



Designing, Implementing and Maintaining Pharmaceutical Supply Networks

6 – 7 June 2012

Baltimore, Maryland USA
Renaissance Baltimore Harborplace Hotel

2
+ Training
Courses



Connecting a World of
Pharmaceutical Knowledge



Create strong, valuable supply chain networks and gain a competitive advantage in the marketplace!

ISPE has put together this topic-specific program on how to develop and manage complex supply networks, reduce risk and ensure high quality reliability. The conference will include a plenary session, two education tracks and plenty of networking opportunities.

Tracks include

- **Designing and Establishing Supply Networks**
- **Maintaining and Optimizing Supply Networks**

Take a look inside to start customizing your agenda!



ISPE PINNACLE PROGRAMME
2012 Global Sponsor

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Sponsorship Opportunities Available

Sponsoring an ISPE educational seminar or training program is a cost-effective way to gain competitive advantage, increase name recognition, and create top-of-mind awareness in today's pharmaceutical science and biotechnology manufacturing industry. Sponsorships include pre-event exposure on the ISPE website as well as the delegate mailing list, onsite exposure with exhibit opportunities, company logo on signage, and mentions in print and electronic communication. For more information or to secure your sponsorships, contact John Phillips at jphillips@ispe.org or Daniel Murphy at dmurphy@ispe.org.

CONFERENCE SCHEDULE-AT-A-GLANCE ▶▶

Wednesday, 6 June

- 07.30 – 08.45 New Member/First-Time Attendee Breakfast
- 07.30 – 18.30 Exhibit Hall Opens
- 09.00 – 12.30 **Plenary Session**
- 10.30 – 11.10 Networking Break in Exhibit Hall
- 11.10 – 12.30 **Plenary Session Continues**
- 12.30 – 13.30 Lunch in Exhibit Hall
- 13.30 – 15.00 **Track 1: Designing and Establishing Supply Networks**
Track 2: Maintaining and Optimizing Supply Networks
- 15.00 – 15.40 Networking Break in Exhibit Hall
- 15.40 – 17.00 **Education Tracks Continue**
- 17.00 – 18.30 Evening Reception in Exhibit Hall

Thursday, 7 June

- 08.30 – 10.00 **Track 1: Designing and Establishing Supply Networks**
Track 2: Maintaining and Optimizing Supply Networks
- 10.00 – 10.40 Networking Break
- 10.40 – 12.30 **Education Tracks Continue**
- 12.30 – 13.30 Lunch Break
- 13.30 – 15.00 **Education Tracks Continue**
- 15.00 – 15.40 Networking Break
- 15.40 – 17.00 **Education Tracks Continue**

For full agenda, visit www.ISPE.org/SupplyNetworks

PLENARY SESSION ▶▶

Attendees from around the world will gather on Wednesday morning to get their questions answered from high-level industry experts. This interactive Plenary Session will begin the Conference as speakers address the current challenges in the global supply network.

For a current list of plenary speakers and topics, visit the Conference website or look for email updates from ISPE.



EDUCATION

Designing and Establishing Supply Networks

Learn how to create new supply sources utilizing effective tech transfer and CMOs.

Session 1 – Defining and Designing an Efficient Supply Network

- Choice Between Make or Buy
- How are Suppliers Chosen
- Moving from Islands of Supply (Inventory Control) to a Fully Integrated/Flexible Supply Chain
- Supplier Assessment and Selection

Session 2 – Regulatory Challenges in a Global Supply Network

- Global Regulatory Harmonization
- Q11 in a Global Environment
- Cost of Continuous Improvement
- Highly Regulated Markets
- Emerging Markets/BRIC Supply
- Multimarket Supply

Session 3 – Quality Expectations and Challenges (with Track 2)

- Quality Oversight of the Supply Network
- CMO Perspective on Quality Management when Dealing with Multiple Customers
- Consequences of Negative Audits/Inspections

Session 4 – Local Manufacture and Impact to Global Supply Business Case Development & Challenges to Market Entry

- Local Requirements by Region or Country
- Case Studies that Could be Used to Manage Impact of Local Requirements
- Make vs. Buy
- In-Country vs. Import
- Import and Export Traffic
- Impact of Transportation Cost and Time

Session 5 – Managing Suppliers through the Product Lifecycle: Supplier Integration, Supplier and 3rd Party Quality Assurance

- Demand and Visibility Across the Supply Chain
- Customer – CMO Relationships
- Change Management Through the Lifecycle

Session 6 – Technology Transfer

- IP Implications
- Registration Responsibilities
- Transfer CMO to CMO

LEADERS:

- **Nick Davies**, CEO & Principal Consultant, NDA Consultants, USA
- **Gary Primes**, Vice President of Operations, PURE Bioscience, USA

SPEAKERS:

- **Bill Connell**, Vice President & Supply Chain Practice Leader, Maxiom Group
- **Thomas Eckrich**, Advisor, Sourcing Development, Chemical Process Research and Development, Eli Lilly & Co
- **Hans Engels**, President & CEO, DSM Pharmaceuticals, Inc., FDA
- **Junning Lee**, Vice President, Technical Operations, Theravance, Inc.
- **Erik Roggeman**, Associate Quality Consultant, Eli Lilly & Co.
- **Nick Thomson**, Director Chemical Research and Development, Pfizer, Inc.

Register Now and Save!

Member
Prices reflect

Register for one track and attend two!
Delegates are free to attend presentations in each track throughout the Conference.

EDUCATION

Maintaining and Optimizing Supply Networks

Efficiently manage existing supply sources using effective risk-management.

Session 1 – Challenges and Threats to Supply Networks

- Globalization of the Supply Chain – Management Challenges
- Cultural Challenges
- Cost/Quality and Customer Expectations
- Risk Management Strategies for Political/Economic Instability

Session 2 – Insuring Reliable Supplies

- What Can Go Wrong
- Risk Management
- Dual Supply – Regulatory Constraints
- Quality History
- Cold Chain

Session 3 – Quality Expectations and Challenges (with Track 1)

- ICH Q11 Expectations
- Regulators Expectations
- Quality Oversight of the Supply Chain
- CMO and 3rd Party Quality Management
- Impact of Supplier Compliance Issues

Session 4 – Maintaining Supply Security

- Anti-Counterfeiting
- Supply Chain Diversion
- E-Pedigree and Serialization
- Theft & Substitution

Session 5 – Global Market Case Studies

- Examples of What Others Have Done
- Sharing Audits Across Multiple Companies

Session 6 – Trends and Technologies

- Lessons Learned from Non-Pharma Industries
- Software Solutions – Tracking/MRP/ERP/etc.

LEADER:

John Donaubaauer, Project Leader, Scientific Affairs, Abbott Laboratories, USA

SPEAKERS:

- **Bill Bonaccorsi**, Director of Marketing and Product Management, Domino North America
- **Charles Costanzo**, Senior Process Scientist, Merck & Co., Inc.
- **Tee Migliori**, President & CEO, ADC Technologies
- **Angela Wong**, Vice President, Emerging Markets, Pfizer, Inc.
- **Yao Zhao**, Ph.D., Department of Supply Chain Management and Marketing Science Rutgers University, The State University of New Jersey

Member: \$1,495 New Member: \$1,734 Non Member: \$1,825
Reflect Early Bird rates. Register before 7 May and save \$200. Visit website for more information.

RELATED TRAINING COURSES

Extend your stay to attend one of these valuable training courses.*

4 – 5 June
08.30 – 17.00

A Risk-Based Approach to GxP Process Control Systems (T21)

Instructor: James (Jim) John, Project Manager, ProPharma Group Company

Level: Intermediate

CEUs: 1.3

This new, highly interactive, course describes how the *GAMP® Good Practice Guide: 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 will also cover both regulated company and supplier quality management systems, and the full system life cycle from concept to retirement.

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

Sterile Product Manufacturing Facilities (T12) - New Course and Guide!

Instructor: Mark Von Stwolinski, Vice President of Architectural Services, Clark Richardson & Biskup (CRB) Consulting Engineers

Level: Intermediate

CEUs: 1.3

This course uses the newly published second edition of the *ISPE Baseline® Guide: Sterile Product Manufacturing Facilities* and the FDA's newly published *Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice* to provide an understanding of the key requirements and GMPs for sterile manufacturing facilities.

Using the referenced documents, this course will cover regulatory philosophy, aseptic process and equipment considerations, aseptic clean room design and operation, differential pressure requirements, airlocks, basic utility systems, European HVAC considerations, basic commissioning and qualification issues, and a brief introduction to barrier isolation technology.

Immediately apply the course learning objectives using the complimentary copy of the *ISPE Baseline® Guide: Sterile Product Manufacturing Facilities (Second Edition)*.

*Training Course registration is not included in the Conference Registration fee. Training materials are not available for download.

FEES

Prices reflect Early Bird rates. Register before 7 May and save \$200.

Visit website for more information.

Member: \$1,610 New Member: \$1,849 NonMember: \$1,945

NETWORKING OPPORTUNITIES

ISPE Chesapeake Bay Area Chapter Proudly Presents

Riverboat Casino Night Cruise

Tuesday, 5 June
19.00 – 22.00

Climb aboard the Black-Eyed Susan, to experience Baltimore's only authentic paddlewheel driven dinner riverboat. Test your luck at the onboard casino where your winnings are converted into chances to win fabulous door prizes. Enjoy the open bar, pasta station, local favorites including shrimp, crab cakes and hot crab dip, and carved tenderloin.

The Victorian-style paddleboat is only steps away from the Renaissance Harborplace Hotel. Boarding begins 30 minutes prior to departure. Don't miss a chance to experience a little of Baltimore's Inner Harbor, while mingling with colleagues from the Chesapeake Bay Area Chapter and other Conference attendees. Book your spot today!

Members: \$90

NonMembers: \$100

ISPE Bookstore

Stock up on the latest guidance documents from ISPE.

Members receive a **20% discount**.

New Member/First-Time Attendee Breakfast

Wednesday, 6 June
07.30 – 08.45

Join us for this special networking breakfast hosted by the Membership Development Committee. Meet fellow Society Members during breakfast to foster new relationships, learn about ISPE and how to make the most out of your membership!

Networking Reception

Wednesday, 6 June
17.00 – 18.30

Certified Pharmaceutical Industry Professional™ (CPIP™) Information Workshop

Thursday, 7 June

This complimentary one-hour workshop provides an overview of the CPIP™ Certification Program, a pharmaceutical industry-focused, international competency-based credential made available through the ISPE Professional Certification Commission. Topics include: CPIP™ Introduction, eligibility criteria, overview of the application, examination and recertification processes, and information on CPIP™ Study Groups.

How to Register

Online: Visit www.ISPE.org/SupplyNetworks

Via Fax: Complete the registration form online and fax it to: +1-813-264-2816

Via Mail: Complete the registration form online and mail it with payment to: ISPE Headquarters, 600 N. Westshore Blvd., Suite 900, Tampa, Florida 33609 USA

Questions? Call ISPE at tel: +1-813-960-2105, or email: ask@ispe.org
Written confirmation will be sent to you after your registration is processed (time permitting). In order to be listed in the official delegate roster, you must be registered and paid by 7 May.

Hotel Information

For room reservations at the Conference venue, Renaissance Baltimore Harborplace Hotel, Baltimore, Maryland USA, call tel: 1-800-HOTELS1 or +1-410-547-1200. When making your reservation by phone, mention ISPE for a discounted rate of \$195 single/double. This rate is good until 7 May 2012, or until the room block is full, whichever comes first. Or you may make your reservation online at www.renaissanceharborplace.com using group code ISPISPA. Please contact the hotel as early as possible to make your reservations to ensure you are in the headquarters hotel. We thank you for staying at the Renaissance as this enables ISPE to meet contract requirements.

ISPE – Membership Has its Benefits

Did you know that ISPE Members attend training programs and other events at discounted rates? New Member registration fees include a one-year ISPE membership, a \$239 value. Visit www.ISPE.org/Join for details on Member benefits and special rates for Young Professionals, Students, Regulators, and persons from countries with Emerging Economies.



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