



## One Health Initiative

- STP Support of One Health Initiative

## Data Interpretation/Management

- Recommended ("Best") Practices for Determining, Communicating, and Using Adverse Effect Data from Nonclinical Studies
- Recommendations for the Evaluation of Pathology Data in Nonclinical Safety Biomarker Qualification Studies
- Best Practices for Use of Historical Control Data of Proliferative Rodent Lesions
  - > Points to Consider on the Statistical Analysis of Rodent Cancer Bioassay Data When Incorporating Historical Control Data
  - > Examples of Historical Data Presentation
  - > Stand Alone HCD Reference List
- Evaluation of Organ Weights for Rodent and Non-Rodent Toxicity Studies: A Review of Regulatory Guidelines and a Survey of Current Practices
- Pathology Image Data: Compliance with 21 CFR Parts 58 and 11
- Pathology Position on Histopathology Data Collection and Audit Trail
- Assessment of Hyperplastic Lesions in Rodent Carcinogenicity Studies
- Best Practices for Evaluating Clinical Pathology in Pharmaceutical Recovery Studies
- Recommendations on Classification of Rodent Neoplasms for Peto Analysis

## Study Design

- Best Practices for Veterinary Toxicologic Clinical Pathology, with Emphasis on the Pharmaceutical and Biotechnology Industries
- Society of Toxicologic Pathology Position Paper on Best Practices on Recovery Studies: The Role of the Anatomic Pathologist
- Interpreting Stress Responses during Routine Toxicity Studies: A Review of the Biology, Impact, and Assessment
- Use of Animal Models of Human Disease for Nonclinical Safety Assessment of Novel Pharmaceuticals
- Scientific and Regulatory Policy Committee (SRPC) Paper: Validation of Digital Pathology Systems in the Regulated Nonclinical Environment
- Organ Weight Recommendations for Toxicology Studies
- Best Practices Guideline: Toxicologic Histopathology
- Recommended Tissue List for Histopathologic Examination in Repeat-Dose Toxicity and Carcinogenicity Studies

- Diet As a Variable in Rodent Toxicology and Carcinogenicity Studies

### **Study Reports/Peer Review**

- Pathology Peer Review Recommendations—2010
- Best Practices for Reporting Pathology Interpretations within GLP Toxicology Studies
- Documentation of Pathology Peer Review
- Peer Review in Toxicologic Pathology: Some Recommendations

### **System/Organ Specific**

- STP Position Paper: Recommended Practices for Sampling and Processing the Nervous System (Brain, Spinal Cord, Nerve, and Eye) during Nonclinical General Toxicity Studies
- Scientific and Regulatory Policy Committee (SRPC) Paper: Assessment of Circulating Hormones in Nonclinical Toxicity Studies III. Female Reproductive Hormones
- Society of Toxicologic Pathology Position Paper: Review Series: Assessment of Circulating Hormones in Nonclinical Toxicity Studies: General Concepts and Considerations
- Assessment of Circulating Hormones in Regulatory Toxicity Studies II. Male Reproductive Hormones
- Best Practice Guideline for Routine Pathology Evaluation of the Immune System
- Ovarian Follicular Counting in the Assessment of Rodent Reproductive Toxicity
- Guidelines for the Evaluation of Testicular Toxicity
  
- STP Position Paper: A 'Best Practices' Approach to Neuropathologic Assessment in Developmental Neurotoxicity Testing—For Today
- (ASVCP) Selection and Interpretation of Clinical Pathology Indicators of Hepatic Injury in Preclinical Studies

### **Training**

- Proposed Training for Future Toxicologic Pathologists