

ISPE Boston Area Chapter Presents:
**Single Use & Shiny Stuff,
Combine So You Can Produce Enough**

Thursday, December 7, 2017

5:00 pm to 9:00 pm

Amgen Process Development Scale-up Laboratory

360 Binney Street

Cambridge, MA 02142



EVENT INFORMATION:

Join the ISPE Boston Chapter at the Amgen Laboratory to listen to two process engineer perspectives on single-use systems. This program will be of particular interest to those working with older facilities. All are welcome so register today!

PROGRAM SUMMARY:

In the past ten to fifteen years biotech manufacturers have struggled with the decision to continue using stainless steel equipment or switch to single-use technologies. The decision largely depends on product volume and the amount of flexibility needed. Disposables are often the choice for rapid-turnaround, smaller batches and stainless steel is often the best choice for larger volumes or highly automated processes. However, increases in the available volumes of single use equipment and development of novel single use automation and instrumentation continually shift the landscape of available options. In addition, as the design of single use equipment becomes more specialized, challenges with secondary supply, complex set-up, and interconnectivity emerge. This talk will survey the recent developments in single use equipment and accessories and present case studies that demonstrate manufacturing challenges and the chosen path forward.

SPEAKER: Teaching an Old Facility New Tricks

Rob Boulanger, Product Specialist, CRB

Rob joined CRB in April 2015 where he implements his process and operational expertise in both a design and consulting role by supporting biopharm clients through their various growth stages. In addition he is an active volunteer with the ASME BPE and currently leads the Design of SIP task group.

Rob obtained a Ph.D. in Biochemistry from Boston College in 2005 and was at Protein Sciences Corporation (PSC) prior to joining CRB. He managed PSC's Production Department starting in 2006 through the beginning of 2010. During his tenure in the Production department, the processes for over 15 recombinant protein products were transferred from development scale (10L) to the 450L scale. While Rob was Production Manager, Protein Sciences filed a Biologics License Application (BLA) in 2008 for Flublok, PSC's seasonal influenza vaccine candidate. From 2010 to July of 2012, Rob managed the Upstream Processing development group. Rob was a member of the PSC's Technology Transfer Core Team which scaled up the Flublok influenza vaccine process from the 450L scale in Meriden, CT to the 2000L scale at an available facility in Pearl River, NY (which obtain licensure in May 2015).

Continued on the next page...

SPEAKER: Media & Buffer Prep – Stainless vs. Single Use

Mihir Sanghvi, Process Engineer, CRB

Mihir has over 10 years of process engineering experience serving the Biotech and Pharmaceutical Industries. Mihir has experience with nearly all phases of facility and process engineering project execution, including conceptual design, Process Flow Diagrams (PFDs), Piping and Instrumentation Diagrams (P&IDs), process calculations, equipment & instrument specification, construction support, plant start-up and debug, commissioning and validation (FAT/SAT, IQ, OQ, PQ). He also has technical expertise in Clean-in-Place (CIP) and Steam-In-Place (SIP) processes, including design, cycle development, commissioning and qualification. Mihir obtained Masters of Science in Chemical Engineering from Illinois Institute of Technology in 2006. He joined CRB in Feb 2015. He works as a process engineer at CRB and has been working extensively on Single Use Equipment.

MEETING MANAGER:

Bill Garvey, William Garvey and Associates

ISPE Boston Area Chapter Presents:
**Single Use & Shiny Stuff,
Combine So You Can Produce Enough**

Thursday, December 7, 2017
5:00 pm to 9:00 pm

Amgen Process Development Scale-up Laboratory
360 Binney Street
Cambridge, MA 02142



PROGRAM SCHEDULE:

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

REGISTRATION FEES:

	Registration by 11/30/2017	Registration After 11/30/2017
<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

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 NOVEMBER 30TH ARE SUBJECT TO BILLING****

ISPE Boston Area Chapter Presents:
**Single Use & Shiny Stuff,
Combine So You Can Produce Enough**

Thursday, December 7, 2017

5:00 pm to 9:00 pm

Amgen Process Development Scale-up Laboratory

360 Binney Street
Cambridge, MA 02142

DIRECTIONS AND PARKING:

[Click here](#) for door to door directions.

Street parking and garage parking are both available for a fee.



ISPE®

**Boston Area
Chapter**

Serving All of New England