

SAFETY ASSESSMENT OF PHARMACEUTICALS

16:963:513

Course Directors:

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Course Description: This two credit course is designed for students who have completed at least their first year of graduate course work in the JGPT as well as the Introduction to Drug Development course (Advanced Topics in Toxicology) taught by scientists from Bristol Myers-Squibb. In this course, students explore the drug development process through a series of advanced case studies focused on different aspects (e.g. clinical dose selection, metabolite toxicity, pediatric drug development, carcinogenicity, imaging, immunotoxicology) of preclinical safety assessment and challenges faced during the clinical phases of developing a new drug. Case studies will include traditional low molecular weight and biotherapeutic compounds.

Course Objectives:

Upon completion of this course, the learner is expected to:

- Gain a deeper understanding of various disciplines associated with toxicology in the pharmaceutical industry, regulatory aspects and execution of animal studies to support clinical drug development.
- Understand the difference between hazard/safety identification and risk assessment.
- Integrate the toxicology results into a cohesive risk assessment by weighing the impact/adversity of preclinical findings to the benefits to potential patient populations.
- Challenge the reasoning of particular study options and be able to propose alternative preclinical approaches (new models, diverse combinations of existing models, etc) for evaluating safety risks.

LECTURE SCHEDULE

Topics	Instructors
Drug Development from a Toxicology Perspective	R. Bergeron, J.Kinyamu-Akunda, I. Hanna
Development of a Biologic Drug	R. Bergeron, J.Kinyamu-Akunda
Mechanistic and Investigative Safety	L. Li
Safety Pharmacology	G. Friedrichs
Carcinogenicity	B. Johnson, F. Fonyuy-Tukov
Imaging and Pathology	G. Normand, D. Ibrahim Aibo
Drug Development from a Drug Metabolism Perspective	I. Hanna
Metabolite Toxicity	I. Hanna, T. Heimbach
Pregnancy, Lactation, etc	T. DeLise, R. Dugyala
Pediatric Drug Development	T. DeLise, R. Dugyala