

PHAR 328: FDA Perspective on Drug Development

This course will cover drug development from the FDA perspective. The FDA's roles and responsibilities related to the various components of the Investigational New Drug (IND) phase of drug development will be covered in detail, including Chemistry, Manufacturing and Controls (CMC), Pharmacology/Toxicology, Biometrics, Clinical Trials, Statistics and Inspection. In addition, a comparison of the development of biologic drugs versus small molecule drugs will be presented. Discussion of pediatric testing and the use of juvenile animal studies in this respect will also be included. The New Drug Application (NDA) process will be discussed in terms of product-label development. Aspects of the post-approval phase of drug development will be covered, in addition to OTC products and drug shortage issues. Finally, attendees will have the opportunity to discuss case studies, labels, and to analyze data and make approval decisions. This course is an elective for Advanced Studies in Technology Transfer.

Learning Objectives

- Understand drug development from the FDA perspective, including data analysis, label review, and final approval decisions
- Participate in case studies of real-world drug development scenarios
- Apply knowledge gained in this course to positions in industry and government

Credits: 2

Class Type: Graduate Course

Prerequisites:

college-level biological sciences.

Program: Biochemistry, Chemistry, Pharmacology, and Toxicology

Availability Currently Not Available