



# New Strategies and Business Benefits

## ISPE Frankfurt Conference

### Conference Seminars:

#### ▶ 11 - 12 April 2011

- OSD Manufacturing: Facility and Technology Advances
- Quality Risk Management: Focused, Practical Application
- Sterile Products Manufacturing: Maintaining Compliance

#### ▶ 13 April 2011

- Regulatory Affairs Forum

#### ▶ 13 - 14 April 2011

- GAMP®: IT Infrastructure Innovation and Compliance
- Pharmaceutical Water Systems: Cost Effective Design and Maintenance Trends
- Supply Chain Integration to Maximise Profit and Compliance

### Training Courses:

#### ▶ 13 - 15 April 2011

- HVAC for Pharmaceutical Facilities – **New!**

#### ▶ 14 - 15 April 2011

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

### Conference Highlights:

- Regulatory Q&A
- Workshops
- Case Studies
- Networking Reception
- Training
- Table Top Exhibition

# Need a great occasion to boost your pharmaceutical engineering career ?

ISPE Frankfurt Conference offers you the knowledge updates, expertise, case studies learnings and professional contacts you need. Seminars will be lead by subject-matter experts and the Regulatory Affairs forum will offer you a unique opportunity to join EMA, FDA and other regulatory representatives. Take advantage of our networking opportunities to meet like-minded professionals and make new business contacts.

## OSD Manufacturing: Facility and Technology Advances

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**Seminar Leaders:** **Clemens Stief**, Pfizer Manufacturing Deutschland GmbH (Germany)  
**Richard Denk**, Hecht Technologie (Germany)

► 11 - 12 April

The pharmaceutical manufacturing industry faces many challenges, such as global markets, outsourcing, and cost reduction. Large scale production will be increasingly substituted by small scale multiproduct/multipurpose production.

Attend this two-day interactive seminar with a comprehensive insight into the world of OSD multiproduct/multipurpose manufacturing. We will review the critical factors when designing new or retrofitting an existing OSD manufacturing facility for multiproduct/multipurpose manufacture.

Topics will include:

- Continuous processing versus batch production
- Facility and process design and key factors for conversion of existing process equipment and facility layout
- High potency products
- Outsourcing and product transfer to CMOs
- Risks and benefits of emerging markets such as China, India, and Brazil

The seminar will include two workshops, one on process and facilities and the other on outsourcing and local market manufacture. Participants will have the opportunity to discuss various topics in small groups. Specially-developed case studies covering new industry trends will be used to focus the discussion. Afterwards, there will be a panel discussion with subject-matter experts.

### Related Guidance Documents, Articles and Publications:

- *ISPE Baseline® Guide: Oral Solid Dosage Forms (2<sup>nd</sup> Edition)*
- *ISPE Baseline® Guide: Risk-Based Manufacture of Pharmaceutical Products (Risk-MaPP)*
- *GAMP® 5: A Risk-Based Approach to Compliant GxP Computerised Systems*

## Quality Risk Management: Focused, Practical Application

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**Seminar Leaders:** **Trish Melton**, MIME Solutions, Ltd. (UK)  
**David Selby**, Selby Hope International Ltd. (UK)

► 11 - 12 April

Right now the pharmaceutical industry needs quality risk management (QRM) advice that is focused, tried and proven useful, to save time, effort, and ultimately cost. Overcome reticence in applying QRM. Learn how to document it effectively within your company culture and embed it into everyone's understanding. This highly-interactive two-day seminar will include discussions, real-life case studies, and the opportunity to practice a variety of techniques.

Five years down the road from the implementation of ICH Q9, many companies have developed their systems for quality risk management, while some are still working through the process.

This is an opportunity for practitioners to share experiences and swap ideas. It is also an opportunity for the less-experienced to try out some tools and techniques.

### Related Guidance Documents, Articles and Publications:

- *A Risk-Based Approach to Defining Levels of Protection within API Facility Design: The Concept of Briefly Exposed (Briefly Open)* by Stan Newberger, Trish Melton (*Pharmaceutical Engineering*, November/December Issue 2008)

# Sterile Products Manufacturing: Maintaining Compliance

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**Seminar Leader:** Gordon Farquharson, Critical Systems, Ltd. (UK)  
Lef Leroy, SNC LAVALIN Pharma (Belgium)

► 11 - 12 April

In a mature pharmaceutical market and a difficult economic climate, the challenges facing manufacturers of sterile products are substantial. They must maintain GMP compliance in established manufacturing facilities, while taking into account evolving technologies and regulatory requirements. The facilities need to balance the requirements of the entire product life-cycle: the existing product portfolio together with product and process development for new launches. The seminar opens with an examination of the regulatory environment for aseptic manufacturing, two years on from full implementation of the latest revision to EU GMP Annex 1.

The keynote speaker will be a senior EU regulator. An industry response will follow. The revised *ISPE Baseline® Guide for Sterile Product Manufacturing Facilities* will be launched. **Delegates will receive a copy of the guide as part of their registration package.**

The seminar will address ways of using technology to reduce costs, improve quality, and meet markets demands. Case studies will be presented on industry best practice in energy saving; upgrading of existing facilities; and the use of Process Analytical Technology (PAT).

Finally, the seminar will look into the future of pharmaceutical manufacturing: the role of rapid microbiology methods in environmental monitoring; the use of disposables; green pharmaceuticals; and the factors critical to taking the facility of today into the pharmaceutical manufacturing future.

## Related Guidance Documents, Articles and Publications:

- *ISPE Baseline® Guide: Sterile Product Manufacturing Facilities (2<sup>nd</sup> Edition)* \* \* Release date of Guide subject to change

# Regulatory Affairs Forum

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**Seminar Leaders:** Gordon Muirhead, GSK (UK)  
Joe Famulare, Genentech (USA) (*Invited*)

► 13 April

The Regulatory Affairs Forum offers the unique opportunity for you to join EMA, FDA and other regulatory representatives in dialogue over critical quality compliance and review topics. You will hear distinguished regulatory speakers providing updates on current and future initiatives impacting the global industry; together with an industry response. Listen to the regulators' views on the impact on industry of FDA joining PIC/S.

Put your questions directly to a panel of FDA and other regional regulatory authorities and take back to your job a wealth of best quality practices.

To ensure your questions and issues receive priority treatment, email them to the following address by 01 April 2011:  
nina.todorova@associationhq.com

# GAMP®: IT Infrastructure Innovation and Compliance

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**Seminar Leaders:** Sam Brooks, Novartis (UK)  
Dirk Spingat, Bayer Healthcare (Germany)

► 13 - 14 April

This seminar will explore the innovations in IT infrastructure services and solutions and the resultant impact on industry's approach to compliance. Cloud computing, virtualisation and continuing shift towards outsourced services has led to a rethink in how IT infrastructure controls are established and verified and the interactions between regulated companies and their suppliers and service providers.

This seminar defines the changing risk profile, issues of ownership and accountabilities and strategies for addressing the new operating environment.

## Related Guidance Documents, Articles and Publications:

- *GAMP® 5: A Risk-Based Approach to Compliant GxP Computerised Systems*
- *GAMP® Good Practice Guide: IT Infrastructure Control and Compliance*
- *GAMP® Good Practice Guide: A Risk-Based Approach to Operation of GxP Computerised Systems*
- *GAMP® Good Practice Guide: A Risk-Based Approach to Compliant Electronic Records and Signatures*
- *Pharmaceutical Engineering articles pertaining to Outsourcing*
- *Pharmaceutical Engineering articles pertaining to Risk-Based Quality Management*

# Pharmaceutical Water Systems - Cost Effective Design and Maintenance Trends

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**Seminar Leaders:** **Anthony Bevilacqua**, Mettler-Toledo Thornton Inc. (USA)  
**Anders Widov**, FR Pharma (Sweden)

► 13 - 14 April

This seminar features practical and relevant topics from industry end-users, experts, and engineers.

Specifically, the session topics are based on engineering, design, and maintenance from an owner's point of view.

Water is the most widely used material in pharmaceutical and biotechnical manufacturing and testing. It is used as an ingredient, reagent, solvent, product, cleaning material, and as a testing reagent. While the water is a critical material, the focus of this session will be on the water facility.

Topics include:

- The application of ozone as a sanitising agent in a high purity water system
- Good (and cost saving) maintenance practices and how to compile a maintenance plan for water systems
- Recent views on alternative methods of production for WFI
- Regulatory news impacting water quality specifications
- Good engineering design practices

- An overview of the pending *ISPE Ozone Sanitisation of Pharmaceutical Water Systems Good Practice Guide*
- Practical guidance on how to keep in touch with peers from the industry by using the ISPE Critical Utilities (CU) COP forum
- How to make changes to critical utility systems without leaving a validated state

The session will conclude with a comprehensive open Questions and Answers on all water-related topics.

## Related Guidance Documents, Articles and Publications:

- *ISPE Baseline® Guide: Water and Steam Systems*
- *ISPE Good Practice Guide: Commissioning and Qualification of Pharmaceutical Water and Steam Systems*
- *ISPE Good Practice Guide: Ozone Sanitisation of Pharmaceutical Water Systems (under development)*
- *FDA Guide to High Purity Water Systems*

# Supply Chain Integration to Maximise Profit and Compliance

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**Seminar Leaders:** **Jim McKiernan**, McKiernan Associates GmbH (Switzerland)  
**Titus Krauss**, Systec & Services GmbH (Germany)

► 13 - 14 April

This seminar will address best practices in optimising manufacturing and supply chain operations. Costs are under continued pressure. The pharmaceutical supply chain is undergoing a profound change as companies look to respond quickly and responsively in an increasingly dynamic market.

Explore:

- Best practice examples from outside the pharmaceutical industry (food, consumer goods)
- The application of operational excellence including Lean, Six Sigma, Kaizen and new measures of performance

- Maximising supply flexibility with optimal service at low cost through push-pull supply models (including product postponement)
- The application of ICH Q8, 9 and 10 in supply chain
- Technologies to support greater transparency across the supply chain
- Driving effective change through process oriented organisations

Participants will hear case studies first hand from leading experts as well as participating in interactive workshops.

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

New!

**Instructor:** Hilary Mills-Baker, CEL (UK)

▶ 14 - 15 April – CEUs: 1.5

This new, highly interactive, course describes how the GAMP® *Good Practice Guide: A Risk-Based Approach to GxP Process Control Systems*, may be applied to achieve process control systems that are fit for intended use and meet current regulatory requirements.

The course covers recommended good practice based on a life cycle approach for the development and management of process control systems and shows how the principles and concepts of GAMP® 5 may be practically applied to process control systems. The course covers both regulated company and supplier quality management systems, and the full system life cycle from concept to retirement.

The course shows how appropriate quality risk management and specification and verification activities should be an integral part of the normal system life cycle. Many suppliers of systems now have mature quality management systems and system

development, test, and support documentation. The course promotes the leveraging of supplier documentation and activities to avoid unnecessary duplication, cost and waste.

## Related Guidance Documents, Articles, and Publications:

- Immediately apply the course objectives using the complimentary copy of the GAMP® *Good Practice Guide: A Risk-Based Approach to GxP Process Control Systems (2<sup>nd</sup> Edition)*

# HVAC for Pharmaceutical Facilities

New!

**Instructor:** Gordon Farquharson, Critical Systems, Ltd. (UK)

▶ This is a three-day course  
13 - 15 April – CEUs: 2

This course will provide a detailed description of HVAC system fundamentals, including a discussion of primary system components such as fans, coils, humidifiers, and filters. Participants will receive an overview of critical parameters for products and processes that can be affected by HVAC, and explore the basic concepts of controlling these parameters using properly designed HVAC control systems. Participants will discuss what HVAC can and cannot do to maintain good manufacturing practices (GMPs) as they are addressed for facilities designed to manufacture bulk pharmaceutical chemicals (BPC), oral solid dosage (OSD) products, sterile products, and bulk biopharmaceuticals. HVAC systems for production laboratories and warehouse facilities utilised for the storage of product, raw materials, and components are also covered.

On completion of facility-specific systems, the requirements for commissioning and qualification are explored with emphasis on distinguishing between critical and noncritical parameters. Other course topics include HVAC controls, monitoring of critical

parameters, and system construction. Dust collection systems and laboratory fume hoods are not covered, as these systems are addressed by other sources. The course concludes with suggestions for system maintenance.

Attendees will be provided with updates to course materials if GMPs or technology related to meeting GMPs change within 12 months of attending the course (email address required). Participants should be familiar with basic pharmaceutical product forms and GMPs.

## Related Guidance Documents, Articles, and Publications:

Immediately apply the course objectives using the complimentary copy of the ISPE *Good Practice Guide: Heating, Ventilation, and Air Conditioning*.

FULL COURSE DESCRIPTIONS CAN BE FOUND: [www.ISPE.org/2011FrankfurtConference](http://www.ISPE.org/2011FrankfurtConference)

## Registration Form

**SAVE TIME – REGISTER ONLINE: [www.ISPE.org/2011FrankfurtConference](http://www.ISPE.org/2011FrankfurtConference)**

Prices below do not include VAT – 19% German VAT is applicable on registration and networking evening fees only.

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.

For registration, general information, and terms and conditions, please visit [www.ISPE.org/2011FrankfurtConference](http://www.ISPE.org/2011FrankfurtConference)

SEMINARS		EARLY BIRD ON OR BEFORE 4 MARCH 2011			REGULAR / ONSITE AFTER 4 MARCH 2011		
		Member	New Member	Non-member	Member	New Member	Non-member
Monday 11 – Tuesday 12 April	OSD Manufacturing: Facility and Technology Advances	€1.100	€1.310	€1.365	€1.400	€1.610	€1.680
	Quality Risk Management: Focused, Practical Application	€1.100	€1.310	€1.365	€1.400	€1.610	€1.680
	Sterile Products Manufacturing: Maintenance Compliance (Price includes the New ISPE Baseline® Guide: Sterile Product Manufacturing Facilities – 2nd Edition)	€1.200	€1.410	€1.465	€1.500	€1.710	€1.780
Wednesday 13 – Thursday 14 April	GAMP® : IT Infrastructure Innovation and Compliance (includes participation to the Regulatory Forum)	€1.100	€1.310	€1.365	€1.400	€1.610	€1.680
	Pharmaceutical Water Systems: Cost Effective Design and Maintenance Trends (includes participation to the Regulatory Forum)	€1.100	€1.310	€1.365	€1.400	€1.610	€1.680
	Supply Chain Integration to Maximise Profit and Compliance (includes participation to the Regulatory Forum)	€1.100	€1.310	€1.365	€1.400	€1.610	€1.680
Full congress package - Select two seminars above - One per two-day series - and save 20% on the second seminar. Includes two seminars and the forum (four days)		€1.760	€1.970	€2.025	€2.060	€2.270	€2.340
Regulatory Forum (Wednesday morning only – Can be added to the Monday-Tuesday Registration )		€305	€305	€570	€605	€605	€885
Networking Evening		€65/person – Accompanying partners are welcome to attend this event (same fee applies)					

TRAINING COURSES		EARLY BIRD ON OR BEFORE 4 MARCH 2011			REGULAR / ONSITE AFTER 4 MARCH 2011		
		Member	New Member	Non-member	Member	New Member	Non-member
Wednesday 13 – Friday 15 April							
HVAC for Pharmaceutical Facilities		€2.115	€2.325	€2.430	€2.415	€2.625	€2.745
Thursday 14 – Friday 15 April							
A Risk-Based Approach to GxP Process Control Systems		€1.510	€1.720	€1.795	€1.810	€2.020	€2.110

DATE	CONFERENCE SEMINARS			NETWORKING EVENTS
Monday 11 April Tuesday 12 April	OSD Manufacturing: Facility and Technology Advances	Quality Risk Management: Focused, Practical Application	Sterile Products Manufacturing: Maintaining Compliance	Exhibition Networking
Wednesday 13 April AM	Regulatory Affairs Forum (Wednesday morning only)			
Wednesday 13 April PM Thursday 14 April	GAMP®: IT Infrastructure Innovations and Compliance	Pharmaceutical Water Systems: Cost Effective Design and Maintenance Trends	Supply Chain Integration to Maximise Profit and Compliance	Exhibition Networking
<b>Training Courses</b>				
Wednesday 13 April to Friday 15 April	HVAC for Pharmaceutical Facilities (three-day course)			
Thursday 14 April Friday 15 April	A Risk-Based Approach to GxP Process Control Systems			