

Challenges to Safety Evaluation of Small Molecule Pharmaceuticals and Biologics  
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Safety evaluation is one of most critical drug development activities to identify potential safety and toxicity of products intended for human use. While qualitatively, the end points in toxicity testing are similar, the safety testing of small molecules and biologics differ considerably. This is largely due to differences in physico-chemical, pharmacodynamic (e.g., target specificity of biologics) and immunological activity of these molecules. The presentation will discuss the principles of safety testing of small molecule pharmaceuticals and biologics and toxicity study design consideration, including species, dose, schedule, duration selection for products, including oncology and non-oncology products. Specific case studies will be presented to underscore the importance of understanding mechanisms and relevance of animal models in predicting human safety from nonclinical toxicology studies. Additionally, the presentation will describe recommendations regarding "First in Human dose" selection for small molecules versus high risk biologics.