

## **Module 6 Abstract: Genetic Toxicology**

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

This module will provide an overview of genetic toxicology with a focus on the ICH S2(R1) guideline. Genetic toxicology testing is conducted to assess the ability of drugs to induce gene mutations as well as chromosomal damage (i.e., clastogenicity and aneugenicity). A battery of tests is used to evaluate these endpoints with the goal of predicting human carcinogenic potential. The presentation will cover both *in vitro* and *in vivo* genetic toxicology tests with specific discussion of principles and mechanisms, study design, and data interpretation. Decision making including discussion of follow-up strategies to mitigate concern with positive results will be reviewed. In addition, differences in genetic toxicology testing strategies for small molecules drugs, non-small molecule drugs, and impurities will be described. Finally, key points will be highlighted through the use of case studies.