ISPE Boston Area Chapter Presents:

"How We Trained the FDA…"

Thursday, February 20, 2014

5:30 pm to 8:30 pm

Johnson Matthey Pharma Services
25 Patton Road
Devens, Massachusetts 01434

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

PROGRAM SUMMARY:

Both presentations are based on a series of half-day training session workshops that were given directly by several members of ProPharma Group's Senior Management to FDA Inspectors and CBER Leadership within the U.S. Food and Drug Administration's headquarters in Maryland.

TOUR: Members Only

The tour will provide a look at the new addition to Johnson Matthey's Devens facility consisting of state of the art, self-contained manufacturing suites featuring 300 gallon to 750 gallon glass lined reactors with 1000 gallon supporting vessels to the large scale chromatography system. The facility consist of research and development laboratories, Kilo laboratories, and 100 to 500 gallon glass line and Hastelloy vessels with cryogenic capabilities. The facility has the ability to handle highly potent compounds up to SafeBridge Category 4, and Controlled Substances Schedule I-IV. It is FDA inspected, and regulatory filings are fully supported. Don't miss out on this event!

PRESENTATION ONE:

Industry Implementation of Current Guidance and Regulation on Process Validation
This presentation covers the 2011 released U.S. guidance and regulation pertaining to Process Development/Design, Process Validation/Process Performance Qualification and Continued Process Verification. It details regulatory expectations and industry's best practices efforts to establish a Process Validation Program and the inclusion of Risk Management strategies.

Presentation topics include how industry leaders have implemented the new approach-both prospectively and retrospectively, specific successes and benefits of the new approach and the novel shifts in quality philosophies both within industry and the Agency that have facilitated successful implementations

You will learn directly:

- What interested the FDA concerning the current state of the Guidance implementation;
- The best practices that other companies are currently employing;
- The points of emphasis that the FDA remarked upon.

SPEAKER ONE:

Alfredo Canhoto is an Associate Director of the Technical Solutions consulting practice at ProPharma Group, an industry leader in offering comprehensive compliance services for the pharmaceutical, biotechnology, medical device and related industries. Alfredo has over 15 years' experience in the biotechnology and pharmaceutical industries providing consulting, compliance, audit and validation engineering services, both domestic and international. Alfredo has a doctorate in Biochemistry and Molecular Biology from the University of South Carolina after which he has did a Post-Doctoral Fellowship at the Dana Farber Cancer Institute and the Harvard Medical School. Since then he has worked as a Validation Engineer and Program Manager at numerous biopharmaceutical companies both multinational and small. Alfredo has published extensively on numerous topics including cleaning validation and has received patents on the same.

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PRESENTATION TWO:

Computer System Validation

This presentation highlights practical and technical information on CSV and electronic record requirements. The presentation will include General CSV principles, Compliance implications of electronic batch records and related manufacturing execution systems, recent issues regarding data integrity, and compliance aspects of emerging technologies such as mobile devices and cloud computing.

You will learn:

- About CSV topics of specific interest to FDA inspectors;
- Obtain a refresher on the regulatory basis for CSV and supporting industry best practice;
- Approaches to assessing computerized system risk and its impact on critical data and record integrity;
- Insights into the compliance impacts of emerging computer technologies and integrated manufacturing system environments.

SPEAKER TWO:

Mike Byrd Mike Byrd has over 30 years of Quality compliance and IT experience, and over 25 years in the pharmaceutical and biotechnology industries, Mike Byrd brings a broad and diverse perspective to his role as Director of Computer System Validation (CSV) for ProPharma Group. Mike's educational credentials include a Bachelor of Science in Chemistry and a Masters in Business Administration with an emphasis in Technology Management.

Over his extensive career, Mike has developed, implemented, administered, and validated a wide variety of computer based solutions supporting critical regulated business processes. He is a Certified Quality Auditor (CQA), a Senior/Section Board member of the American Society for Quality, and is ITIL Foundation certified.

Through participation in industry forums, Mike continues to exchange ideas with other CSV professionals in advancing computer system compliance and quality. He has made numerous presentations at industry conferences covering a variety of CSV related topics.

MEETING MANAGERS:

Sean Brown, Barry-Wehmiller Design Group
Michael Denault, Denault Associates

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PROGRAM SCHEDULE:

5:00 – 6:00 PM Tour **(MEMBERS ONLY)**

5:30 – 6:30 PM Registration & Networking Reception

6:30 – 8:30 PM Welcome and Program

REGISTRATION FEES:

		Registration by 2/13/2014	After 2/13/2014
☐	Members	$50	$60
☐	Young Professional Members	$20	$30
☐	Non-members **	$95	$115
☐	Student Members	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: ☐

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 February 13 ARE SUBJECT TO BILLING****

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DIRECTIONS AND PARKING:

From Boston/Logan Airport
- Take the I-90 West (Mass Pike) to Rte 495 North (exit 11A)
- Take Exit 29B, Rte 2 West off of Rte 495
- Take Exit 37B (Jackson Road/Devens) off of Rte 2 West
- Turn right off of the exit onto Jackson Road
- Take your first right onto Patton Road

Johnson Matthey Pharma Services is the first building on the left.

OR
- Take I-90 West (Mass Pike) to Rte 95 North
- Take Exit 29B, Rte 2 West off of Rte 495
- Take Exit 37B (Jackson Road/Devens) off of Rte 2 West
- Turn right off of the exit onto Jackson Road
- Take your first right onto Patton Road

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From Cambridge
- Take Memorial Drive Westbound to Rte 2 West
- Take Exit 37B (Jackson Road/Devens) off of Rte 2 West
- Turn right off of the exit onto Jackson Road
- Take your first right onto Patton Road

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From The North
- Take Rte 495 South to Exit 29B, Rte 2 West
- Take Exit 37B (Jackson Road/Devens)
- Turn right off of the exit onto Jackson Road
- Take your first right onto Patton Road

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OR
- Take Rte 95 South to Exit
- Take Exit 29B, Rte 2 West off of Rte 495
- Take Exit 37B (Jackson Road/Devens) off of Rte 2 West
- Turn right off of the exit onto Jackson Road
- Take your first right onto Patton Road

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From The South - Rte. 495
- Take Rte 495 North to Exit 29B, Rte 2 West
- Take Exit 37B (Devens/Jackson Road) off of Rte 2 West
- Turn right off of the exit onto Jackson Road
- Take your first right onto Patton Road

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From Worcester
- Take I-190 North to Rte 2 East
- Take Exit 37B (Devens/Jackson Road)
- Turn right off of the exit onto Jackson Road
- Take your first right onto Patton Road

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