

## JAPAN

December in Japan is certainly a festive time as the New Year traditional celebrations and accompanying holidays approach. Meetings and gatherings of all types, with friends, colleagues and clients, quickly fill the calendar. However, even in this busy period, many among the Affiliate membership recognize the value of participating in the Winter Meeting.

Under the theme of "ISPE-led Globalization", the 7<sup>th</sup> ISPE Japan Winter Meeting was held on December 5<sup>th</sup> at the Yokohama Chamber of Commerce and Industry, with a total of 164 in attendance, including 117 registrants, 23 invited guests from government, industry, and academe, as well as others in a staff and/or support role. Survey results show that the Winter Meeting was well evaluated.

Led by Affiliate Chairman Tsutomu Samura and Organizing Committee Head/Affiliate Board Member Masatoshi Takemata, the success of the Meeting was due to the high level of cooperation achieved among Committee members and Affiliate staff. Moreover, a total of 20 companies supported the Meeting in various sponsorship roles.

The morning of the Meeting opened with two keynote speakers: Dr. Toshihiko Kobayashi, Pharmaceutical Research and Manufacturing of America, followed by Dr. Janet Woodcock (FDA CDER)'s Keynote Speech recorded at the October 2008 ISPE Annual Meeting in Boca Raton, Florida, simultaneously interpreted into the Japanese language.

After lunch (Japanese "bento" box provided for all!), the event continued with four presentations introducing HQ and Affiliate activities. Among the afternoon speakers, Bruce Davis, former Chairman of ISPE International, gave an update on PQLI implementation, and current International Board Member Tomiyasu Hirachi talked about the CPIP (Certified Pharmaceutical Industry Professional) initiative.

Shigeru Nakamura, Affiliate Head of Secretariat, and Osamu Matsumoto, Board Member, then reported in detail on the highly successful October 2008 US Plant Tour/Boca Raton Annual Meeting Attendance, organized for Affiliate membership.

On December 11<sup>th</sup> and 12<sup>th</sup>, the Risk-MaPP Seminar was held at Tower Hall Funabori, in Tokyo, participated in by 91 registrants. For this highly international event, invitations were accepted by Stephanie Wilkins, Julian Wilkins, Dr. Bruce Naumann, Paul Wregglesworth, Andrew Walsh, and Morihiko Takeda, who together ensured the satisfaction of all who attended. Simultaneous interpreting was provided throughout.

Prior to Risk-MaPP, all six instructors had jointly given on December 10<sup>th</sup> a containment-based seminar at Japan's PMDA (Pharmaceuticals and Medical Devices Agency) which was remarkably well received. Chaired by ISPE member Tetsuhito Takarada, a total of 33 PMDA key persons and staff attended. The session served to reinforce for PMDA the excellent work done by the International and Japanese Containment COPs, and the importance of the Containment Baseline Guide, as ISPE increasingly seeks the involvement and input of Japan's regulators.

Meanwhile, preparations are well under way for the GAMP5 Seminar, scheduled over two days, to be held in March in the Tokyo area. This event will serve to launch the much anticipated GAMP5 translation into the Japanese language undertaken by the Affiliate's GAMP COP volunteers. One month later (in April), the Affiliate's full-scale Annual Meeting will be held.

For more information on the Japan Affiliate and its activities, please visit [www.ispe.org](http://www.ispe.org) or contact Ms. Natsumi Sahara, Office Manager, at [ispe-japan@iris.ocn.ne.jp](mailto:ispe-japan@iris.ocn.ne.jp) or tel: 81-3-3818-6737. Alternatively, contact Shigeru Nakamura, Head of Secretariat, at [shigeru.nakamura@shimz.co.jp](mailto:shigeru.nakamura@shimz.co.jp).