

*ISPE Boston Area Chapter Presents:*  
**Continuous Manufacturing of  
Biopharmaceuticals**

**Thursday, March 16, 2017**  
5:30 pm to 9:00 pm



Serving All of New England

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PROGRAM SPONSOR



***Takeda Pharmaceuticals***

35 Landsdowne Street  
Cambridge, MA 02139

**EVENT INFORMATION:**

Join us to learn about the latest developments in continuous manufacturing of biopharmaceuticals. The event will feature a networking reception with hors d'oeuvres and refreshments *including complimentary wine and beer*. The main event includes three presentations followed by a panel discussion. **Register now for this great program!**

**PROGRAM SUMMARY:**

***Continuous Biopharmaceutical Manufacturing: Challenges & Possibilities*** (Andre Walker, CPIP)

Continuous processing has transformed industries from petrochemicals to steel. Endless case studies highlight how early adopters thrived while laggards, often leading firms in the industry, withered. However, in the highly regulated space of the biopharmaceutical industry, impediments to adoption of this technology range from simple lack of vision and leadership, as well as significant economic and cultural factors.

Do these challenges conspire to make continuous manufacturing of biologics impractical, uneconomical, and simply too risky? Andre's presentation will address the hype, the key concerns, and present a possible future of continuous manufacturing of biologics.

***Protein A Resin Lifetime Study: Evaluation of Protein A Resin Performance with a Model based approach in continuous capture*** (Ketki Behere)

Increased product yield at reduced cost and time is the driving force of many bio-manufacturing process improvements. Within the mAb platform, Protein A has played a critical role as an affinity moiety in traditional bind-and-elute (batch) chromatography. As product demand and upstream titer continue to increase, continuous Protein A chromatography is being explored to keep up.

Although Protein A resins possess unique stability, degradation of resin particles takes place under continuous chromatographic conditions - mainly caused by caustic during the sanitization phase of chromatography. A modified shrinking core model (MSCM) has been employed to describe the mechanism and rate at which the degradation occurs. The kinetic model utilizes semi-empirical parameters estimated from breakthrough experiments for three distinct resins. This study proved the utility and functionality of the designed model, which can be built upon to design effective cleaning strategies. In turn this should improve resin performance, and extend resin lifetime for continuous downstream processing.

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***Transforming Downstream Processing through Multi-Column Chromatography*** (Kathleen Mihlbachler)  
Implementation of continuous processing in bio-manufacturing requires rethinking process chromatography and its equipment design. After years of development and many successes, continuously operating technologies are becoming part of the downstream processing (DSP) platform. This presentation will focus on multi-column technology including:

- Basics of multi-column chromatography
- Design requirements: Equipment and Automation
- Optimization: Reducing the complexity in process and system design
- Regulatory aspects and Performance Verification (PV)
- Current developments and future trends

## **WHO SHOULD ATTEND?**

Engineers, Scientists, and Quality Personnel who are interested in learning more about continuous manufacturing.

## **SPEAKERS:**

### **Andre Walker, CPIP, Principal, Andre Walker Consulting, LLC**

Andre Walker has over 30 years of experience providing engineering and technical support for manufacturing operations in consumer products, medical devices, and biotechnology. His biologics industry experience includes Director of Engineering and Manufacturing Sciences at several bio-manufacturing facilities ranging in scale from 2000 to 15,000 liters. He has held leadership roles in commercial cGMP facilities in the US and Denmark, and has served as Chairman of ISPE's Board of Directors. Andre holds the Certified Pharmaceutical Industry Professional (CPIP) credential and is a recipient of the Hank Moes Lifetime Achievement Award.

### **Ketki Behere, PhD Candidate, Chemical Engineering, UMass Lowell**

Ketki Behere's research focusses on characterization of Protein A resin in downstream chromatography for purification of antibodies. She has worked at Lonza Biologics, Portsmouth as a co-op student in the Manufacturing Sciences and Technology (MSAT) group and as a Research Associate at Lonza Biologics, Hopkinton in the Downstream Process Development (PD) group. Previously she worked as Production executive in bio-manufacturing at Reliance Life Sciences (RIL), India. She has a Bachelor of Engineering degree in Biotechnology Engineering from Shivaji University, India.

### **Dr. Kathleen Mihlbachler, Global Director of Separation Development, LEWA Bioprocess**

Dr. Mihlbachler has 20 years' experiences in the field of process chromatography. In her current position as Global Director of Separation Development, she is responsible for the establishment of innovative technologies at LEWA Bioprocess, in particular for continuous processing applications in pharma. She is the principal designer/developer of the EcoPrime Twin platform by successfully leading the tech transfer of the ChromaCon's CaptureSMB technology to the process scale. Dr. Mihlbachler has also been involved in hands-on training of engineers and scientists, as well as advisory roles for bachelor and PhD theses. Dr. Mihlbachler presents technical and scientific results at international meetings and in peer-reviewed publications.

Prior to joining LEWA Bioprocess, Dr. Mihlbachler was Sr. Researcher for 10 years in the pharmaceutical industry. She was involved in the development and scale-up of purification/separation processes for numerous biologic compounds, peptides and proteins, implementing continuous processes at BMS, Eli Lilly and Pfizer. She has taught undergraduate courses in chemical and biomedical engineering at New Jersey Institute of Technology. She also lead process chromatographic workshops (Prep Symposium) for more than 10 years.

## **MEETING MANAGERS:**

**Dan Pratt**, Takeda Pharmaceuticals

**Jack Campion**, The Hart Companies

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**PROGRAM SCHEDULE:**

5:30 – 6:30 PM Registration and Networking Reception  
6:30 – 8:30 PM Presentations  
8:30 – 9:00 PM Q&A Session

**REGISTRATION FEES:**

	<b>Registration by 3/9/2017</b>	<b>Registration After 3/9/2017</b>
<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

\*\* 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](http://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: \_\_\_\_\_

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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](mailto:office@ispeboston.org)

**\*\*PLEASE NOTE: CANCELLATIONS RECEIVED AFTER MARCH 9<sup>TH</sup> ARE SUBJECT TO BILLING\*\***

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**DIRECTIONS AND PARKING:**

**Directions from the Massachusetts Turnpike (I-90):**

Head east on I-90 E to Exit 22 toward Copley Square/Prudential Center. Keep right at the fork and merge onto Stuart St. Turn left at Dartmouth St and a slight left onto Dartmouth St for a quarter mile. Turn left onto Commonwealth Ave for a half mile and make a right onto Massachusetts Ave for 1 mile, turn left onto Landsdowne St. Destination will be on the right.

**From I-95 (Route 128):**

Take I-95 N to Exit 12 to merge onto I-93 N toward Boston. Keep left to continue on I-93 N/US-1 N, follow signs for State Route 3 N/Boston. Take Exit 26 toward Storrow Dr for a half mile. Keep right, follow signs for MA-28 S/MA-3 N/Storrow Dr. Take Storrow Dr and MA-2A W/Massachusetts Ave to Landsdowne St and take a left. Destination will be on the right.

**From Route 495:**

Take Exit 22 to the Massachusetts Turnpike (I-90) East, and follow the directions above.

**Parking**

Parking can be found directly across the street at 55 Franklin Street

**Public Transportation**

Take the 70 Central Square, Cambridge via Arsenal St Bus to Franklin St @ Sidney St. Walk approximately one block SE onto Landsdowne St., turn left to 35 Landsdowne St.