

A View to Pharma Excellence in US – Japan Affiliate on the Road Again

by Shigeru Nakamura and Michael J. Lucey

The yearly US Plant Tour by Japan Affiliate members was held 5 - 9 November 2012, combined as always with follow-up participation in the ISPE Annual Meeting. During the tour, members visited six plants in five days.

A total of 18 ISPE members traveled to the US, including Plant Tour Organizing Committee Members Shigeru Nakamura as Affiliate Officer/Head of Secretariat, Michael Lucey, Adjunct Director, and two other Committee members who also serve on the Affiliate Board, in addition to the 14 tour registrants. Effective advance support also was provided by Affiliate Executive Director Masayuki Akutagawa and Adjunct Director Mason Waterbury.

The group comprised seven visitors from pharmaceutical companies, five from engineering companies, four from construction companies, and two from equipment-related companies. The following are highlights from each plant visit.

Merck

Merck's Vaccine Bulk Manufacturing Facility (VBF) Program of Projects is the Facility of the Year Award (FOYA) Overall Winner for 2012. Located in Durham, North Carolina, the project addresses a shortage of urgently required vaccines. Planning called for design and construction within four years, adopting an innovative hybrid modular construction method. Engineering and construction work were executed in parallel, dividing into factory buildings and process modules, enabling a greatly shortened construction period. Visi-



Affiliate members and hosts at the Merck VBF Facility in Durham, North Carolina.



Affiliate members and hosts at GSK in Research Triangle Park, North Carolina.

tors saw the interstitial modules and HVAC modules for the utility facilities which support production facility operations.

GlaxoSmithKline (GSK)

The Girolami Research Center located in Research Triangle Park (RTP), North Carolina, combines laboratory and pilot plant functions and is capable of producing up to P2a class of solid medicines, injections, inhalants, vaccines, topical formulations, among others. This impressive GSK facility features seven production lines and 32 process rooms, with a production scale of 10 - 100 kg. Each production room has an independent HVAC system which allows temperature and humidity control. The center adopted QbD two years ago, with significant advances achieved.

Bristol-Myers Squibb (BMS)

The tour group was fortunate to be permitted to visit BMS's R&D Center in New Brunswick, New Jersey, despite the recent adverse impact in the area caused by Hurricane Sandy. The center had been constructed by completely renovating the original building which dated back to 1995. It consists of three facility zones with the concept of promoting technical innovation: process, laboratory, and office. The office zone is ingeniously designed so as to encourage staff communication, with the free atmosphere stimulating staff creativity.

Abbott Laboratories

The tour group visited the investigational solid medicine production facility located in Abbott Park, Illinois. Capable of handling investigational drugs whose pharmacological

...Japan Affiliate on the Road Again

Continued.

activities are in the ranges of OEL 1 - 10 µg/m³ and OEL ≤ 10 µg/m³, the plant was constructed under a design concept of human safety, facility safety, and environmental safety. A high level of ISS is achieved by prioritizing maintainability, and corridors for visitor access are laid out around the process room with careful consideration given to visibility.

CMC Biologics

Sited 45 km from the airport in Seattle, Washington, CMC Biologics is a contract manufacturer for R&D and production. The company has fully segregated microbial fermentation and mammalian cell culture suites. Disposable bags are used in the preparation of culture media and buffers. In the biological production facility, the tour group was given a close-up view and detailed explanations throughout. With its clients in Seattle already including a major Japanese manufacturer, it was learned that CMC Biologics' acquisition of facilities in Berkeley, California, would enhance services to industry.


Genentech

Genentech Vacaville facilities are located about 50 miles to the northeast of San Francisco. The major site footprint includes a total of 10 facility buildings. Production, QC, warehouse, utility, and other buildings are laid out along its spine, in axis-like formation. The three-story production facility building was built under a clear design concept featuring unidirectional flow, with discrete and automated upstream and downstream processes, as well as gravity feed. As always, a remarkable and highly informative guided tour characterized the visit.

A highlight of the tour is the yearly opportunity to enjoy a networking reception together with a local Chapter. This year's event was graciously hosted by the Pacific Northwest Chapter. As always, a brief introduction to the Affiliate's activities was given by S. Nakamura, and the food and beverages kindly provided by the Chapter made for a very pleasant evening.

Sightseeing in New York City as well as in Napa Valley, California offered relaxation and enhanced the total US experience. The NYC stay came just one week after Hurricane Sandy struck, but before the Nor'easter which brought further severe weather. Uncollected waste and long lines of cars at gas stations were visible, although a remarkable clean-up operation was under way. This all left a lasting impression on the visitors from Japan as a further reminder of the force of nature. Moreover, because of Election Day, long lines of voters appeared at polling stations.

At the Affiliate's Winter Meeting held in Osaka shortly after return, summary information on the tour was provided to ISPE Members by a poster display, further promoting the tour as a benefit for membership. The Affiliate organizes annual reunion events for its plant tour participants. This year, a joint reunion was attended by a total of 35 "alumni" from 2008, 2009, 2010, 2011, and 2012. The tour and follow-up events contribute to further expanding the networking possibilities made possible through ISPE membership.

Finally, the Japan Affiliate wishes to express its gratitude to all of the individuals at host organizations who made a very special effort and helped realize a successful 2012 tour. 

ISPE QbD Conference Endorsed by CASSS

The ISPE Conference, "The State of QbD in the BioPharmaceutical Industry: Critical Assessment, Design Space Implementation and Control," has been endorsed by CASSS, an international separation science society.

CASSS, headquartered in Emeryville, California, USA, is a not-for-profit professional society made up of more than 4,000 industry, academic, and public sector professionals who focus on separation science, including the chromatography process used to determine impurities in pharmaceuticals. A mutual interest of ISPE and CASSS is the end quality of pharmaceutical products through Quality by Design efforts.

The ISPE Conference, to be held 10-11 April in San Francisco, California, USA, will present case studies including best practices and documented opportunities and challenges resulting from the implementation of Quality by Design. The event will be global in scope and focused on how smart companies are designing and developing formulations and manufacturing processes to insure pre-designed product quality. Outcomes are intended to build an understanding on how planning and controlling the evolution of a pharmaceutical product will lead to superior quality, better use of resources and more effective business results.

For more information on the conference, visit www.ispe.org/2013qbdconference. 