

JAPAN

Under the guidance of its realigned Officers, and with the support of its Directors and volunteers, the Affiliate continues to aim at offering the best possible services to its membership. The goal is to take the Affiliate through a further period of growth by providing a variety of benefits, including educational events in a number of formats, key documents translated into the Japanese language, and the opportunity to network throughout the industry.

Meanwhile, the COPs are operating efficiently and working to attract new volunteers, while interfacing with their counterpart organizations in the U.S.

As an example, on July 26 the Containment COP, under the leadership of Morihiko Takeda, hosted in Tokyo a meeting at which Stephanie (International Board of Directors) and Julian (Steering Committee Chair, Containment COP) Wilkins were invited to participate. Julian gave a presentation to the gathered members, and on the same day Stephanie joined Affiliate Chairman Munetaka Hattori and Morihiko Takeda for a meeting with Japan's Ministry of Health, Labor and Welfare on Risk Management.

Events-wise elsewhere, the Affiliate's regular Kansai Regional Meeting on August 3 in Osaka was attended by 36 people. This well harmonized occasion, built around a networking party, provided an excellent platform for an exchange of ideas on diverse technical issues related to the industry.

On August 8 the 14th SAM & GMP Meeting, organized by the Regulatory COP, was held at GSK's plant in Imaichi and attended by 39 members. Plant General Manager Tomonobu Sato, who also serves as ISPE Vice Chairman, welcomed the Meeting participants through his address. The lecture given was on the subject of Risk Management, with an active exchange of opinions among those joining the Meeting followed by a very well-executed plant tour and well-received networking reception.

On August 24 and 25 the 3rd GAMP Summer Training Course was organized by the GAMP COP, in cooperation with the Japan Red Cross. Held on the northern island of Hokkaido, a total of 18 participants were joined by Affiliate Chairman Hattori as a liaison officer. The first day program included a GAMP Japan Forum presentation given by ISPE Member Ishibashi, of TEC, and a blood facility visit. The evening featured a networking party. The second day was given over to group discussions, and as always the Training Course was deemed a great success.

On September 14 the 5th Kanto Regional Meeting was hosted by Eisai Co., Ltd. at the company's plant in Misato, Saitama Prefecture, beyond the suburbs of Tokyo. From the very first announcement of the Meeting, the number of registrants reached the maximum of 40, testimony to the popularity of events of this type with their well-accepted "recipe" of lecture, plant tour and reception.

The Affiliate's COP volunteers continue to pursue the translation into the Japanese language of the newly revised *API (Bulk) Baseline Guide* as well as the *Good Practice Guide: Commissioning and Qualification of Pharmaceutical Water and Steam Systems*. The Japan Affiliate Office coordinates throughout with Headquarters to ensure that all requirements of the translation and

publishing process are fully met until final distribution of the completed document.

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