ISPE Boston Area Chapter Presents:

WEBINAR

ISPE Baseline Guide Volume 5 Second Edition: Adopting the New Paradigm

Thursday, February 18, 2021

12:00 PM – 1:00 PM EST

Zoom.com

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PROGRAM SUMMARY:

In 2019, after many years of new guidance updates (which include ASTM E2500, ICH Q8, Q9, 10, as well as FDA Guidance for industry), ISPE updated its paramount baseline guide for Commissioning and Qualification.

The purpose of this updated guidance is to define the Baseline® approach for the Commissioning and Qualification of facilities, utilities, and equipment regulated by the FDA. This will assist in optimizing the commissioning and qualification processes at regulated facilities.

Despite this monumental effort, adoption in industry by end users is slow at best, and has not been widely accepted. These presentations, and breakout panel discussions by the speakers, will address challenges in adopting the updated methodology, and will also include how to manage change to encourage adoption. The discussion will also include testimonials directly from end users, and show how adoption can lead to more integrated qualification approach, allowing for faster project turnaround and cost savings.

PROGRAM SPONSORS:

DPS GENESIS ICQ ENGINEERING BETTER SOLUTIONS Masy BioServices

WHO SHOULD ATTEND THIS WEBINAR:

This program is geared towards professionals interested in general equipment facilities validation.

SPEAKERS:

Michael Polansky, Director, Corporate Quality, AstraZeneca

As a Director of Corporate Quality at AstraZeneca, Mike is the Quality Process Champion for Premises and Equipment, functioning as the primary Quality liaison with Global Engineering in the development of Engineering standards and improved quality focus of Engineering processes. Prior to working in Corporate Quality, Mike was the site lead of Quality Systems and Compliance at AstraZeneca's biopharmaceutical bulk manufacturing facility in Frederick, MD. Over his 23 years of pharmaceutical industry experience, Mike has also held various Quality and CQV roles at Sanofi Pasteur, Centocor, Inc. (now Janssen Biotech) and GlaxoSmithKline. During his tenure at Sanofi Pasteur, Mike was responsible for the successful program development of Integrated Commissioning and Qualification, under the site Engineering function, as the Director of Commissioning and Qualification Best Practices.

Deborah Wild, President, DW BioPharma

Deborah Wild is the President of DW BioPharma and was previously Chief of Staff/Head Global Cell and Gene Therapy Business management for Catalent, Cell and Gene Therapy. Deb is an accomplished C-Suite Executive with over 30 years' experience and has effectively lead large groups that include Quality Assurance, Quality Control, Validation, Regulatory Affairs, and Manufacturing departments throughout her career. Deb was a key executive team member that transitioned a family owned business into a hyper growth Private Equity (PE) backed success, resulting in a $1.2B purchase by Catalent in 2019, delivering record returns for PE investment partners. She is a biotechnology and pharmaceutical leader with a proven record in bringing products to market and an entrepreneur's perspective as an owner of a successful consulting business.

MEETING MANAGERS:

Michael Bogan, ICQ Consultants
Chris Ciampa, CAI

REGISTRATION FEES:

		Registration by 02/17/2021
☐	Members	FREE
☐	Young Professional Members	FREE
☐	Student Members	FREE
☐	Nonmembers	$15

LOG-ON INFORMATION:

A confirmation email will be sent one day prior to the webinar with the Zoom login information. Should you have any questions or concerns, contact the office by calling (781) 647-4773 or e-mailing office@ispeboston.org. The webinar can be accessed through phone, online, or through the Zoom webinar app.

****PLEASE NOTE: CANCELLATIONS RECEIVED AFTER February 17, 2021 ARE SUBJECT TO BILLING****

REGISTRATION IS NOW OPEN ONLINE!

Please complete the online registration at www.ISPEBoston.org/Events.
Pay by credit card OR check.