ISPE Boston Area Chapter Presents:

Focused Trends from FDA: What are they focusing on during their inspection?

Thursday, September 21, 2017

4:30 pm to 9:00 pm

Shire
Fortis Lecture Hall
200 Shire Way
Lexington, MA 02421

EVENT INFORMATION:

Attend a live program at Shire in Lexington, MA on the FDA's inspection trends and focuses featuring an ex-FDA inspector and an industry Quality representative. This program will feature a facility tour, networking reception including refreshments and a live Q&A session at the end of presentation. Register now to stay current on FDA inspection trends and be inspection-ready at all times!

Membership has its privileges!
This tour is open **only** to ISPE Members!
Please check-in at Fortis Lecture Hall at 200 Shire Way, Lexington and you will be given your tour group schedule. Tours start at 4:30PM and the last tour leaves at 5:15PM.

PROGRAM SUMMARY:

Staying up-to-date on the regulatory guidance and health authority expectations is critical for any GMP-regulated organization. With fast growth in technology and changes in how organizations are run, it's critical to understand the requirements for maintaining regulatory compliance. In this event focused on the FDA, we will hear from both sides of the compliance dilemma: a Director of Quality Assurance in the industry, and an ex-FDA inspector. Come to this event to find out the most current perspective on preparing for your inspection, and to learn about upcoming trends in FDA oversight. Our speakers will participate in a joint Q&A after their presentations for discussion and to answer your questions.

WHO SHOULD ATTEND:

Quality Engineers and Quality Assurance Professionals, Validation Engineers, Compliance Professionals, QC Microbiology and Contamination Control Professionals, and anyone responsible for maintaining inspection-readiness for their organization.

PART 1: Inspection Readiness – The Industry Perspective

As more and more pharmaceutical companies move towards building their products around contract research, test, and manufacturing organizations, our industry must adapt our understanding of how to operate in compliance with FDA and global regulations when operations are not within our immediate control. The first presentation of the evening, delivered by Jolly Bhatia, Senior Director of Supply Chain Quality Assurance at

Continued on the next page…

Alnylam Pharmaceutials, will focus on current trends in regulatory inspections from the perspective of a CMO-based quality organization. Jolly will present a case study on inspection planning for a CMO-based organization, and will answer questions on the ever-changing regulatory landscape impacting them.

SPEAKER:

Jolly Bhatia, Senior Diector, Quality Assurance, Alnylam Pharmaceuticals

Jolly Bhatia currently works at Alynylam Pharmaceuticals as the Senior Director of Supply Chain Quality Assurance. His responsibilities include quality oversight of manufacturing and supply chain operations, starting from procurement of raw materials to delivery of product to the patient. In his more than 20 years of experience in the bio pharmaceutical industry, Jolly has worked with several internal and contract manufacturing sites, in validation and quality leadership roles, preparing for routine and Pre-Approval Inspections.

PART 2: Regulatory Developments and Areas of Concern

The FDA continues to issue the most warning letters for rudimentary cGMP issues worldwide, but in this presentation Mark Lookabaugh (ex-FDA, Parexel Consulting) will focus on the most modern inspections trends and issues effecting FDA-regulated organizations. Mark will discuss ongoing issues with data integrity, and provide his most current perspective on which guidance to follow to deal with those issues. Mark will also discuss the FDA's program alignment initiative and how it may affect inspection schedules, turn-around times, as well as the effects of EU / FDA Mutual Recognition Initiative and Responsible Corporate Officer Doctrine.

SPEAKER:

Mark Lookabaugh, Principal Consultant, PAREXEL Consulting

Mark Lookabaugh, Principal Consultant, provides GMP and QSR auditing and consulting services to PAREXEL clients worldwide.

Prior to joining PAREXEL, he served 30 years with the FDA. His career included work as an Analytical Chemist in the New England District laboratory, specializing in pharmaceutical chemistry. He performed Pre-Approval Inspections (PAIs) in the pharmaceutical and biotechnology industries in the US and overseas. He also served for 8 years as a Compliance Officer in the New England District Office, processing FDA enforcement actions in the 6 New England States. During this period, he managed several medical device cases and gained knowledge of the QSR and MDR regulations. In 2004, he was promoted to Director, Compliance Branch, with responsibility for oversight of all FDA enforcement activities in the New England District. He has published scientific papers in the Journal of Chromatography, and is the recipient of several FDA awards. Mark received a BS degree (Chemistry) with high honors from Worcester Polytechnic Institute, Worcester, Massachusetts.

MEETING MANAGERS:

Brijesh Patel, Shire
James Hughes, Boston Technology Research

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4:30 – 5:15 PM	Members Only Tours
5:30 – 6:30 PM	Registration and Networking Reception
6:30 – 8:30 PM	Presentations

REGISTRATION FEES:

		Registration by 9/14/2017	Registration After 9/14/2017
☐	Members	$50	$60
☐	Young Professional Members	$20	$30
☐	Nonmembers	$95	$115
☐	Student Members	FREE	FREE

☐ I'm an ISPE member and I would like to attend a tour

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 SEPTEMBER 14th ARE SUBJECT TO BILLING****

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DIRECTIONS:

For door to door directions, click here.

Free parking is available