

## JAPAN

Several events to choose between in the early February through April period kept the Affiliate membership busy. The first of these was the Kansai Regional Meeting held on February 6 in Osaka. Formatted as a dinner and attended by 33 people, it allowed for excellent networking opportunities and exchanges of information between participants. The event was led by Affiliate Board Member Takeshi Hoshino of Takeda.

On March 5 and 6, a two-day seminar titled "GAMP5: Updated Guidance on Computer System Validation (CSV)" was organized by GAMP Japan Forum (a COP), under Organizing Committee Leader (Mr.) Michihiro Osakabe of JGC Corp. This highly popular Seminar was held in the spacious and comfortable environment of Tower Hall Funabori, Tokyo, attended by 230 paid registrants. The event marked the completion of the Japanese-language translation and publication of GAMP5 by the COP members, which took the volunteers almost a year.

Commemorating the translation milestone, the Seminar was organized with the dual purposes of 1. tribute to COP members, and 2. opportunity to share with the Affiliate membership learning acquired during the translation efforts.

The first day of the Seminar served as an overall explanation of GAMP5, with emphasis on differences between GAMP4 and GAMP5. The second day provided a total of six sessions addressing specific areas and themes of GAMP5. The final of these sessions was formatted as Q&A time. All of the Seminar lectures were given by the COP members who had had contributed so extensively to the translation work.

On April 3, the 19th SAM & GMP Meeting was held at the Settsu Plant of Shionogi & Co., Ltd., in Osaka. Titled "Pharmaceutical Quality Systems (PQS)", the three-part program comprised discussion on ICH Q10, plant tour, and networking party. The event was ably led by (Mr.) Masaki Hasegawa for the 60 registrants.

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).