

**Pharmacy Student Rotation in the Food and Drug Administration's
Center for Drug Evaluation and Research (CDER)
Office of Clinical Pharmacology (OCP)**

Goals: The purpose of this rotation is to familiarize the student with the role of the Food and Drug Administration (FDA) in the drug development, review, and post-marketing phases, as well as offer more in-depth experience in general clinical pharmacology and its role in drug development.

I. Learning Objectives: Upon completion of this rotation the student will be able to:

- A. Explain the development of a new drug from laboratory to commercial distribution of the product and the FDA's role in that process.
- B. Distinguish between the three phases of clinical trials in the drug development process.
- C. Identify the basic elements of clinical pharmacology that are assessed during drug development including:
 - Drug-drug interaction studies
 - Special population studies (e.g., renal impairment, hepatic impairment)
 - Pharmacogenomics
 - Pharmacometrics
 - Bioequivalence and Bioavailability
 - Effects of food
 - QT prolongation
- D. Distinguish between sections of FDA product labeling, and demonstrate how clinical pharmacology information gets incorporated into product labeling.

II. Student Requirements: The student will be exposed to a variety of agents in various stages of drug development. The program will focus on familiarizing the student with the drug development process and general clinical pharmacology aspects of drug development. To meet these objectives the student will be expected to:

- A. Review assigned textbook material and complete relevant modules from the Clinical Pharmacology for Regulatory Scientist course.
- B. Review clinical pharmacology sections of assigned material (e.g., original IND, meeting package &/or protocol).
- C. Attend internal meetings with medical team.
- D. Attend Clinical Pharmacology Briefings.
- E. Be familiar with clinical pharmacology guidance documents.
- F. Give a presentation and/or conduct a project assigned by the preceptor.
- G. Attend the lecture series given by the FDA Pharmacy Student Experiential Program.
- H. Attend an Advisory Committee Meeting (if scheduling permits).
- I. Fulfill required hours.