

FDA approval for Daiichi Sankyo packaging facility

26 June 2012 | Regulatory | By BioSpectrum Bureau

FDA approval for Daiichi Sankyo packaging facility



Singapore: Daiichi Sankyo has received US Food and Drug Administration (FDA) approval to package products at its first US-based packaging facility in Bethlehem, PA. With this approval, the company expands its global supply chain capability, helping to ensure the supply of medicine to US physicians and their patients.

The 140,000 square foot facility will package some of the company's portfolio of marketed products for cardiovascular and metabolic therapies, including treatments for hypertension and heart disease, diabetes and hyperlipidemia. Looking ahead, the facility could assume additional responsibilities related to clinical trial materials and perform formulation and analytical testing for select products.

"From facility and process design to quality control and personnel flow, we incorporated leading-edge technology in the design and development of the Bethlehem facility," said Jeff Lane, vice president, operations, Daiichi Sankyo. "The commissioning of this facility is a major milestone for our U.S. organization and augments our ability to manufacture and distribute quality medicines."

The plant currently employs approximately 39 full-time employees and will continue to add employees until realizing its full operational goals. Responsibilities range from Line Operators and Material Handlers to Project Engineers and Quality Specialists. Daiichi Sankyo worked with a number of regional and local business leaders and organizations, including the Governor's Action Team, Lehigh Valley Economic Development Corporation, Northampton County and City of Bethlehem to make this milestone possible.

Mr Lane added that by expanding the company's business operations to include manufacturing in the US, the company is helping to minimize risks associated with product supply, and is able to gain greater control over the life cycle of its products, from research and development through packaging and distribution.