

ISPE Boston Area Chapter Presents:

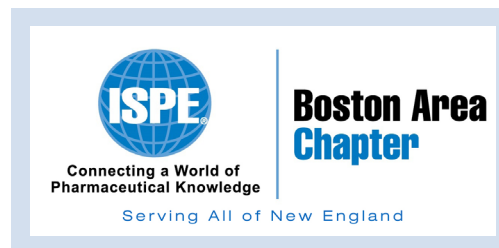
Downstream Processing, How it's Done and How to do it Faster & Better

Thursday, April 16, 2015

5:30 pm to 8:30 pm

***WPI Biomanufacturing Education and
Training Center (BETC) at Gateway Park***

50 Prescott Street, Worcester, MA 01605



OR VIA SIMULCAST AT

Crowne Plaza Hotel Providence - Warwick

801 Greenwich Street, Warwick, RI 02886

EVENT INFORMATION:

Join ISPE at WPI's Gateway Park for this dual track event that has something for everyone. Attend the live program or a simulcast presentation at the Crowne Plaza Providence in Warwick, RI. The programs at both locations will feature a networking reception including appetizers. Tours of the BETC facility will be offered during the reception hour or cheer on the Student Poster Contestants during the final phase of judging.

TRACK 1: Downstream Processing Techniques and Single Use Applications

This interactive presentation will introduce participants to the unit operations typically carried out to purify a cell culture product. Understanding what the contaminants are and how they can be removed is the first step in understanding how the downstream process should be designed. This discussion will provide insight as to how virus inactivation and removal, chromatography and UF/DF are achieved and best arranged in a process. In addition, the opportunities and merits of single use options for downstream processing will be discussed.

SPEAKER:

Stuart Green, VP of Process Engineering for Pall Corporation's Life Science Division of North America

Stuart has worked in the biotechnology field since the early 90s after completing his degree at University of the Sciences in Philadelphia. After spending time at various start-ups in PA, Stuart settled in at Centocor for approximately 9 years working in process sciences and eventually became manager of a GMP pilot plant. After leaving Centocor, Stuart was Director of Manufacturing for ImClone systems for 5 years prior to joining Pall as VP of process Engineering in early 2014.

TRACK 2: Integrated Continuous Downstream Processing – an Enabling Approach that will Break the Bottleneck

This presentation is for seasoned professionals who are familiar with the purification process and want to learn about the newest technologies.

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TRACK 2 Continued:

Over the last decade, the expression levels have tremendously increased for the upstream fermentations; thus, the downstream processes (DSP) became the “bottleneck” in manufacturing process of bio-pharmaceutical, especially for monoclonal antibodies. Additionally, biosimilars/biobetters are introduced to the market which demands new downstream approaches that are cost and time effective by retaining the properties of the biomolecules. Consequently, different integrated DSP and/or multi-column continuous chromatographic technologies are investigated that showed promising results in reducing manufacturing costs. However, up to today there has not been a reported case at the production scale. What are the remaining barriers when implementing the approaches into the downstream processing? This presentation will outline the integrated continuous downstream process by focusing on the continuous chromatography and highlight major barriers and how to overcome them in the GMP environment.

SPEAKER: Dr. Kathleen Mihlbachler, Global Director of Separations Development, LEWA Process Technologies, Devens, MA.

Dr. Mihlbachler has worked in the field of process chromatography for almost 20 years. Currently, she is the Global Director of Separations Development at LEWA Process Technologies. She is responsible for the development of separation technologies for synthetic and biological molecules, in particular for continuous processing. Prior to this appointment Dr. Mihlbachler worked as an external consultant for LEWA-NIKKISO where she supported the technical transfer of process chromatographic technology and consulted in customer projects. Previously, Dr. Mihlbachler was involved as a Sr. Researcher at BMS, Eli Lilly and Pfizer in the development, scale-up and manufacturing of purification/separation processes for chiral and non-chiral compounds, peptides and proteins, in particular to implement continuous processes. From 2011 to 2013, Dr. Mihlbachler taught undergraduate courses for chemical and biomedical students at New Jersey Institute of Technology.

MEETING MANAGERS:

Dan Mardirosian, Worcester Polytechnic Institute

Christopher Ciampa, Thermo Fisher

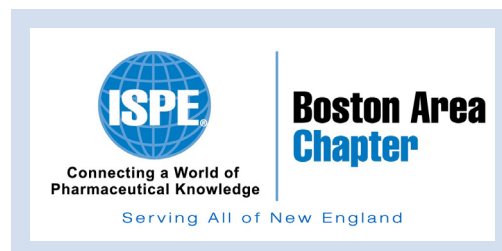
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PROGRAM SCHEDULE: *Applies to all sites*

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

6:30 – 8:30 PM Presentations

REGISTRATION FEES:

	Registration by 4/9/2015	Registration After 4/9/2015
<input type="checkbox"/> Members	\$50	\$60
<input type="checkbox"/> Young Professional Members	\$20	\$30
<input type="checkbox"/> Nonmembers **	\$95	\$115
<input type="checkbox"/> Student Members	FREE	FREE
<input type="checkbox"/> Simulcast in Warwick, RI	FREE	FREE

** Attendees may only attend one program as a nonmember.

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 APRIL 9 ARE SUBJECT TO BILLING****

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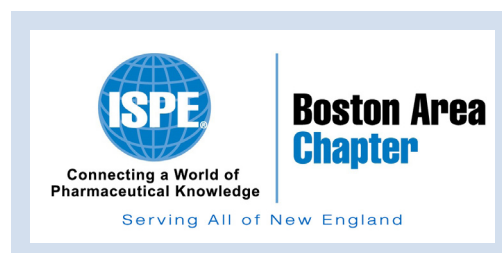
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DIRECTIONS:

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 The WPI Life Sciences and Bioengineering Center (which will be the building on your left). Visitor parking is next to the building.

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 The WPI Life Sciences and Bioengineering Center (which will be the building on your left). Visitor parking is next to the building.

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 The WPI Life Sciences and Bioengineering Center (which will be the building on your left). Visitor parking is next to the building.

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). Visitor parking is next to the building.

Parking options include:

Parking lot on the Right side as you approach the Parking Garage located on Washburn way.

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.

Please pay close attention to no parking signs to avoid being ticketed.

For door to door directions, click [here](#).

SIMULCAST LOCATIONS:

Crowne Plaza Hotel Providence - Warwick

801 Greenwich Street, Warwick, RI 02886

To the Crowne Plaza Hotel Providence – Warwick, RI:

For door to door directions, click [here](#)

<http://www.crownehotelwarwick.com/index.cfm/page/Contact-Us/pid/10269>