

ISPE Boston Area Chapter Presents:
**Integrated Commissioning and Qualification:
Saving Time and Money Without Compromising Quality**

Thursday, December 15, 2011

5:30 pm to 8:30 pm

Genzyme Center

500 Kendall Street, Cambridge, MA 02142

PROGRAM: Use of Integrated Commissioning and Qualification models based on ASTM E2500 offers a rare opportunity – a chance to deliver projects that meet user and product needs, with the full documentation package required by regulatory authorities, and do it on time and within budget. However, having your cake and eating it too requires a departure from the traditional approach. This evening's program will lay out a series of C&Q models, explain how they work (or do not work) and use first hand case studies to highlight the benefits and risks of each. This workshop will be presented in two parts, the first will be a presentation of various models and chronicle their history and the second will address how to set up integrated C&Q programs. Bring your questions and do not hesitate to interrupt in this interactive workshop!

PART ONE: Commissioning and Qualification Models – A Historical Perspective

In the end, the goals are simple – delivering systems that work and meet user and process needs. But what is the relationship between meeting these goals and C&Q? What is the relationship between C&Q and Process Validation? Our industry has struggled with these issues for years. This portion of the workshop will try to answer this question by relating this history of C&Q and the changing pitfalls we have encountered as the models evolved over time.

PART TWO: How to set up a C&Q Program

The ASTM-E2500 guidance tries to shed light on the topic by establishing a standard framework and terminology for planning, executing and documenting an integrated C&Q program. However, this standard, much like other standards, presents a guiding philosophy on C&Q – not an instruction manual. The guidance defines a continuum of C&Q approaches and it is important that thorough planning goes into choosing what approach is right for each situation as one size does *NOT* fit all. This portion of the workshop will describe various approaches to integrated C&Q and the key factors to consider when setting up a program.

SPEAKER: Jack E. Greene

Jack Greene is an independent consultant with over 15 years of Commissioning and Qualification, Plant-Wide Automation Design, Continuous Improvement and Compliance experience in the biologic API, oral solid dosage and parenteral drug product area.

Jack's extensive background and experience in the Pharmaceutical industry includes previous positions as QC Chemist, PLC/DCS Architect and Quality Engineer. He is an expert in helping scientists and engineers express complex issues such that they can be understood by non-technical people. He has worked at Eli Lilly & Co, Alnara Pharmaceuticals, Altus Pharmaceuticals, Alkermes, Genzyme and Ares-Serono.

MEETING MANAGERS:

David Greenberg, Saint-Gobain Performance Plastics

Joyce Chiu, CPIP, Honeywell Safety Products



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MASY SYSTEMS, INC.

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PROGRAM SCHEDULE:

5:30 – 6:20 PM Registration and Networking Reception
6:20 – 6:30 PM Welcome and Program Introduction
6:30 – 8:30 PM Program

REGISTRATION FEES:

Registration by 12/8/2011 After 12/8/2011

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

* Join ISPE now and pay the Member rate. Join within one week of this meeting, and we'll refund you the difference between the Member and Non-Member rate! Contact the office at (781) 647-4773 or office@ispeboston.org for more information.

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): _____

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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: ispe@camihq.com

****PLEASE NOTE: CANCELLATIONS RECEIVED AFTER December 8th ARE SUBJECT TO BILLING****

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DIRECTIONS AND PARKING:

From the Expressway North/South

Take the exit for Storrow Drive
Follow Storrow Drive to the Kendall Square/Government Center exit
Follow the signs for Kendall Square
Cross the Longfellow Bridge and into Cambridge
After crossing the river, take a right at the first set of lights onto Third Street
Turn right onto Kendall Street
The parking garage is on your right

From the Massachusetts Turnpike (I-90 Eastbound)

Take the Mass Turnpike East
Take Exit 18 (Allston/Cambridge)
Follow signs toward Cambridge/Somerville
The Doubletree Guest Suites Hotel will be on your right
At the traffic light take a right onto Storrow Drive
Do not cross the river
Take the Kendall Square/Government Center exit off Storrow Drive
Follow the signs for Kendall Square, bearing left around the rotary and across the Longfellow Bridge into Cambridge
After crossing the river, take a right at the first set of lights onto Third Street
Turn right onto Kendall Street
The parking garage is on your right

From the "T"

Take the Red Line to the Kendall Square stop
When you exit the station, you will be on Main Street
Walk East - towards Boston - and you will see a traffic light at the corner of Broadway and Third Street
Cross at the intersection and walk down Third Street
Take your first right onto Kendall Street
Genzyme Center is the first building on the left