

JAPAN

The second half of 2008 calls for Office Manager Natsumi Sahara and her staff, as well as specialists Messrs Toma and Obata, to exert the maximum level of efforts in support of numerous events aimed at meeting the diverse requirements of the Japanese membership, and culminating in the Winter Meeting in Yokohama in December.

On August 8, the Japan Affiliate Regulatory Committee's 17th SAM & GMP Meeting was held at Taiho Pharmaceutical Co., Ltd.'s Tokushima Plant, under the theme of "Pharmaceuticals' Quality and Risk Management." The program included a plant tour for the nearly 100 attending, as well as lectures by Yutaka Ueno, Plant Manager of Taiho Pharmaceutical Co., Ltd., and individuals from Shionogi & Co., Ltd., on GMP philosophy, risk management, and quality systems.

The 6th Kanto Regional Networking Meeting on September 26 was the first of its kind in a new format, with a Tokyo restaurant being the selected venue. The Meeting enabled free discussions and exchanges of information in a social atmosphere, attendees also having the opportunity to learn about the various ISPE activities to which they can contribute. Participants were greeted at this inaugural event by the organizers: Board Members, T. Sugimoto, T. Omori and S. Nakamura.

The Affiliate validation training course, "Validation for the 21st Century: Concepts, Risk Assessments and Documentation", was held September 29 and 30 September, in Tokyo, with Diana Knittel-Pace as the invited ISPE trainer. The approximately 100 participants reflected the heightened level of interest in receiving professional training to meet validation requirements. The goal was to deliver training in new validation corresponding to the latest guidance issued by US regulatory authorities, including the US Food and Drug Administration.

Translations of "GAMP 5 Good Automated Manufacturing Practice" and "Commissioning and Qualification of Pharmaceutical Water and Steam Systems" into the Japanese language are proceeding, drawing on considerable time and effort contributed by COP members. The Affiliate regards the translation of ISPE key documents as an important part of COP activities, beneficial for the Affiliate and its membership.

Meanwhile, the Affiliate's 2008 US Plant Tour (October 21-24) was announced in late August, and will include a series of visits to plants located in the eastern U.S., among which is Facility of the Year (FOYA) Category Winning Bristol-Myers Squibb in New Brunswick, New Jersey. The Plant Tour is scheduled so that participants consecutively attend the Annual Meeting in Boca Raton (October 26-29.)

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 Shigeru Nakamura, Head of Secretariat, at shigeru.nakamura@shimz.co.jp.