ISPE Boston Area Chapter Presents:

What's Next in Risk Management: Human Factors and Root Cause Analysis

Wednesday, September 14, 2011

5:30 pm to 8:30 pm

Royal Sonesta Boston Hotel

5 Cambridge Parkway, Cambridge, MA 02142

ISPE Connecting a World of Pharmaceutical Knowledge | Boston Area Chapter

THANK YOU TO OUR PROGRAM SPONSOR

MASY SYSTEMS, INC.

PROGRAM:

Risk Management is more than performing a one-time risk assessment; it is about imbedding it within the product and process lifecycle. This evening's program spotlights its use at two different points along the life cycle, in equipment design, and in manufacturing. Please join your fellow colleagues in learning how to better use risk management in the exciting field of Human Factors and the important Root Cause Analysis process.

PRESENTATION ONE:

Investigating the Problem: Use of Risk Management in CAPA Root Cause Analysis

FDA's current enforcement activities make it very clear, a robust CAPA process is essential. This presentation will provide audience with tools for ranking and prioritizing CAPAs utilizing risk management. The presentation will also address basic tools and techniques for defining the CAPA problem statement and identifying root cause.

SPEAKER ONE:

Susan Reilly

Susan Reilly has over 25 years of quality system, quality engineering, and regulatory compliance experience in the medical device area. Her company provides practical and cost-effective quality and regulatory consulting services to ensure conformance with FDA regulations, EU requirements, Canadian requirements, and ISO Standards. Ms. Reilly has served as an expert witness on behalf of the Food and Drug Administration and was an active participant in the FDA/Medical Device Industry Initiative Task Force. Ms. Reilly is a contributing author to "The Biomedical Quality Auditor Handbook" (ASQ) and the original technical editor for "The Quality System Compendium - GMP Requirements and Industry Practice" (AAMI). Ms. Reilly holds a B.S. degree in Chemical Engineering from The Pennsylvania State University.

PRESENTATION TWO:

Mitigating Pharma Equipment Risk Through Human Factors

Companies go to great lengths to ensure that their products and equipment have met various standards, guidelines, technical feasibility and that it leverages the appropriate technology. These same companies institute

development design controls and quality management systems to ensure that product requirements have been met and are actualized in the end product. Perhaps, most importantly, a great deal of attention is on mitigating product risk using multiple methodologies such as hazard analyses and failure mode and effects analyses for instance. This same level of rigor, traceability, and risk management is not applied, however, to the human element of the product or equipment. The integration of Human Factors and supporting research is a critical part of developing and maintaining the integrity of user requirements and mitigating any potential use-error risks. This presentation will provide a couple of case studies (e.g. bioreactor, filtration system) in which human factors integration has resulted in equipment design that not only meet product requirements from a technical perspective but also support user requirements in a manner that fosters product compliance while minimizing use-errors.

SPEAKER TWO:

Christina Mendat, PhD

Christina is the Director of Research and Human Factors at Radius Product Development where her primary role is to provide technical oversight to the research and HF teams and champion the integration of human factors in the product development process. Christina has contributed technical expertise to a number of projects ranging from large scale medical devices and systems to consumer goods. She is an expert at translating research findings such as user needs, requirements, product strengths and product weaknesses into compelling design directions and solutions. She speaks frequently on and human factors integration in quality management systems. Christina has a doctorate in experimental psychology and ergonomics from North Carolina State University and is a member of the Human Factors and Ergonomics Society and the Association for the Advancement of Medical Instrumentation.

MEETING MANAGERS:

Mike Long, ConcordiaValSource
Sean Brown, Barry-Wehmiller Design Group

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PROGRAM SCHEDULE:

5:30 – 6:20 PM	General Registration and Networking Reception
6:20 – 6:30 PM	Welcome and Program Introduction
6:30 – 8:30 PM	Program

REGISTRATION FEES:

	Registration by 9/7/2011	After 9/7/2011
☐ Members	$50	$60
☐ Non-members	$95	$115
☐ Students	$5	$10

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: ispe@camihq.com

****PLEASE NOTE: CANCELLATIONS RECEIVED AFTER September 7th ARE SUBJECT TO BILLING****

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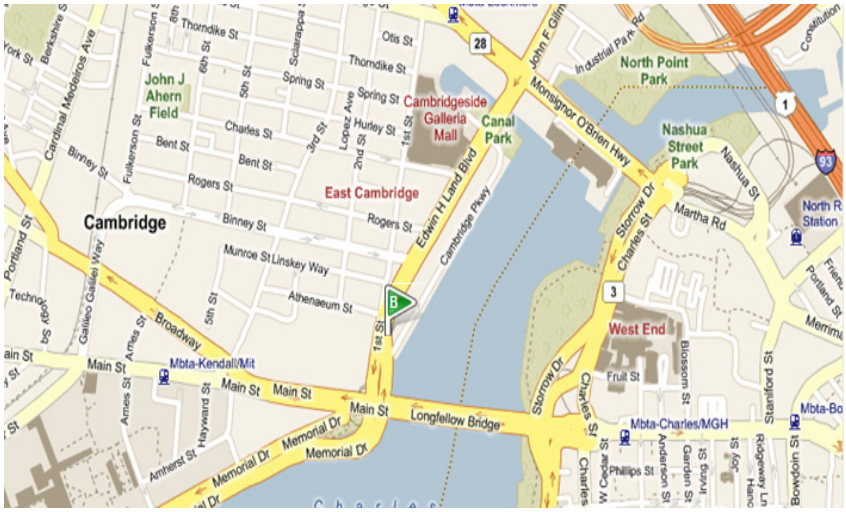
617-806-4200

DIRECTIONS AND PARKING:

Parking Rate: $18 Flat Rate for Single Entry. Payment can be made in cash at the garage booth or by credit card at the front desk.



From the West via the Massachusetts Turnpike (I-90 Toll Road):
While Eastbound, make left turn to Exit 18 following signs to Brighton/Cambridge; stay in the right lane following signs to Cambridge/Somerville; cross over the Charles River on the River Street Bridge (Cambridge Street) and turn right at the traffic light onto Memorial Drive (Route #3). Follow Memorial Drive East (Route #3 South) using the "cars only" option twice, then stay in the extreme right lane, along the Charles River, as Memorial Drive will become Edwin Land Boulevard. The hotel is on the right at the second traffic signal, directly across from the CambridgeSide Galleria.

From the West via Storrow Drive:
Proceed East on Storrow Drive to Leverett Circle. Remain in the left or middle lane to proceed left onto Route 28 North/Msgr O'Brien Highway. Pass the Museum of Science on your left. Proceed to the second traffic light and turn left onto Edwin Land Boulevard. The hotel is on the left at the next traffic signal, across from the CambridgeSide Galleria.

From the South (Route 93N):
Take Route 93 North to the Liberty Tunnel (move to the right lane after Exit 23). Take Exit 26, "Storrow Drive". Stay to the right moving onto Storrow Drive. Take immediate left exit "Government Center/Kendall Square" and turn right at the top of the ramp, onto the Longfellow Bridge. Proceed to the traffic signal and turn right onto Third Street. Proceed to the traffic signal and turn right onto Binney Street and proceed to the end. At the traffic signal, turn left onto Edwin Land Boulevard. The hotel entrance and garage are located on the right at the next traffic signal, across from the CambridgeSide Galleria.

From the North (Route 93S):
Take Route 93 South to Exit 26 (not accessible from carpool lane), "Storrow Drive/Cambridge/Route 28N/Route 3N." Stay to the right, moving to the middle lane, following signs for "Route 28 North/Cambridge/North Station." At the traffic signal, turn left onto Nashua Street. Take the first right onto Route 28 North/Msgr O'Brien Highway. Pass the Museum of Science on your left. Proceed to the second traffic light and turn left onto Edwin Land Boulevard. The hotel is on the left at the next traffic signal, across from the CambridgeSide Galleria.