ISPE Boston Area Chapter Presents: Single Use Manufacturing: A Preview of the ISPE Guidance Document

Thursday, April 13, 2017

5:30 pm to 9:00 pm

WPI – BETC at Gateway Park

50 Prescott Street Worcester, MA 01605



EVENT INFORMATION:

Dive into the contents of ISPE's Guidance Document. At this event you'll hear different perspectives of Single Use Manufacturing and the importance each aspect of single use design has to different individuals. This event is generously hosted by WPI-BETC and will start with a networking reception with hors d'oeuvres and refreshments, **Register now for this great program!**

PROGRAM SUMMARY:

The session provides a preview of ISPE's Good Practice Guide to Single-Use Technology, provide insight into how it was generated, what challenges the authors faced, and solutions they developed. The presentation will highlight successes that can occur when applying this technology, and guidance, in the manufacturing processes. Participants will also learn about different perspectives of the document from a material scientist and an end user and how the guidance is important to each of them.

WHO SHOULD ATTEND?

Anyone associated and concerned with the quality and consistency of products produced with single use manufacturing technologies.

SPEAKERS:

Pietro Perrone, Product Surveillance Lead Engineer, GE Healthcare

Pietro is a Professional Engineer registered in Massachusetts with degrees in Chemical Engineering from Tufts University and in Biomedical Engineering and Biotechnology from the University of Massachusetts. Pietro has more than 20 years of purification/separation technology experience in process development/optimization, equipment scale-up, and project management. Pietro chaired of the Disposables Community of Practice and is currently on its Steering Committee. He is a member of the Pharmaceutical Engineering Committee and an Editorial Reviewer for Pharmaceutical Engineering Magazine. As part of his activity with the Boston Chapter of ISPE, he is the Industry Advisor to the Tufts University Student Chapter.

Sally Kline, Director of Process Development - Materials Science, Amgen

Sally joined Amgen in 2011 as a plastics subject matter expert specializing in Single Use Technology (SUT) design, commercialization, and Extractables & Leachables (E&L) topics. She has extensive experience in biotechnology, polymers and chemical industries focusing on R&D, manufacturing and supply chain. In her role, Sally serves as an industry thought leader and active member for consensus standards and industry trade

organizations including Biophorum Operations Groups (BPOG), ASTM E-55, ACS, ISPE, and ELSIE. Sally received a B.S in Chemistry from Baldwin Wallace College, a M.S and Ph.D in Macromolecular Sciences from Case Western Reserve University, and completed a Post-Doctorate Fellowship at the Max Planck Institut fur Festkorperforshung, Germany.

Jillian Willard, Senior Process Engineer - Manufacturing Sciences and Technology, Sanofi

Jillian has a Chemical Engineering degree from Tufts University. Jillian has more than 12 years of experience in validation, manufacturing technical support, and facility design/startup. She recently worked on a team tasked with the process and equipment design for a commercial scale biologics purification facility, including the selection and implementation of single use technology. Jillian is also an adjunct instructor at WPI's Biomanufacturing Education and Training Center and served on the ISPE Boston Chapter Board of Directors for four years.

MEETING MANAGERS:

Brody Stara, Amgen Dan Mardirosian, WPI

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PROGRAM SCHEDULE:

5:30 - 6:30 PMRegistration and Networking Reception6:30 - 8:30 PMPresentations8:30 - 9:00 PMQ&A Session

REGISTRATION FEES:		Registration by 4/6/2017	Registration After 4/6/2017	
	Members	\$50	\$60	
	Young Professional Members	\$20	\$30	
	Nonmembers	\$95	\$115	
	Student Members	FREE	FREE	

REGISTRATION IS NOW OPEN ONLINE!

Don't waste time filling in the form! Register online at <u>www.ISPEBoston.org/Events</u>. Pay by credit card OR check.

Name:	Title				
Do you wish to opt out of being	g listed on the attendee ros	ter?:			
Company:		Mem	nber #:		
Address:	Ci				
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PAY BY CREDIT CARD:	🗆 Visa 🗖 Maste	rCard I	🗆 American Exp	oress	
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Cardholder Name (as it appea					
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: <u>office@ispeboston.org</u>

PLEASE NOTE: CANCELLATIONS RECEIVED AFTER APRIL 6TH ARE SUBJECT TO BILLING



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DIRECTIONS AND PARKING:

From the East (Mass. Turnpike, including Logan Airport)

Take Mass. Turnpike (I-90) to Exit 11A (I-495). Proceed north to exit 25B (I-290), then west into Worcester. Take Exit 18 (Lincoln Sq., Rte. 9). Turn right at end of ramp, bear right (again) onto Concord St., and take an immediate right onto Prescott St. Take your first right onto Washburn Way and follow past the WPI Life Sciences and Bioengineering Center (which will be the building on your left).

From the East (Rte. 9)

Follow Rte. 9 to Worcester. After crossing I-290, proceed down the hill to Lincoln Sq. Bear right onto Lincoln St., getting into the middle lane. At the next set of lights, turn left onto Concord St. and take an immediate right onto Prescott St. Take your first right onto Washburn Way and follow past the WPI Life Sciences and Bioengineering Center (which will be the building on your left).

From the North

Take I-495 south to I-290. Follow directions from east (Mass. Turnpike). Take Exit 18 (Lincoln Sq., Rte. 9). Turn right at end of ramp, bear right (again) onto Concord St., and take an immediate right onto Prescott St. Take your first right onto Washburn Way and follow past the WPI Life Sciences and Bioengineering Center (which will be the building on your left).

From the South and West

From western Massachusetts and Connecticut: Take I-84 to Mass. Turnpike (I-90). Take Exit 10 (Auburn) and proceed east on I-290 into Worcester. Take Exit 17 (Lincoln Sq., Rte. 9). Turn left at end of ramp and follow Rte. 9 west, down the hill, to Lincoln Sq. Bear right onto Lincoln St., getting into the middle lane. At the next set of lights, turn left onto Concord St. and take an immediate right onto Prescott St. Take your first right onto Washburn Way and follow past the WPI Life Sciences and Bioengineering Center (which will be the building on your left).

Parking options include:

Parking lot adjacent to the Parking Garage

The WPI Visitors Lot is adjacent to Gateway Park I (60 Prescott Street).

Park on far side of 50 and 60 Prescott Street, across from both Gateway Park buildings.

Park on Washburn Street, the street behind the two Gateway Park buildings and in front of the parking garage.