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**2010 Facility of the Year Awards (FOYA) Winners Announced**

**(TAMPA, FLORIDA, USA, 11 JANUARY 2010)** – Five pharmaceutical manufacturing facilities constructed in Singapore, Ireland, and the USA have been selected as Category Winners in the sixth annual Facility of the Year Awards (FOYA) program sponsored by ISPE, INTERPHEX, and *Pharmaceutical Processing* magazine. The winning companies and respective award categories are:

- **Biogen Idec**, winner of the Facility of the Year Award for Operational Excellence for its facility in Research Triangle Park, North Carolina, USA
- **Genentech**, winner of the Facility of the Year Award for Project Execution for its facility in Tuas, Singapore
- **MannKind Corporation**, winner of the Facility of the Year Award for both Equipment Innovation and Process Innovation for its facility in Connecticut, USA
- **Pfizer Biotechnology Ireland**, winner of the Facility of the Year Award for Sustainability for its facility in County Cork, Ireland
- **Pfizer Ireland Pharmaceuticals**, winner of the Facility of the Year Award for Facility Integration for its facility in Dublin, Ireland

The Facility of the Year Awards program recognizes state-of-the-art pharmaceutical manufacturing projects that utilize new and innovative technologies to enhance the delivery of a quality project, as well as reduce the cost of producing high-quality medicines. Now in its fifth year, the awards program effectively spotlights the accomplishments, shared commitment, and dedication of individuals in companies worldwide to innovate and advance pharmaceutical manufacturing technology for the benefit of all global consumers.

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The Facility of the Year Awards program is truly global, as submissions over the past six years have been received from more than 25 different countries and territories. Each of the submissions was reviewed by an independent, blue-ribbon judging panel of global representatives from the pharmaceutical design, construction, and manufacturing sectors.

**Facility of the Year Award Winner for Operational Excellence: *Biogen Idec***

The over-arching mission of Biogen Idec's global Technology Map Program was to upgrade the infrastructure of the company's bulk biologics production facilities and reduce challenges associated with downstream processing bottlenecks. The program involved analyzing the assets in its facilities, evaluating new technologies, preparing for newly developed processes, incorporating sustainability methods, and balancing current commercial operations with future strategic capabilities to support the company's growing product pipeline.

Upon conclusion of the Large Scale Manufacturing (LSM) Technology Map project at the company's world-class Research Triangle Park, North Carolina, USA site, Biogen Idec completed the largest renovation of a licensed manufacturing facility in the company's 30-year history. The upgraded facility provides a 300% increase in yield over its previous production output by incorporating new technologies and de-bottlenecking operations at an existing site at a fraction of the cost of building new facilities. The resulting higher throughput comes, in part, from facility and equipment improvements that achieve faster and more streamlined technology transfers and process changeovers within the multi-product facility. It further provides more flexibility to take advantage of increasing external collaborations and acquisitions.

The project team — including IPS, Yonkers and CAI — successfully implemented and achieved this strategic upgrade utilizing exceptional up-front project planning; project management; integrated, lean design and construction techniques; and rolling plant shut-downs at a scale that few, if any, have attempted to execute at one time.

**Facility of the Year Award Winner for Project Execution: *Genentech***

Genentech's bacterial manufacturing facility was built in Tuas, Singapore to increase the production capacity of Lucentis<sup>®</sup> (ranibizumab injection), which is used to treat patients with wet age-related macular degeneration. Genentech established a highly ambitious schedule that would be the defining challenge: to take a project from engineering kick-off through initiation of GMP qualification batches in 24 months. The facility was initially developed by Genentech, a wholly owned member of the Roche Group, and is now operating as Roche Singapore Technical Operations.

Meeting an ultra-fast-track schedule on an international project required a collaborative team to develop and execute an innovative strategy. With its contractors Jacobs Engineering Group and Bovis Lend Lease Pharmaceutical, Genentech developed a strategy utilizing large-bay modules integrated with traditional stick build construction. The team also developed a parallel work strategy that enabled a 90% overlap of design and construction efforts — as well as the most aggressive qualification and validation schedule ever attempted by Genentech for a facility of this scale and type — leading to significant overall schedule savings. With design activity taking place in four locations spanning 12 time zones, the Genentech team selected "typical" design tools and procedures to eliminate learning curves, and their online, real-time data model allowed immediate design review and comment. This online process proved so effective that planned on-site reviews were greatly reduced, saving travel costs and time, as well as the lag between design and design approval.

As with any project of this size and complexity, the Genentech team encountered numerous challenges but overcame each through outstanding project execution techniques. The team's planning, dedication, and innovation enabled delivery of a fully integrated, high-quality facility in record time.

**Facility of the Year Award Winner for Equipment Innovation and Process Innovation:  
*MannKind Corporation***

MannKind Corporation's signature drug, an ultra rapid-acting insulin therapy, was developed to offer the millions of people suffering from diabetes a non-invasive treatment option. At the heart of the drug lies MannKind's proprietary Technosphere<sup>®</sup> molecule that can deliver not only insulin, but also a wide variety of other macromolecules into systemic circulation through the pulmonary route. The Technosphere particle and Technosphere<sup>®</sup> Insulin (TI) were so revolutionary and specialized that no existing facility in the world was capable of producing them. For this reason, the company designed and built its own production facility.

While the facility itself is a striking merger of form, function, and efficiency, it is the custom process line it houses that impressed the judging panel and inspired them to also award this project the Facility of the Year Award for Process Innovation. MannKind engineered an innovative manufacturing process line from start to finish. It begins with the creation of the Technosphere particle itself. The particle is then combined with insulin in a specialty mixer, and the resultant slurry is 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.

Begun in early 2007 and completed in mid-2008, another distinguishing feature of MannKind's \$163 million, 23,400 square meter facility is a first-ever solid-dosage pharmaceutical adaptation of a cryopelletizer, for which the judges awarded the Facility of the Year for Equipment Innovation. MannKind worked with Cryogenic Equipment Services to modify the cryopelletizer to create uniform pellets from the slurry so that the water could be removed quickly and consistently during the bulk lyophilisation process. This revolutionary adaptation dramatically improved the quality of the drug and the efficiency of its production. In addition to the new lyophilization technique, MannKind also made unique adaptations to the specialty mixer where the TI particle and the insulin are combined; designed a highly cost-effective method to move bulk powder from the lyophilizer to the filler; and designed a filling system that could work at high speed while remaining safe for the operators and supremely precise in the metering of the bulk powder. All test batches and full-scale development batches of TI were produced successfully in the new facility.

**Facility of the Year Award Winner for Sustainability: *Pfizer Biotechnology Ireland***

Pfizer Biotechnology's Ireland's Monoclonal Antibodies Small-scale Facility was built using industry best practices for sustainability and Pfizer's green building guidelines that included the extensive re-use of existing assets, waste minimization procedures, recycling utilization in both construction and operations, the inclusion of energy-efficient fixtures and equipment, and minimized air change rates to meet comfort conditions and classification standards.

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This Phase 2B/3 clinical trial product facility is Pfizer's first biotechnology greenfield development and the site was chosen for a variety of reasons, including its proximity to the adjacent Pfizer Ringaskiddy site which allowed the new facility to use spare capacity of the existing wastewater treatment plant and fire main system rather than building a new treatment plant or bringing in new tanks and pumps for fire water retention. Other outstanding sustainability elements of this project included the re-use of 5,000 cube meters of crushed rubble from an old adjacent facility for the new facility substructure and 30,000 cubic meters of excavated material for general site fill and landscaping; the use of an eco-seal, grey, insulated roof membrane to reduce the heat island effect; and site orientation to optimize solar gain.

The project was executed with an excellent safety record and delivered on target according to a very aggressive timeline of 29 months, 35% better than the biotechnology industry benchmark average.

#### **Facility of the Year Award Winner for Facility Integration: *Pfizer Ireland Pharmaceuticals***

Pfizer Ireland Pharmaceuticals' Aseptic Expansion project is notable for the way in which its new facility successfully integrates a new production module, warehouse, central utilities building, and personnel support facility within the surrounding community and the operations of Pfizer's existing Dun Laoghaire site with no impact to manufacturing output. The final site was selected with consideration to manufacturing adjacency and synergy with the existing Pfizer facility. To break down the visual scale and optimize manufacturing function, the overall manufacturing program was divided into five distinct buildings, each with smaller massing and impacts, but linked to a coherent site manufacturing pattern.

To respond to community and environmental issues associated with building a manufacturing facility so close to neighboring residential properties, the project team used a series of site analyses and options diagrams to optimize the current and future use of the very tight suburban site. The proposed design was specifically tailored to respond to its context and to ensure that the rising topography screened the new building, thus minimizing any impact to the neighboring residences. The bermed and landscaped enclosure of the site also significantly reduces and removes any residual noise or night lights from the site. The project team also took the opportunity to integrate a new, safer entrance for improved fire truck access to the entire Pfizer complex. These measures, coupled with the extensive consultation with local residents groups, resulted in an aesthetically pleasing facility that is carefully integrated with existing manufacturing operations and the surrounding suburban landscape.

#### **2010 Facility of the Year Events**

There will be several opportunities to meet the 2009 Facility of the Year Award Winners and learn first-hand about the facilities being honored as "best in their class." These events include:

- **INTERPHEX2010** – Meet the Category Award Winners at the Facility of the Year Awards Display Area at booth number 1059 in the exhibit hall of the Jacob K. Javits Convention Center. This is your opportunity to meet personally with representatives from companies of the Category Winners to discuss the success stories associated with these pharmaceutical manufacturing facilities. To register, or for more information, visit [www.interphex.com](http://www.interphex.com).
- **ISPE 2010 Annual Meeting** – Learn first-hand who the Overall Winner of the coveted 2010 Facility of the Year Award is during ISPE's 2010 Annual Meeting, 7-10 November in Orlando, Florida, USA. For more information, visit [www.ISPE.org](http://www.ISPE.org).

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At each event, a Facility of the Year Awards display will feature the 2010 Category Award Winners. Additionally, comprehensive coverage and publicity will be conducted by ISPE and *Pharmaceutical Engineering* magazine, INTERPHEX, and *Pharmaceutical Processing* magazine.

Visit [www.facilityoftheyear.org](http://www.facilityoftheyear.org) for more information about the awards program and detailed information about each Category Winner's project participants.

#### **About ISPE**

ISPE, the International Society for Pharmaceutical Engineering, is the Society of choice for 24,000 technical professionals working in or serving the manufacturing sector or drug development in the pharmaceutical industry in 90 countries. ISPE aims to be the catalyst for "Engineering Pharmaceutical Innovation" by providing Members with opportunities to develop their technical [knowledge](#), exchange practical experience within their [community](#), enhance their [professional](#) skills, and collaborate with global regulatory agencies and industry leaders. Founded in 1980, ISPE offers online learning opportunities for a global audience and has its worldwide headquarters in Tampa, Florida, USA; its European office in Brussels, Belgium; an Asia Pacific office in Singapore; and its newest office in Shanghai, China. Visit [www.ISPE.org](http://www.ISPE.org) for additional Society news and information.

#### **About INTERPHEX**

Now in its 31<sup>st</sup> year, INTERPHEX is the world's most trusted source for leading-edge technology, education, and sourcing of the products and services that drive scientific innovation for Life Sciences manufacturing from drug development to market – accelerating regulated products for patient care globally. Scheduled for 20-22 April at the Jacob K. Javits Convention Center in New York City, New York, USA, the 2010 exhibition will feature more than 950 exhibitors, an expanded conference program, and a high-profile roster of industry professionals and speakers. For information, visit [www.interphex.com](http://www.interphex.com).

#### **About *Pharmaceutical Processing***

*Pharmaceutical Processing* magazine is the pharmaceutical industry's leading information provider, reporting on a full range of innovative new products, equipment, technology and trends for 31,000 engineers and managers responsible for the development, manufacture, validation and packaging of pharmaceuticals. An official sponsor of INTERPHEX, *Pharmaceutical Processing* distributes critical information to these professionals in a timely manner through a full range of print, electronic and online media. For information, visit [www.pharmpro.com](http://www.pharmpro.com).

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