ISPE Boston Area Chapter Presents:

WEBINAR
Post Approval Changes for Analytical Methods in Regulated Labs

Thursday, March 24, 2022
12:00 PM – 1:00 PM EST
Via Zoom

ISPE Boston Area Chapter
Serving All of New England

PROGRAM SPONSORS:

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PROGRAM SUMMARY:

Regulated laboratories often struggle with restrictions associated with 'registered analytical procedures' or methods. Despite encouraging a culture of continuous improvements, regulatory affairs groups are often reluctant to address the burden and cost of gathering pre-approval from regulatory health authorities for changes, even when these offer clear robustness improvements, or offer significant laboratory cost savings.

The ICH harmonization group issued a Quality guidelines Q12, in 2019, which offered a suite of tools to ease the regulatory burden of post approval changes. While the main focus of this was on manufacturing processes, one section plus an entire Annex was devoted to changes to analytical procedures. A separate ICH working group, specializing in analytical procedures, has been collaborating with a variety of global pharmacopoeia, on a lifecycle approach to analytical procedures, and devised an enhanced method development concept, to be published in ICH Q14, to support the ICH Q12 overarching concept. This promises to be a game changer for regulated laboratories looking to regularly improve and modernize the sensitivity and robustness of their analytical procedures.

In addition, the EU and US pharmacopeia , again through the ICH harmonization process, plan to expand their scope for minor adaptations to chromatographic analyses, from purely restricted to isocratic separations to include well defined changes for gradient separations as well.

Both of these topics will be discussed in this webinar with time to ask questions for live answer, or post event responses.

SPEAKERS:

Shreekant Karmarkar, PhD
Dr. Karmarkar has over thirty years of leadership experience at analytical instrumentation and pharmaceutical companies. At Lachat Instruments (now a Danaher-Hach company), he led development of ion chromatography and flow injection analysis instrumental techniques. During his 16 years of career at Baxter Healthcare, he successfully implemented AQbD for chromatographic and non-chromatographic methods. Dr. Karmarkar led analytical development global teams on validation and transfer of hundreds of methods for excipients, drug substance, drug products at in-process, release, stability testing, and cleaning validation.

Now, as an independent consultant, Dr. Karmarkar provides analytical leadership to startup and mid-size Pharma companies, compliance issue resolution support, CMC sections submission services and technology transfer programs. One significant achievement was conceptualization of a new Analytical Center of Excellence for a major Indian CRO.

Jonathan E. Turner, Principal Product Marketing Manager, Analytical Columns
Jonathan E. Turner is the Product Marketing Manager for analytical LC columns at Waters Corporation. He joined Waters Corporation in 2006 as a research chemist in the Chemistry Research and Development Group. In 2015 Jonathan transitioned from the laboratory to the Chemistry Product Management Group. In this new role he uses his expertise in chromatographic media to help design, develop, and commercialize new modern stationary phases.

MEETING MANAGER:

Quincy Logan, Boston Analytical

REGISTRATION FEES:

		Registration by 3/24/2022
☐	Members	FREE
☐	Young Professional Members	FREE
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☐	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.

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Please complete the online registration at www.ISPEBoston.org/Events.
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