

JAPAN

The 10th Kansai Regional Networking Meeting, formatted as a dinner in a Chinese restaurant, nicely began the Affiliate's monthly events. Held on February 5 in Osaka, and with 28 attending, the Meeting was presided over by Takashi Hoshino. Largely a networking occasion, members meet twice yearly. In contrast, the 8th Kanto Regional Networking Meeting was set up as a golf competition, for the first time, in Chiba Prefecture east of Tokyo. Among the 18 sign-ups were non-members who later opted for ISPE membership!

The second meeting of the CPIP Course was held on February 13, led by Tetsuhito Takarada, with the focus on Product Development. The Course resumed with the third and fourth meetings on March 6 and March 20, adopting ISPE Webinars and/or externally-sourced teaching to prepare the candidates for qualification to take the CPIP test. All such meetings are organized at the Affiliate's offices in Yushima, Tokyo.

The largest event for the Affiliate in the period under review was the PIC/S GMP Seminar. Led by Bob Tribe and taking place on March 1 and 2 in Funabori, Tokyo, the Seminar attracted over 100 participants, including regulators, as PIC/S is regarded as a hot topic and the Seminar was tailored to the needs of Japan.

Day 1 included a PIC/S overview, comparison tables between PIC/S and Japanese regulations, categorization of GMP deficiencies in accordance with PIC/S criteria and discussions on Risk Assessment, with case studies and group exercises adopted so as to reinforce the learning. Day 2 focused on PIC/S inspections, and comparisons were made between criteria, as well as actual inspections, for Japan, the U.S., and PIC/S-based.

The two-day program featured a networking party with access to Bob Tribe for further clarifications. The entire event was very well received as a most stimulating Seminar in line with current trends in the industry.

Preparations are now in full swing for the Affiliate's Annual Meeting on April 22 and 23 in Tokyo, under the theme "Innovation for Diversity and Consistency", featuring perspectives from Japan's regulators, the US FDA, and Europe. The two days will be simultaneously interpreted, as multiple overseas speakers are to present at the Keynote Sessions and Workshops.

For more information on the Japan Affiliate and its activities, please visit www.ispe.org or contact 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.