TECH 528: Preclinical Evaluation of Novel Drugs and Beyond

This course will discuss in detail various aspects of nonclinical evaluation of novel drugs. Students will gain an understanding of animal studies submitted to support the safety of clinical studies and marketing application. Specific nonclinical study design, interpretation, and risk assessment for general toxicity, genotoxicity, reproductive toxicity, immunotoxicity, local toxicity, and carcinogenicity will be discussed in detail. Nonclinical studies that address alternate routes of administration, such as inhalation or intravaginal application, will be explored. Further, students will explore how the pharmaceutical industry uses nonclinical studies to prioritize and make business decisions, including in-licensing, academic/professional partnering, and entering the international market. Students will also investigate how nonclinical studies can be used to address the new paradigm of pharmacy compounding and after-market safety evaluations. By the end of the class, students will have the opportunity to discuss case studies, analyze nonclinical studies of various drugs, and make decisions based on the interpretation of these studies.

Learning Objectives

- Review the history and fundamentals of pharmacology/toxicology and challenges faced by these disciplines in the drug-approval process
- Discuss how non-clinical study results are interpreted, and how the pharmacology/toxicology discipline assesses hazard identification that affects advice provided regarding safety and efficacy in human clinical trials and for drug approval
- Explain the nonclinical study requirements and types of data reviewed by the pharmacology/toxicology Center for Drug Evaluation and Research (CDER) reviewer discipline
- Discuss how the pharmaceutical industry uses nonclinical studies to make business decisions, including partnering with academic and contract-research organizations, in-licensing, and moving to international markets
- Explore post-marketing safety of drugs via epidemiology, and how nonclinical studies can be used to address after-market safety concerns as well as pharmacy compounding

Credits: 2
Class Type: Graduate Course
Prerequisites:
college-level biology.
Program: Technology Transfer, Business, and Industry