ISPE Boston Area Chapter Presents:

Risk-Based Commissioning and Qualification – What's Everybody Else Doing?

Thursday, June 19, 2014

5:30 pm to 8:30 pm

Tufts Gordon Institute
200 College Ave, Suite 2400, Medford, MA 02155

OR VIA SIMULCAST AT

Crowne Plaza Hotel Providence - Warwick
801 Greenwich Street, Warwick, RI 02886

EVENT INFORMATION:

Attend the live program at Tufts Gordon Institute in Medford, MA or a simulcast presentation at the Crowne Plaza Providence in Warwick, RI. Both location programs will include a networking reception prior to the presentation.

PROGRAM SUMMARY:

Industry's latest regulations and guidances direct Lifescience companies to employ risk and science based methods to ensure that the focus of their compliance activities are directed on the elements that are most impactful to the quality, safety and integrity of their products. These directives do not necessarily formalize a singular method to attain that end goal, outside of their focus on techniques based on science, process, product, and system knowledge. As a result, organizations typically have their own way of interpreting the requirements, as well as their own programs and tools to complete the effort.

WHO SHOULD ATTEND:

This presentation and panel Q&A is intended for industry professionals seeking to gain a better understanding of risk management as it applies to commissioning and qualification. The presentation will highlight the principles of the various regulatory standards available including:

- ICH Q8 – Pharmaceutical Development
- ICH Q9 – Quality Risk Management
- ICH Q10 – Pharmaceutical Quality System
- ASTM E2500 - Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment
- ISPE Guid: Science and Risk-Based Approach for the Delivery of Facilities, Systems and Equipment.

The presentation will also cover risk management implementation strategies including real-world examples, past success stories and lessons learned.
The panel Q&A will allow for the audience to pose questions to industry experts and learn how their organizations employ risk-based approaches. A significant portion of the session will be dedicated to audience participation. Don't miss this timely topic!

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SPEAKER:

Geoffrey von Holten has over twelve years of engineering consulting experience in the biopharmaceutical and biotech industry. Geoff specializes in the start-up, commissioning and qualification of new manufacturing facilities. He holds a BS in Chemical Engineering from Northeastern University.

Geoff established GvH Consulting, Inc. in 2007 to focus on engineering and compliance services. He previously worked as a project manager for Bosch Packaging Technology, where he oversaw contract validation and engineering services. He served as the lead project engineer and validation lead for MannKind Corporation's commercial expansion project in Danbury, CT. He was also the process equipment commissioning team lead for Shire's Project Atlas in Lexington, MA.

PANEL MEMBERS:

Eric Felz, Associate Director of Validation, Shire Eric Felz is the Associate Director of Validation at Shire, responsible for Equipment, Facility, and Utility qualification for the Alewife and Lexington Facilities. Eric is currently involved in updating the commissioning and qualification program at Shire facilitating the effort to move to an ASTM E2500 based C&Q methodology. Eric is involved with the ISPE Community of Practice for commissioning and qualification as part of the Owners' Team and the Web Team. Eric holds a BS in chemical engineering from Cornell University and an MBA from Babson College

Steve Kuzil, Associate Director Commissioning and Qualification, Genzyme Stephen Kuzil, has over 23 years of experience in pharmaceutical and biotechnology plant commissioning, qualification, and validation. He is currently the C&Q Associate Director at Genzyme (Framingham Biologics). Recently he was with BioMerieux responsible for leading the Industrialization Engineering C&Q. Previously he was with Stryker Biotech as the Senior Project Manager for Validation leading validation efforts for capital projects and prior to this the Associate Director for MT at Organon Teknika leading validation and manufacturing technology efforts for the site.

Michelle Whipple, Senior Manager, Validation, Baxter Michelle Whipple, is currently the Senior Manager Validation at Baxter Healthcare Corporation, Milford, MA. Michelle has over 18 years of experience in startup and qualification of pharmaceutical and biotech equipment and facilities. She began her career at Genzyme at the Allston, MA facility followed by eight years within the validation group at AstraZeneca in Westborough, MA. From 2006 to 2011, Michelle led the Bristol Myers-Squibb QA Validation group through the startup of the Devens, MA facility.

Michelle received a B.S. in Chemical Engineering from the University of Massachusetts and an M.S. in Chemical Engineering from Worcester Polytechnic Institute. She was a member of the ISPE C&Q community of Practice (COP) Leadership team from 2006 to 2013

MEETING MANAGER:

Robert Beane, B.W Design Group

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PROGRAM SCHEDULE: Applies to both locations

5:30 – 6:30 PM Registration and Networking Reception
6:30 – 8:30 PM Presentation

REGISTRATION FEES:

		Registration by 06/12/2014	Registration After 06/12/2014
☐	Members	$50	$60
☐	Young Professional Members	$20	$30
☐	Non-members **	$95	$115
☐	Students Members	FREE	FREE
☐	Simulcast in Rhode Island	FREE	FREE

** Attendees may only attend one program as a non-member.

REGISTRATION IS NOW OPEN ONLINE!

Don't waste time filling in the form! Register online at www.ISPEBoston.org/Events.
Pay by credit card OR check.

Name: _____ Title: _____

Do you wish to opt out of being listed on the attendee roster: ☐

Company: _____ Member #: _____
Address: _____ City: _____ State: _____ Zip: _____
Tel: _____ Fax: _____ Email: _____

PAY BY CREDIT CARD: ☐ Visa ☐ MasterCard ☐ American Express
Card #: _____ Expiration Date: _____

Cardholder Name (as it appears on card): _____
Cardholder Signature: _____

Payment may be mailed to: ISPE, Boston Area Chapter, 411 Waverley Oaks Road, Suite 331B, Waltham, MA 02452
Telephone: 781-647-ISPE (4773) Fax: 781-647-7222 Email: office@ispeboston.org

****PLEASE NOTE: CANCELLATIONS RECEIVED AFTER JUNE 12TH ARE SUBJECT TO BILLING****

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DIRECTIONS:

To Tufts Gordon Institute, Medford, MA:

For door to door directions, click here

Parking options include:
Parking at 196 and 200 Boston Avenue is free.

To the Crowne Plaza Hotel Providence – Warwick, RI:

For door to door directions, click here

http://www.crownehotelwarwick.com/index.cfm/page/Contact-Us/pid/10269