

## **Module 2 Abstract: General Toxicology**

### ***Basic Topics in Toxicology eLearning Seminar***

This eLearning module will focus on the principles of general toxicology. The presentation will provide an overview of the basic tenants of toxicology testing and the general assumptions made during the generation of nonclinical data. It will teach you how to develop a nonclinical safety assessment plan showing you how the safety assessment program is designed regarding general regulations and guidelines and how specific aspects of a chemical/product class can influence the design of the program. The module will also discuss study design considerations for toxicology studies and general regulatory requirements as well as specific design parameters (route of administration, duration of treatment, selection of species, dose selection, and parameters assessed) briefly explaining large v. small molecule development considerations. Moreover, it will highlight the importance of the interpretation of toxicology study results, especially as it concerns to what is an adverse finding and in defining the NOAEL. Finally, the regulatory application of the nonclinical data to clinical dose selection will be covered so that a comprehensive and robust nonclinical safety assessment package can be submitted in support of new drug applications to regulatory agencies across the world.