

*ISPE Boston Area Chapter Presents:*  
**Biomanufacturing Science & Technology,  
Preparing for Tomorrow**

**Wednesday, April 20, 2016**

5:30 pm to 9:00 pm

***WPI Life Sciences and Bioengineering Center at  
Gateway Park***

60 Prescott Street, Worcester, MA 01605

**OR VIA SIMULCAST AT**

***Biogen, 300 Binney Street, Cambridge, MA 02142***

**OR VIA SIMULCAST AT**

***Redhook Ale Brewery, 1 Redhook Way, Portsmouth, NH 03801***

**OR VIA SIMULCAST AT**

***The Tech Collective, 166 Valley Street, Providence, RI 02909***

**EVENT INFORMATION:**

Join us for this event and the ISPE student poster contest! Attend the live program or a simulcast presentation at Biogen in Cambridge, MA; Redhook Ale Brewery in Portsmouth, NH; or the Tech Collective in Providence, RI. The programs at all locations will feature a networking reception including appetizers. Cheer on the Student Poster Contestants during the final phase of judging at WPI during the reception hour.

**WHO SHOULD ATTEND:**

Those working in process development, manufacturing development, equipment designers and facility design & construction companies. Anyone interested in the future of Biomanufacturing and the new manufacturing technologies they should be expecting and planning for.

**Science, Technology, and Society, What Will the Next Ten Years Bring?**

The Global demand for Biologics and manufacturing capacity is exploding. To meet this demand, medicines need to be affordable and available in mass quantities and the facilities need to be cost effective and flexible.

This program will present information surrounding the direction science is heading, the manufacturing required to deliver new products and the innovative approach to facilities. Our panel consists of educators and industry professionals that will share some of the latest developments in science, manufacturing, and technologies that will shape the future of Biomanufacturing. Join us in a panel discussion with our speakers who will present what they are working on to address these needs.

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**“Design and Development of Next Generation Nanomedicines” by Prakash Rai**

Nanomedicine has the potential to deliver therapeutic agents for enhancing treatment outcome while reducing morbidity. This could dramatically improve treatment responses in several diseases including infectious diseases and especially cancer where the survival statistics have been, so far, dismal. However, progress to date in translating these innovative medicines into commercial success stories is currently limited by the inability to manufacture batches of the nanopharmaceuticals at the required scale and in line with stringent quality control measures required for medical products. Success in developing nanomedicines for clinical use depends on understanding the complex biology, the use of predictive animal models, and the importance of sharing data as key denominators for potential successful translation of nanocarriers from a bench scale into clinical modality for patient care. The global market for nanomedicine, including neurology, cardiovascular, anti-inflammatory, anti-infective, and oncology applications, was valued at \$79 billion in 2012 and is expected to reach a value of \$178 billion in 2019, predicted to grow 12.3% from 2013 to 2019. It is predicted that nanocarriers will account for 40% of the \$136 billion nanotechnology-enabled drug delivery market by 2021. Manufacturing issues in nanomedicine may halt the predicted progress of this field and its imperative that these concerns are tackled in a collaborative way with industry and academia working together to translate nanomedicines

**“Aducanumab and Next-Generation Manufacturing at Biogen” by Philippe de Vilmorin**

Aducanumab is a monoclonal antibody currently in Phase 3 clinical trials, and it has shown tremendous potential as a disease modifying therapy in Alzheimer’s Disease. Leveraging the optimism about aducanumab and other promising clinical products, Biogen is building a multi-billion dollar biologics manufacturing facility in Solothurn, Switzerland. The facility is planned to be the largest ever of its kind, with a total mammalian cell culture capacity that may ultimately exceed 500,000 liters. This presentation will review the clinical success of aducanumab and introduce the next-generation manufacturing concepts which will enable the Solothurn facility to deliver consistent product quality and unprecedented productivity.

**“Avoiding Facility Obsolescence: Immortal Facilities for Increasing Drug Diversity” by Parrish Galliher**

As worldwide annual sales of biologics increase toward the 200 bn USD mark, so has the diversity of treatment modalities and drug pipelines increased. Pipeline diversity has grown from recombinant hormones and cytokines to monoclonal antibodies (MAb), MAb-toxin conjugates, Mab antibody fragments, multivalent MAbs, cell-based and rDNA vaccines, precision cell and gene therapies, therapeutic enzymes, biobetters, biosimilars, biofuels and more. Over the decades, many manufacturing facilities have been unable to accommodate this increasing diversity and have become underutilized, mothballed or obsolete. The presentation will discuss the challenges of increasingly diverse pipelines and process flow architectures and how innovations in manufacturing facility design and operations can maximize facility utilization and help avoid facility obsolescence.

**MODERATOR:**

**Kamal Rashid, PhD, Director and Research Professor, WPI BETC**

Kamal has over thirty years of academic experience in both research and biotechnology educational program development plus an additional focus on training at universities including WPI, Utah State University, and Penn State University.

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**PANELISTS:**

**Parrish Galliher, Founder and Chief Technology Officer, Xcellerex, a GE Healthcare Life Sciences company**

Mr. Galliher earned his BA in Biology at Boston University (1975) and then joined the Biofuels R/D Laboratories of Dynatech R/D Corporation where he built and studied the performance of biomethanation stirred tank and packed bed fermenters to convert coal synthesis gas, kelp seaweed, freshwater algae and municipal solid waste to methane and higher alkanes. Mr. Galliher then earned his MS degree in Biochemical Engineering at MIT (1981) after which he joined Biogen, Inc. in 1981 where he was responsible for design, commissioning, validation and operation of Biogen's Cambridge MA. biomanufacturing facilities for both 1500L microbial fermentation and Verax continuous perfusion mammalian cell manufacturing facilities. As Director of Process Engineering, he led the team responsible for the development of the commercial upstream process for Avonex® (beta-Interferon) and the startup, initial validation and commissioning of Biogen's 2000L stirred tank Avonex® commercial manufacturing facility, later licensed by the FDA. Mr. Galliher joined Alpha-Beta Technology (ABT) in 1994 as Director of Manufacturing Development and led the technology transfer, startup, validation, and commissioning of ABT's commercial biopharmaceutical manufacturing plant in Smithfield, RI at which he became Vice President of Operations and General Manager in 1997. Mr. Galliher joined LeukoSite, Inc. in 1999 as Vice President of Biologics Manufacturing and continued in that role after Millennium Pharmaceuticals acquired LeukoSite in 1999. At Millennium, Mr. Galliher led the CMC Team that contributed to FDA and EMA commercial licensure of CAMPATH® monoclonal antibody in 2001-2002. At Millennium, he created and led the \$18M biologics single use manufacturing "Factory of the Future" Program which enabled high speed development of Millennium's monoclonal antibodies for clinical trials (from clone to new facility to drug in the clinic in 12 months). In December 2002, Mr. Galliher became Founder, President and CEO of Xcellerex, Inc., an advanced single use biomanufacturing technology and services company, at which he led the creation and commercialization of the single use (SU) XDR™ mammalian and microbial bioreactor, XDM™ SU mixing systems and the turnkey SU modular FlexFactory® biomanufacturing platform. As Principal Investigator, Mr. Galliher led Xcellerex's \$19M US Gov't DoD DARPA/DTRA prime contract for the "Accelerated Manufacture of Pharmaceuticals Program" (AMP), awarded in 2007 and continued through Phase 2 and successful Swine flu Live Fire Test in 2010. In 2012 GE Healthcare acquired Xcellerex Inc. and Mr. Galliher took on the new role of Chief Technology Officer, Upstream for GEHC. In 2012 Mr. Galliher was awarded Bioprocess International's 2012 "Thought Leader of the Decade, Upstream". Mr. Galliher is committed to the potential of biotechnology to transform human health, and is a co-inventor of numerous patents in the field of advanced, high efficiency biomanufacturing technologies.

**Philippe de Vilmorin, Senior Engineer, Biogen**

Philippe de Vilmorin is a Senior Engineer at Biogen and Technical Development Lead for the Next Generation Manufacturing project. During more than 13 years at Biogen, he has contributed to development of manufacturing processes and control strategies for biologics including Tysabri, Alprolix, Eloctate, and Plegridy. Recently he has been leading development teams for early-stage biologics, applying innovative approaches to minimize the time between discovery and clinical studies. His latest focus is on the design of Biogen's next-generation manufacturing facility for mass production of future commercial products. Phil has a Bachelor of Science degree in Chemical Engineering from MIT.

**Prakash Rai, PhD, Assistant Professor, UMass Lowell**

Prakash Rai, Ph.D., joined the Department of Chemical Engineering at UMass Lowell in 2012 as a tenure-track Assistant Professor. Prior to this he was an Instructor at the Center for Engineering in Medicine at Massachusetts General Hospital (MGH) and Harvard Medical School. Dr. Rai is currently working on developing translational nanotechnology-based platforms for imaging, prevention and treatment of breast

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cancer. His research involves designing, synthesizing, characterizing, and evaluating the efficacy of these nano-platforms in cell culture, as well as animal models of the disease. Dr. Rai has several first author publications in journals including Nature Biotechnology, Proceedings of the National Academy of Sciences, Angewandte Chemie, and Cancer Research. In 2010, Dr. Rai was chosen to receive the "Scholar in Training" award by the American Association of Cancer Research. Dr. Rai received his Bachelor's degree in Chemical Engineering from the University of Mumbai, India in 2003 and his Ph.D. in Chemical and Biological Engineering from Rensselaer Polytechnic Institute in 2007. Recently he received a grant award from the National Cancer institute to carry out research in the area of cancer nanomedicine

**MEETING MANAGERS:**

**Cheryl Huie**, Axiom Collaborative

**Joe Kifer**, RDK Engineers

**Dan Mardirosian**, WPI BETC

**Zoey Shen**, WPI

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**PROGRAM SCHEDULE:**

- 4:00 – 6:30 PM Student Poster Contest
- 5:30 – 6:30 PM Registration and Networking Reception
- 6:30 – 9:00 PM Presentations

**REGISTRATION FEES:**

	<b>Registration by 4/13/2016</b>	<b>Registration After 4/13/2016</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
<input type="checkbox"/> Simulcast in Cambridge, MA	FREE	FREE
<input type="checkbox"/> Simulcast in Portsmouth, NH	FREE	FREE
<input type="checkbox"/> Simulcast in Providence, 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](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: \_\_\_\_\_

**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](mailto:office@ispeboston.org)

**\*\*PLEASE NOTE: CANCELLATIONS RECEIVED AFTER APRIL 13<sup>th</sup> ARE SUBJECT TO BILLING\*\***

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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 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](#).**



**THANK YOU TO OUR  
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## **SIMULCAST LOCATIONS:**

### ***Biogen***

300 Binney Street, Cambridge, MA 02142

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

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### ***Redhook Ale Brewery – Alemaker's Hale***

1 Redhook Way, Portsmouth, NH 03801

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