

ISPE Boston Area Chapter Presents:
**Process Design: From Scientific Concept to Engineering Reality
(A Panel Discussion)**

Thursday, May 10, 2012

5:30 pm to 8:30 pm

Genzyme Center

500 Kendall Street, Cambridge, MA 02142



Connecting a World of
Pharmaceutical Knowledge

**Boston Area
Chapter**

PROGRAM SUMMARY:

The Process Design is one of the most challenging areas for Biopharm manufacturers. There are three unit operations that require consideration: Cell Culture, Clarification, and Downstream Purification. Each of these unit Operations informs the design of facilities and equipment. There are Regulatory, Quality, Science and Engineering considerations that are always part of successful Process Design, but also important is experience of what "works" in a Production environment and what doesn't. This session will examine all of this in the hope of explaining how processes end up getting designed and also provide hints on how to avoid common pitfalls. The Panelists represent leading figures who have designed many such processes and will share their wisdom and experiences.

MODERATOR:

Doyle Johnson, New England Operations Leader, Hargrove Engineers + Constructors

Mr. Johnson is the New England Operations Leader for Hargrove Engineers + Constructors. Previously, he was the Senior Director of Facilities Operations at Genzyme's Biologics Division. He has more than 25 years of experience designing, building and operating BioPharma and Chemical Process Plants. Mr. Johnson currently serves on the ISPE International Board of Directors. Mr. Johnson served as President of the ISPE Boston Chapter, and prior to that served for five years on the Board of Directors of the Boston Chapter. Under his leadership the Boston Chapter implemented a Young Professionals Initiative, a GAMP program at the Product Show and won the Chapter Excellence award for North America. He has lived and worked in both the US and Europe. He holds a BS degree in Chemical Engineering from Cornell University, an MS in Organic Chemistry from Northeastern University and an MBA from Babson College.

PANELISTS:

Rajesh Beri, Ph.D., Director, Manufacturing Sciences and Technology, Lonza Biologics

Rajesh Beri received his Bachelors of Technology in Chemical Engineering from the Indian Institute of Technology, Mumbai, India in 1987 and his Masters and Doctorate degrees in Chemical Engineering from Worcester Polytechnic Institute, Worcester, MA. He has over 17 years' experience working in the Biotech Industry in process development, process scale up, manufacturing and facility / equipment design for over 30 biologics products derived from either mammalian or microbial cultures. He has previously worked at BioChem Pharma, Dow Chemicals, GlaxoSmithKline and Amgen. In his current role as Director, Manufacturing Sciences and Technology at Lonza Biologics, Portsmouth, NH and Hopkinton, MA he manages a group of 50 scientists and engineers responsible for process transfer and scale up, process characterization, manufacturing and regulatory support. His hobbies include hiking, biking and coaching youth basketball.

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PANELISTS Continued:

Judy Bodette, Deputy Director of Process Engineering, Sanofi Pasteur

Judy Bodette received her Bachelor's of Engineering in Chemical Engineering from Northeastern University in 1988. She has over 17 years experience working in the Pharmaceutical and Biotech Industry, in facility and equipment design as well as process engineering. She has previously worked at Badger Engineers Inc and Process Facilities Inc. In her current role as Deputy Director of Process Engineering at Sanofi Pasteur, Canton, MA (formerly Acambis, Inc.) she is responsible for process engineering projects to support live viral vaccine production, as well as facility and equipment design.

Anton R. Edmund, Ph.D.

Dr. Edmund has more than 15 years of Bioprocess Engineering and management experience in Biopharmaceutical and medical device industries. Dr. Edmund earned his PhD (Biomedical Engineering), MS (Biomedical engineering and Biotechnology), and BS (Biotechnology) from University of Massachusetts at Lowell. Dr. Edmund worked at Genzyme, a leading bio-pharmaceutical company, for more than 14 years where he proved success in managing complex projects especially startup upstream & downstream operations, and implemented numerous process improvements. Dr. Edmund has an extensive experience in mammalian and microbial cell cultures. Additionally, Dr. Edmund serves as a president at applied bioinformatics consulting firm.

Christian Lim, Process Engineer and Project Manager, CRB

Christian is a process engineer and project manager with over ten years' experience in the biopharmaceutical and vaccine manufacturing industries. He has a broad knowledge of engineering design, manufacturing processes and regulatory requirements. He has participated in the basis of design, process modeling simulations, equipment design and selection, acceptance testing, commissioning, and validation. In addition, Christian has successfully led, managed, and scheduled large capital engineering projects and facility start-up operations. He has earned a Green Belt in Lean Six Sigma for operational excellence and supply chain management. Prior to joining CRB, Christian has worked for Johnson & Johnson, Amgen, Wyeth Biotech, Pfizer, and Genzyme.

MEETING MANAGERS:

Yuk Chun Chiu, Genzyme

Michael Levesque, Olympus Biotech Corporation

John Spohn, CPIP, Castle Hill Technologies

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PROGRAM SCHEDULE:

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

REGISTRATION FEES:

Registration by 5/03/2012 After 5/03/2012

<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

Card #: _____ Expiration Date: _____

Cardholder Name (as it appears on card): _____

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

****PLEASE NOTE: CANCELLATIONS RECEIVED AFTER May 3rd ARE SUBJECT TO BILLING****

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DIRECTIONS AND PARKING:

From the Expressway North/South

Take the exit for Storrow Drive

Follow Storrow Drive to the Kendall Square/Government Center exit

Follow the signs for Kendall Square

Cross the Longfellow Bridge and into Cambridge

After crossing the river, take a right at the first set of lights onto Third Street

Turn right onto Kendall Street

The parking garage is on your right

From the Massachusetts Turnpike (I-90 Eastbound)

Take the Mass Turnpike East

Take Exit 18 (Allston/Cambridge)

Follow signs toward Cambridge/Somerville

The Doubletree Guest Suites Hotel will be on your right

At the traffic light take a right onto Storrow Drive

Do not cross the river

Take the Kendall Square/Government Center exit off Storrow Drive

Follow the signs for Kendall Square, bearing left around the rotary and across the Longfellow Bridge into Cambridge

After crossing the river, take a right at the first set of lights onto Third Street

Turn right onto Kendall Street

The parking garage is on your right

From the "T"

Take the Red Line to the Kendall Square stop

When you exit the station, you will be on Main Street

Walk East - towards Boston - and you will see a traffic light at the corner of Broadway and Third Street

Cross at the intersection and walk down Third Street

Take your first right onto Kendall Street

Genzyme Center is the first building on the left