

PHAR 328: Regulatory Perspective on Drug Development

This course focuses on the responsibilities of the federal agency throughout the drug development process and understanding the processes and regulations surrounding drug and biologic approvals that guide how regulatory decisions are made. Course content will include lectures, weekly readings (including journal publications, articles, and regulatory documents). Assignments will include weekly discussion posts, midterm paper, final presentation, and final case study.

Specific topics covered will include: Animal Studies, In Vitro Studies, Good Laboratory Practice (GLP), Good Clinical practice (GCP), current Good Manufacturing Practices (cGMP), Chemistry, Manufacturing and Controls (CMC), Pharmacology/Toxicology, Clinical Trials, Statistics, Ethics, Inspections, and Labeling.

Note: This course is NOT meant to cover anything outside of the scope of what the FDA Regulates. This course is focused on drug and biologic regulation, not device regulation.

Learning Objectives

Upon successful completion of this course, students will be able to:

- Recognize the FDA drug development process, the laws and regulations that govern it in the United States.
- Identify the role of the regulatory affairs professional and other team members in the drug development process within industry and government settings.
- Address real-world drug development challenges through case studies.
- Understand the policies and procedures available to speed drug approvals for certain types of medical products.
- Demonstrate excellent communication skills through writing assignments related to ongoing course discussions.

Credits: 2

Class Type: Graduate Course

Prerequisites:

College-level biological sciences.

Program: Biochemistry, Chemistry, Pharmacology, and Toxicology

Availability Spring 2022

Session Session B