

An Eastern Experience – Japan Affiliate on Tour in the US

by Osamu Matsumoto and Michael Lucey

A valuable and well regarded service provided by the Japan Affiliate to its membership is the US Pharmaceutical Plant Tour, an event organized on an annual basis. The Tour is invariably combined with (mandated!) participation in ISPE's Annual Meeting, which in 2010 was held in Orlando, Florida. With this in mind, the Plant Tour Organizing Committee focused on pharmaceutical plants located in the general vicinity of the US East Coast.

The Committee, comprising Messrs O. Matsumoto, S. Nakamura, and M. Akutagawa, who serve on the Affiliate's Board, together with Japan-based members Mason Waterbury and Michael Lucey who took the lead in coordinating with candidate plants, allowed itself a lead-time of six months, recognizing that ample time is required for approaches and formalities to proceed and for acceptance of the visits to be obtained.

Ultimately, the 20-member Tour party, comprised of 15 industry representatives and the five planning members, visited six pharmaceutical plants during the five days from 1 to 5 November. Details of the plant tour were compiled into a report and developed real time while on the road by the industry representatives. Reporting was later made at the Affiliate's Winter Meeting in December, in Yokohama, Japan, partly to encourage future generations of US Plant Tour participants.

Pfizer

At Pfizer's core bio-plant located in Andover in the suburbs of Boston, Massachusetts, the Tour had an opportunity to closely observe the bioreactor line. Through the helpfulness of an interpreted pre-meeting after lunch, Pfizer described its aims of cost reductions by manufacturing standardization and acceleration of product development.

MannKind Corporation

As a biopharmaceutical company located in Danbury, Connecticut, whose business ranges from drug design and development to commercial production, MannKind was a double winner of the 2010 Facility of the Year Award for both Process Innovation and Equipment Innovation. Using the company's proprietary Technosphere technology, MannKind has developed an inhalant called Afrezza. Following an explanation of the Afrezza production process, the group was shown the manufacturing line. It was noted with interest that QbD and PAT had been adopted for production management.

Johnson and Johnson

Johnson and Johnson's Sterile Process Technology Center is located in Raritan, New Jersey. As a technology hub for the Johnson and Johnson Group, the Center provides guidance on optimal sterilization methods, studies sterilization methods for new medical equipment, and provides sterilization training



Plant tour group at Johnson & Johnson's Sterile Processing Technology Center.

and related seminars. The facility is a "one-stop sterilization center" with a full range of sterilization equipment.

Merck

Located in West Point, New Jersey, Merck's facility is the largest-scale pharmaceutical plant in North America. The group was shown the vaccine production line where Merck clarified that its process is characterized by the production of safe vaccines, applying ultra-filtration technology. Additionally, the opportunity was provided to observe the utilities which support the production system.

Biogen Idec

Located in Research Triangle Park, North Carolina, the bio-product production plant is the winner of 2010 Facility of the Year Award for Operational Excellence. Having six bioreactors with a capacity of 15 m³, the plant was once the largest-scale bio-plant in the world. The group was guided right up to the bioreactors and invited to observe culture conditions directly through a viewing window.

In addition to the visits to the pharmaceutical plants, the



Plant tour group at Biogen IDEC in North Carolina.

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