

# WHERE DRUGS COME FROM: HOW THEY ARE DISCOVERED, DEVELOPED, REGULATED AND MARKETED



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**Type of course:** UC Davis School of Medicine, Fourth Year Elective (3 units)

**Course format:** This is a 2-week clinical didactic (classroom only; no patient contact). There will be 3 class sessions per week, each 2 hours in duration, at UC Davis Medical Center. The total class time is 12 hours. Self-study is required. Students will take the on-line eLearning Course: "Making Medicines, The Process of Drug Development." Students will have the option of attending lectures and participating in the 10-week, 2 unit Drug Discovery and Development (PHA 207) graduate course, offered in Winter Quarter 2018 on Wednesday evenings (4:00 p.m. to 6:00 p.m.) from January 10 to March 14.

**Pre-requisites:** UC Davis School of Medicine Year 4 in good standing, or with approval of instructor.

**Course objectives:** All physicians with direct patient care responsibilities prescribe or use medications. The correct selection and use of medications is critical to providing optimal patient care and avoiding harm. In order to properly prescribe and use medications, physicians must be able to locate, assimilate and critically evaluate scientific evidence pertaining to the safety and efficacy of drug products. Acquiring and properly evaluating information on which to base the selection and use of medications is becoming increasingly difficult as the amount of information available to physicians increases and the quality of information becomes more variable. Forces within the health care system that seek to mandate or limit prescribing also increasingly challenge physicians, particularly in an environment where the cost of medications is rising dramatically. The goal of this course is to educate medical students on the many facets of the process by which drugs are discovered, developed, regulated and marketed, and to raise awareness of the economic, political and social factors that shape the process.

**Topics:** The course curriculum includes the following topics: Overview of the Drug Discovery Process; Drug Regulation in the United States; Patents and Other Forms of Exclusivity; Drug Targets and Pharmacology; Identification of Lead Candidates; Preclinical Assessment; ADME Including Basic Pharmacokinetic Principles; Principles of Drug Toxicity; Principles of Drug Safety; Clinical Trials; Generic Drugs; Pharmaceutical Industry; Drug Distribution and Marketing; Dietary Supplements; Controlled Substances

**Course project:** Students will participate in a course research project where they will select a specific drug, and do a deep dive to search for information on how the drug was discovered and developed, and how it is regulated and marketed.

**Relevance to clinical medicine:** The course is intended to provide fourth-year medical students with habits of thought that will be of immediate use to them in the practice of clinical medicine, whether in training or in their eventual careers. Any physician who prescribes drugs should be familiar with the broad concepts to be taught in this course. Additionally, any such physician should be familiar with the information resources to which students will be exposed in the course. An understanding of how to find relevant information and critically evaluate it will enhance the student's eventual medical practice. The instructor is a practicing physician. During lectures and class discussions, the instructor will give real world examples from clinical practice to illustrate didactic points and to bring the discussion to life.

**Evaluation:** Each student will receive a one-paragraph narrative description of their overall performance prepared by the instructor as well as a grade. A pass grade will be assigned for students meeting the following minimum requirements: (1) satisfactory completion of eLearning course; (2) attend at least 5 of 6 class sessions; (3) satisfactory contribution to class discussions; and (3) satisfactory completion of course project. A grade of "honors" will be assigned for students who meet all the requirements for a grade of "pass" but in addition have produced a course project that exceeds expectations.