# The Future is NOW for Continuous Manufacturing

## Thursday, January 15, 2015

5:30 pm to 8:30 pm

## Biogen Idec

15 Cambridge Center, Bio 8 Auditorium Cambridge, MA 02142

#### OR VIA SIMULCAST AT

## Crowne Plaza Hotel Providence - Warwick

801 Greenwich Street, Warwick, RI 02886



Attend the live program at Biogen Idec, Cambridge, MA or a simulcast presentation at the Crowne Plaza Providence in Warwick, RI. The programs at both locations will include a networking reception including appetizers.

#### **PROGRAM SUMMARY:**

If your initial reaction is: Impossible! Can't be done! Not with MY process! You may be surprised to learn that continuous manufacturing is much closer than you think. As our industry evolves and matures, we continue investigating ways to produce biopharmaceutical products more efficiently. Come and learn from three cutting edge speakers working on different areas of this same complex issue as the Chapter presents a "future trends" program to kick off the 2015 educational program year!

Following up on the Lean and Six Sigma concepts covered during the Chapter's December educational program, continuous manufacturing can offer process efficiencies that appeared unimaginable just a short time ago. This program focuses on the science and technology behind different strategies successfully used to continuously manufacture products.

Salvatore Mascia will speak about how integrated continuous manufacturing (ICM) has been implemented at the first ever ICM pilot plant, developed by Novartis and MIT's Center for Continuous Manufacturing to convert raw materials into finished products on a continuous basis.

Maurizio Cattaneo will speak about how to leverage the science behind the design of experiments (DOE) and quality by design (QbD) concepts to create efficiencies in monoclonal antibody production which have increased yields ten-fold by using continuous manufacturing techniques.

Kathleen Mihlbachler will speak about the use of multi-column continuous (MCC) chromatography for the effective separation of chiral (mirror image) compounds on a continuous basis and how this approach can be integrated into a more complex manufacturing strategy.



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#### **SPEAKERS:**

# Salvatore Mascia, Ph.D., Founder and CEO, CONTINUUS Pharmaceuticals

Salvatore Mascia is the Founder & CEO of CONTINUUS Pharmaceuticals. He was the former Strategic Project Manager at the Novartis-MIT Center for Continuous Manufacturing, where he led the integration of the first end-to-end continuous



manufacturing process for pharmaceuticals. At the end of the project, he was presented with the "Leadership Award" that recognized his leadership role at the Center. Dr. Mascia gained experience in strategic management and fund raising in addition to leadership skills via various roles of responsibility within the entrepreneurial ecosystem. Among those, he co-founded "Professional Italians in Boston" in 2009, and served as President of the "Cambridge University Technology and Enterprise Club" in 2006/07. He also ran a pharmacy business for 2 years. Dr. Mascia completed a post-doc at MIT in Chemical Engineering and holds a PhD in Chemical Engineering from the University of Cambridge, UK and a BS and MS in Pharmacy (summa cum laude) from University of Perugia, Italy.

#### Maurizio Cattaneo, Ph.D., CEO, BioVolutions, Inc.

Dr. Cattaneo obtained his Bachelor of Applied Sciences Degree in Chemical Engineering from the University of Toronto and his MS and Ph.D. from McGill University. Dr. Cattaneo was a Research Officer at the National Research Council of Canada where he specialized in the development of human monoclonal antibodies by phage display. Most recently, Dr. Cattaneo spent one year at MIT developing single use systems for manufacturing monoclonal antibodies by cell culture. Dr. Cattaneo holds 6 patents in the field of bioprocess and biotechnology. Dr. Cattaneo is now CEO of BioVolutions, Inc. a local CMO offering diagnostic and therapeutic monoclonal antibodies made by Continuous Manufacturing. Dr. Cattaneo attained his Certified Pharmaceutical Industry Professional (CPIP) credential in 2013.

Kathleen Mihlbachler, Ph.D., Director of Global Separation Development, LEWA Process Technologies Dr. Mihlbachler has worked in the field of process chromatography for more than 15 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 since 2012 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 MANAGER:**

Brent Arbogast, CPIP, Angel Analytical Brian Hagopian, CPIP, Clear Water Consulting, Inc.

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Boston Area Chapter

Serving All of New England

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### PROGRAM SCHEDULE: Applies to both sites

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

6:30 – 8:30 PM Presentations

REGISTRATION FEES:		Registration by 1/8/2015	Registration After 1/8/2015	
	Members	\$50	\$60	
	Young Professional Members	\$20	\$30	
	Nonmembers **	\$95	\$115	
	Students Members	FREE	FREE	
	Simulcast in Rhode Island	FREE	FREE	

<sup>\*\*</sup> 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 <a href="www.ISPEBoston.org/Events">www.ISPEBoston.org/Events</a>.
Pay by credit card OR check.

Do you wish to opt out of beir	ng 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 Signature:			

Payment may be mailed to: ISPE, Boston Area Chapter, 411 Waverley Oaks Road, Suite 331B, Waltham, MA 02452 Telephone: 781-647-ISPE (4773) Fax: 781-647-7222 Email: office@ispeboston.org

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#### **DIRECTIONS AND PARKING:**

#### From MBTA (The "T"):

Take the Red Line "T" to Kendall Square/MIT stop. Walk straight up the stairs.

#### From North or South:

Rte. 93 to the Storrow Drive Exit. Follow signs for Storrow Drive. Take Storrow Drive to Exit marked Kendall Square. Go across Longfellow Bridge over Charles River. Once you cross the Charles River, the road turns into Broadway.





#### From Waltham & Route 2:

Rte. 2 to Memorial Drive eastbound. (You will pass Harvard University, The B.U. Bridge, The Mass Ave. Bridge and MIT.) After passing MIT, stay to the right. Take left at first set of lights (2nd Kendall Square sign) onto Binney Street. Take left at 2nd light onto Third Street. Proceed to end and turn right onto Broadway.

#### From Mass Ave:

Follow Mass Ave. onto Main Street. Take left onto Ames Street at Legal Seafood.

#### From West & Mass Pike:

Take Mass Pike to Exit 18 (Cambridge/Allston/Brighton Exit). After toll, bear right (Cambridge/Somerville). Go straight across River Street Bridge. Turn right onto Memorial Drive eastbound. After passing MIT, stay to the right. Take left at first set of lights (2nd Kendall Square sign) onto Binney Street. Take left at 2nd light onto Third Street. Proceed to end and turn right onto driveway.

**PARKING:** Street parking meters are free after 6PM.

The closest Parking Garage, "Central Parking System," is at 4 Cambridge Center where parking is \$18 for up to three hours and \$24 for over three hours.

#### **SIMULCAST LOCATION:**

#### 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