Genentech plant named 2007 ISPE facility of the year

Author: Industrial Info Resources

Unlike the flashy unreality of the casino halls and the lure of an easy win, it took a rigorous year of evaluation by a panel of judges before the International Society of Pharmaceutical Engineers (ISPE) issued its prestigious 2007 Facility of the Year Award to Genentech for its Oceanside, Calif., NIMO facility.

The award was a major highlight of the annual ISPE meeting held in Las Vegas November 3-7.

For 2007, the award process for excellence in pharmaceutical manufacturing technology, design and construction was a two-phase event. This year, five winners in individual categories were named at the Interphex annual pharmaceutical conference in New York. Underscoring the global nature of the industry, this year's individual category winners were from the United States, China, Japan and Germany.

Genentech purchased the biologics manufacturing plant in 2005 from Biogen Idec for $450 million. Dubbed NIMO (New Idec Manufacturing Operation) the six-building 500,000-square-foot plant was originally planned to produce Biogen-Idec's Tysabri, a multiple sclerosis drug that was abruptly pulled from the market after being linked to a potentially fatal brain infection. Genentech was quick to recognize the value of the impressive facility, which was constructed using an innovative Design-Build Hybrid approach that employed an integrated project team with 19 major participants.

With the recent U.S. Food and Drug Administration (FDA) licensing approval in April 2007 for the Oceanside facility, Genentech added 90,000 liters of capacity that will be initially dedicated to producing Avastin, a therapeutic antibody for the treatment.

Located on a 60-acre site, more than half of the NIMO facility is dedicated to manufacturing. The project added a fermentation and purification production facility (NIMO manufacturing building 1), a combination three-story QC lab and administration building, a GMP warehouse including a central weighing/dispense area (warehouse building), a central utilities building with a connecting corridor and utilities services...
running to all the buildings on campus (CUB-spine building) and an operations building with office, shop and service facilities. Nearly 600 people are employed at the site.

The closely knit Design-Build Hybrid team for NIMO consisted of the owner, engineering company, architect and general contractor. The initial project members of Ferguson Pape Baldwin Architects (San Diego, Calif.) and general contractor DPR Construction (San Diego) together selected Clark, Richardson & Biskup Consulting Engineers (Carlsbad, Calif.) to oversee all engineering performed by the design-build subcontractors in the mechanical, electrical, process and I&C engineering disciplines. The group worked closely together throughout the life of the project, instituting an innovative approach whereas the civil, architectural, and structural work were executed design-bid-build and mechanical, electrical, process, and instrumentation and controls (I&C) were completed design-build under the management of the general contractor. As a result of utilizing this type of project execution, the $400 million first phase project was delivered on time and under budget.

Four other contenders in this year's facility-of-the-year competition were recognized for their individual areas of excellence. Those outstanding companies and project teams are as follows:

**Cook Pharmica LLC**, in Bloomington, Ind., was selected as winner of the Facility of the Year Award for Facility Integration.

**Engineering Design Firm**: CRB Consulting Engineers Inc., St. Louis, Mo.

**Construction Manager**: R.L. Turner Corporation, Zionsville, Ind.

**Manufacturing Facility Design/Build**: AES Clean Technology Incorporated, Montgomeryville, Pa.

**Shanghai Roche Pharmaceuticals Limited** in Shanghai, China, won for Project Execution Regional Excellence.

**Project Management and Start-up**: Shanghai Roche Pharmaceuticals Limited

**Architect and Construction Manager**: Meissnert & Wurst Zander (Shanghai) Limited

**Taiyo Pharmaceutical Industry Company Limited**, located in Takayama City, Japan, selected as winner of the Facility of the Year Award for Equipment Innovation.

**Designer - Production Facilities**: Horiuchi Architectural Associates

**Designer - Production Equipment**: Taiyo Pharmaceutical Industry Company Limited

**Construction Management**: Kashima Construction K.K.

**Vetter Pharma-Fertigung GmbH & Co. KG**, in Ravensburg, Germany, won for Process Innovation.

**Architect**: Vetter Planning Team, Ravensburg, Germany

**Technical Building Management**: Axima GmbH, Cologne, Germany

**Structural planning**: Schneider & Partner Planungsgesellschaft mbH, Ravensburg, Germany

Judging this year's competition was a completely volunteer, independent panel of global representatives from the pharmaceutical design, construction and manufacturing sectors. Challenged by having to choose from such a diverse field of outstanding facilities, the judges must adhere to the detailed submission criteria in order to distinguish those sites that are truly outstanding and worthy of being selected as a category winner and ultimately, overall Facility of the Year Award winner. This year's judges included:

**Andy Skibo**
Judging Panel Chair
Vice President, Corporate Engineering and Capital Production, Amgen

**Nigel Barnes**
Vice President, Global Project Management, GlaxoSmithKline

**Chaz Calitri**
Senior Director/Team Leader, Pfizer Global Engineering

**Christian Ilsoe**
Vice President, Quality & Validation Assurance, NNE A/S

**Brian H. Lange, P.E.**
Director, Sterile & Packaging Operations Engineering, Merck

**Thomas G. Lyon**