



**Greater  
Los Angeles Area  
Chapter**  
ENGINEERING  
PHARMACEUTICAL  
INNOVATION

# 17TH ANNUAL VENDOR NIGHT

EXHIBIT SHOW

AND TECHNICAL SESSION

2010 FACILITY OF THE YEAR AWARD WINNERS

AND CURRENT FDA ENFORCEMENT TRENDS AND RECALLS

**THURSDAY, SEPTEMBER 23, 2010**

JOIN US AS WE RETURN TO THE HISTORICAL SHIP

THE QUEEN MARY IN LONG BEACH  
1126 Queens Highway, Long Beach, CA



This year's theme  
Surfin Safari Beach  
Party

## VENDOR NIGHT SCHEDULE

- 12:30 - 1:00 pm      Registration for Technical Session Attendees
- 1:00 - 4:30 pm      Facility of the Year Presentations and FDA Presentation
- 1:00 - 1:30 pm      MannKind Corp, winner of the Facility of the Year Award for both Equipment Innovation and Process Innovation for its Technospere Insulin Manufacturing Facility in Connecticut  
"Changing the Face of Bulk Lyophilization"  
Joseph A. Masi, Sr Director, Manufacturing, MannKind Corp
- 1:30 - 2:15 pm      Genentech, winner of the Facility of the Year Award for Project Execution for its ECP-1 Bacterial Manufacturing Facility, Tuas, Singapore  
"Innovative Project Execution Outpaces Ambitious Schedule"  
Kelly Keen, Sr. Project Manager, Genentech, Inc.
- 2:15 - 2:30 pm      Break
- 2:30 - 3:15 pm      Biogen Idec, Winner of the Facility of the Year Award for Operational Excellence for its Large-Scale Manufacturing (LSM) Technology Map Project in ResearchTriangle Park, NC  
"Realizing the Value of Renovation"  
M. Dean Mattice, PE, Biogen Idec  
Gerald Cerulli, Integrated Project Services
- 3:15 - 3:30 pm      Panel Discussion with Speakers
- 3:30 - 4:30 pm      Current FDA Enforcement Trends and Recalls  
Dr. Raymond Brullo, Compliance Officer  
U.S. Food & Drug Administration, Los Angeles District
- 2:00 - 4:00 pm      Exhibitor Display Set-Up
- 4:30 - 8:00 pm      Exhibit Show Open  
Free to All Attendees
- 5:30 - 7:30 pm      Reception-Appetizers & Door Prizes

**FREE TO WALK THE  
SHOW  
4:30-8pm  
949-387-9046  
www.ispe.org/greaterla  
FREE PARKING  
WITH ISPE VALIDATION  
FREE FOOD  
LOTS OF DOOR PRIZES**

# 2010 Facility of the Year Award Write Ups and Speaker Bios

## MannKind Corporation

### Facility of the Year Award Winner for Equipment Innovation and Process Innovation

FOYA 2010 Process Innovation LogoMannKind Corporation's signature rapid-acting insulin therapy, and the Technosphere® particle that delivers it, were so revolutionary that the company needed to build its own facility to produce them. The \$163 million, 23,400-sq.-m. facility included the first-ever solid-dosage pharmaceutical adaptation of a cryopelletizer; MannKind worked with their vendor to modify the cryopelletizer to create uniform pellets from the Technosphere Insulin slurry so that the water could be removed quickly and consistently during the bulk lyophilization process. This revolutionary adaptation dramatically improved the quality of the drug and the efficiency of its production.

FOYA 2010 Equipment Innovation LogoThis winning facility also houses an innovative, custom manufacturing process line that was engineered by MannKind from start to finish. It begins with the creation of the Technosphere particle itself in a specialty reactor. The particle is combined with insulin, flash frozen into pellets, and then freeze-dried to isolate the powder. Once dried, the powder is transported to the fillers, and then filled into capsules and packaged for distribution. At every point in this process, MannKind designed new technology or applied innovative adaptations to existing technology to meet their needs.

## Genentech

### Facility of the Year Award Winner for Project Execution

FOYA 2010 Project Execution LogoGenentech established a highly ambitious schedule to take their project from engineering kick-off through initiation of GMP qualification batches in 24 months. As with any project of this size and complexity, the Genentech team encountered numerous challenges, including the fact that Singapore was uncharted territory for the company, with unfamiliar codes, regulations, and practices. In addition, the Asian island city-state was experiencing a highly active construction environment that reduced availability of building materials and skilled labor resources. However, the team overcame each of these challenges using outstanding project execution techniques, dedication, and innovation to deliver a fully integrated, high-quality facility in record time.

## Biogen Idec

### Facility of the Year Award Winner for Operational Excellence

The over arching mission of Biogen Idec's Technology Map program was to enhance its world-class bulk biologics production facility in Research Triangle Park, North Carolina to support long-term corporate initiatives. Since the late 1990s, when the present Large-Scale Manufacturing (LSM) facility was designed and constructed, significant investments have been made in the bio-pharmaceutical drug and process development. These investments have yielded improvements in media, process, and cell-lines. Ultimately these improvements have significantly increased product yields. The increase in titers and improved expression yields create pressure on downstream processing.

FOYA 2010 Operational Excellence LogoThe Building 22 (LSM) Technology Map Project was aimed at upgrading the infrastructure and eliminating this traditional process bottleneck. The team successfully implemented and achieved this strategic upgrade utilizing exceptional upfront project planning, project management, integrated, lean design and construction techniques and rolling plant shutdowns at a scale that few, if any, have attempted to tackle at one time. The finished facility provides a 300% increase in yield over its previous production output, effectively avoiding investment in new facilities at a substantial cost.

## Speaker Bios

### Dr. Raymond W. Brullo, D.P.M., F.A.P.W.C.A., Compliance Officer, Office of Regulatory Affairs (ORA), Los Angeles District Office, U.S. Food and Drug Administration

Dr. Raymond Brullo is currently a compliance officer at the FDA's Los Angeles District office in Irvine, CA. Prior to this position he served as a FDA investigator for biologics, bioresearch monitoring and medical devices. He has been with the agency for eight years.

He received his BS in Biology, Pre-Med at Loyola University of Chicago. He received his Doctor of Podiatric Medicine (DPM) from Rosalind Franklin University of Medicine and Science, the Dr. William M. School College of Podiatric Medicine.

His internship was on foot and ankle surgery at Marshalltown Medical & Surgical Center in Marshalltown, Iowa. Prior to joining the FDA he was in private practice in Podiatric Medicine and Surgery in Chicago & Park Ridge, IL. He is a certified Diplomate, American Board of Podiatric Orthopedics and a Fellow, American Professional Wound Care Association.

### Kelly Keen, Senior Project Manager, Genentech, Inc.

Kelly Keen is a Senior Project Manager in the Corporate Engineering at Genentech, Inc. In May 2007, she began work on Genentech's first Greenfield site in Singapore for the ECP1 Lucentis manufacturing plant. The process modules for this project were constructed in the United States and were shipped through the Suez Canal to Singapore to integrate into the 7,500 m<sup>2</sup>/ 80,000sf, US\$200M facility.

She received a Masters Degree of Architecture from the University of Illinois in Champaign, attended L'ecole d'Architecture et d'Urbanisme in Versailles, France and completed an MBA in International Business in December 2009.

She serves on the International Society of Pharmaceutical Engineering (ISPE) Board of Directors in San Francisco and was a member of the Executive Board in Singapore as the Vice President and Student advisor. She also chairs a class in Bio-Engineering at the University of California at Berkeley.

### Gerald J. Cerulli, P.E., Process Engineer, Integrate Project Services, IPS

Jerry has 29 years of experience with batch and continuous process engineering. Considered an expert in best practices for the containment of potent compounds CIP, Jerry also has extensive experience with batch hydrogenation facilities. He also has extensive knowledge of contamination control strategies (Airflow and Barrier technology) and CIP approaches for bulk chemical production. Jerry is a welcomed speaker and presenter at many association and industry meetings and conferences. Additionally, Jerry has written and co-authored articles, technical papers and book chapters in peer reviewed industry journal and publications. He holds a BS in Chemical Engineering from Georgia Institute of Technology and a BA in Chemistry from Franklin and Marshall College.



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**THURSDAY  
SEPTEMBER 23, 2010**

ON THE HISTORICAL SHIP, THE QUEEN MARY IN LONG BEACH

**REGISTRATION FORM**

Please use the Chapter's on-line payment site to register and pay for the event:

[http://event-confirmation.com/ispela\\_meetings.htm](http://event-confirmation.com/ispela_meetings.htm)

Or you can fax your registration to 949-266-8461 or 949-387-9047.

If possible, please pre-pay with your credit card or make check payable to: ISPE Greater Los Angeles Chapter, 5319 University Dr., Suite 641, Irvine, CA 92612 and mail by September 13 to ensure it is received in time.

For questions email: [ksyre@cox.net](mailto:ksyre@cox.net). **Receipts for payment and name badges will be given at the on-site registration desk.**

**EXHIBIT TABLES**

\$610 Per Table *Includes Electricity*

**VISIT EXHIBIT SHOW**

Free to Attend

**Facility of the Year & FDA Presentations**

\$75 ISPE Members

\$125 Non Members

First Name: \_\_\_\_\_

Last Name: \_\_\_\_\_

Company: \_\_\_\_\_

Title: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_ Zip: \_\_\_\_\_

E-Mail: \_\_\_\_\_

Tel: \_\_\_\_\_

Fax: \_\_\_\_\_

Exhibitors: Please List Your Company Coordinator. We will copy your coordinator with the email confirmation package (table diagram/shipping and set-up instructions).

NAME: \_\_\_\_\_

COORDINATOR EMAIL: \_\_\_\_\_

**Note: All exhibit tables are 6' long by 2.5' wide. Maximum Height: 60"/Maximum Width: 72". Everything must fit on your table top (not on the floor or wall). One table per exhibitor.**

**CREDIT CARD INFORMATION**

Type of Credit Card



Circle One

Name on Card: \_\_\_\_\_

Credit Card #: \_\_\_\_\_

Exp Date: \_\_\_\_\_

Signature: \_\_\_\_\_