The State of QbD in the Biopharmaceutical Industry Conference

Criticality Assessment, Design Space Implementation and Control

10 – 11 April 2013
Sheraton Fisherman’s Wharf
San Francisco, California USA

Sponsored by ISPE -
Endorsed by CASSS With a Mutual Commitment to Quality Products

www.ISPE.org/2013QbDConference
Plan for Quality Throughout the Lifecycle

An opportunity for industry and regulators to find common ground in understanding, assessing and mitigating risk.

How do smart companies design and develop formulations and manufacturing processes to insure pre-designed product quality? Understand how planning and controlling pharmaceutical product evolution can lead to superior quality, better resource use and increased business effectiveness.

This conference offers an opportunity for industry and regulators to find common ground in understanding, assessing and mitigating risk related to product development, approval and commercialization.

Attend and you’ll be able to answer questions like these with confidence:
• Does your scientific story effectively link and support high quality/low risk manufacturing?
• Can you assure applicability of your design space studies to the commercial scale?
• What is an acceptable level of risk for a regulatory authority?

Keynote presentations will focus on international regulatory expectations, as well as lessons learned during various QbD implementations.

Workshops

• **Scalability of the Design Space**
  Examine the effectiveness of and the process for qualifying design space models in biotech to reduce risk. Explore approaches to assure applicability of your design space studies to the commercial scale.

• **Developing and Implementing an Effective Control Strategy**
  With increased focus on the implications of the Quality Target Product Profile, determining critical quality attributes and understanding critical parameters are crucial to a comprehensive control strategy.

• **Communicating an Effective Scientific Story in the Dossier & Pre-Approval Inspection**
  Reports QbD implementation requires greater understanding of the challenges to register a successful design space and related control strategy. Discover how you can support design space implementation by aligning concepts that use common QbD language during inspections and providing appropriate PQS element summaries in dossiers.

• **Demonstrating and Maintaining a State of Control Throughout the Lifecycle**
  Regulatory authorities want increased clarity on how change control within companies’ pharmaceutical quality system assures continued quality of the product. Understand criticality assessment and its determination as it applies to ensuring a robust control strategy for Biotech products.
Plenary

Roger Nosal, Pfizer, Inc., USA

The State of QbD 10 years after the Small Molecule Pilot

Roger Nosal is currently Vice President of Global Chemistry, Manufacturing & Controls (GCMC) at Pfizer. Roger has been instrumental in developing and establishing Pfizer’s regulatory approach and position for application of Quality by Design, including the introduction of Real Time Release testing (RTRt), Continuous Quality Verification (CQV), Continuous Processing and extension of QbD for development of analytical methods and stability protocols.

Roger led Pfizer’s engagement and negotiation in FDA’s Pilot Program, (Submission of Chemistry, Manufacturing and Controls Information in a New Drug Application Under the New Pharmaceutical Quality Assessment System) as well as introduction of the application of QbD for MAAs and JNDA’s and in presentations to FDA, EMA and PMDA. He has been an active leader and contributor on behalf of the ISPE Pharmaceutical Quality Lifecycle Implementation (PQLI) program, as co-chair of PQLI sessions in Washington D.C. (2009 & 2011) and a lead author for the Product Realization Good Practice Guides and frequent speaker and author of position papers, journal articles and textbook chapters on topics related to the application of QbD.

Complimentary Guide with Conference Registration

After you register for the QbD Conference, choose one of the ISPE Guide Series: Product Quality Lifecycle Implementation (PQLI® from Concept to Continual Improvement (electronic download) of your choice.

- Part 3 – Change Management System as a Key Element of a Pharmaceutical Quality System (First Edition, June 2012)

Thank you to our Event Planning Team Members:

Joanne Barrick Advisor, Global Validation Support, Eli Lilly & Co., USA
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John Lepore Senior Director, Chemical Process Development, Merck & Co., USA
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Roger Nosal Vice President, Global Chemical Manufacturing-Controls, Pfizer Inc., USA
Chris Potter CMC Pharma Consultant, UK
Steve Tyler Director, Quality Assurance, AbbVie, Inc., USA
Wendy Zabolenski-Lambert Director, Pharma Business Support, Abbott Laboratories, USA
Conference Fees

Quality by Design

<table>
<thead>
<tr>
<th>Conference</th>
<th>Date</th>
<th>Location</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Supply Management Summit</td>
<td>14 – 15 May</td>
<td>Indianapolis, Indiana USA</td>
<td>Redefining the “C” in CGMP: Creating, Implementing and Sustaining a Culture of Quality</td>
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<tr>
<td>World Class Supply - End to End Effective Approaches to Optimising Drug Supply and Ensuring Security: Exploring Best Practices in Both Investigational Products and Commercial Supply Chains</td>
<td>13 – 14 June</td>
<td>Prague, Czech Republic</td>
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<td>Biotechnology 2013: Looking Ahead to the 4th Decade</td>
<td>27 – 28 August</td>
<td>Durham, North Carolina USA</td>
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<td>September</td>
<td>France</td>
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<td>Proactive Compliance Conference</td>
<td>7 – 8 October</td>
<td>New Brunswick, New Jersey USA</td>
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<tr>
<td>Process Validation Intensive</td>
<td>9 – 10 October</td>
<td>New Brunswick, New Jersey USA</td>
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<tr>
<td>Lean Manufacturing</td>
<td>October</td>
<td>Berlin, Germany</td>
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<td>2013 Annual Meeting: Quality Throughout the Product Lifecycle</td>
<td>3 – 6 November</td>
<td>Washington, DC USA</td>
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How to Register

Online: www.ISPE.org/2013QbDConference
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). For more information visit the event website.

Hotel Information

For room reservations at the Conference venue, Sheraton Fisherman’s Wharf, San Francisco, California, call tel: 1-888-627-7024 or +1-415-362-5500. When making your reservation, mention ISPE for a discounted rate of $179 single/double. This rate is good until 19 March 2013, or until the room block is full, whichever comes first. 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 Sheraton as this enables ISPE to meet contract requirements.
Valuable Training Courses!
Get the most out of your time away from the office.

Add one of these in-depth, topic-focused training courses to your schedule:

**10 - 11 April 2013**
San Francisco, California USA

**Risk-MaPP (T41)**
Instructor: *Stephanie Wilkins, PE, President, PharmaConsult, US, Inc.*

By properly managing the risk of cross contamination, manufacturers can reap the benefits while also maintaining product quality and patient safety. This course outlines a scientific, risk-based methodology that can be used to lead teams through the process to satisfy auditors as well as global regulators.

**Process Validation in Biotechnology Manufacturing (T32)**
Instructor: *Mark Witcher, PhD, Principal Consultant, IPS*

This course is designed to provide a clear understanding of the regulatory, scientific, and engineering tools required to successfully develop and validate bioprocesses.

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

For more information visit www.ISPE.org/2013AprilSanFranciscoTraining

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<tr>
<th>Early Bird Ends 12 March</th>
<th>Risk-MaPP (T41)</th>
<th>Process Validation in Biotechnology Manufacturing (T32)</th>
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<tr>
<td>(Early bird pricing is the lower fee)</td>
<td>10 - 11 April</td>
<td>10 – 11 April</td>
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<tr>
<td>Member</td>
<td>$1,750</td>
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<tr>
<td>Student/Academia/Emerging Economy</td>
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Some courses include a pre-recorded course primer. Access information will be provided via email one week prior to the start of the training event.

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, 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.
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