the material and products) • The Success of this Project based on our Efficient Partnership <p>Skan Presentation:</p> <ul style="list-style-type: none"> • Target of Project and the Process • Development vs. Qualification, Structure and Validity of the generated Data • Evaluation of physical Parameter and their Influence on Process Performance • Overview and Challenges of the applied analysing Methods • Process compatibility of Materials; Deco Effect, Penetration, Aeration • Process Challenges of cold Loads • Resulting Process and its Performance • Data Transfer from Prototype to Production Systems • Summary and Conclusion of the Project |
| 15:00 - 15:45 | <p>Regulatory Perspective, Q&A</p> |
| 15:45 - 16:00 | <p>Questions and Answers, Close of Seminar <i>Jack Lysfjord, Lysfjord Consulting LLC (USA); Charlotte Enghave-Fruergaard, NNE Pharmaplan (Denmark)</i></p> |

Seminar Leaders: Yves Samson, Kereon AG (Switzerland)
Charlie Wakeham, Pall Life Sciences (UK)

The pharmaceutical industry is ever more pressured to reduce costs without compromising quality. At the same time, there are major revisions to key computerised systems regulations coming into force this year.

This two-day Seminar aims to provide practical guidance on the effective project management and implementation of computerised systems. Representatives of several major pharmaceutical companies will share their experiences on complying with latest regulations, while industry experts will provide direction and insights on valuable tools and updates to *GAMP® Good Practice Guides*, which can assist with cost-effective compliance.

Looking at the changes introduced into Annex 11 and Chapter 4, this Seminar will focus on leveraging existing guidance and supplier input to achieve compliance. Participate in case study workshops with the guidance of subject matter experts and gain insights on how these guides should be applied. Participants will be given an opportunity to explore the various interpretations with peers, sharing differing company philosophies, and with the *GAMP®* SMEs.

Communities of Practice (COPs):

Good Automated Manufacturing Practice (*GAMP®*), Project Management (PM).

Take Back to Your Job:

- Identify ways to improve the compliance of computerised systems
- More effectively manage projects from initial planning right through to decommissioning

Who Should Attend?

- Process Control Engineers, IT Engineers, Project Managers, Quality and Validation Engineers, e-Compliance Managers, Business Managers.

Related Guidance Documents, Articles, and Publications:

- *GAMP® 5 : A Risk-Based Approach to Compliant GxP Computerized Systems*
- *GAMP® Good Practice Guide: A Risk-Based Approach to Operation of GxP Computerized Systems – A Companion Volume to GAMP® 5*
- *GAMP® Good Practice Guide: Testing of GxP Systems*

Seminar Content Level:



Monday 19 September 2011

- 10:00 - 10:20** **Welcome and Introduction**
*Charlie Wakeham, Pall Life Sciences (UK);
Yves Samson, Kereon AG (Switzerland)*
- 10:20 - 11:10** **Planning for Success: the Project "Big Picture"**
Yves Samson, Kereon AG (Switzerland)
- Planning for compliance
 - Benefits of managing requirements
 - Traceability to specification
- 11:10 - 12:00** **Annex 11, Version 2011**
Audny Stenbråten, Statens Legemiddelverk (Norway)
- Requirements and intentions
 - Electronic signatures
 - Chapter 4
 - Practical guidance
- 12:00 - 13:00** **Lunch and Networking Break**
- 13:00 - 13:45** **Managing Suppliers and Service Providers**
Chris Reid, Integrity Solutions (UK)
- Leveraging supplier effort
 - How to deal with internal service providers?
 - Effective use of SLAs
- 13:45 - 14:30** **Implementation of the new Annex 11**
Tim Goosens, Merck (Belgium)
- Regulated company shares experiences of Annex 11
 - The changes needed for compliance
- 14:30 - 15:15** **Risk Based Testing**
Charlie Wakeham, Pall Life Sciences (UK)
- A preview of the updated GPG
 - Annex 11 requirements for testing
- 15:15 - 15:45** **Networking Break**
- 15:45 - 16:15** **Update on 21 CFR Part 11**
Siôn Wyn, Conformity (UK)
- Status of inspections / feedback on the inspection assignment
 - Possible timeline for the revised rule
 - Impact of FDA's PIC/S membership
- 16:15 - 17:15** **Discussion Panel - Q&A around Annex 11**
Siôn Wyn, Conformity (UK); Audny Stenbråten, Statens Legemiddelverk (Norway); Yves Samson, Kereon AG (Switzerland)
- 17:15 - 17:30** **Summation and Close of Day 1**
Charlie Wakeham, Pall Life Sciences (UK); Yves Samson, Kereon AG (Switzerland)
- 17:30 - 18:30** **Exhibition Networking Reception**

Tuesday 20 September 2011

- 9:00 - 9:15** **Review of Day 1, Introduction of Day 2**
*Charlie Wakeham, Pall Life Sciences (UK);
Yves Samson, Kereon AG (Switzerland)*
- 9:15 - 10:00** **Risk Management Case Study**
- Practical examples of project implementation using GAMP® 5 Risk-Based Approach
- 10:00 - 10:45** **Integrating IT into a Project Team**
- 10:45 - 11:15** **Networking Break**
- 11:15 - 11:45** **Business Continuity**
Paul Dols, Atos Origin (Netherlands)
- Plan for business continuity, right from the initial project design phase
 - Apply a risk-based approach to determine the time to implement an alternative (recovered) system
- 11:45 - 12:45** **Workshop 1 - Effective Change Management**
Chris Reid, Integrity Solutions (UK)
- What is needed?
 - How can it be scaled for different systems?
- Workshop 2 - Periodic Evaluation**
Yves Samson, Kereon AG (Switzerland)
- What is needed?
 - How can it be scaled for different systems?
- 12:45 - 13:45** **Lunch and Networking Break**
- 13:45 - 14:30** **Benefits of Effective Project Management**
René Van Opstal, Van Opstal Consulting (Netherlands)
- Project management framework
 - Impact on compliance
 - Cost-savings on project implementation
- 14:30 - 15:15** **Decommissioning Case Study**
Rob Stephenson, Rob Stephenson Consultancy (UK)
- System retirement
 - Data migration
- 15:15 - 15:45** **Feedback from Workshops**
*Chris Reid, Integrity Solutions (UK);
Yves Samson, Kereon AG (Switzerland)*
- 15:45 - 16:00** **Questions and Answers, Close of Seminar**
*Charlie Wakeham, Pall Life Sciences (UK);
Yves Samson, Kereon AG (Switzerland)*

Seminar Leaders: **Mette Bryder**, H. Lundbeck (Denmark)
Mette Kraemmer Hansen, Novo Nordisk (Denmark)

Recent FDA warnings have cited failure 'to assure adequate process design' and failure to identify 'the component attributes and process parameters that are important...' Many companies are still trying to understand how application of Quality by Design (QbD) principles can improve process understanding and increase confidence of demonstrating successful validation and GMP compliance.

ISPE is developing a series of PQLI® Good Practice Guides (GPGs)* that describe science- and risk-based product development options to provide a practical and pragmatic pathway to product realisation consistent with the ICH guidelines.

In this two-day Seminar you will see the business value in applying the useful tools in the guides, learning how critical quality attributes and critical process parameters may be delineated, how design space can be developed and adopted, and how a control strategy is established and applied in manufacturing as preparation for process validation and as a foundation for GMP compliance. These tools are applicable to new and existing products, and to small and large molecules.

An illustrative example GPG of application of these QbD guides serves to integrate Active Pharmaceutical Ingredients (API) and drug product development. These guides also help set the direction for a joint ISPE/PDA effort on Process Validation. (Guides are in final development and will be published soon).

* *The Overview is available as a free download to ISPE members (\$25 for non-members).*

Communities of Practice (COPs):

Active Pharmaceutical Ingredients (API), Biotechnology, Commissioning and Qualification (C&Q), Good Automated Manufacturing Practice (GAMP®), Good Control Laboratory Practices (GCLP), Investigational Products (IP), Packaging, Process Analytical Technology (PAT), Process/Product Development (PPD), Project Management (PM).

Take Back to Your Job:

- Understand how QbD adds value to your business
- Appreciate the risk to process validation and maintenance of compliance when QbD is not applied
- See how ISPE GPGs are helpful aids to implementing QbD
- Learn about QbD tools and their application to new and existing products

Who Should Attend?

- Of interest to all Communities of Practice, and Regulatory content areas.

Related Guidance Documents, Articles, and Publications:

- *ISPE Product Quality Lifecycle Implementation (PQLI®) Guide: Overview of Product Design, Development, and Realization: A Science- and Risk-Based Approach to Implementation*
- *ISPE Article in J Pharm Innov, March 2009, PQLI Application of Science- and Risk-based Approaches (ICH Q8, Q9, and Q10) to Existing Products*

Seminar Content Level:



Monday 19 September 2011

- 9:30 - 9:40 **QbD Practical Applications for Lifecycle Approach and Regulatory Compliance: Introduction and Agenda Review**
Mette Bryder, H. Lundbeck (Denmark); Mette Kraemmer Hansen, Novo Nordisk (Denmark)
- 9:40 - 10:10 **PQLI® Good Practice Guide Series: Product Realisation Using Quality by Design (Key Note Session)**
Chris Potter, CMC Pharmaceutical Consultant (UK)
- 10:10 - 10:40 **Summary of Discussions from the Washington June 2011 Meeting**
Chris Sinko, Bristol-Myers Squibb (USA); Roger Nosal, Pfizer (USA)
- 10:40 - 11:20 **QbD Practical Applications for Lifecycle Approach and Regulatory Compliance: From a Regulatory Perspective**
Evdokia Korakianiti, European Medicines Agency (EMA) (UK) (invited)
- 11:20 - 12:00 **QbD Practical Applications for Lifecycle Approach and Regulatory Compliance: From an Industry Perspective**
Stephen M. Tyler, Abbott (USA)
- 12:00 - 13:00 **Lunch and Networking Break**
- 13:00 - 14:30 **Workshop on the Assignment of Criticality - What does a Continuum of Criticality mean for Product Realisation and Process Validation?**
Mette Kraemmer Hansen, Novo Nordisk (Denmark); Roger Nosal, Pfizer (USA); Grace McNally, FDA (USA) (invited)
- 14:30 - 15:00 **Networking Break**
- 15:00 - 15:45 **A Lifecycle Approach to Process Validation**
Grace McNally, FDA (USA) (invited)
- 15:45 - 17:15 **Workshop on Lifecycle Approach to Process Validation - What does the Lifecycle Approach mean for Industry?**
Bruce Davis, Global Consulting (UK); Joanne Barrick, Eli Lilly (USA) or Gretchen Allison, Pfizer (USA); Grace McNally, FDA (USA) (invited)
- 17:15 - 17:30 **Questions and Answers, Close of Day 1**
Mette Bryder, H. Lundbeck (Denmark); Mette Kraemmer Hansen, Novo Nordisk (Denmark)
- 17:30 - 18:30 **Exhibition Networking Reception**

Tuesday 20 September 2011

- 8:30 - 9:00 **How Process Performance, Product Quality Monitoring and Robust Change Management Provide Continual Improvement**
Rob Hughes, AstraZeneca (UK)
- 9:00 - 10:00 **Practical Experiences from Joint Inspections**
Grace McNally, FDA (USA) (invited); Evdokia Korakianiti, European Medicines Agency (EMA) (UK) (invited); Dora Kourti, GSK (UK)
- 10:00 - 10:30 **Networking Break**
- 10:30 - 12:00 **Workshop on Approaches for Establishing Design Space - What does the Use of Design Space provide?**
John LePore, Merck (USA); Evdokia Korakianiti, European Medicines Agency (EMA) (UK) (invited)
- 12:00 - 13:00 **Lunch and Networking Break**
- 13:00 - 14:30 **Workshop on Approaches for Establishing Control Strategy - Implications for Submissions, Technology Transfer and Manufacturing. How does Control Strategy relate to Process Validation?**
Mette Bryder, H. Lundbeck (Denmark); Line Lundsberg-Nielsen, NNE Pharmaplan (UK); Evdokia Korakianiti, European Medicines Agency (EMA) (UK) (invited)
- 14:30 - 15:15 **QbD - An Industry Example**
Paul Stott, AstraZeneca (UK)
- 15:15 - 16:00 **Current Status of QbD and Future Expectations**
John Berridge, ISPE (UK)
- 16:00 - 16:15 **Questions and Answers, Close of Seminar**
Mette Bryder, H. Lundbeck (Denmark); Mette Kraemmer Hansen, Novo Nordisk (Denmark)

Seminar Leaders: **Richard Denk**, Hecht Technologie GmbH (Germany)
Frans Willemsen, Janssen Pharmaceutica NV (Belgium)

How to implement a new highly potent or hazardous product in an existing facility or design a new multi-purpose facility for potent compounds? Where are the critical areas of dust exposure and for product quality? This and much more will be covered during this interactive two-day Seminar.

The Seminar will examine the latest scientific, risk-based approaches to the containment of potent compounds. Join a panel discussion with subject matter experts on how to evaluate containment systems and approaches specifically for potent and highly hazardous substances. What happens when the design/approach does not work? How do you overcome risk of failure? Be part of this Seminar and achieve compliance with quality and safety requirements.

A European regulatory overview will be presented. Get latest trends and insights directly from pharmaceutical industry professionals and subject matter experts who have successfully implemented containment techniques in new and /or existing facilities. Real-life workshops, one on Risk Assessment and the other one on Containment Implementation, will be featured highlights at this Seminar.

With an increasing focus on containment approaches for pharmaceutical manufacturing, Active Pharmaceutical Ingredients (API) are becoming more targeted, hence more potent and more prolific. Environment, health and safety (EHS) pressures push for the use of engineering control systems.

RABS and isolation technologies may be an ideal solution for some pharmaceutical manufacturers, but may not be the most efficient processing solution, nor the most cost effective solution for others. Be part of workshop exercises and real-life case studies supported by engineering experts that will profile alternative methods.

Communities of Practice (COPs):

Active Pharmaceutical Ingredients (API), Containment, Disposables, Good Control Laboratory Practices (GCLP), Operations Management, Oral Solid Dosage (OSD), Packaging, Process Analytical Technology (PAT), Process/Product Development (PPD), Project Management (PM), Sustainable Facilities.

Take Back to Your Job:

- Recognise that different types of toxicology limits are set for workers, product and environmental protection
- Recognise or describe the following containment concepts: Contain at source, Containment challenge, Material migration and Risk
- Identify containment technologies and their position in the containment hierarchy
- Recognise applications of hierarchy of containment solutions to real-world containment challenges
- Describe how other industry professionals solved containment challenges
- Understand new technologies available and how they impact containment and cross- contamination

Who Should Attend?

- Engineers, EH&S, Project Management, Product Managers, Purchasers of Containment Equipment, Production Managers and Specialists, Technical Operations, Maintenance, Quality Control and Quality Managers and Specialists, CMOs, Toxicologists.

Related Guidance Documents, Articles, and Publications:

- *ISPE Knowledge Brief: Risk-Based Approaches to Cross Contamination*
- *ISPE Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment*
- *ISPE Baseline® Guide Volume 7: Risk-Based Manufacture of Pharmaceutical Products (Risk-MaPP)*
- *ISPE Baseline® Guide Volume 2: Oral Solid Dosage Forms (Second Edition)*
- *ISPE Baseline® Guide Volume 1: Active Pharmaceutical Ingredients (Second Edition)*

Seminar Content Level:



Wednesday 21 September 2011

- 10:00 - 10:15** **Welcome and Introduction**
Richard Denk, Hecht Technologie GmbH (Germany); Frans Willemsen, Janssen Pharmaceutica NV (Belgium)
- 10:15 - 11:00** **Regulator View on Quality Requirements on Manufacturing of Highly Hazardous or Highly Active Pharmaceuticals**
Catherine Le Febvre, AFSSAPS (France) (invited)
- Why is a detailed risk assessment required from the regulators?
 - Update on the current regulations on high potent production
 - When do you need a dedicated facility for your potent product?
- 11:00 - 12:00** **Occupational Health and Safety Considerations for Highly Active Substance Manufacture**
Dr. Walter Spieler, Roche (Switzerland)
- Effects of non-uniform high potent category classification system
 - Discrepancies arising between GMP & SHE requirements and possible solutions from a pharmaceutical perspective
 - Experiences from retrofitting facilities - risk assessments and occupational exposure inspections
- 12:00 - 13:00** **Lunch and Networking Break**
- 13:00 - 13:45** **Case Study: Project HCDP. Multipurpose API Facility for high potent products. OEL requirement <50ng/m³**
Christoph Doerr, Roche (Switzerland)
- Design concepts for the multi-purpose plant as an isolated area integrated in an existing production
 - Technical Containment Solutions and Barrier Systems
 - What was good and what should we have made better
- 13:45 - 14:30** **Use of flexible Containment Technologies for high potent API's**
Dr. Rainer Nicolai, Roche (Switzerland)
- Transfer from Centrifuge to Dryer
 - Challenge of using flexible containment system
 - What was good and what should we have made better
- 14:30 - 15:00** **Networking Break**
- 15:00 - 15:30** **Risk Assessment GMP and IH Compliance**
Richard Denk, Hecht Technologie GmbH (Germany)
- Quality Assurance and Containment control friend or foe
 - What is important to consider during the Risk Assessment to fulfil the product quality and EH&S
- 15:30 - 17:00** **Workshop Risk Assessment**
Richard Denk, Hecht Technologie GmbH (Germany); Frans Willemsen, Janssen Pharmaceutica NV (Belgium)
- Different case studies to work in groups to perform a risk assessment
 - Case studies for API, R&D, pharmaceutical production of potent compounds
- 17:00 - 17:15** **Summation and Close of Day 1**
Richard Denk, Hecht Technologie GmbH (Germany); Frans Willemsen, Janssen Pharmaceutica NV (Belgium)
- 17:30 - 18:30** **Exhibition Networking Reception**

Thursday 22 September 2011

- 9:00 - 9:15** **Review of Day 1, Introduction of Day 2**
Richard Denk, Hecht Technologie GmbH (Germany); Frans Willemsen, Janssen Pharmaceutica NV (Belgium)
- 9:15 - 10:00** **Controlling exposures to Active Pharmaceutical Ingredients API's in Chemical Production**
Michael Vangeel, Janssen Pharmaceutica NV (Belgium)
- Risk-based Exposure Assessment Process (RBEAP) model
 - Containment strategy
 - Risk-based Exposure and Assessment Control (RBEAC) Guideline
- 10:00 - 10:45** **Evaluating the Occupational Hazards of Potent Compounds**
Justin Mason, Safebridge (UK)
- Developing a data set for hazard evaluation
 - Qualitative assessments - Assigning occupational health categorisations aka "Control Banding"
 - Quantitative assessments - Determining & setting occupational exposure limits (OEL)
 - Communicating hazards to workers and outside contractors
- 10:45 - 11:15** **Networking Break**
- 11:15 - 12:00** **Clean or dispose? Contained micronisation in Lab Scale**
Olaf Born, Hosokawa (Germany)
- Solution for R&D and small scale production
 - Comparison between single and multi-use equipment
 - Cost evaluation
- 12:00 - 13:00** **Lunch and Networking Break**
- 13:00 - 13:45** **Overview of the Developments in Containment Technologies in the Pharmaceutical or API Industry**
Paul O'Brian, PM (Ireland)
- Containment technologies solutions and equipment for API and pharmaceutical facilities
 - Operations and challenges with the range of available technologies, their application and the performance
- 13:45 - 14:30** **Assessing the Performance of Contained Dust Collection Systems**
Alan Sweeney, Camfill (Ireland)
- What is surrogate testing?
 - Why perform surrogate testing?
 - What impact does surrogate testing have on business?
- 14:30 - 15:15** **Case Study: High containment implementation in existing API manufacturing**
Frans Willemsen, Janssen Pharmaceutica NV (Belgium)
- Containment system selection for an existing API production facility
 - Introducing a new technology in production - Technical challenges
 - Getting the technology embedded into daily operation - Organisation challenges
- 15:15 - 16:45** **Workshop Implementation on Containment**
Richard Denk, Hecht Technologie GmbH (Germany); Frans Willemsen, Janssen Pharmaceutica NV (Belgium)
- Different case studies to work in groups to evaluate different containment solutions
 - Case studies for API, R&D, pharmaceutical production of potent compounds
- 16:45 - 17:00** **Questions and Answers, Close of Seminar**

Seminar Leaders: **Petra Bielmeier**, F. Hoffmann-La Roche AG (Switzerland)
Bernd Steffens, Boehringer Ingelheim Pharma GmbH & Co KG (Germany)

This two-day Seminar is dedicated towards professionals working in Investigational Products (IP)/Clinical Trials, who want to understand, develop and create opportunities, strategies and efficient ways along the Supply Chain for Investigational Medicinal Products (IMP) while being globally compliant with Clinical Trials Regulations. Meet other IP COP members, be part of workshop exercises and interactive presentations led by senior pharmaceutical regulators and key opinion leaders within our industry.

Three main subject areas will be covered:

- Regulatory updates and trends provided by senior regulators from European Agencies, discussing the efficient usage of IRT and our GCP-interface
- Distribution strategies, including emerging markets and customs/tax aspects
- Strategies optimising the Clinical Supply Chain

This Seminar will provide a valuable forum to challenge existing preconceptions, demonstrate usage of new tools and technologies, and to explore alternative approaches and share “Best Practice” ideas.

Based on real-life case study examples, share experiences with a wide range of industry professionals from leading pharmaceutical companies involved in all Supply Chain activities for IMPs.

Communities of Practice (COPs):

Investigational Products (IP), Packaging, Project Management (PM).

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?

- Managers and Professionals involved in the Clinical Supply Chain, belonging to Industry or Service Providers.

Seminar Content Level:



Wednesday 21 September 2011

- 10:00 - 10:15** **Welcome and Introduction**
Petra Bielmeier, F. Hoffmann-La Roche AG (Switzerland); Bernd Steffens, Boehringer Ingelheim Pharma GmbH & Co KG (Germany)
- 10:15 - 11:00** **Interactive Response Technologies, Friend or Foe? A Regulatory perspective**
Rebecca Stanbrook, MHRA (UK)
- 11:00 - 11:45** **Distribution to and Storage at Clinical Trial Sites Considerations from a Regulatory Perspective**
Anne Raison, AFSSAPS (France)
- 11:45 - 13:00** **Regulatory Forum**
- 13:00 - 14:00** **Lunch and Networking Break**
- 14:00 - 14:45** **GMP in Interviews in GCP-Inspections – a Case Study**
Negin Hosan-Aghaie, Boehringer Ingelheim GmbH & Co KG (Germany)
- 14:45 - 15:30** **Report - Out of the ISPE IRT (Interactive Response Technology) Investigational Sites Survey**
Christine Milligan, Fisher (UK)
- 15:30 - 16:00** **Networking Break**
- 16:00 - 17:15** **Introduction to Workshops and Workshop 1**
Petra Bielmeier, F. Hoffmann-La Roche AG (Switzerland); Bernd Steffens, Boehringer Ingelheim Pharma GmbH & Co KG (Germany)
- 17:30 - 18:30** **Exhibition Networking Reception**

Thursday 22 September 2011

- 8:30 - 8:45** **Review of Day 1, Introduction of Day 2 – Audience to vote for Workshop 3**
Petra Bielmeier, F. Hoffmann-La Roche AG (Switzerland); Bernd Steffens, Boehringer Ingelheim Pharma GmbH & Co KG (Germany)
- 8:45 - 9:00** **IP COP Introduction**
Robert Smith, Genzyme (UK)
- 9:00 - 9:45** **The Roche IMP Distribution Strategy**
Matthias Wehrle, Roche (Switzerland)
- 9:45 - 10:30** **Minimising Costs & Risks across an Integrated Supply Chain by the Effective & Innovative Management of Duty**
David Box, GSK (UK)
- 10:30 - 11:00** **Networking Break**
- 11:00 - 11:45** **IP COP Booklet Label Task Team – Booklet Label Strategy**
Kirsteen Magee, Pfizer (UK)
- 11:45 - 13:00** **Workshop 2**
- 13:00 - 14:00** **Lunch and Networking Break**
- 14:00 - 15:15** **Workshop 3 (Repeats Top 3 Topics from Workshop 1 & Workshop 2)**
- 15:15 - 16:00** **Clarifying the Definition, Handling and Use of Non IMPs – Status of the ISPE Guideline Document**
Esther Sadler-Williams, Aptuit (UK)
- 16:00 - 16:45** **Panel Discussion for Voting Topics**
- 16:45 - 17:00** **Voting for Themes for 2012, Close of Seminar**
Petra Bielmeier, F. Hoffmann-La Roche AG (Switzerland); Bernd Steffens, Boehringer Ingelheim Pharma GmbH & Co KG (Germany)

Seminar Leaders: **Nuala Calnan**, Dublin Institute of Technology (Ireland)
Jörg Block, Bayer HealthCare AG (Germany)

Optimising operation and maintenance of existing technical systems is a challenge for all those involved with the design, specification, verification, acceptance, operation and maintenance of new or existing facilities, systems and equipment supporting pharmaceutical or biopharmaceutical operations.

This two-day Seminar includes guidance, real-life case studies, and workshops to provide you with strategies you can immediately apply. Hear the views of representatives of US FDA and subject matter experts from industry.

Two new ISPE Documents, anticipated for release, will support this Seminar:

- Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment*
- Applied Risk Management for Commissioning and Qualification*

* *Electronic copies will be included in your Registration Package.*

Communities of Practice (COPs):

Commissioning and Qualification (C&Q), Good Automated Manufacturing Practice (GAMP®), Project Management (PM).

Take Back to Your Job:

- Understand risk-based delivery approaches
- Align the new guidance concepts with GAMP® and VPCS
- Apply successful strategies and lessons learned from industry case studies to implement on your own projects
- Apply risk management to your own company projects
- Using control strategy and associated CQAs and CPPs to provide the basis for determination of critical aspects for validation
- Utilise risk-based delivery approaches to optimise the operation and maintenance of existing systems

Who Should Attend?

- Individuals involved with the Design, Specification, Verification, Acceptance, Operation and Maintenance of new/existing Facilities, Systems and Equipment supporting Pharmaceutical or Biopharmaceutical operations. This includes Designers, Equipment Vendors, Construction Management, Verification and Testing Personnel, Quality Assurance, Operations, Maintenance, Process Automation and Instrumentation, and Facilities Management.

Related Guidance Documents, Articles, and Publications:

- *ISPE Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment**
- *ISPE Good Practice Guide: Applied Risk Management for Commissioning and Qualification**

Seminar Content Level:



Wednesday 21 September 2011

- 10:00 - 10:20** **Welcome and Introduction**
Nuala Calnan, Dublin Institute of Technology (Ireland); Jörg Block, Bayer HealthCare AG (Germany)
- 10:20 - 11:20** **Introduction to ISPE Baseline® Guide 12 - Science and Risk-Based Approach for Delivery of Facilities, Systems and Equipment**
Steve Wisniewski, Commissioning Agents Inc. (USA)
- 11:20 - 12:00** **Introduction to ISPE Good Practice Guide - Applied Risk Management for Commissioning and Qualification**
Jörg Block, Bayer HealthCare AG (Germany)
- 12:00 - 13:00** **Lunch and Networking Break**
- 13:00 - 13:55** **Case Study - Greenfield Biotech Facility with Applied RM for C&Q**
Bob Chew, Commissioning Agents Inc. (USA)
- 13:55 - 14:50** **Risk Management Exercise - Small Group Breakouts**
Bob Chew, Commissioning Agents Inc. (USA)
- 14:50 - 15:30** **Networking Break**
- 15:30 - 16:15** **Bridging the Gap between Industry and Regulator views of current Science & Risk-Based Implementations : Academic Research Update (Includes an interview with a European Regulator)**
Nuala Calnan, Dublin Institute of Technology (Ireland)
- 16:15 - 17:00** **US FDA Speaker**
Steve Hertz, FDA (USA) (invited)
- 17:00 - 17:15** **Summation and Close of Day 1**
Nuala Calnan, Dublin Institute of Technology (Ireland); Jörg Block, Bayer HealthCare AG (Germany)
- 17:30 - 18:30** **Exhibition Networking Reception**

Thursday 22 September 2011

- 9:00 - 9:10** **Review of Day 1, Introduction of Day 2**
Nuala Calnan, Dublin Institute of Technology (Ireland); Jörg Block, Bayer HealthCare AG (Germany)
- 9:10 - 10:00** **Case Study – Risk-Based Approach to API Containment**
Machteld Deconinck, Johnson and Johnson (Ireland); Rose Marie Dollard, Johnson and Johnson (USA)
- 10:00 - 10:40** **Networking Break**
- 10:40 - 11:20** **PQLI® Overview - How Facilities and Equipment Fit with the Overall Product Control Strategy**
Stephen Tyler, Abbott (USA)
- 11:20 - 12:00** **Case Study - Application of Pfizer's Verification Programme and the Cultural Lesson's Learned**
Cathy Middelberg, Pfizer (USA); Graham Wrigley, Pfizer (USA)
- 12:00 - 13:00** **Lunch and Networking Break**
- 13:00 - 13:45** **Case Study from Industry – TBC**
- 13:45 - 14:30** **Case Study from Industry – TBC**
- 14:30 - 15:15** **The Journey to ASTM E2500 - What's in it for me?**
Kathleen Waters, Genentech (USA)
- 15:15 - 16:00** **Q&A Panel Discussion**
- 16:00 - 16:20** **Questions and Answers, Close of Seminar**
Nuala Calnan, Dublin Institute of Technology (Ireland); Jörg Block, Bayer HealthCare AG (Germany)

New Training Course!

Instructor: Robert Adamson, Consultant, RBQ Services Ltd.

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. This course was developed by members of the ISPE Commissioning and Qualification Community of Practice (C&Q COP).

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

Who Should Attend?

- 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.

Community of Practice (COP):

Commissioning and Qualification (C&Q).

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 (FSE)* and the *ISPE Good Practice Guide: Applied Risk Management for Commissioning and Qualification*.
- Discuss the information necessary to develop Requirement 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 safety and those that are business / safety related

- Apply risk assessment 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

Instructor Biography:

Robert Adamson is manager of pharmaceutical compliance with Foster Wheeler in Reading, U.K., where he is responsible for all compliance and validation services. He has more than 30 years of experience in the pharmaceutical industry including positions with Foster Wheeler, Beecham, and Glaxo, and experience in R&D, production management for APIs, and sterile manufacturing. He has been responsible for the start-up of new facilities and a number of major refurbishments. He is a chartered chemist and chartered chemical engineer. At Foster Wheeler his recent experience has included compliance and regulatory topics, validation of oral and sterile dosage forms, and biotechnology and API facilities to meet EU, FDA, and MHW requirements. He worked with a wide variety of clients and on occasions has represented them at FDA meetings. He is an active Member of ISPE and has written and presented a number of papers and contributed to a number of books. He has been involved with ISPE's Commissioning and Qualification initiative since its conception, is currently Co-chair of the CoP Steering Committee, and is ISPE's project manager for the development of the *ISPE Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems and Equipment*. He was elected U.K. Fellow of the Year in 2003, and has been past chair of the U.K. Southern Region and is the Chair elect of the U.K. Affiliate taking over April 2009.

Related Guidance Documents, Articles, and Publications:

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

Course Content Level:



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

▶ 19-20 September 2011

New Training Course!

Instructor: Paul Wreglesworth, Independent Consultant, formerly AstraZeneca (UK)

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

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

NOTE: Attendees should be familiar with containment basics and the use of operator exposure limits prior to attending this course (this course does not cover cleaning procedures or processes).

Who Should Attend?

- Anyone dealing with Multi-Product Facilities especially QA, Toxicologists, EH&S Professionals, Engineers, Operations, Cleaning Validation, Project Managers, Regulators/ Inspectors.

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

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

Communities of Practice (COP):

Containment, Oral Solid Dosage (OSD), Active Pharmaceutical Ingredients (API), Biotechnology, Sterile Products Processing (SPP), Process/Product Development (PPD), Project Management (PM), Heating, Ventilation and Air Conditioning (HVAC), Commissioning and Qualification (C&Q).

Take Back to Your Job:

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

Instructor Biography:

Paul Wreglesworth has more than 30 years' experience within the pharmaceutical industry. Formerly with AstraZeneca, he was Global Technology Director within the Supply & Capability Group of AZ's Manufacturing Operations Group based in the UK. Prior to this he was Director of New Product Management with responsibility for the manufacturing strategy for the Company's anti-cancer products in which role he developed a particular interest in the handling and sourcing of hazardous compounds. Paul has a BSc (Hons) in Pharmacy and considerable experience of the development, manufacture and sourcing of pharmaceuticals gained at both local site and corporate level. He was a core member of the ISPE team responsible for developing the *ISPE Risk-MaPP Baseline*[®] *Guide* and has spoken extensively on risk-based manufacture of pharmaceuticals in Europe, North America and Japan. Paul is now an independent consultant in risk management and sourcing and supply of high hazard pharmaceuticals.

Related Guidance Documents, Articles, and Publications:

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

Course Content Level:



Build Brand Awareness, Network with Key Decision Makers, Strengthen Company Image and Discover New Customers

ISPE Conference Sponsorships provide an opportunity to access and interact with key decision makers and buyers in the global pharmaceutical and biotechnology manufacturing industries. Reap great benefits and make a powerful impact in front of industry leaders with a Top Tier Sponsorship at these events. A variety of cost-effective opportunities will build brand awareness, strengthen your company image, generate valuable leads and increase your exhibit traffic.

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On average, ISPE Conferences draw 500+ delegates with unprecedented purchasing power. Conference attendees will include biotechnology professionals, process engineers, automation engineers, IT specialists, validation and quality professionals, project managers, and those involved with regulatory, commissioning, validation, critical utilities, GAMP®, product development, laboratory operations, risk assessment, and environmental health and safety.

€1,550 (+ VAT)

2 Days Table Top Package

- Delegate access to Two Coffee Breaks, Two Standing Lunches and a Networking reception in the exhibition hall
- Your company description and information in the delegates course binder
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This includes:

- Take your brand to centre stage with a 30' commercial presentation
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- Invitation in the Delegates pack
- Dedicated 9m² in the Exhibition hall for maximum exposure

€2,700 (+VAT)

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- Delegate access to Two Coffee Breaks, Two Standing Lunches and a Networking reception in the exhibition hall
- Your company description and information in the delegates course binder
- One-day guest pass for exhibition
- 15% discount for Table Top Personnel to attend a seminar session
- One banquet table (180cm x 80cm) to display your literature, products and services
- Onsite, personnel assistance from ISPE exhibits staff

€4,200 (+VAT)

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This includes:

- Take your brand to centre stage with a 30' commercial presentation
- Presentation advertised in all event marketing tools
- Invitation in the Delegates pack
- Dedicated 9m² in the Exhibition hall for maximum exposure

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Book a Table Top Package and benefit from a 10% discount on a ½ Page Advert, Four colour process on any 2011 issue of Pharmaceutical Engineering (PE), ISPE bi-monthly magazine, leading global information resource for the pharmaceutical and biotechnology manufacturing industry.

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 - o Company logo
 - o 30-word company description

Sponsorship and Exhibition Opportunities

€ 3,000

Direction Signage to Seminar Rooms

Co-branded with sponsoring company logo and ISPE Conference signage

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- Company description on Exhibitors Directory
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€2,000

Standing Lunches

- Signage on Catering Tables
- One day Table Top Guest Pass
- Company description on Exhibitors directory
- Company recognition as specific sponsor in all pre/post event communications

€1,500

Networking Reception

- Company logo displayed on Conference webpage
- A company A4 ad or logo on a clip-holder positioned on all cocktail tables in the reception venue
- A literature display table for promotional literature in the Networking reception venue
- Company's give-aways for all event attendees

€3,500

Lanyards

- Co-branded with sponsoring company logo and ISPE Conference lanyards
- One day Table Top Guest Pass
- Company description on Exhibitors directory
- Company recognition as specific sponsor in all pre/post event communications

€1,000

Coffee Breaks

- Signage on Coffee serving Table
- One day Table Top Guest Pass
- Company description on Exhibitors directory
- Company recognition as specific sponsor in all pre/post event communications

€1,000

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- Sponsorship visibility at Delegates Prize Tombola
- Company's give-aways for all event attendees
- One day Table Top Guest Pass
- Company description on Exhibitors directory
- Company recognition as Delegates Prize Sponsor in all pre/post event communications

Sponsorship and Exhibition Opportunities

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(choose one day)

Monday

Tuesday

Wednesday

Thursday

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Pharmaceutical Engineering (PE)

Premium Table Top € 1,780 (+VAT)

Coffee Breaks € 1,000 (+VAT)

Standing Lunches € 2,000 (+VAT)

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Address: _____
City: _____ Postal Code: _____ Country: _____
Telephone: _____ Fax: _____
Mobile: _____ Email: _____
Company VAT number (mandatory): _____

- 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 – 21% Belgian VAT is applicable on registration fees only.

Are you an ISPE Member? Yes, membership number _____ No

If you wish to become a Member of ISPE and benefit from lower registration fees, please select **New Member** registration fees. €210 (VAT exempt) for your one-year membership is included in the New Member fees indicated below. If you do not wish to become a Member of ISPE, please select the **Nonmember** fees.

- Tick here if you are a first time attendee

| | | EARLY BIRD ON OR BEFORE 12 AUGUST 2011 | | | REGULAR / ONSITE AFTER 12 AUGUST 2011 | | |
|---|---|---|---------------------------------|---------------------------------|--|---------------------------------|---------------------------------|
| | | Member | New Member | Non-member | Member | New Member | Non-member |
| Full Conference Package: Select two seminars below - One per two-day series - and save 20% on the second seminar. | | <input type="checkbox"/> €1.980 | <input type="checkbox"/> €2.360 | <input type="checkbox"/> €2.480 | <input type="checkbox"/> €2.520 | <input type="checkbox"/> €2.900 | <input type="checkbox"/> €3.045 |
| Seminar Package: Select one seminar below | | | | | | | |
| Monday 19 – Tuesday 20 September 2011 | <input type="checkbox"/> Barrier Isolation Technology Forum: Innovation, Updates and New Case Studies | <input type="checkbox"/> €1.100 | <input type="checkbox"/> €1.310 | <input type="checkbox"/> €1.375 | <input type="checkbox"/> €1.400 | <input type="checkbox"/> €1.610 | <input type="checkbox"/> €1.680 |
| | <input type="checkbox"/> GAMP® : Cost-Effective Compliance - Practical Solutions for Computerised Systems | <input type="checkbox"/> €1.100 | <input type="checkbox"/> €1.310 | <input type="checkbox"/> €1.375 | <input type="checkbox"/> €1.400 | <input type="checkbox"/> €1.610 | <input type="checkbox"/> €1.680 |
| | <input type="checkbox"/> QbD and Quality Systems – Practical Applications for Cost Effectiveness and Regulatory Compliance | <input type="checkbox"/> €1.200 | <input type="checkbox"/> €1.410 | <input type="checkbox"/> €1.475 | <input type="checkbox"/> €1.500 | <input type="checkbox"/> €1.710 | <input type="checkbox"/> €1.780 |
| Wednesday 21 – Thursday 22 September 2011 | <input type="checkbox"/> Potent Compounds – A Risk-Based Approach to Reach Quality and Safety Compliance | <input type="checkbox"/> €1.100 | <input type="checkbox"/> €1.310 | <input type="checkbox"/> €1.365 | <input type="checkbox"/> €1.400 | <input type="checkbox"/> €1.610 | <input type="checkbox"/> €1.680 |
| | <input type="checkbox"/> Creating Opportunities and Strategies for the Regulated Clinical Supply Chain | <input type="checkbox"/> €1.100 | <input type="checkbox"/> €1.310 | <input type="checkbox"/> €1.365 | <input type="checkbox"/> €1.400 | <input type="checkbox"/> €1.610 | <input type="checkbox"/> €1.680 |
| | <input type="checkbox"/> Commissioning and Qualification: Science and Risk-Based Approaches – Current Industry Experiences and New Guidances (Price includes the two ISPE Guidance Documents) | <input type="checkbox"/> €1.200 | <input type="checkbox"/> €1.410 | <input type="checkbox"/> €1.475 | <input type="checkbox"/> €1.500 | <input type="checkbox"/> €1.710 | <input type="checkbox"/> €1.780 |
| Training Courses 19-20 September 2011 | | EARLY BIRD ON OR BEFORE 12 AUGUST 2011 | | | REGULAR / ONSITE AFTER 12 AUGUST 2011 | | |
| | | Member | New Member | Non-member | Member | New Member | Non-member |
| <input type="checkbox"/> Modern Approaches to Risk-Based Commissioning and Qualification – New Course! | | <input type="checkbox"/> €1.510 | <input type="checkbox"/> €1.720 | <input type="checkbox"/> €1.805 | <input type="checkbox"/> €1.810 | <input type="checkbox"/> €2.020 | <input type="checkbox"/> €2.120 |
| <input type="checkbox"/> Managing the Risk of Cross Contamination: Applying the <i>Risk-MaPP Baseline® Guide</i> – New Course! | | <input type="checkbox"/> €1.510 | <input type="checkbox"/> €1.720 | <input type="checkbox"/> €1.805 | <input type="checkbox"/> €1.810 | <input type="checkbox"/> €2.020 | <input type="checkbox"/> €2.120 |

III. Method of Payment

(21% Belgian VAT should be included in the total payment, excluding €210 membership fee on New Member registrations)

Seminar Fees: € _____
21% 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 Information

Sheraton Brussels Hotel
Place Rogier 3 – 1210 Brussels, Belgium
<http://www.starwoodhotels.com/sheraton>
Tel: +32 2 22 43 11 / Fax: +32 2 22 43 456

Room rates: Single room: 185 €
Double room: 210 €
(Rates include 6% VAT, 10% city tax, 16% service charge and buffet breakfast)

ISPE has secured a number of bedrooms at a fixed group rate for your convenience. All accommodation bookings must be made directly with the hotel and are subject to availability. To benefit from the ISPE group rate, reservations must be made before **8 August 2011** through the dedicated **booking link available at <http://www.starwoodmeeting.com/Book/ISPE2011>**

VI. Signature By signing I agree with the ISPE Registration and Cancellation Policies (see www.ISPE.org/2011BrusselsConference)

Date: _____ Signature: _____

General Information

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

Always keeping our global impact in mind, ISPE finds ways to conserve resources at its Conferences. Instead of printing education session handouts, ISPE now makes them available online for convenient, 24/7 access. Not applicable for the training courses.

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.

If you wish to become a Member of ISPE and benefit from lower registration fees, please select New Member registration fees. €210 (VAT exempt) for your one-year membership is included in the New Member fees. If you do not wish to become a Member of ISPE, please select the Non Member fees. Your application must be returned within 30 days in order to activate your membership.

Payment: Payment must accompany the registration form. Registration will not be processed nor confirmed without payment in Euro (€). 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 **12 August 2011**. 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 Sheraton Brussels Hotel. 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 / Tel: +322743 4422

In order to be listed in the official delegate roster, you must have registered for the conference and paid by **2 September 2011**.

Cancellation Policies: Full refunds, less a handling fee of €100 per registrant, will be granted to requests received in writing

before or on **2 September 2011**. No refunds will be granted for requests received after **2 September 2011**. Telephone cancellations are not accepted. ISPE cannot be held responsible for loss of airfare or other travel costs due to cancellation.

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 in fees prior to the start of the event.

ISPE Speakers: Speakers selected to present programmes are leading professionals in their fields. However, it may be necessary to make substitutions. If so, every possible effort will be made to substitute a speaker with comparable qualifications. Agendas are subject to change without notice. Every precaution is taken to ensure accuracy, but ISPE cannot accept responsibility for information distributed or contained in the programmes or for any opinion expressed.

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 Hotel

Sheraton Brussels Hotel

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Tel: + 32 2 22 43 11 – Fax: +32 2 22 43 456
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Mark your Calendars for 2011

ISPE Annual Meeting

6–9 November 2011 • Dallas, Texas / USA

The ISPE Annual Meeting is the premier annual gathering for global pharmaceutical and biotechnology manufacturing professionals. The 2011 Annual Meeting is projecting 2,600+ attendees and will feature: Keynote session with global regulators and industry leaders, more than 40 education and training sessions Workshops and unique networking opportunities.

Pharmaceutical Quality Systems (ICH Q10) Conference A practical Approach to Effective Lifecycle Implementation of Systems and Processes for Pharmaceutical Manufacturing

14-16 November 2011 • Sheraton Hotel Brussels/Belgium

PDA, ISPE, the FDA and EMA have created a special joint conference dedicated to teaching the principles of ICH Q10. This will be a unique opportunity to learn these principles from companies that have implemented a Pharmaceutical Quality System across the product lifecycle according to the ICH Q10 model. These companies are reaping the benefits that come from establishing and maintaining a state of control, continual improvement, enhancing regulatory compliance and meeting quality objectives every day.

While this conference is intended to explain the principles of ICH Q10 it is not a conference that only tells you what ICH Q10 says. It is an event where you can learn the practicalities of how to implement Q10 based on real-life case studies. It will show you how senior management commitment and involvement is vital. The conference will take place in Brussels drawing on the best industry and regulator contributors on this topic from both the United States and Europe.

GAMP - Improve Productivity with Risk-Based Systems Validation Conference

14-15 November 2011 • Sheraton Hotel Brussels/Belgium

ISPE is holding a first time *GAMP*[®] event created specifically for you. As the originators of *GAMP*[®], we have the best resources for industry experts which allows you to gain real world experience and get your questions answered. Each track is separated, but themed around validation productivity and will tie together at the end of the conference with a focus on Data Integrity. You'll also have the opportunity to interact with US FDA and EU EMA in workshops and case studies.