# WPI’s Biomanufacturing Education and Training Center (BETC) to Host Education and Networking Event

## *Downstream Processing –*

## *How it’s Done and How to do it Faster & Better*

## Presented by:  International Society for Pharmaceutical Engineering (ISPE)

**Registration is required (please see below for registration fees and info)**

**Apr 16, 2015, 5:30 PM to 8:30 PM**

**EVENT INFORMATION:**Join ISPE at WPI’s Gateway Park for this dual track event that has something for everyone. Attend the live program in Worcester or a simulcast presentation at the Crowne Plaza Providence in Warwick, RI. The programs at both locations will feature a networking reception including appetizers.  Join us for a tour of the BETC facility during the reception hour, or cheer on the student poster contestants during the final phases 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.

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.

**REGISTRATION FEES:**

**Before 4/9/2015:**

Member $50.00    
Young Professional Members $20.00   
Non-Member $95.00\*\*  
ISPE Student Members: Free to attend

**After 4/9/2015:**

Member: $60.00  
Young Professional Members $30.00   
Non-Member: $115.00\*\*  
ISPE Student Members: Free to attend

**\*\*Non-members may only attend one program as a non-member\*\***

[CLICK HERE TO REGISTER](http://www.ispeboston.org/events/registration.htm?eventID=550)

**MEETING MANAGERS:  
Dan Mardirosian,** Worcester Polytechnic Institute **Christopher Ciampa,** Thermo Fisher

Location:  
[WPI Biomanufacturing Education and Training Center (BETC) at Gateway Park, 50 Prescott Street, Worcester, MA 01605](http://www.mapquest.com/maps?2a=50+Prescott+St&2c=Worcester&2s=MA&2z=01605&form=directions)