

ISPE Japan Affiliate

The 7th Annual Meeting Report

The Japan Affiliate's 7th Annual Meeting was held on 17 and 18 April at Tower Hall Funabori, in Edogawa-ku, Tokyo. In line with this year's theme of "Pharmaceutical innovation and the challenge of upgrading our capabilities!" the Affiliate invited prominent speakers from within Japan as well as from overseas to talk about the latest trends and events in the pharmaceutical industry. With more than 350 registrants, the highest attendance for an Annual Meeting in recent years, the high level of interest in ISPE was demonstrated.

On the first day, the keynote address "QbD Approach to Pharmaceutical Development and Manufacturing" was delivered by Dr. Chi-wan Chen of Pfizer Inc., a former FDA Officer. Dr. Chen clearly explained QbD's applications and utilities to the audience.

The Executive Session 1 talk was given by Bruce Davis, Global Capital Director of Astra Zeneca and ISPE Chairman, and Robert P. Best, President and CEO of ISPE, on Product Quality Lifecycle Implementation (PQLI.) They also covered the latest developments and trends at ISPE. In Executive Session 3, Toichi Takenaka, Chairman, Astellas Pharma Inc., presented a convincing case study on "Business Management and Drug Discovery for Patients", based on his own experience and perspective in pharmaceutical discovery research.

On the second day, multiple workshops were held at several different venues within the Tower Hall Funabori facility. These workshops were organised by five COPs: namely, Containment, Engineering Management, Regulatory, Bio, and Solid Dosage Products. Specialists from each field presented cutting-edge information to the attendees. The workshops were a great success as attendees actively participated in question-and-answer sessions with the respective speakers.

Initiating PQLI in Japan

With the recent initiation of Product Quality Lifecycle Implementation (PQLI) activities in Japan, the ISPE Japan Affiliate extended a very cordial invitation to Bruce Davis, Global Capital Director of Astra Zeneca and ISPE Chairman, as well as to Dr. Chi-wan Chen of Pfizer, a former FDA Officer, to present on PQLI at a Regulatory Workshop during the 7th Annual Meeting. Dr. Chen delivered a talk entitled “Implementation of Quality by Design in the U.S.”

Davis spoke on “ISPE's Approach to PQLI” where he provided a detailed summary of topics presented at PQLI Workshops held during the ISPE Copenhagen meeting.

In addition, Dr. Yukio Hiyama of the National Institute of Health Sciences (NIHS), of the Ministry of Health, Labour and Welfare (MHLW), delivered a talk entitled “Challenges and Opportunities in Implementing ICH Q8, Q9 and Q10” and Hirohito Katayama of Astellas Pharma Inc. spoke about “Risk Management in Sterile Drug Manufacturing and Aseptic Handling.”

After the workshop closed, members of the Japan Affiliate’s PQLI group, which is lead by Dr. Takayuki Ohwaki of Eisai, gathered with the four speakers to discuss future activities in Japan, with fruitful results for commencement of the next phase of activities.