

Online POP Course Syllabus

PHA6274: Federal Regulation of Drugs & Pharmacy

3 credit hours

Note: The final syllabus posted in the course Canvas site (accessible to enrolled students) is the most current and supersedes this syllabus.

Class Meeting Times

This course meets synchronously via Zoom. The class meetings are in the evening (Eastern time zone) or on Sundays. Specific class dates will be announced by program administrators to students in the Online POP Graduate program prior to course enrollment.

Class Meeting Location

Class meetings are held in Zoom, which can be accessed via the course Canvas site. If you are having trouble accessing the course Canvas site, please contact Distance Education Support Services at Ahc-dess@ufl.edu.

Instructor

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Course Description

This course is designed to provide an understanding of the regulation of drug products by the US Food and Drug Administration. Among the topics we will explore include discussions of New Drug Applications, Abbreviated New Drug Applications and OTC monographs. We will also examine the areas of patent issues and market exclusivity within the context of FDA regulatory compliance.

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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.

Relationship to Program Outcomes

This course pertains to the following program outcomes: Interpret and apply laws, regulations, guidance, and policies related to drug development and/or use.

Required Textbooks and/or Software

There are no required texts.

This textbook is optional: Hutt, Merrill and Grossman, Food and Drug Law Cases and Materials, 4th Edition. Foundation Press. (2014)

Additional reading assignments from current websites, journal articles, and news articles are assigned for each module. These reading assignments are provided in Canvas.

Recommended Materials

None

Course Pre-Requisites

None

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Structure and Organization

This course is organized into weekly modules in UF's e-learning system, Canvas. The assigned work (eg, readings, videos, discussion boards, and assignments) for each module is clearly detailed in Canvas. In addition, the faculty and students meet synchronously once per week using Zoom. This course is self-paced to accommodate the time constraints of individual students. However, students are expected to complete the assigned work for each module before each weekly synchronous class meetings and by the posted deadline.

Course Schedule

Week	Date	Topic	Assignments due
1	TBA	The Food and Drug Administration's Laws and Regulations	None
2	TBA	Statutory and Regulatory Framework	Topic paper 1
3	TBA	Enforcement	Topic paper 2
4	TBA	Investigational New Drug Applications (INDA) and Filing New Drug Applications (NDA)	Topic paper 3
5	TBA	Generic Drugs	Topic paper 4
6	TBA	Product OTC and DESI II Drugs	Topic paper 5
7	TBA	Intellectual Property for NDAs and Abbreviated New Drug Applications (ANDAs)	Final exam

TBA=to be announced

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Evaluation Methods

<i>Assignment</i>	<i>Total Points</i>	<i>% of Final Grade</i>
Weekly Assignment Papers <ul style="list-style-type: none"> Grades are based on criteria for scoring following the assignment directions. 	100 each	40%
Class Participation* <ul style="list-style-type: none"> Class attendance and online activity will be used to gauge participation. 	100 each	25%
Final Exam <ul style="list-style-type: none"> This online exam is comprised of written (typed) responses to questions. 	100	35 %

*Class participation will be evaluated based on contribution to class discussion. The instructor will call on individual students during synchronous class meetings. This strategy is intended elevate and advance the conversation, not to challenge the student with a question that is difficult to answer. Students are encouraged to be prepared for the discussion, but they should be comfortable responding to the question with another question or expressing points of ambiguity about the topic.

Timeline for instructor feedback: Grades and feedback from the instructor will be posted within 7 calendar days.

Attendance Policy for this Course

Students are expected to attend the synchronous class meetings. Students who miss 30 minutes or more of the synchronous class meeting are considered absent.

Unexcused absences from the synchronous class meetings carry a 4-percentage point (~1/2 letter grade) reduction in the final grade.

Excused absences require a make-up paper to be submitted within 2 weeks of the missed class (unless the class is near the end of the semester and a shorter timeline will be required). Contact the instructor for specifics on the make-up paper. Absences are considered excused when the student (not a peer) has emailed the instructor before the synchronous class meeting begins and conveys why the student will miss class, such as illness, job conflict, and other emergencies. The instructor can be contacted via email (preferred) or text (listed above). Two or more excused absences will be addressed by the course coordinator and may result in an incomplete final grade for the course.

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Attendance Policy for Online POP

Students who do not attend course meetings, log into Canvas, etc., are **not** automatically dropped from the course. The Online POP program does not officially drop students from a course unless the student requests it. Students can request to drop a course by completing a [drop form](#) by the deadline posted on the [Academic Calendar](#).

Make-up Policy:

Each assignment is posted with a clear due date. **Assignments that are not submitted by the due date will be given a zero.** The instructor will consider extenuating circumstances on a case-by-case basis – if she is contacted by the student in advance of the due date. No other makeup assignments are offered. Contact the instructor for any concerns.

Grading Policy

The only passing grades for graduate students are A, A-, B+, B, B-, C+, C, and S. Grades of B-, C+ or C count toward a graduate degree if an equal number of credits in courses numbered 5000 or higher have been earned with grades of B+, A- and A, respectively. Grade points are not given for S and U grades; S and U grades are not used to calculate grade point averages. All letter-graded courses eligible to count toward the graduate degree, except 1000- and 2000-level courses, are used to calculate the cumulative grade-point average. Letter grades of C-, D+, D, D- or E are not considered passing at the graduate level, although the grade points associated with these letter grades are included in grade point average calculations. See the [UF graduate academic regulations](#) for more information.

A	>92.500%
A-	89.500–92.499%
B+	86.500–89.499%
B	82.500–86.499%
B-	79.500–82.499%
C+	76.500–79.499%
C	72.500–76.499%
C-	69.500–72.499%
D+	66.500–69.499%
D	62.500–66.499%
D-	59.500–62.499%
E	<59.499%

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Artificial Intelligence Use Policy

When authorized by the instructor, students may use AI technologies in the completion of coursework if they cite all such use by naming the technology and how it was employed. Students assume full responsibility for all content, including errors and omissions. Assistive technology authorized as part of an accommodation for a disability is always permitted.

Course Technology Support

Your instructor is not able to handle technological issues or answer questions related to computer issues.

- **Assistance accessing course Canvas page:** Contact Distance Education Support Services at DESS@ahc.ufl.edu
- **IT Support:** Contact UF Computing Help Desk at 352-392-HELP (4357) or helpdesk@ufl.edu or submit an [online request form](#). If a technical problem causes you to miss an assignment, you must report the problem to the Help Desk and then email your instructor your Help Desk ticket number to the instructor in order to receive an extension.

Students Requiring Academic Accommodations

Students with disabilities who experience learning barriers and would like to request academic accommodations should connect with the [Disability Resource Center](#). It is important for students to share their accommodation letter with their instructor and discuss their access needs, as early as possible in the semester.

Course technologies meet online learning accessibility standards for sight and hearing-impaired learners. Likewise, course materials are developed in accordance with accessibility standards. Course documents and webpages are formatted for screen-reader accessibility with the use of headings, styles, or alternative text tagging for images. Accessibility design tools in Microsoft Office products and in Canvas are used to evaluate and update accessibility issues detected in the instructional materials. Synchronous class sessions in Zoom are recorded. These recordings are posted to the course site to accommodate students unable to attend.

- [Canvas Accessibility](#)
- [Zoom Accessibility](#)

Course Evaluations

Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. [Click here for guidance on how to give feedback in a professional and respectful manner](#). Students will be notified when the evaluation period opens and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via ufl.bluera.com/ufl/.

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University Honesty Policy and Academic Integrity

UF students are bound by The Honor Pledge which states, “We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honor and integrity by abiding by the Honor Code. On all work submitted for credit by students at the University of Florida, the following pledge is either required or implied: “On my honor, I have neither given nor received unauthorized aid in doing this assignment.” [The Honor Code](#) specifies a number of behaviors that are in violation of this code and the possible sanctions. Furthermore, you are obligated to report any condition that facilitates academic misconduct to appropriate personnel. If you have any questions or concerns, please consult with the instructor or TAs in this class.

Regarding academic integrity, students in the program are strongly encouraged to be mindful of what constitutes plagiarism. Written assignments that contain the research or other original published work of someone else must be properly quoted, cited, paraphrased, or referenced appropriately. A software (TurnItIn) that is integrated with Canvas Assignments may be utilized to help students determine if a written submission meets the criteria for a properly referenced research paper. Please ask for help, utilize resource materials and take advantage of opportunities like creating a draft of your paper to test, ensuring you have addressed any errors prior to the final submission.

Please watch these short videos about this topic:

- [Understanding and Avoiding Plagiarism: Types of Plagiarism](#)
- [Avoiding Plagiarism](#)

Software Use and Course Technology

All faculty, staff, and students of the University are required and expected to obey the laws and legal agreements governing software use. Failure to do so can lead to monetary damages and/or criminal penalties for the individual violator. Because such violations are also against University policies and rules, disciplinary action will be taken as appropriate. We, the members of the University of Florida community, pledge to uphold ourselves and our peers to the highest standards of honesty and integrity.

Educational technology in the program is primarily the Canvas Learning Management System (LMS) and Zoom web conferencing software. These tools firmly support learning objectives and course goals. Writing with communication tools, reading articles from digital collections, and viewing video presentations in high-quality, accessible formats are essential to facilitate meaningful learning experiences. These experiences expand knowledge and influence professional work habits and skills such as information-gathering techniques and evidence-based practice. Synchronous class sessions in Zoom provide learners with opportunities to gain confidence and practice how they interact and collaborate in online meetings.

- [Canvas Student Guide](#)
- [Zoom Resources](#)

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A minimum number of other technical skills are required for success in the online courses. These include accessing course webpages to read text and listen to recorded videos, using word processing tools (MS Word, PowerPoint), downloading/uploading content, submitting online assignments and using a variety of communication tools (Canvas Inbox, Discussions, Zoom Conferences).

Course Communication

Canvas (Inbox tool) will be used as the primary communication tool between the instructor and students. Check daily for new announcements or notifications about course updates. UF email will also be used occasionally for mass communication to the class, so please check your email at least once a day as well. All emails sent out to the entire class will also be posted as an Announcement on Canvas. The instructor will generally respond to student messages within 72 hours.

General questions about course content (e.g., assignments or lectures) or policies should be posted to the course discussion board. We expect students to help each other track down answers as best as possible. Read through all the other posts in the discussion board first before posting to make sure your question has not been addressed/answered already. Please include a clear subject title for your topics to make it clear what your post pertains to. The instructor will generally respond to questions posted on the course discussion board within 72 hours.

Emotions can easily be misinterpreted on a discussion board/emails, so make sure your message is clear before sending it since there are no physical gestures or voice inflections that accompany posts/emails. Any posts/emails deemed inappropriate by the faculty will be dealt with on a case-by-case basis with either the faculty directly or they will be sent on to the Associate Dean for Professional Affairs.

For personal issues/questions, please email your instructor. Be sure to include in your subject line the course listing and then a quick subject (e.g., PHAXXXX – Your Name -). This will allow instructors to quickly identify emails related to the course amongst the many emails that are received each day. Emails not correctly addressed may get lost in the shuffle and unintentionally deleted or ignored so be sure to follow the guidelines exactly.

Student Privacy

There are federal laws protecting your privacy in terms of grades earned in courses and on individual assignments. For more information, please see the [Notification to Students of FERPA Rights](#).

Recordings of weekly class sessions in Zoom are created for the purpose of course teaching and learning, as well as for use as a resource for students who miss a class session.

The use of video (or web camera) feature in Zoom is not a requirement, but rather is voluntary for meeting participants. For both the audio and video features in Zoom, you will have the option to Start or Stop these functions.

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Students who participate with their camera engaged or who utilize a profile image are agreeing to have their video or image recorded. If you are unwilling to consent to have your profile or video image recorded, be sure to keep your camera off and do not use a profile image. Likewise, students who un-mute during class and participate orally are agreeing to have their voices recorded. If you are not willing to consent to have your voice recorded during class, you will need to keep your mute button activated and communicate exclusively using the "chat" feature, which allows students to type questions and comments live. As in all courses, unauthorized recording and unauthorized sharing of recorded materials is prohibited.

- [Zoom Software Privacy Statement](#)
- [Canvas \(by Instructure\) Privacy Policies](#)

Security

Online activity in Canvas requires an active UF GatorLink account to log in, as well as enrollment in courses. The Zoom Conference meetings for weekly classes are accessed within Canvas. These meetings have a pass code applied as an additional security setting. Students in the class do not need to enter the passcode, however anyone not enrolled in the course cannot join the meeting without it.

Library Resources

For remote access to UF library resources such as e-journals or other digital collections, use the [UF VPN or proxy server to connect](#).

Additional University Resources

- **U Matter, We Care:** If you or a friend is in distress, please contact umatter@ufl.edu or 352 392-1575 so that a team member can reach out to the student.
- [Counseling and Wellness Center](#)
- **Sexual Assault Recovery Services (SARS):** Student Health Care Center, 392-1161.
- **University Police Department** at 392-1111 (or 9-1-1 for emergencies), or police.ufl.edu
- **E-learning technical support:** 352-392-4357 (select option 2) or e-mail to Learning-support@ufl.edu.
- **Teaching Center:** Broward Hall, 392-2010 or 392-6420. General study skills and tutoring.
- **Writing Studio:** 302 Tigert Hall, 846-1138. Help brainstorming, formatting, and writing papers.
- [Student Complaints](#)