
PHA 6185 Drug Development

3 Semester Credit Hours

Course Purpose:

This class is targeted toward graduate student and advanced Pharm.D. students interested in learning the process of drug development from discovery to approval. Topics will include GGMP, GLP, GCP and intellectual property issues. NDA/ANDA requirements and processes will be discussed.

Course Faculty and Office Hours

Course Coordinator:

Dr. Anthony Palmieri III

Email: Palmieri@cop.ufl.edu Office: P4-27, MSB

Phone: 352-273-7868

Co-Coordinator: [Include only if there is a co-coordinator]

N/A

Office Hours

By Appt.

Place and Time of Class Sessions

TBD

How This Course Relates to the Learning Outcomes You Will Achieve in the Pharm.D. Program:

N/A

Course Objectives

1. Provide students with knowledge of the drug development and approval process
2. Expose students to case studies of interactions concerning regulatory approval
3. All students to interact with industry and regulatory personnel

Pre-Requisite Knowledge and Skills

General understanding of pharmaceuticals

Course Structure & Outline

Course Structure.

- a) Multiple self-directed learning activities are required (eg, videos, readings, web-based learning) and at selected intervals students come to class for a face-to-face learning session (eg, case discussion, problem set discussion); students must come to class for exams,
- b) All class sessions are face-to-face and the student must complete some self-directed pre-requisite learning activities, or

Course Outline/Activities. [Refer to an outline of course activities] (Refer to an **Appendix**).

1. Introduction and history of drug development. (2 lectures)
2. Lead finding, optimization and pre-clinical activities, formulation development and optimization. Classes will include how companies optimize the API structure, rational dose form decisions. (2 lectures)
3. New chemical entities, biologics, genomics. Classes include how drug discovery and development has moved from rational structure-activity science to biological drugs and genomics (2 lectures)
4. Non-proprietary names, trade names. How USAN and INN names are obtained (1 lecture)
5. Intellectual property concerns, CDA's, MTA's. (1 lecture)
6. FDA, Centers in the FDA, structure of the FDA, non-US agencies. This will be an intensive comprehensive discussion about the FDA, CBER and non-US agencies. (3 lectures)
7. Phase 1, 2, 3, 4. How the various phases of drug development are viewed by the regulatory agencies. What are the requirements and costs involved? How to interact with the agencies at each stage. (3 lectures)
8. IND, NDA, including 505.2b filings. A major part of the course. Process development working through the agencies. (3 lectures)
9. GLP, GMP, GCP, and how they are different. What are the requirements of each? (2 lectures)

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10. Labeling. What are the regulatory agency requirements for labels and how they impact the product development? (2 lectures)
11. Recalls, warning letters, problems. (2 lectures)
12. Generics, combination products, new dose forms. how product line extensions are allowed. Advantages and disadvantages. (2 lectures)
13. Nutraceuticals, cosmetics, natural products. How the regulatory agency evaluates and views these products. (2 lectures)
14. Devices. How approval for medical devices is different than NCI's. (1 lecture)
15. Student presentations. (5 classes)

Textbooks

1. FDA website
2. USP website
3. USPTO website
4. USAN website
5. Various journal readings

Active Learning Requirements

N/A

Student Evaluation & Grading

Evaluation Methods

1. Exams 70%
2. Presentation 20%
3. Class participation 10%

Grading Scale

Per UF standard

Class Attendance Policy

Since this class will use extensive interactions and learning styles, attendance is mandatory . If a student must miss a class, whenever possible it should be pre-approved by the instructor.

Quiz/Exam Policy

Contact Dr. Palmieri

Make-up Quiz/Exam Policy

Exams missed due to illness will be allowed to be made up.

Policy on Old Quizzes and Assignments

N/A

Assignment Deadlines

Late assignments will not be accepted

General College of Pharmacy Course Policies

The College of Pharmacy has a website that lists course policies that are common to all courses. This website covers the following:

1. University Grading Policies
2. Academic Integrity Policy
3. How to request learning accommodations
4. Faculty and course evaluations
5. Student expectations in class
6. Discussion board policy
7. Email communications
8. Religious holidays
9. Counseling & student health
10. How to access services for student success

Please see the following URL for this information:

<http://www.cop.ufl.edu/wp-content/uploads/dept/studaff/policies/General%20COP%20Course%20Policies.pdf>

Complaints

Should you have any complaints with your experience in this course please visit:

<http://www.distancelearning.ufl.edu/student-complaints> to submit a complaint.