

## JAPAN

In the three months since the April 5 Annual Meeting, the Affiliate's newly appointed Vice Chairman Tomonobu Sato (GSK), Head of Secretariat Tsutomu Samura, and Treasurer Shigeru Nakamura, have been diligently working with other Officers and Directors. Their aim has been to ensure the Affiliate has the long-term planning and optimum organization to take it through a further period of growth, while consistently providing the best possible services to the increasing membership. This effort has included integrating Officers, Directors and COP leaders, such that the COPs themselves are operating efficiently for the benefit of the Affiliate as a whole and, where required, with their counterpart organizations in the U.S.

Among activities conducted by the Affiliate's COP volunteers have been the translation into Japanese of the *ISPE Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment* (by Containment COP), as well as the *Good Automated Manufacturing Practice (GAMP) Guide: Validation of Laboratory Computerized Systems* (by GAMP COP). As always, close collaboration has been maintained throughout by the Affiliate office with ISPE HQ to ensure full conformity with the source documents through to final approval and subsequent publication/distribution to the Japanese buyers.

Meanwhile, approval has been received from HQ to proceed with the translation of the newly revised *API (Bulk) Baseline Guide*, originally published in June 1996, with this task currently under way, to be followed by the *Good Practice Guide: Commissioning and Qualification of Pharmaceutical Water and Steam Systems*.

Events participated in by the Affiliate in the period under review included the Washington Conference, June 4-7, and Singapore INTERPHEX ASIA, June 10-12. At the former, the new Treasurer, among others, was able to re-familiarize himself with key persons as well as current activities and practices of ISPE International. In Singapore, Affiliate Chairman Munetaka Hattori took the opportunity to bring himself up to date with trends in the Asia-Pacific region.

Member Yoshimitsu Ishihara of Kaketsuken (The Chemo-Sero-Therapeutic Research Institute) gave an entertainingly delivered and very well received presentation at the Washington Conference's 16<sup>th</sup> Annual Barrier Isolation Technology Forum, where Koji Kawasaki of Airex, member, also spoke.

Meanwhile, a Kansai Regional Meeting, for August 3 in Osaka, as well as a further SAM & GMP Meeting in the long-running series, organized by the Regulatory COP for August 8 at GSK's plant in Imaichi, are under planning, as is a Summer Training Course to be implemented by the GAMP COP.

For more information on the Japan Affiliate and events/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, you may contact Tsutomu Samura, Head of Secretariat at [Tsutomu.Samura@sanofi-aventis.com](mailto:Tsutomu.Samura@sanofi-aventis.com)