

Carcinogenicity Assessment

Speaker: James A. Popp, DVM, PhD, DACVP, ATS, IATP

Presentation is designed to provide a practical overview of carcinogenicity assessment of pharmaceuticals and chemicals as currently required by various national and international regulatory agencies. The following topics will be stressed. The objectives of and requirements for the carcinogenicity studies will be addressed since these points are sometimes confusing. Appropriate planning will for carcinogenicity studies will be discussed since this critical component requires extensive effort that is frequently not given adequate consideration. Study design requires significant thought related to the objective of the study and the current knowledge of known toxic effects and should not be based on a simple standard protocol. Oversight of the in life part of the carcinogenicity study requires detailed and persistent monitoring to assure success. While histopathology evaluation is the providence of experienced pathologists, there are multiple points related to pathology that should be known by all scientific staff involved in the study. The implications of a tumor finding on compound registrations and marketing will be briefly mentioned.