



BMS' Clinical Supplies Manufacturing and Drug Product Technology Expansion Project Selected as Category Winner in Equipment Innovation for 2008 Facility of the Year Award

-Selected from a group of 19 state-of-the-art projects constructed in 6 different countries-

The Facility of the Year Awards (FOYA) competition 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. Sponsored by ISPE, INTERPHEX and *Pharmaceutical Processing*, 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 global consumers. Each submission was reviewed by an independent, blue-ribbon judging panel of global representatives from the pharmaceutical design, construction and manufacturing sectors.

On behalf of Bristol-Myers Squibb (BMS), IPS submitted the Clinical Supplies Operations (CSO) Expansion and Drug Product Technology Center (DPTC) facilities as a worthy candidate for the Equipment Innovation Category of the 2008 Facility of the Year Award. The Equipment Innovation category recognizes novel application of commercially available and custom developed process manufacturing and facility management tools, which yield superior results, advanced processing understanding and improved competitive position. In addition, the project must demonstrate imaginative collaboration with vendors, suppliers and manufacturers.

Project Description

The expansion of Building 115 brought early and late phase cGMP clinical manufacturing and development scale-up areas together within a single facility to create a Pharmaceutical Development Center of Excellence on the New Brunswick, NJ campus. Construction of the project was phased to allow full implementation of lessons learned as containment and process automation technology was integrated into existing operations. The finished facility is a full service clinical manufacturing area with the capability to scale-up and deliver a variety of oral solid and liquid dosage forms, including sterile products, regardless of product potency or the use of solvents in the manufacturing process.

Project Highlights

- State-of-the-art Oral Solid Dosage (OSD) manufacturing operations including classified Band 1-4 potent and cyto-toxic compounds
- Flexible clinical-scale barrier line for sterile and liquid manufacturing including classified Band 1-5 potent compounds and solvent operations
- First GMP Operational Clinical Sterile Continuous Process Isolation Facility in the United States
- Innovative Integration of Overall Manufacturing Strategy with Scalable Design for Sterile and Oral Solid Dosage Products
- Incorporates Innovative Technologies into Existing Facility for Solvent-Based and Potent Compounds to Promote Safety, Quality and Compliance
- Wireless Technology and Electronic Batch Records Allow Development Data to be Automatically Gathered During GMP Manufacture
- Increased GMP Development Capabilities Allow Quality by Design Throughout the Clinical Program
- Increases Overall Capacity and Productivity for the Pipeline
- Minimal Site and Environmental Disruption
- Simultaneous Multi-Product Processing
- Technology Lessons Learned could be Implemented for the Later Phase Development and Transfer
- Facilitates Technology Transfer to Commercial Sites
- Accommodates New FDA Vision for Quality by Design (QbD) and Process Analytical Technology (PAT)
- Cutting Edge, Wireless Delta V Data Gathering

