

JAPAN

The Affiliate's newly reconstructed Website was officially opened to ISPE's global membership on January 9. The task of revising the Website was undertaken by the volunteers of the Website Committee, under the leadership of Shigeru Nakamura, in collaboration with ISPE HQ. The aim of the Committee was to realize a site that is unified with ISPE worldwide, and is functional in appealing the activities as well as merits of the Affiliate for members.

It was learned in the fall of 2006 in a notification from ISPE HQ that Tomiyasu Hirachi, former Chairman of the Affiliate and present Officer, had been elected to ISPE's International Board of Directors, and would succeed the Affiliate's Head of Secretariat, Shinichi Osada, whose second two-year term as a Director was to conclude at a timing to coincide with the 2006 ISPE Annual Meeting in Orlando, Florida. On Tuesday, November 7, attendees at the Membership Luncheon & Awards Ceremony heard recognition and appreciation given to Osada for his four years served on the Board.

Since Orlando, Hirachi has taken up his duties and is closely working with the other Officers and members of the Board in all aspects of its functions, including participation in the multiple meetings scheduled each year in the U.S. and Europe to review the Society's operations and decide its future direction.

Meanwhile, in Japan, the 5th Affiliate Annual Winter Meeting was held at the Nagoya Congress Center on December 14, the first such major ISPE meeting in the Chubu region, making it a landmark event. The meeting took as its theme *The Trend of Pharmaceutical Manufacturing - New Technology and Quality Assurance*. The Organizing Committee was headed by Mitsuhiro Mizutani. Meeting attendees included Japan's Pharmaceuticals and Medical Devices Agency (PMDA), and a well balanced representation of pharmaceutical manufacturers, engineers/constructors and suppliers, as well as academe. From now, full-scale preparations will proceed in preparation for the April 5 and 6, 2007 Annual Meeting scheduled to be held in Funabori, Tokyo.

Affiliate volunteers have long devoted themselves to the translation into the Japanese language of technical documents; recent achievements are the *ISPE Baseline Guide: Volume 6 - Biopharmaceutical Manufacturing Facilities*, and the *GAMP ISPE Good Practice Guide: IT Infrastructure Control and Compliance*. The translators coordinate with the Affiliate's office to cover all phases of this major task, including preparation for publishing, sale and distribution, with overall guidance and support received from ISPE HQ. Efforts are now being directed at additional translations to be undertaken, for which translation teams within respective COPs of the Affiliate will be formed and take charge.

The Affiliate's COPs continue to be active in a range of activities. COPs and their leaders meet regularly in the Yushima, Tokyo, offices or locations offered by members that may offer greater convenience and space, should such need and numbers require a different site. Moreover, the Containment COP, effectively led by Morihiko Takeda, has benefited from the telephone conferencing facilities offered in Yushima to "meet" with experts 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.