ISPE Boston Area Chapter Presents:

Good Engineering Practice, aka How to Make Friends with your Validation Group

Thursday, September 18, 2014

5:30 pm to 8:30 pm

Genzyme Center
500 Kendall Street, Cambridge, MA 02142

OR VIA SIMULCAST AT

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

ISPE Connecting a World of Pharmaceutical Knowledge | Boston Area Chapter
Serving All of New England

THANK YOU TO OUR PROGRAM SPONSOR

Tufts University | Gordon Institute
Advancing Innovation, Entrepreneurship, and Leadership

EVENT INFORMATION:

Attend the live program at Genzyme Center in Cambridge, MA or a simulcast presentation at the Crowne Plaza Providence in Warwick, RI. The programs at both locations will include a networking reception including appetizers

PROGRAM SUMMARY:

Has engineering come full circle in the biotech market over the past 30 years? Those old enough to remember projects executed before ISPE was founded, will also remember FDA and quality groups inconsistently judging the quality of design. ISPE has, to its credit, created many guidelines to provide a basis for best practice, but they do not necessarily address the design basis, nor level of risk.

The "new" standard for engineering is risk based design. Whether it is defined in ASTM 2500, IQH Q9, or ISPE Good Engineering Practice Guideline, the new approach is to follow a multi-step process for defining the requirements, evaluating risk, detail design, and validation/qualification.

The intent of this program is to provide 3 different perspectives of cGEP: the owner/drug producer, the outside engineering consultant, and the quality group that needs to justify to the regulatory authorities that the design process is robust. After short presentations, the floor will be opened for feedback and panel comments.

PRESENTATION 1:

Maintaining Focus on GEP in a Careful Balance with Compliance

The regulated nature of the biotech industry requires that certain aspects of its facilities and systems are heavily scrutinized and documented, with Quality oversight, in order to ensure the highest degree of patient safety and product quality. However, somewhere along the way, the focus on regulations has eclipsed the focus on Good Engineering Practice. While it is not our intent to diminish the emphasis on regulations and, therefore, patient safety and product quality, at times our method of achieving those goals is not efficient. By refocusing our efforts on Good Engineering Practice within the Engineering Lifecycle, in conjunction with the Regulatory requirements, we can provide a better product.

This program will provide a venue to discuss the GEP elements of the Engineering Lifecycle, their relationship to the Regulatory requirements associated with manufacturing within our industry, and the definition of roles and responsibilities for these elements.

Continued…

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SPEAKER 1:

Jeanine Gigante is the Associate Director of Global Engineering and Technology for Genzyme and has 27 years of experience in process and project work in the biotechnology, chemical process and environmental fields. She worked in the engineering design and construction field for 10 years before her 17 year tenure at Genzyme. In that time, her experience has included the evaluation and modification of existing systems, and design of new systems for both clean and dirty utilities. In addition to the utility systems, Jeanine has supported projects requiring the design, installation, and commissioning of new or modified process equipment and facilities for clinical operations, upstream and downstream processing, and fill/finish. Most recently, her role has included the development and implementation of an engineering quality program, which is designed to ensure that the Genzyme engineering lifecycle incorporates Good Engineering Practice and Regulatory Compliance consistently across the corporation.

Ms. Gigante holds a BS degree in Chemical Engineering from Northeastern University, and is a certified Project Management Professional. She has been a longtime ISPE Member.

PRESENTATION 2:

Get Excellent Performance from Good Engineering Practice

In the past ten years the definition of Good Engineering Practice (GEP) has evolved. The focus of GEP has shifted from application of rule of thumb and compliance with the state of the art to a method ensuring that engineering endeavors provide the anticipated result. This is achieved by ensuring the scope of the project is well established, that the engineering design thoroughly addresses the project need, and all aspects of the design have a factor of safety commensurate with the level of risk.

Good Engineering Practice has also expanded to include the mechanisms for managing, documenting, and reviewing the engineering design throughout the project life cycle to ensure continued operational success. Within regulated industries the outputs of GEP are verified and scrutinized to provide an additional level of assurance. Occasionally this review is complicated by differences of opinion about the project scope, the approach to the engineering design and the project risk assessment. This program will provide a venue to discuss how scope, design and risk assessment can be better communicated to simplify and add value to the engineering, qualification/verification and validation project phases. *Continued…*

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SPEAKER 2:

Howard Sneider is a Senior Process Engineer at Clark, Richardson & Biskup (CRB) Consulting Engineers. He has over fifteen years of experience in all phases of process design, process modeling simulations, equipment design and selection, acceptance testing, start-up, commissioning and validation. Mr. Sneider has participated in, and directed, the design of: biological, vaccine and API manufacturing processes, clean utilities and facilities. His experience includes green-field and renovation projects at the lab, pilot and commercial scale. He has worked closely with clients, vendors and construction managers to successfully execute and deliver design packages and construction support services. Mr. Sneider is a member of ISPE, Boston Chapter. Previously, he was a Senior Process Engineer at Wyeth Biotech. He holds a BS degree in Chemical Engineering from Columbia University and an MS in Chemical Engineering from the University of Connecticut.

PRESENTATION 3:

Building Quality into GEP

Recent changes in the industry have focused validation to providing documented evidence that critical aspects for new or modified direct impact systems meet process user requirements. Building quality into GEP provides cost effective assurance to Validate that a system's critical aspects meet its process user requirements. This presentation will provide an overview of validations role in GEP and how it connects to regulatory audits

SPEAKER 3:

Paul Meehan is a Validation Manager at Shire and has 17 years of experience in commissioning and qualification work in the biotechnology and pharmaceutical industries. He worked previously as an employee at AbbVie and Abbott, and prior to that as an independent contractor and with KMI/Parexel. In that time, his experience has included managing validation personnel, participating on commissioning and qualifications team for equipment, facility, utilities, control systems and cleaning validations and defending validation reports in audits.

Mr. Meehan holds a BS degree in Mechanical Engineering from Boston University, an MBA from Boston College, and an ISPE CPIP certification.

MEETING MANAGERS:

Robert Mitchell, Robert Mitchell Engineering
Bill McCarthy, CRB Consulting Engineers

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PROGRAM SCHEDULE: Applies to both sites

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

REGISTRATION FEES:

		Registration by 09/11/2014	Registration After 09/11/2014
☐	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: ☐YES ☐NO

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 SEPTEMBER 11TH ARE SUBJECT TO BILLING****

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DIRECTIONS AND PARKING:

Genzyme Center

500 Kendall Street, Cambridge, MA 02142

From the Expressway North/South
Take the exit for Storrow Drive. Follow Storrow Drive to the Kendall Square/Government Center exit, and follow the signs for Kendall Square, which will send you across 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.

OR VIA SIMULCAST AT

Crowne Plaza Hotel Providence - Warwick

801 Greenwich Street, Warwick, RI 02886

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