

JAPAN

The first of several events held in the period under review were the twin (identical) PAT Seminars held on 18 July in Osaka and 24 July in Tokyo, planned, organized and executed by the related PAT Community of Practice (COP) and for which Affiliate Chairman Munetaka Hattori, took the lead. Speakers were Messrs Tsuyoshi Miura, Noriaki Nishiuchi, and Munetaka Hattori. In preparation for the Seminars, Mr. Hattori visited the D.C. area in June, gathering updated information and data on FDA and ASTM-related issues. Both of the Tokyo and Osaka meetings proved to be exceptionally popular, and the events a success.

In the following month, the GAMP Japan Forum, the largest COP, held its second Summer Seminar on 24 and 25 August. This year's event took place at Eizai Kawashima Koen, in Gifu Prefecture, and attracted about 20 participants who received two speakers. GAMP COP Chairman Ken-ichi Ogihara spoke of differences in computer system validation regulation between Japan and the U.S., while the speaker from Eizai provided a case study of Eizai's own computer system modification. The evening of 24 August was enjoyably spent in an attractive spa hotel, with plenty of opportunity for networking between the participants. *(Photo is of 2006 GAMP Summer Seminar participants at Eizai's Pharmaceutical Museum.)*

Two Regional Meetings have also been held: one in the Kanto area and the second in the Chubu region, each comprising of a tour, lecture and networking reception for the approximately 60 registrants per event. On 8 September, Daiichi Asubio Pharma hosted the first of the Meetings at its Biopharma Center, in Gunma Prefecture. The popularity of the Meeting stemmed from Asubio's New Bio Plant having been selected in January of this year as a Finalist in the global 2006 Facility of the Year Award (FOYA) competition, with the Company's representatives later participating in the related ceremonies at INTERPHEX New York. On 20 September, the second, also successful, Regional Meeting was held at the Astellas Pharma plant in Yaizu, Shizuoka Prefecture. Visitors were allowed to observe the company's injectable as well as solid dosage facilities.

In addition to meetings and plant visits, the past several months have seen a significant focus at the Affiliate on the development of COPs and their respective activities. Permanent office space occupied in Yushima, Tokyo, by the Office Manager and her staff is maximally utilized by COPs to accommodate the regular meetings required. Among the COPs, Containment has benefited from an increased number of manufacturers among its members, and is targeting an enhanced level of participation by Japan's Ministry of Health, Labor and Welfare as part of an overall alignment and coordination program in support of potent product manufacturing.

In the meantime, the Biopharma COP has busied itself with the translation of the Biopharma Baseline Guide into the Japanese language, calling on its team of 10 or so volunteers for the task. *(Photo is of Biopharma COP members in Affiliate's Yushima Offices for translation meeting.)* Although somewhat delayed schedule-wise, it is still expected that the finished product will be available for launch at the Affiliate's 2006 Winter Meeting, in December, in Nagoya.

With its eyes on the 2006 ISPE Annual Meeting in Orlando, planning is underway by the Affiliate Secretariat for a mission that will take in attendance at the Meeting in Florida, as well as a number of visits to pharmaceutical plants in the U.S.

For more information on the Japan Affiliate, please visit www.ispe.org or contact Ms. Natsumi Sahara, Office Manager, by e-mail: ispe-japan@iris.ocn.ne.jp or tel: 81-3-3818-6737. Alternatively, you may contact Shinichi Osada, Affiliate Secretary, by e-mail: shinichi.osada.bf@hitachi-pt.com.