

ISPE Boston Area Chapter Presents:
Process Scale-up & Technology Transfer
“Beyond *E. coli* and CHO:
Case Studies in Alternative Host Platforms”

Thursday, May 19, 2011

5:30 pm to 8:30 pm

Biogen Idec

14 Cambridge Center, Cambridge, MA 02142

(Building 8 Auditorium)

PROGRAM:

We are delighted to present two lectures focusing on the challenges and successes of process scale-up and technology transfer of biopharmaceutical manufacturing processes that use emerging, novel production host organisms. Our speakers have participated in the development of cutting edge production technologies that provide new, robust alternatives to the biotechnology industry. They will provide an overview of the benefits of the following novel technologies followed by case studies:

- *Pseudomonas fluorescens* developed by Pfenex, and
- PER.C6® human cell lines developed by Percivia.

Pfenex PRESENTATION:

Pfenex has successfully transferred its *Pseudomonas fluorescens* fermentation process to several manufacturing sites of collaborators, clients, and CMOs. Challenges encountered and their solutions will be shared, including:

- Development of a fermentation process that not only optimizes productivity and product quality, but also is simple and flexible to ensure successful process transfer to facilities with a diverse range of equipment and capabilities,
- Selection of suitable growth media that can be easily and consistently formulated in many facilities, and that is free from animal-derived raw materials,
- Addressing the unique regulatory and safety concerns that emerge for the first adapters of a novel production host for biotherapeutics.

Pfenex SPEAKER:

Lawrence Chew, Ph.D. is Director of Fermentation Development and technical lead of two vaccine development programs at Pfenex Inc. Dr. Chew has over 20 years of experience in industrial strain and fermentation development, from research to manufacturing scale, involving various bacterial and yeast strains producing useful agricultural, food and biopharmaceutical products. After an industrial post-doctoral position in the Life Sciences group at Monsanto Company, he held various positions at Mycogen Corporation, Nutrasweet-Kelco division of Monsanto Company and The Dow Chemical Company before joining Pfenex. He received his B.Sc. and Ph.D. in biochemistry from University of Birmingham, England.



Boston Area Chapter

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Percivia PRESENTATION:

Percivia, a joint venture of Crucell and DSM, is focused on the development of PER.C6®-based biobetter proteins and MAbs and the licensing of the PER.C6® human cell line to third parties around the world.

Production processes for use with the PER.C6® human cell lines will be presented, including:

- platform batch and fed-batch processes, which are safe and consistent, chemically defined and free of animal-derived material with predictable growth and production from shake flask to bioreactor.
- the XD® process, a new production platform with demonstrated volumetric productivity of over 27 g/L of IgG in just over 2 weeks of process time.

In addition, a study will be presented, which compares the following three purification processes in terms of product recovery, impurity levels, cost and scalability:

- A protein A-based purification process, used as a benchmark,
- A high capacity ion exchange (column based) purification process, and
- A process based solely on single-use technologies.

The comparison is based on harvests from Percivia's platform fed-batch process and Percivia's intensified XD® process, both of which are challenging for downstream processes.

Percivia SPEAKERS:

Rachel Hoff, Associate Scientist in the Upstream Process Development group, is currently a technical lead on a number of high priority internal R&D projects. Prior to working at Percivia, Rachel worked in formulations development at J & J. She received her B.S. in Chemical Engineering from Princeton University in 2005.

Anna Tchoudakova, Ph.D., who is a Scientist in the Cell Line Development group which has contributed to the development of the PER.C6® cell line, will help answer technical questions. Her group has successfully generated highly productive cell lines of hard to express proteins such as polymeric and heavily glycosylated IgMs. She received her Ph.D. in Biology in 1999 from Boston University, and then worked at the MGH Cancer Center performing structure-function analysis of the neurofibromatosis type one (NF1) gene.

MODERATOR:

Susan Dana Jones, Ph.D., VP and Senior Consultant with BioProcess Technology Consultants, is a seasoned biotechnology entrepreneur with experience in product development, technology transfer, and strategic planning. She co-founded two successful biotechnology companies and has managed multiple discovery and product development programs, including many outsourced development programs. Dr. Jones was formerly VP Manufacturing at Waratah Pharma and has held positions at Dyax, Avant (now Celldex), and the Dana Farber Cancer Institute. She received her Ph.D. in Genetics from the University of California, San Francisco.

MEETING MANAGERS:

Joyce Chiu, MBA, CPIP, Honeywell Safety Products

Shelly Henderson, MBA, Business Development Professional

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PROGRAM SCHEDULE:

5:30 – 6:20 PM	General Registration and Networking Reception
6:20 – 6:30 PM	Welcome and Program Introduction
6:30 – 8:30 PM	Program

REGISTRATION FEES:

Registration by 5/12/2011 After 5/12/2011

<input type="checkbox"/> Members	\$50	\$60
<input type="checkbox"/> Non-members	\$95	\$115
<input type="checkbox"/> Students	\$5	\$10

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

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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: ispe@camihq.com

****PLEASE NOTE: CANCELLATIONS RECEIVED AFTER May 12th ARE SUBJECT TO BILLING****

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LOCATION:

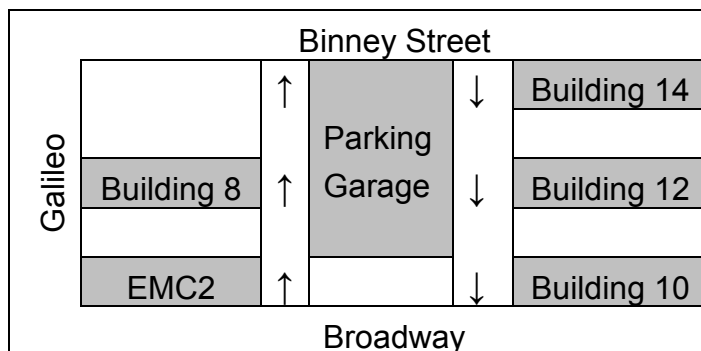
Biogen Idec - Building 8 Auditorium
14 Cambridge Center, Cambridge, MA 02142
617 679-2000

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DIRECTIONS to Biogen Idec, Cambridge, MA:

http://maps.google.com/maps?f=q&source=s_q&hl=en&geocode=&q=10+Cambridge+Center,+Cambridge,+Massachusetts+02142&sl=42.2855,-71.4149&sspn=0.010953,0.019076&ie=UTF8&hq=&hnear=10+Cambridge+Center,+Cambridge,+Middlesex,+Massachusetts+02142&z=16



The EMC2 building sits on the corner of Broadway and Gallileo. As you walk from Broadway to Binney Street, Building 8 is behind the EMC2 building to the left of the parking garage with the entrance facing the parking garage.

PARKING: On 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.