

Japan Affiliate “On the Road” Again

by Shigeru Nakamura and Michael J. Lucey

This past year’s “US Pharmaceutical Plant Tour” by the Japan Affiliate included six plant visits, a networking reception and participation in the ISPE Annual Meeting in Washington, DC, the itinerary of which started on 27 October and concluded on 7 November.

Organized by Shigeru Nakamura, Affiliate Vice Chairman, and Michael Lucey, Adjunct Director, with the support of four Board Members, the traveling group totaled 22 persons: eight from pharmaceutical manufacturers, 10 from engineering companies, two from construction firms, and two from equipment fabricators. The following month, in December, the ISPE membership was informed of the Tour through a poster display at the Affiliate’s Winter Meeting.

- 27 Oct: Departed Japan/Arrived Columbus, Ohio
- 28 Oct: Visited Boehringer Ingelheim and moved to Newark late in the evening
- 29 Oct: Visited Morphotek and hosted by New Jersey Chapter in the evening
- 30 Oct: Visited Genzyme and moved to Raleigh-Durham in the evening
- 31 Oct: Visited Novartis and then Biogen Idec
- 1 Nov: Moved to Washington, visited MedImmune and dined with former FDA
- 2 Nov: Sightseeing in Washington, DC
- 3 to 6 Nov: Annual Meeting
- 7 Nov: Departed for Japan

Boehringer Ingelheim (BI)

Boehringer Ingelheim Roxane, located in a central area of Columbus, functions as an important center for BI production. The high-containment operations (HCO) plant visited on this tour has a dedicated building built on the extensive



site for the production of a large variety of products in a wide range of batch sizes.

Morphotek (2013 Facility of the Year (FOYA) Sustainability Category Winner)

Located in Exton, Pennsylvania, Morphotek, a US subsidiary of Eisai Co., Ltd., a leading Japanese pharmaceutical manufacturing company, is remarkable for its sustainability-oriented architectural design and environmental management realized at its Pilot Manufacturing Plant. The facility supports the manufacturing of advanced therapeutic candidates with either cell culture or microbial systems.



Genzyme

The Ridgefield Plant, located approximately 40 minutes’ drive from New York, began operations in 1983 and expanded its facilities in 2009. This impressive plant is a multi-product manufacturing plant, with its focus on syringe filling. As with many of the US host organizations, the Affiliate was very well cared for, with outstanding explanations and noontime hospitality.

Novartis (2013 FOYA Overall Winner)

A highlight of this plant tour was the visit to Novartis which was to be the 2013 FOYA Overall Award winner. Located in Holly Springs, North Carolina, the plant visited is a cell culture facility for influenza vaccine production, with its mission being to secure a supply of influenza vaccine for a great number of people throughout the US within six months in the event of pandemic influenza.

Biogen Idec (2013 FOYA Facility Integration Category Winner)

Located in Research Triangle Park (RTP), North Carolina, 

Biogen Idec constructed its Flexible Volume Manufacturing Facility (FVM), for the manufacture of multiple products, flexibly responding to requirements such as “smaller batch sizes,” “batch size changes,” and “shorter manufacturing periods.” The facility features a 100% single use flow path in a validated closed system, giving the impression that the US, compared with Japan, was advanced in the application of “single use” technology.

MedImmune (2011 FOYA Overall Winner)

Completed in 2010, MedImmune’s Frederick Manufacturing Center (FMC) expansion facility is the biologics arm of AstraZeneca, a large-scale mammalian cell culture-based production facility. For the minimization of human errors, an advanced and intensive education and training program based on simulation control panels ensures that operators are most effectively transitioned to the facility. It was the great pleasure of the Japan Affiliate to be received at Frederick for this return visit.

A yearly feature of the Plant Tour is a networking reception with a US Chapter nearby to a plant visited. The New Jersey Chapter made a special effort to receive the visitors from Japan. Introductions were provided of the activities of Chapter and Affiliate. Tour members spent an exceptionally pleasant time in a friendly and informative setting.

With the plant visits and mixer complete, the group relaxed while sightseeing in Washington. Spectacular autumn tints gave the impression of strolling in a city in the woods. The grave of the late President Kennedy in Arlington Cemetery was an important part of the tour and timely as upon returning to Japan it was heard that Caroline had been appointed as US Ambassador to Japan, on the 50th anniversary of President Kennedy’s assassination.

On behalf of the tour participants, deep gratitude is expressed to all concerned at the organizations which so willingly and so thoroughly accepted the plant visits, as well as to the good people of the NJ Chapter for their hospitality.

As a final remark, the Japan Affiliate also holds reunion events for its US plant tour members, for networking purposes. The joint reunion held in January 2014 was attended by the participants in six years of tours, from 2008 to 2013!