ISPE Boston Area Chapter Presents:

Regulatory Symposium: Quality by Design and Regulatory Fundamentals

Thursday, November 10, 2016

5:30 pm to 9:00 pm

ISPE Boston Area Chapter
Serving All of New England

THANK YOU TO OUR PROGRAM SPONSOR

CAI

Northeastern University – Egan Research Center
120 Forsyth Street, Boston, MA 02115

OR VIA SIMULCAST AT
WPI BETC, 50 Prescott Street, Worcester, MA 01605
OR VIA SIMULCAST AT
Redhook Ale Brewery, 1 Redhook Way, Portsmouth, NH 03801
OR VIA SIMULCAST AT
Community College of Rhode Island, 400 East Avenue, Warwick, RI 02886

EVENT INFORMATION:

Join ISPE at Northeastern University and participate in either one of two Regulatory programs: Quality by Design or Regulatory Fundamentals. This is a dual track event designed to give seasoned professionals, as well as young professionals/students the opportunity to learn about crucial regulatory information in the industry.

The QbD program will be simulcast to locations in NH, MA and RI. The program at each location will feature a networking reception including appetizers. The chapter will also have an outreach to non-member students at Northeastern during the reception.

Each track will feature two presentations by esteemed members of the regulatory community. Please see below for further details and who should attend each track.

TRACK 1: Quality by Design, in Raytheon Amphitheater

Nearly a decade after the 2007 *PDA/FDA Joint Regulatory Conference on QBD for Biopharmaceuticals* in Washington, DC, Janet Woodcock's vision of QbD as a "scientific, risk-based, holistic and proactive approach to pharmaceutical development" endures. The original intent of QbD was to enable a "maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high quality drug products without extensive regulatory oversight." Manufactures have indeed achieved FDA approval by leveraging QbD, but may not have capitalized on all the benefits of that approach. Our speakers will present a historical overview and an industry perspective, as well as a practitioner's perspective on how to achieve the most benefit for the least effort and how to get started on implementing QbD quickly.

WHO SHOULD ATTEND?

Research and Development, Process Development, Engineering, Manufacturing, Quality, Regulatory professionals who want to lead and contribute to the industry's effort in creating more efficient, lower cost and reliable products to their patients.

Presentation I: The Unfinished Story of QbD in the Pharmaceutical Industry

This talk will trace the progression of Quality by Design (QbD) from the introduction of its concepts to the pharmaceutical industry to its current status. The presentation will address practical application to the design

and control of pharmaceutical manufacturing processes. While the initial promise of greater regulatory flexibility through QbD-based submissions has not yet been realized, industry generally accepts QbD and risk-management methodologies as a systematic approach to control strategy construction. Arguably, a comprehensive process and analytical control strategy for a pharmaceutical product is the more important outcome of QbD and the first step towards greater self-regulation. Some experiences and observations along the way will be shared as well as thoughts on the future direction of QbD and opportunities for alignment and collaboration among industry manufacturers, suppliers and regulators.

Bert Frohlich, Director of Strategy and Technology Lifecycle, Shire
Bert is a Ph.D. Biochemical Engineer with 25+ years of experience in the biotechnology, pharmaceutical, and chemical industries. He is currently Director of Technology Management at Shire Pharmaceuticals within the Process Development and Technical Services organization but has held positions at Roche, Genzyme, EMD, Amgen and Acambis (now Sanofi) in process/facility design and bioprocess development. Starting from the publication of summary article on Quality-by-Design (*QbD: Still in Design? A Report from PDA's QbD Workshop*. PDA Letter, Vol. XLIII – Issue #9 (October 2007)], Bert has maintained an interest in QbD, speaking on the subject at several conferences and leading the design of the QbD business processes at Shire.

Presentation II: A Simple & Pragmatic Approach to Implementing QbD

The knowledge gathered of a drug substance during early stage research is a vital asset to a company and should be leveraged. The tools used in Quality by Design provide a framework to transform R&D data into knowledge and useable asset. However, the terminology and basic statistical concepts of QbD do not always seem to be aligned with R&D teams. The ICH guidelines refer to patient-centric focus, risk management, and process control. This terminology may not appear to be relevant to R&D, thus QbD is often implemented during the drug development phase. This talk is designed to explain research goals in a manner that aligns with ICH guidelines and provide an understanding of the benefits of implementing basic statistical practices early in the product development when the costs are the lowest. The talk will use examples to demonstrate the value of statistical tools then move to the value of statistically sound data in supply chain management (CROs/CMOs) and technology transfer through the development pipeline.

Amy Lachapelle, Lead Consultant & Founder, QbD Strategies, LLC
Amy is currently the Lead Consultant at QBD Strategies LLC where she teaches and assists companies with approaches to implementing quality by design. She has 16+ years' experience with biological research and development, working on purification, development, and characterization of viral vectors for gene therapy at Genzyme then later creating a product stream of protein characterization services for GlycoSolutions. Amy's knowledge of biochemistry, mathematics, and cGMP requirements led to her belief that implementation of QbD can benefit the biopharmaceutical industry. She has spoken on the topic at the R&D 100 conference ("The Hurdles and Benefits of Designing Quality into Your Drug Product in Early Stage Development", November 2015) as well as two publications on the subject in BioProcess Online.

MEETING MANAGERS:

Mark Braatz, F.W. Webb
Joyce Chiu, Corning Life Sciences

TRACK 2: Regulatory Affairs Fundamentals, in Room 206

Intended for young professionals and student members, this program provides an overview of Regulatory Affairs fundamentals, with an introduction of the drug development cycle and key considerations for interfacing with external regulatory bodies as well as internal product life cycle management.

WHO SHOULD ATTEND?

Biopharmaceutical industry young professionals, chemical and biomedical engineering students interested in the industry, and new entrants into the industry who wish to gain an overview.

Presentation I: Overview of Regulatory Affairs and its Role in the Biotech and Pharmaceutical Industry

Regulatory bodies such as the FDA and the EMA play an important role in the drug development lifecycle, from drug discovery, through clinical trials, to commercial production. This introductory overview of regulatory affairs will cover a brief history of drug development regulations as well as the drug development lifecycle. The presentation will also delve into what happens when a manufacturer is not compliant with GMP standards, and the possible repercussions from a regulatory standpoint. The different regulatory challenges between large and small pharmaceutical companies will be examined, as well as the future of the industry from a regulatory perspective.

G. Louise Dowling, Senior Manager Regulatory Affairs, Pfizer

Louise Dowling has 20 years of experience in the (bio) pharmaceutical industry. This experience ranges from start-up drug discovery (small molecule) to start-up of a multinational manufacturing site for large scale biologics. Her role includes analytical development, experience in process development and process validation for new manufacturing processes and process tech transfer for the manufacture of biologics. She has supported several global submissions across a wide array of products (therapeutic MAb/fusion proteins, pegylated proteins, drug substance, lyophilized and prefilled syringe drug product) and more recently comparative phase 3 clinical study applications for a proposed Biosimilar.

Since 2014, Louise's role is as a Senior Regulatory Manager at Pfizer, Inc., in Andover, MA. Louise obtained a B.Sc. and Ph.D. in Biochemistry from Dublin, Ireland.

Presentation II: Introduction to Chemistry, Manufacturing and Controls (CMC) Regulatory Affairs

The primary responsibility of Regulatory Affairs group is to liaison with regulatory bodies such as FDA, EMA, Health Canada, etc. to ensure products are safe and efficacious for clinical and commercial use. The CMC group within Regulatory Affairs has knowledge and understanding of regulations pertaining to the chemistry, manufacturing and controls of the medicinal product. CMC group will interpret regulations and collaborate with other technical functions such as manufacturing, supply chain, analytical groups in authoring Modules 2 and 3 of regulatory dossiers. This presentation will delve into CMC, its role in Regulatory Affairs and the strategic leadership it provides in safety and efficacy of products. In addition the presentation will provide an overview of Quality Module within regulatory dossiers for clinical and marketing applications.

Bharathi Mamidipudi, Regulatory Affairs Consultant II-CMC, SynerG Pharma Consulting

Bharathi Mamidipudi has 4 years of experience in CMC regulatory affairs for both small and large molecules. She has worked with pharma companies both as consultant and full time employee. She has supported/ led numerous of pre and post approval submissions to US FDA and other global health authorities. She has experience in working with CMC regulatory affairs team with clients both big and small pharma companies. Currently she works as Regulatory consultant II at SynerG Pharma Consulting, LLC, South borough, MA.

Bharathi has a Bachelor's degree in Pharmacy from Jawaharlal Nehru Technological University in Hyderabad, India and Master's degree in Regulatory Affairs of Drugs, Biologics and Medical Devices from Northeastern University, MA.

MEETING MANAGERS:

Chris Ciampa, Thermo Fisher
Binesh Prabhakar, Cambridge IT Compliance
Brian Kennedy, Sanofi Genzyme

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PROGRAM SCHEDULE:

5:30 – 6:30 PM	Registration and Networking Reception (440 Egan)
6:30 – 8:30 PM	Dual Track Presentations (Advanced Track: Raytheon, Intro Track: Egan 2016)
8:30 – 9:00 PM	Q&A Sessions

REGISTRATION FEES:

	Registration by 11/3/2016	Registration After 11/3/2016
☐ Members	$50	$60
☐ Young Professional Members	$20	$30
☐ Nonmembers **	$95	$115
☐ Student Members	FREE	FREE
☐ Simulcast in Worcerster, MA	FREE	FREE
☐ Simulcast in Portsmouth, NH	FREE	FREE
☐ Simulcast in Warwick, RI	FREE	FREE

** Attendees may only attend one program as a nonmember.

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, 465 Waverley Oaks Road, Suite 421, Waltham, MA 02452
Telephone: 781-647-ISPE (4773) Fax: 781-647-7222 Email: office@ispeboston.org
****PLEASE NOTE: CANCELLATIONS RECEIVED AFTER NOVEMBER 3rd SUBJECT TO BILLING****

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DIRECTIONS AND PARKING:

Northeastern University – Egan Research Center:

http://www.emri.neu.edu/mainpage_files/directions/emri_directions_top.htm

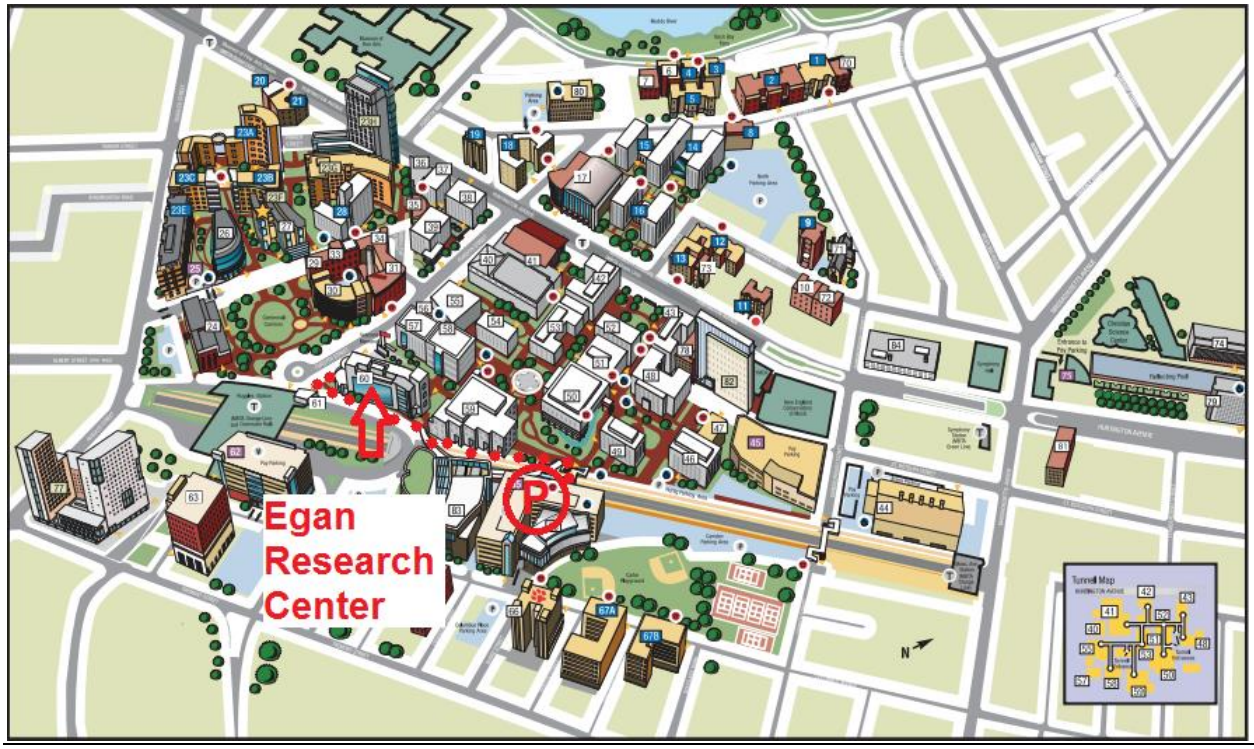
Taking the T?

Take the Orange Line to Ruggles Station. Exit towards Forsyth Street and the Egan Research Center is on your right.

Driving?

Renaissance Parking Garage
835 Columbus Avenue, Roxbury Crossing, MA 02120
For door to door driving directions, click here
Walk through Ruggles T- Station towards Forsyth Street and the Egan Research Center is on your right.

Columbus Parking Garage
795 Columbus Avenue, Boston, MA 02120
For door to door directions, click here
Follow the Columbus Parking Garage Overpass. Turn left toward Forsyth Street. Egan Research Center will be on your right.



SIMULCAST LOCATIONS:

WPI BETC
50 Prescott Street, Worcester, MA 01605

For door to door directions, click here

Free parking is available directly across the street.

Redhook Ale Brewery
1 Redhook Way, Portsmouth, NH 03801

For door to door directions, click here

Community College of Rhode Island
400 East Avenue, Warwick, RI 02886 (Room 1134)
For door to door directions, click here