

Module 5 Abstract: Safety Pharmacology

Basic Topics in Toxicology eLearning Seminar

This presentation will focus on considerations for Safety Pharmacology studies that best fit your program and support regulatory submission. Trends have ebbed and flowed over the past two decades from conducting standalone studies versus combining within a repeat dose toxicology study. The critical concern is how to evaluate the vital organ systems in the most appropriate manner (environment) for the drug development program. This presentation will help provide some context and information that may help make a decision on which approach is best for your program. With such a diverse set of modalities, from small molecules to biologics, including cell and gene therapies, the decision on how to conduct the Safety Pharmacology studies or not conduct them at all could be critical to keeping the drug development process on track. Topics covered will be the regulations that support Safety Pharmacology, the vital organ systems that make up the core battery of studies required prior to first in human studies, examples of study designs, and a summary of changes based on the new draft ICH S7B Q&As for both *in-vitro* and *in-vivo* QT assessments.