

ISPE Japan Affiliate Tours US Pharmaceutical Companies

by Osamu Matsumoto and Michael Lucey, ISPE Japan Affiliate

Since its establishment in 2002, the ISPE Japan Affiliate has each year offered its members the opportunity to join a tour of pharmaceutical facilities in the US, combined with follow-up participation at the ISPE Annual Meeting. Planning for the 2008 Plant Tour was provided by Affiliate Directors/Members Shigeru Nakamura, Osamu Matsumoto, Masayuki Akutagawa, and Michael Lucey.

In addition to overseas plant visits, the Tour brings the benefit of broad exposure to ISPE. The 2008 version included a Facility of the Year Award (FOYA) Category Winner, while attendance at the Annual Meeting brought participants into contact with diverse areas of the Society's activities. The expectation is for future broad interaction between Japanese and international COPs, as well as a further level of participation in future ISPE-organized meetings through attendance at educational sessions and presentations.

A total of 13 applicants from Japan signed up for the 2008 Plant Tour/Annual Meeting in Boca Raton, Florida. The mission was made up of three representatives from pharmaceutical manufacturers in Japan, four from engineering companies, three from construction companies, and three from equipment suppliers. The overall itinerary was as follows:

October

- 21 Depart for United States
- 22 Lonza Biologics (Hopkinton, Massachusetts) and Abbott Laboratories (Worcester, Massachusetts)
- 23 Bristol-Myers Squibb (New Brunswick, New Jersey)
- 24 Schering-Plough (Kenilworth, New Jersey) and Cephalon (Frazer, Pennsylvania)
- 25-29 Attend Annual Meeting (Boca Raton, Florida)
- 30 Paul Mueller Company (Springfield, Missouri, as optional tour)

November

- 1 Return to Japan

For the Japanese, the period in the US prior to Boca Raton proved to be an invaluable preparation for the Annual Meeting itself; for some, this was even a time to work at overcoming language and cultural challenges. Moreover, the several days together permitted valuable bonding, as well as information exchanges, between Tour members.

The Tour was coordinated around visits to diverse pharmaceutical facilities: an existing biopharmaceutical development facility and a soon-to-be-completed leading-edge bio plant; new as well as renovated facilities for bio-based investigational drugs through to early phase of production; a mega-sized manufacturing plant and its automated warehouse; and a pilot plant for (small molecule) chemical-based drugs synthesis.

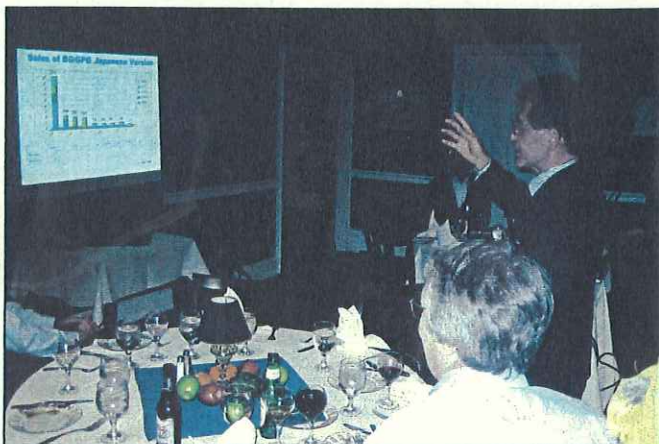


Neil Martin of BMS welcomes the plant visitors.

Additionally, Tour participants saw for themselves actual operation of the full-containment facilities, which had contributed to Bristol-Myers Squibb being selected as a Category Winner of 2008 FOYA.

After each plant visit, an internal meeting of Tour members was held in the evening of the same day; general information from observations made and explanations given by plant owners were compiled into a summary report completed while in the US. It was understood throughout that no inside photography of plants visited was permitted and proprietary information had to be respected.

A range of benefits were gained from the Tour. These included a further enhanced recognition of the progress made by pharmaceutical manufacturers and equipment makers in containment, the track record pointing to a mature industry; a better understanding of the development status of biophar-

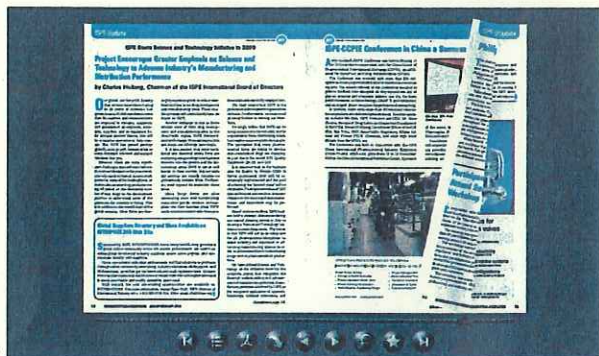


Japan Affiliate gives an overview presentation at welcome party hosted by the ISPE Delaware Valley Chapter.

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Pharmaceutical Engineering Launches Digital Edition

ISPE is pleased to introduce a new ISPE Member benefit: the digital edition of *Pharmaceutical Engineering* magazine. The inaugural digital issue (January/February 2009) was delivered to the global membership in a browser-based electronic format. In addition to the digital edition, Members will continue to receive the print version.



The digital edition is a flexible electronic version of the magazine that delivers the look and feel of the print edition. It contains all of the content found in the print edition and is easily accessible via the Internet. In addition, the digital edition of *Pharmaceutical Engineering* contains hotlinks to URLs and email addresses that are referenced within articles and advertising so members will gain instant access to additional information and necessary resources.

Members will get all of the features of the *Pharmaceutical Engineering* magazine print edition with the interactive capabilities only available online. Added benefits of the digital edition of *Pharmaceutical Engineering* include:

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...Japan Affiliate Mission

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maceutical drugs in the industry; and an improved grasp of the extent to which plant owners challenge new technologies in the quest for excellence.

A highlight of the US experience was the Delaware Valley Chapter-hosted "Welcome Party" on 24 October 2008, organized by Chapter Secretary Shannah Schodde, an ideal social environment where lively exchanges of information took place in a dignified, but relaxed setting.

Conversations during the Chapter evening extended from the professional through to the cultural: visitors from Japan learned World Series baseball chants to support the local Phillies, and US hosts were taught the traditional Japanese synchronized hand-clap close-out of an event, the so-called "san-bon-jime!"

Certainly, a very special relationship was created between US hosts and Japanese guests, and between Chapter/Affiliate.



Members of the Japan Affiliate and ISPE Delaware Valley Chapter end a memorable evening.

Logistics for the entire trip from Japan were provided by an experienced travel agent with chartered buses at US airports for transfers to hotel and plant. A merit of this arrangement was, for example, the ability to quickly move the visitors from Newark hotel to Manhattan for an evening of sightseeing and dining, a much appreciated interlude after a demanding international and domestic travel schedule!

After returning to Japan, Tour Leader Osamu Matsumoto – the self-styled "Cheerleader" – delivered a summary presentation of the Tour at the Affiliate's Winter Meeting in Yokohama, on 5 December 2008.

Meanwhile, planning is already under way for the Affiliate's 2009 Tour with the focus this year on pharmaceutical-related companies located on the US West Coast, to be followed by participation in the Annual Meeting in San Diego. Hopes are high for an equal level of success in approaching companies to visit, and securing the interest of Japanese membership in participation.

Finally, the Japan Affiliate and its Tour members greatly appreciated the very kind cooperation shown by the US Plants to the visitors from overseas, permitting an unforgettable opportunity to visit their excellent facilities!