PH A 6274  Federal Regulation of Drugs and Pharmacy

3 Semester Credit Hours

Course Purpose:

This course is designed to provide an understanding of the regulation of drug products by the US Food and Drug Administration. There will be discussion of New Drug Applications, Abbreviated New Drug Applications and OTC monographs in addition to patent issues and market exclusivity.

COURSE FACULTY AND OFFICE HOURS

Varies

Office Hours

You may contact the Course Co-Coordinators via email.

PLACE AND TIME OF CLASS SESSIONS

The seven pre-recorded lectures will be available online in Canvas. You will be required to have your microphone so you can participate in class. There will be a weekly question posted after class.

<table>
<thead>
<tr>
<th>Week One</th>
<th>Pre-recorded lecture (Lecture 1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week Two</td>
<td>Lecture 2</td>
</tr>
<tr>
<td>Week Three</td>
<td>Lecture 3</td>
</tr>
<tr>
<td>Week Four</td>
<td>Lecture 4</td>
</tr>
<tr>
<td>Week Five</td>
<td>Lecture 5</td>
</tr>
<tr>
<td>Week Six</td>
<td>Lecture 6</td>
</tr>
<tr>
<td>Week Seven</td>
<td>Lecture 7</td>
</tr>
<tr>
<td>Final Exam</td>
<td>Final Exam</td>
</tr>
</tbody>
</table>

Course Objectives

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

1. List critical events in the evolution of U.S. drug laws.

2. Distinguish between drugs, dietary supplements, foods and medical devices.

3. Discuss the implications of “new drug” status.

4. Describe FDA practices and procedures.

5. Describe the process of drug discovery and testing.

6. List the criteria for IRB review of research with human subjects.
7. Explain the elements of an NDA and ANDA.
8. Describe the process of post-marketing surveillance.
9. List labeling requirements for drugs.
10. Discuss labeling and advertising regulations under the FDCA.
11. Describe Congressional oversight of FDA actions.
12. Understand the role of the FDA, the Courts and Congress in the regulation of drugs.

Pre-Requisite Knowledge and Skills
None.

COURSE STRUCTURE & OUTLINE

Course Structure. Course will be 7 pre-recorded lectures, 7 online classes, a weekly graded question and a final exam.

Textbooks
Vary

Active Learning Requirements
Reading assignments, videotapes.

STUDENT EVALUATION & GRADING

Evaluation Methods
Students will be evaluated by grades received on weekly questions, the grade on the course final, and the class participation. The final will count for 50%, the weekly question 40%, and class participation 10%. The class participation grade will be based on discussion of the case or cases assigned and in responding to questions asked during class. A failure to respond will be non-participation.

Grading Scale

<table>
<thead>
<tr>
<th>Grade</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>A+</td>
<td>100 - 97</td>
</tr>
<tr>
<td>A-</td>
<td>96 - 94</td>
</tr>
<tr>
<td>A</td>
<td>93 - 90</td>
</tr>
<tr>
<td>B+</td>
<td>89 - 87</td>
</tr>
<tr>
<td>B</td>
<td>86 - 80</td>
</tr>
<tr>
<td>C+</td>
<td>79 - 77</td>
</tr>
<tr>
<td>C</td>
<td>76 - 74</td>
</tr>
<tr>
<td>C-</td>
<td>73 - 70</td>
</tr>
</tbody>
</table>
CLASS ATTENDANCE POLICY
Every student is expected to participate in the weekly on-line class. To be excused, please contact a TA concerning your inability to attend. Failure to notify will be marked as non-participation.

Quiz/Exam Policy
Any questions about quiz or final exam grades should be addressed to the instructor.

Make-up Quiz/Exam Policy
THERE WILL BE NO MAKE-UP EXAMS.

Policy on Old Quizzes and Assignments
No old quizzes will be provided.

Assignment Deadlines
For quizzes, one point will be deducted for late papers.

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.

Other Course Information
N/A
Directions for Contacting Course Faculty
Contact should be to the Course Coordinators via email.

Instructors
Vary