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| **Title of the Presentation:** | Peer Review in Toxicologic Pathology - Current Situation in Japan |
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| **Abstract Text:** | It is generally accepted that pathology peer review (PPR) is an important procedure to verify and improve the accuracy and quality of histopathology data generated by the study pathologist in toxicological studies of xenobiotics including pharmaceuticals and agrochemicals with experimental animals. However, the timing of PPR relative to data locking and the definition of raw data differ among countries. In the United States and Europe, PPR is usually conducted before pathology data are fixed or locked. In Japan, internal PPR within the testing facility is conducted before data locking, but sponsor PPR is mostly performed after pathology findings are fixed, which is in line with the guidance described in the GLP Guidebook 2006 that is recommended by the Japanese representative regulatory agency, Pharmaceuticals and Medical Devices Agency (PMDA). The purpose of the guidance by PMDA appears to ensure transparency of PPR process and to minimize the influence of sponsor power on the original data by the study pathologist. In order to clarify differences in definition of pathology raw data and peer review process among countries, a Panel Discussion on Regulatory Perspective for Pathology Data was held during the 25th Annual Meeting of the Japanese Society of Toxicologic Pathology (JSTP) at Hamamatsu in 2009. The panelists who participated in the discussion represented multiple societies of toxicologic pathology including the JSTP, Society of Toxicologic Pathology (STP), and European Society of Toxicologic Pathology (ESTP) together with the Japanese Society of Quality Assurance (JSQA). It was also cooperated by the International Federation of Societies of Toxicologic Pathology (IFSTP) and its Regulatory Interaction Committee (RIC) for assistance in pursuing a globally acceptable approach to peer review. At that meeting, it was revealed that USA and European regulatory agencies do not request that data be locked before peer review or an audit trail of changes in the pathology report be produced, which is different from that in Japan. Since international harmonization of PPR practices is very important, the JSTP and other relevant parties including JSQA had a face to face meeting with PMDA in 2010 to discuss the differences between Japan and other countries and also the content of a draft OECD guidance on pathology peer review. At the meeting, the JSTP recommended to PMDA that PPR prior to data locking would be more suitable to improve the quality and reliability of pathology data to be submitted to regulatory agencies. The JSTP position is consistent with that of STP which is shown in “Recommendations for Pathology Peer Review” by the STP Peer Review Working Group published in *Toxicologic Pathology* in 2010. PMDA also gathered information on PPR in other countries as much as possible. Taken together, PMDA showed new draft viewpoints on PPR at the 3rd Global Quality Assurance Conference which was held at Kyoto in 2011. The PMDA’s draft viewpoints are summarized as follows:<br>• PPR is not mandatory to nonclinical studies of pharmaceutical products, but if PPR is carried out, then it is subject to GLP inspection.<br>• At the moment, PMDA considers that pathology raw data is the report or |

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| | data signed and dated by the study pathologist.<br>• PPR before or after data locking would be acceptable either way, but PPR by pathologists outside from sponsors or academia may be required to ensure the transparency of review process and to be described in the protocol if the conduct is scheduled in advance.<br>• In addition, the name of the pathology peer reviewer and reviewed organs with disagreement should be described in the final report.<br>• The report or data generated by the peer reviewer should be archived together with the other study documents.<br>The JSTP basically agree with the new draft viewpoints of PMDA, although we need further discussions in details before it is finalized. |