

ISPE Boston Area Chapter Presents:
**The Science and Risk Based Approach to C&Q:
The Road to ASTM E2500**

Thursday, March 21, 2013

5:30 pm to 8:30 pm

Goulston & Storrs

400 Atlantic Avenue
Boston, MA 02110



PROGRAM SUMMARY:

The introduction of ASTM E2500 and ICH Q9 (Quality Risk Management) have provided the Pharmaceutical Industry with a methodology to optimize commissioning and qualification activities resulting in improved compliance and a defined focus on product quality and patient safety. Efficient implementation of these practices provides the additional opportunity to reduce capital project timelines, and reduce life cycle costs.

Although the ASTM and ICH documents indicated the “What” in defining a science and risk based approach to system verification, the “How’s” of practical and efficient implementation of the supporting work processes had not been fully described and associated best practices had not been developed.

In order to help fill this need, the C&Q CoP sponsored the development of the *ISPE Guide: Science and Risk Based-Approach for the Delivery Facilities, Systems, and Equipment* that presents a structured life cycle approach to the delivery and verification of GxP regulated facilities, systems, and equipment. It supports the ASTM industry and ICH regulatory initiatives, including science based risk management approaches, a focus on product and process understanding, and the application of Quality by Design concept. In addition the C&Q COP formed a Task Team to develop a *Good Practice Guide - Applied Risk Management for C&Q* that maps the transition and provides implementation strategies for moving from the traditional, or “Baseline Guide 5 approach” based on Impact Assessment to ICH Q9/ASTM quality risk management implementation.

This presentation will provide an overview these recent ISPE guidance documents and provide an overview of the implementation principles and elements contained therein.

SPEAKERS:

Dave Dolgin, Senior Quality Program Manager, Quality Systems Group, AbbVie

Dave Dolgin is currently a Senior Quality Program Manager in the Quality Systems group of AbbVie (formerly Abbott). Dave has more than 35 years of Quality Assurance and Validation experience in the pharmaceutical industry and has been with Abbott/AbbVie since 1991. Dave led the C&Q task team in development of ISPE’s Good Practice Guide - *Applied Risk Management for C&Q*.

Steve Wisniewski, Principal Compliance Consultant, Commissioning Agents, Inc.

Steven J. Wisniewski is Principal Compliance Consultant for Commissioning Agents, Inc. (CAI), provider of technical services for biotech and pharmaceutical manufacturers world-wide. Commissioning Agents focuses on

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SPEAKERS (Continued):

Steve Wisniewski

the manufacturing process, with services including commissioning, validation, technology transfer, PAT, maintenance programs, SOPs, training and cGMP compliance.

Mr. Wisniewski offers more than 30 years experience in the pharmaceutical, biotech, and device industries. Prior to joining CAI he was Senior Associate and Director of Compliance for Drug and Device Associates. Mr. Wisniewski has served in senior management roles at Sterling Winthrop and Bausch & Lomb. He has completed a wide variety of pharmaceutical manufacturing, filling and critical support operations to major R&D laboratories, facilities and upgrades. He holds a BSME from Rensselaer Polytechnic Institute, is a Member of PDA, and an active Member of ISPE. He served on the ISPE Board of Directors beginning in 1982, and was Chairman of the Board in 1991. He served four terms as Chairman of the ISPE Community of Practice for Commissioning and Qualification, was a lead on the Task Team that drafted the recent ISPE Guide in support of Risk-based Qualification and served on the Task Team that completed the ISPE Good Practice Guide to address transitional Science and Risk-based (ICH Q9) approaches for C&Q. He was on the Team that developed the ASTM E2500 Standard and has also served as course leader and/or presenter at multiple ISPE C&Q conferences and co-authored several C&Q related articles.

MEETING MANAGER:

Armen Nahabedian, Pfizer

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PROGRAM SCHEDULE:

5:30 – 6:30 PM Registration & Networking Reception

6:30 – 8:30 PM Welcome & Program

REGISTRATION FEES:

Registration by 03/14/2013

After 03/14/2013

<input type="checkbox"/> Members	\$50	\$60
<input type="checkbox"/> Non-members **	\$95	\$115
<input type="checkbox"/> Students	\$5	\$10

** 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 March 14th ARE SUBJECT TO BILLING****

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DIRECTIONS:

By Automobile

From the North Shore: Take I-93 South to Purchase Street, Exit 23. Stay right off the exit onto Purchase St. Follow Purchase St for two blocks and turn left onto Congress St. Take an immediate left onto Atlantic Avenue. Follow Atlantic Ave for three blocks. Our building will be on the right just before the Boston Harbor Hotel.

From the South Shore: Take I-93 North to Exit 20 South Station. Follow signs to South Station/Downtown. Turn right at the end of the ramp onto Kneeland St and turn at the second left onto Atlantic Avenue. Continue straight on Atlantic Avenue. Our building is on the right just before the Boston Harbor Hotel.

From the West: Take the Massachusetts Turnpike/RTE I-90E to exit 24A for South Station. This will put you onto Atlantic Avenue. Follow Atlantic Avenue to our building, which is on the right just before the Boston Harbor Hotel.

Parking: Parking is available at the Boston Harbor Hotel garage, right next door to our office. To access the parking garage, continue beyond our building on Atlantic Avenue to the garage entrance which is just past the Boston Harbor Hotel rotunda on the right. For information, call the Rowes Wharf Garage at (617) 439-0328.

By Subway

From South Station (Red & Silver Lines): Take the Red Line to South Station. The Red Line may be reached at both Park Street and Downtown Crossing stops, where there is a free transfer of trains available. From South Station, walk north along Atlantic Avenue to our building located just before the Boston Harbor Hotel.

From the Aquarium Stop (Blue Line): Take the Blue Line to the Aquarium stop, be sure to come out of the Atlantic Avenue exit. Continue south on Atlantic Avenue to our building which is located on the left just beyond the Boston Harbor Hotel. The Blue Line also provides travelers access to and from Logan Airport.

From North Station (Orange & Green Lines): Take the Orange Line to Downtown Crossing, where there is a free transfer to the Red Line available. Take the Red Line to South Station and walk north along Atlantic Avenue to our building, which is located just before the Boston Harbor Hotel on the left.

Google Map:

<http://maps.google.com/maps?f=q&hl=en&geocode=&q=400+Atlantic+Avenue+Boston+Mass&sll=37.0625,-95.677068&sspn=41.411029,69.785156&ie=UTF8&ll=42.355309,-71.059828&spn=0.018933,0.050383&z=15&iwloc=addr>