JAPAN

Held at the aesthetic yet impressively functional and publicly owned Tower Hall Funabori facilities, in Edogawa Ward, Tokyo, the 8th Annual Meeting on April 16 and 17 drew almost 240 paid registrants to the conference and accompanying networking reception. Titled “Road Map for Quality by Design”, the Meeting was made up of a first day at which incoming Affiliate Chairman Tatsuro Miyagawa started the proceedings through his welcome address, guest remarks were delivered on behalf of Japan MHLW’s Fumi Yamamoto, and ISPE Chairman/CEO Bob Best provided an ISPE update.

Keynote Speeches and Special Lectures immediately followed in the same 5th floor theater, by Hiroshi Tanaka of Mizuho Securities giving a Securities Analyst View on the Present and Future Pharma Industry, by FDA’s Richard Friedman (prerecorded) discussing a Regulatory Perspective on the Pharma Ingredient Supply Chain, Pfizer’s Jim Spavins emphasizing the Value to Industry of Quality by Design, and Sion Wyn of Conformity elaborating Science and Risk-based Approaches in ISPE Initiatives and Documents. As customary, a very popular and well attended Networking Reception was hosted by the Affiliate in the evening, with the table tops of the more than 15 subscribing (sponsoring!) organizations arranged around the perimeter of the room, and live jazz music at the front led by Takeda’s Takeshi Hoshino.

The second day of the Meeting was arranged in the size variable multipurpose rooms forming the 2nd floor of the conference facilities. The five segments included the Session 1 PQLI Seminar (all day, jointly led by Chris Potter and Yoshio Kitazawa) at which Yukio Hiyama of Japan’s National Institute of Health Science gave a highly informative presentation on the Japan Regulator’s Views on Quality by Design. He summarized current activities in Japan, particularly the work of the study groups. The subject of real time-release testing figured prominently in Hiyama’s presentation, as well as on the audience’s agenda.

The audience of approximately 120 represented many leading Japan-based Companies (Eisai, Daiichi-Sankyo, Mochida, etc.) as well as the local Japan based entities of majors, (Pfizer, GSK, Sanofi-Aventis and Banyu (Merck)), with company representation at senior level: Director Drug Development, Eisai, and Senior Director, Banyu. Notably, Tetsuhito Takarada from Mochida, the JPMA ICH representative on the Q8, 9 and 10 IWG was present and was active in the Q&A session.

Sessions 2 to 5 comprised IP COP’s Global Practices for IP Supply (led by Hiroaki Ishii of Pfizer Japan); API COP’s Innovation in API Manufacturing Now (Tsutomu Kojima of Ono Pharmaceutical); Containment COP’s Risk-based Approach for Manufacturing of Highly Potent Compounds (Morihiko Takeda of Pharma Solutions); and Manufacturing Management COP’s Business Continuity Plan (Tomiyasu Hirachi, EEM, with Yoshiya Yoshida, Schering-Plough, and Yasuyuki Suzuki, Banyu.)

Throughout the two days, a range of translated ISPE Baseline Guides and Good Practice Guides were sold, with the highest sales reached by the very popular recently translated GAMP5.

Earlier in the month, on April 3, the 19th SAM & GMP Meeting had been held at the Settsu Plant of Shionogi & Co., Ltd., in Osaka. Titled "Pharmaceutical Quality Systems (PQS)", the three-part program comprised discussion on ICH Q10, plant tour, and networking party. The sell-out event was led by Masaki Hasegawa for the 60 registrants.

For more information on the Japan Affiliate and its 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 Shigeru Nakamura, Head of Secretariat, at shigeru.nakamura@shimz.co.jp.