

JAPAN

On-line registration for Japan Affiliate-organized events began through the Affiliate website on January 17 for the 15th SAM & GMP Seminar held on March 7. The system functioned very satisfactorily and will be applied for all event registrations in Japan. A facility for on-line payment by credit card is in the planning phase. This Seminar attracted the maximally allowed 60 registrants and offered a good test case for the on-line system and its functionality.

February 28 and 29 saw a very successful and fully subscribed to (84 registrants) *Auditing for GMP Seminar*, in Tokyo, led by Robert W. Tribe. It was organized to provide suggestions and guidance on auditing skills, achieve efficiency in vendor selection, and acquire the ability to fully prepare for inspections and audits. Simultaneous interpreting was provided for both days of the Seminar, and the event included a networking reception in the evening of the February 28.

At the March 7 SAM & GMP Seminar, hosted by Shionogi & Co., Ltd.'s Kanegasaki Plant in Iwate Prefecture, presentations were given by Junichi Hirai, Plant Manager, on a "Comparison of Auditing Contents between Three Parties (Japan, US, and Europe)" and by Akifumi Nagatomo, Group Manager, Mitsubishi Tanabe Pharma Corporation, on "Japanese Companies' reaction to ICH, Q8, Q9 and PAT Guidelines." Presentations were followed by a plant tour and a networking reception.

On April 17 and 18, the Affiliate's 7th Annual Meeting was held at Tower Hall Funabori, in Edogawa Ward, Tokyo, under the theme of "Pharmaceutical Innovation! - Challenging New Steps". On the first day, greetings were given by Fumi Yamamoto of Japan's Ministry of Health, Labor and Welfare (MHLW), and by Bruce Davis, Chairman of the ISPE International Board.

The pre-lunch Keynote Session was provided by the US FDA, followed after the break by a second Keynote Session ISPE in the form of international updates by Bob Best, ISPE President and CEO, and by Bruce Davis. The remaining two Keynote sessions were given by Sonosuke Kadogawa, Director, McKinsey & Company, Inc., Japan, on "Pervasive Innovation", and by Tohichi Takenaka, Chairman of Astellas Pharma Inc. on "Astellas, Successful Integration and Innovative Strategy. Simultaneous Japanese-English interpretation was provided.

On April 18, six workshops were held, three of which offered simultaneous Japanese-English interpretation: WS1: Containment "The Latest Information about RISK-MaPP1"; WS3: Regulatory "Global Trends of Regulation (tentative title)" by FDA (tentative); WS6: Solid Dosage "General Introduction to New Solidification Base Line Guide." A networking reception was held in the evening of April 17, while "bento box" lunches were provided to speakers and registrants on both days.

The Annual Meeting included the 2nd PQLI Meeting, led by Bruce Davis. Presentation materials from the Washington and Berlin Conferences had been previously analyzed and separated into: 1. Design Space, 2. Critical vs Non-Critical, 3. Control Strategies.

To coincide with the Annual Meeting, the Japanese translation of the Baseline Guide Volume 1 – API (Revised Bulk) Guide was released, following a

period of intensive work by a volunteer group of ISPE members.

Preparations are currently under way for the GAMP 5 Seminar at Ochanomizu Business Center, Tokyo. Organized by the GAMP Japan Forum, and led by Sion Wyn, GAMP Editorial Board, this one-day Seminar is aimed at providing early information on GAMP 5 by providing the flavor of a real, full-scale training program. Simultaneous Japanese-English interpretation will be available.

For more information on the Japan Affiliate and events/activities, please visit www.ispe.org or contact Ms. Natsumi Sahara, Office Manager, at 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