

ISPE Boston Area Chapter Presents:
Panel Discussion:
Practical Risk-Based Commissioning & Qualification

Thursday, February 17, 2011

Genzyme Science Center,
49 New York Avenue, Framingham, MA



**Boston Area
Chapter**

ENGINEERING
PHARMACEUTICAL
INNOVATION

PLEASE NOTE:

The networking reception and following panel discussion are open to Members and non-members.

PANEL DISCUSSION:

Practical Risk-Based Commissioning & Qualification

Pharmaceutical companies are challenged to develop manufacturing quickly and cost effectively while maintaining product quality and patient safety. This challenge can create apparent conflicts between these two objectives. Such conflicts have resulted in everything from costly, labor intensive and duplicative commissioning and qualification to the pitfalls of skipping commissioning and going straight to qualification. Risk management isn't new to pharmaceutical manufacturing, but it's often misunderstood, misused, or not used at all. The risk-based approach to C&Q is part of the FDA's 21st Century Risk Based Approach initiative whereby projects are completed using techniques based on science, process, product, and system knowledge. These help identify critical user and regulatory requirements, then establish challenges and acceptance criteria to verify them. The result is a "right-sized" program that mitigates risk to an acceptable level, satisfies regulators, and pays dividends in operability, reliability, maintainability and adaptability.

This panel discussion will include short presentations of methods and case studies of how this risk-based approach has been utilized. The successes and challenges of implementation will be discussed. A significant portion of the session will be dedicated to audience participation. Don't miss this timely topic!

WHO SHOULD ATTEND:

Validation scientists, engineers, managers; Facilities engineers, managers; Process engineers, managers; Automation engineers, managers; QA scientists, engineers, managers; Regulatory specialists, managers

PANELISTS:

Michelle Whipple, Associate Director of QA Validation, Bristol Myers-Squibb, Devens, MA. Previously, Michelle was at AstraZeneca where she advanced from Validation Engineer to Manager, Quality Assurance Validation. Prior to joining AstraZeneca, she served as a Validation Engineer for Genzyme.

Michelle received a B.S. in Chemical Engineering from the University of Massachusetts and an M.S. ChE from Worcester Polytechnic Institute. She is a member of ISPE's C&Q Community of Practice (COP) Owner's Task Team and presented at the November 2010 ISPE Annual Meeting.

Armen Nahabedian, Director, Commissioning/Qualification, Pfizer Global Engineering. Armen has 26 years experience in startup and qualification of biotech equipment and facilities. He began his career at Genetics Institute at the Andover, MA biotech facility, which was subsequently acquired by Wyeth. Armen came to Pfizer when it acquired Wyeth in 2009.

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From 1988 to 2002 Armen led validation activities at the Andover facility, having planned and executed many capitol expansions and product changeovers at the rapidly expanding site and he successfully presented the site validation program during numerous pre-approval and routine board of health inspections. In 2002, Armen joined the Wyeth Biotech Operations Network to support global capital projects in qualification. He also established the Wyeth Biotech Community of Practice Program and led the Wyeth Biotech Validation CoP with emphasis on cleaning and sterilization. Most recently, Armen led the Wyeth company-wide Validation Standards program that included ASTM-2500 awareness and training.

Armen is currently a member of the Pfizer Global Engineering group and co-leads the development and roll out of the Pfizer Verification Program. He is a member of the ISPE C&Q COP Owner's Task Team and presented at the November 2010 ISPE Annual Meeting.

Eric Felz, Validation Manager, Genzyme Corporation, Framingham MA. Eric has 13 years of experience in equipment, facilities and utilities validation. He spent seven years at BASF/Abbott first as a contractor and then as an employee where he was responsible for equipment validation. As a contractor he filled the role of Director of Operations for Validation Professionals. As validation manager at Abbott his responsibilities included the qualification of all capital projects on the site. Eric joined Genzyme in 2009. He is responsible for the validation of equipment, facilities, utilities and processes for Buildings 45 and 51 New York Avenue.

Eric graduated from Cornell University with a degree in Chemical Engineering. He has been an instructor in validation at WPI for the past five years as part of the Fundamentals of Biotechnology program. Eric is a member of the ISPE C&Q COP and is pursuing an MBA at Babson.

MEETING MANAGERS:

Jack Champion, P.E., Genzyme Corporation
Aaron Jordan, MassBiologics (UMASS Medical School)

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PROGRAM SCHEDULE:

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

REGISTRATION FEES:

	Registration by 2/10/2011	After 2/10/2011
<input type="checkbox"/> Members	\$50	\$60
<input type="checkbox"/> Non-members	\$95	\$115
<input type="checkbox"/> Students	\$5	\$10

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: ispe@camihq.com

****PLEASE NOTE: CANCELLATIONS RECEIVED AFTER February 10th ARE SUBJECT TO BILLING****

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DIRECTIONS to 49 New York Ave., Framingham MA:

From Mass Turnpike,

- Take exit 12 for MA-9 toward Framingham and go 0.4 miles
- Keep left at the fork and merge onto MA Route 9 West, Boston Worcester Turnpike/Worcester Rd and go 0.9 miles.
- Turn right at California Ave. and go 0.3 miles.
- Take the 2nd left onto New York Ave
- Destination is on the right

For Door to Door Directions click here: <http://maps.google.com/maps?hl=en&tab=wl>

