

## **Meeting Summary- IATP-STPI Seminar on Pathology Peer Review, Bengaluru, India**



As part of the international outreach and education initiative, the International Academy of Toxicologic Pathology (IATP) seminar on Pathology peer review, sponsored and supported by Society of Toxicologic pathology India (STP-I), International Federation of Societies of Toxicologic Pathologists (IFSTP) and Society of Toxicologic Pathology (STP) was held on November 2, 2014 at Bengaluru, India.

This program started with an introductory talk by the STP-I president, Dr. S. K. Vijayasarithi. He described the formation and activities of STP-I and different continuing education programs offered by the society since 2004. This was followed by an introduction to IATP by Dr. Bhanu Singh. He also previewed the seminar topics for the day. The half day seminar was co-chaired by Dr. Kamala Kannan (Advinus Therapeutics Pvt Ltd, India) and Dr. Yogesh Murkude (IIBAT, India).

The first talk was given by Dr. Peter Mann (EPL Inc., USA) on Pathology peer review. The regulatory agencies' requirements, reasons for pathology peer review and the recent recommendations in the OECD guidance document were the key points discussed in his talk.

The following presentation was given by Dr. Jerry Hardisty (EPL Inc., USA) on the retrospective peer review/Pathology working groups (PWG). He explained the purpose of a PWG, requirement for PWG data for the regulatory agencies and role of the PWG chairperson. A few examples were also presented in the talk.

A webinar given by Dr. Sabine Francke, (CFSAN, FDA, USA) began with the functions of CFSAN in the FDA. Presented examples conveyed to the audience the importance of adherence to the protocol requirements for peer review in regulatory studies in order to avoid the time delays during product data submission to regulatory agencies.

Clinical pathology data peer review was explained by Dr. Lila Ramaiah (HLS, USA). She outlined GLP procedures and QA procedures to be followed for clinical pathology data.

Dr. Kalai Selvan (Syngene International Limited, India) presented the regulatory framework in India and Indian regulatory framework for toxicity testing in India. Survey data on pathology peer review processes followed in different Indian Pharma Industries/CROs was well presented. He also discussed the challenges faced in the documentation of peer review findings in relation to the current OECD document.

This programme was completed with a Panel discussion where the speakers and the eminent pathologists in the forum answered questions raised by the audience on the various procedures in peer review. The session gave a thorough understating of current peer review procedures followed across different industries and countries in performing regulatory toxicology studies.

Further detail of this event along with copy of presentations given in this meeting is available at:

[http://toxpathindia.com/conferences\\_stpi\\_conference\\_2014.html](http://toxpathindia.com/conferences_stpi_conference_2014.html)