

## JAPAN

The period under review was again a very busy one for the Affiliate as it continues its efforts to provide a further enhanced level of services for ISPE members. In addition to the translation work of Baseline Guides and Good Practice Guides into the Japanese language by Affiliate volunteers, several events in Japan and overseas were organized.

The 4<sup>th</sup> Chubu Regional Meeting was hosted by Taiyo Pharmaceutical Industry Co., Ltd., whose pre-filled syringes (PFS) manufacturing facility plant in beautiful and historic Takayama City, Gifu Prefecture, has been selected as one of the five Category Winners in the third annual Facility of the Year Awards (FOYA) competition. Held on October 25 and 26, and attended by 80 professionals, the meeting comprised of an afternoon of presentations on RiskMaPP, as well as the latest isolation technology, and an evening networking reception, followed by a comprehensive plant tour in the morning of the second day. Golfing and sightseeing were options for participants after the program was concluded.

On November 20, the Affiliate's Educational Committee and the API COP held the Revised API Baseline Guide Seminar. Patrick Wong of Global Engineering, BMS, was invited by the Affiliate to lead the event in Tokyo. The 70 participants were given an overview of the newly released API Baseline Guide, with focus on key considerations in facility design, and were led through a "hands-on" experience in the application of the Guide through the workshop format of the Seminar. This highly interactive and very educational event was simultaneously interpreted between the Japanese and English languages.

The second major meeting of the Affiliate's calendar year, the 6<sup>th</sup> Winter Meeting, took place on November 28 in Kyoto Kaikan, Kyoto City, again a very popular destination where work and pleasure can be combined, time permitting of course. The chosen theme for this year's event was "Pharmaceutical Innovation". With participation by more than 120 specialists, it can be called a success for the Affiliate and the organizing team.

The keynote speech was delivered by Professor Hiroaoki Okumura of Keio University on multiple aspects associated with innovation, and was followed by an address given Kenzo Toyoshima, Boehringer Ingelheim, which included an introduction to BPE (Business Process Excellence). The further program included discussions by ISPE International Director Tomiyasu Hirachi on PQLI. A review was provided by Tsutomu Samura, Leader, and Shinichi Osada, Co-leader, of the recently concluded Japan Affiliate yearly mission tour to U.S. pharmaceutical plants, arranged around the Las Vegas Annual Meeting, and which included Cook Pharmica, LLC, winner of the Facility of the Year award for Facility Integration.

The Winter Meeting concluded by explanations on RiskMaPP given by Morihiko Takeda of Pharma Solutions. Takeda is leading the Affiliate's Steering Committee in providing from Japan comment on Rev. B of the draft RiskMaPP Baseline Guide. This input is a first from Japan. Finally, words were given by Fujio Isemoto, Head of the Organizing Committee, on aspects of Kyoto the city including its environmental considerations.

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, contact Tsutomu Samura, Head of Secretariat at [Tsutomu.Samura@sanofi-aventis.com](mailto:Tsutomu.Samura@sanofi-aventis.com)