No Two Are Ever the Same: "Approaches to the Nonclinical Safety Assessment of Biologics"

Webinar Date/Time

Tuesday, October 21st from 10 - 11am EST

Presenter(s)

Shawn Heidel, DVM, PhD, Executive Director, Global Lead Optimization and Solutions Management, Covance Inc.

Janice Lansita, PhD, DABT, Senior Managing Scientist, ToxStrategies, Inc.

FULL ABSTRACT

The approach a company applies for the development of biological therapies is not from a scripted, single approach. Each biological product has unique properties and development challenges that need to be taken into consideration when designing the toxicology program. Since no two biologics are the same, a standard "check the box" list of studies and study designs for the nonclinical safety assessment of biologics simply does not exist. Due to the various characteristics that can be unique to each biological product, the development program should be specifically tailored for each biologic based on various factors, including the quality, product attributes, pharmacological action and mechanism of action (e.g., target- and/or Fc-mediated) of the molecule.

This webinar will highlight the various properties and challenges unique to biological products, and review how they influence major decisions in the nonclinical development program. Particular focus will be given to the types of studies that provide informative data for science-based decisions. Various topics will be reviewed, including species selection, points to consider in the design of non-GLP and GLP toxicology studies, immunogenicity and assessment of anti-drug antibodies in toxicology studies, tissue cross-reactivity studies and appropriate use of recovery animals in toxicology studies.