## JAPAN

With the large-scale presence of Affiliate members at the November 4-7 2007 ISPE Annual Meeting in Las Vegas, bolstered by the attendance of the Japanese mission led by Affiliate Head of Secretariat Tsutomu Samura, and following the Affiliate's 6<sup>th</sup> Winter Meeting on November 28 in Kyoto, events-wise a quieter time was had in the period under review as the calendar year gradually came to a close and the New Year began. Formal gatherings were replaced by the smaller and more local end-of-year parties, the so-called *bonenkai*.

To kick off Affiliate activities for 2008, the 6th Kansai Annual Regional Meeting was held on January 23 in Osaka, a combination of Japanese-style New Year's party and informal information exchange over dinner on pharmaceutical-related technologies as well as on latest industrial trends. Participants, numbering approximately 50, included manufacturers, contractors and vendors/suppliers.

Continuing a tradition of concerted effort directed at ensuring the availability of quality documents in the Japanese language, translation of the *ISPE Good Practice Guide: Commissioning & Qualification of Pharmaceutical Water and Steam Systems* by Affiliate volunteers is steadily progressing, with the aim of publication of the completed document to coincide with the Annual Meeting in April.

In parallel, translation of the revised *API* (*Bulk*) Baseline Guide is ongoing, with a target publication date in the spring. A further task undertaken is the translation of the *GAMP Good Practice Guide:* Testing of *GxP Systems*, with the product to be available to members only on a non-commercial basis through the Affiliate website.

Preparations are well under way for the February 28 and 29 Auditing for *GMP Seminar*, in Tokyo, to be led by Robert W. Tribe, as well as for the 15<sup>th</sup> SAM & GMP Meeting on March 7 hosted by Shionogi & Co., Ltd.'s Kanegasaki Plant, in Iwate Prefecture.

Planning continues too for the Affiliate's Annual Meeting, a major and international event which will be held in Tokyo on April 17 and 18, immediately prior to which the election and reelection of Directors takes place at the General Meeting.

For more information on the Japan Affiliate and events/activities, please visit www.ispe.org or contact Ms. Natsumi Sahara, Office Manager, at ispe-japan@iris.ocn.ne.jp or tel: 81-3-3818-6737. Alternatively, contact Tsutomu Samura, Head of Secretariat, at Tsutomu.Samura@sanofi-aventis.com