

JAPAN

In the early evening of April 4th, the Japan Affiliate hosted a two-hour meeting in Tokyo with international guests. Attending from the ISPE Board of Directors were Jane Brown, Chairman, and Bruce Davis, Vice Chairman; from ISPE Asia Pacific Operations, Mr. Balwant Grewal, Vice President; and from the ISPE Japan Affiliate Mr. Munetaka Hattori, Chairman, Mr. Tsutomu Samura, Head of Secretariat, and other Board Members. Jane Brown gave a presentation on ISPE's new Strategic Plan describing the 10 business priorities for the Year 2007.

Through this joint meeting it was confirmed that: a good relationship exists with the US FDA, as well as with Japan's Ministry of Health, Labor and Welfare; individual effort will be required to further improve the Affiliate's finances; and the Affiliate will also work towards promoting CPIP. A welcome reception was then held for a fuller level of personal introductions by ISPE Japan to its guests, which included additional distinguished speakers from overseas, all of whom were contributing as speakers and/or Workshop participants in the following April 5th and 6th ISPE Japan Affiliate Annual Meeting in Funabori, Tokyo, attended by more than 250 registrants.

The Keynote Sessions of April 5th started with Carl Fearn of IMS talking on the prospect of the pharmaceutical industry in Japan and globally; followed by Dr. Moheb Nasr of the FDA on Quality by Design; Ms. Fumi Yamamoto of Japan's Ministry of Health, Labor and Welfare (MHLW) on Japanese regulatory issues; and Norikazu Eiki, Chairman of Bayer Yakuhin, Ltd. on management strategy and features of the pharmaceutical industry in Japan. For this day and the next full day of Workshops, the Japanese and English languages were simultaneously interpreted.

Highlights from two of the six Workshops held on April 6th are provided to give an idea of their content.

Workshop 4: "GMP Revised Trend based on ICH Q9 and Perspective of Containment Technologies". In excess of 100 attended this very active session which included various debates on RISK MAPP, Cleaning Validation, RABS, among others. The atmosphere reflected the keen interest in ISPE Guide RISK MAPP and the ISPE definition of RABS. The Workshop itself was divided into four parts:

1. "Risk Assessment based on cGMP Quality & EHS" by Dr. Edward Sargent
An update on ISPE Guide RISK MAPP was provided by Dr. Sargent, Executive Editor together with Mrs. Stephanie Wilkins (Director of ISPE) of Baseline Guide RISK MAPP. The speaker's contributions to EHS have been helpful for Japan pharmaceutical industry and through this presentation a better understanding was gained of the importance of RISK MAPP as well as of EHS.
2. "Global Perspective of Aseptic Isolators and RABS" by Mr. Jack Lysfjord of Valicare
The presentation focused on the 2006 ISPE Isolation Technology Surveying Report. It was noted that since the Affiliate as yet has no Sterile Products Processing COP, the C(Containment)-COP assumes a role for Sterile Processing matters.
3. Good Practice Guide "Assessing the Particulate Containment Performance of Pharmaceutical Equipment" (SMEPAC Guide)" by Yukio Fukushima of Hitachi Plant Technology
Japan's C-COP is currently translating the Guide into Japanese, with ISPE approval having been obtained for its publication. Through the presentation given, the Guide was introduced to participants.

4. "Japan Perspective of EHS" by Chisato Ueki of Pfizer Japan Ltd.
In Japan's local pharmaceutical industries, a system of responsibility for EHS has not been sufficiently established. The C-COP has surveyed EHS and, where necessary, will develop a protocol guide reflecting EHS responsibilities. The presentation reported on the survey results and the requirement for EHS in the domestic pharmaceutical industry.

Workshop 6: "Introduction of New Facilities – Facility of the Year Award (FOYA)". The Workshop was organized as a part of the "Manufacturing Management COP" activities. Recently established, the COP focuses on 1) Key Performance Index; 2) Factory Innovation; and 3) Factory Management Issues such as HRM, etc. The facilities introduced were:

1. Kowa Nagoya plant (Best 5 of 2005 FOYA) presented by Mr. Takanori Yokoi.
2. Asubio Pharma's New Bio Plant (Best 5 of 2006 FOYA) presented by Mr. Keita Nishida.
3. Taiyo Takayama Plant (Category Award of 2007 FOYA) presented by Mr. Hiroaki Mizuno.

A panel discussion followed to which the presenters and four factory managers contributed. Numerous questions and comments were provided from the floor, with discussion points mainly concerning concept, facility design, budget, capital application, new technologies and operation excellence, among other items.

For more information on the Japan Affiliate and its 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, you may contact Tsutomu Samura, Head of Secretariat at Tsutomu.Samura@sanofi-aventis.com