

# Online POP Course Syllabus

## PHA6186: Foundations of Pharmaceutical Outcomes and Policy I: Drug Discovery, Development, and Approval 3 credit hours

**Note:** The final syllabus posted on the course Canvas site is the most current and supersedes the online syllabus.

### Class Meeting Times

Sundays, 6:00-8:00 pm Eastern

\*There is an optional class meeting on September 3, 2023 [Labor Day]

### Class Meeting Location

Class meetings are held in Zoom, which can be accessed via the course Canvas site. If you have trouble accessing the course Canvas site, please contact Distance Education Support Services at [DESS@ahc.ufl.edu](mailto:DESS@ahc.ufl.edu).

### Instructor

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Office Hours: By appointment  
Office Location: via Zoom or phone

### Course Description

Foundations of Pharmaceutical Outcomes and Policy I is the first course in a two-course series designed to provide students in the Master of Science in Pharmaceutical Sciences with a Focus on Pharmaceutical Outcomes & Policy an overview of drug discovery, development, approval, marketing, regulation, and use in the United States. These courses show how the "US medication system" pieces fit together.

These courses will give participants a basic understanding of topics ranging from drug discovery to disposal. This high-level overview introduces issues detailed in the Master of Science tracks (i.e., Applied Pharmacoeconomics, Managed Care Pharmacy Systems, Medication Safety and Quality Systems, and Pharmaceutical Regulation). "Foundations I" will focus on before a drug is marketed.

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In addition to recorded video lectures and online weekly class meetings, this course will include readings from various sources and perspectives. It will provide a balanced view of controversial topics and invites discussion using the presented content, supplemental information posted to the Discussion Boards, and students' and faculty experiences. The concepts and principles in this course will provide perspective for students' various chosen specialty areas, which will be addressed in studies that follow this foundational course.

## Course Objectives

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

1. Contrast the roles of academia, government, industry, and serendipity in drug discovery.
2. Explain the Bayh-Dole Act's effects on drug discovery.
3. State barriers to drug development and discuss incentives that might overcome these barriers.
4. Explain the cost of drug discovery and development.
5. List the phases of the Food and Drug Administration's drug approval process and explain the key characteristics of each phase.
6. Compare and contrast the approval processes for drugs, biologicals, generics, biosimilars, and dietary supplements.
7. List and explain the various types of unapproved drugs marketed in the United States
8. Explain the creation of a drug label and its various components.
9. Identify the types of "drug products" on the US market and evaluate the regulations that affect their approval and use.
10. Explain the sources of raw materials to make pharmaceuticals, how pharmaceutical drugs are made, and how FDA regulates manufacturing before and after a drug is approved.
11. Debate current controversies in drug discovery, development, and regulation.

## Relationship to Program Outcomes

This course pertains to the following program outcomes:

1. Identify, interpret, and utilize core knowledge across the spectrum of Pharmaceutical Sciences.
2. Analyze and apply material from foundation courses in the curriculum, interpret data, and synthesize a response to a complex problem or case.
3. Deliver a presentation on a discipline-specific topic related to Pharmaceutical Sciences for internal academic review. These presentations will provide information appropriate to the audience, providing the necessary and relevant background from the literature.

## Required Textbooks and/or Software

This course has no required textbook; however, students must subscribe to *STAT+*, a pharma/health care news and analysis website. To subscribe, go to [www.statnews.com/subscribe](http://www.statnews.com/subscribe). Use code ACADEMIC75 to receive a 75% student discount on the subscription rate on the payment page. Reading assignments from online textbooks, journal articles, lay media articles (e.g., *New York Times* and *Wall Street Journal*), and websites will

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be assigned for each module. UF students can access the *New York Times* and *Wall Street Journal* at no cost (<https://news.hr.ufl.edu/technology/did-you-know-uf-offers-free-online-subscriptions-to-the-new-york-times-wall-street-journal/>). Thus, students will have access to the latest in the ever-changing landscape of pharmaceutical information.

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

## Structure and Organization

The concepts and principles in this course will provide perspective for students' various chosen specialty areas, which are addressed in courses that follow this foundational course. The course structure consists of seven weeks of learning content and assignments online in UF's e-Learning system, Canvas. The course also features weekly class meetings using Zoom Conferences. In addition to recorded video lectures and online weekly class meetings, this course will include readings from various sources and perspectives. It will provide a balanced view of controversial topics and invites discussion using the presented content, supplemental information posted to the Discussion Boards, and students and faculty experiences. Students are expected to complete the assigned work for each module before each weekly synchronous class meeting and by the posted deadline.

## Course Schedule

| Week | Date  | Topic                                    | Assignments  |
|------|---|--|--|
| 0    | August 27, 2023                                   | Course Introduction Meeting              | <ul style="list-style-type: none"> <li>Syllabus quiz</li> </ul>  |
| 1    | September 3, 2023<br><b>*Optional attendance*</b> | Drug Discovery & Development             | <ul style="list-style-type: none"> <li>Drug Discovery &amp; Development</li> <li>Industry, Academia, and the Government's Role</li> <li>Serendipity</li> <li>Preclinical Drug Development</li> </ul> |
| 2    | September 10, 2023                                | Drug Discovery & Development (continued) | <ul style="list-style-type: none"> <li>Barriers &amp; Incentives</li> <li>The Bayh-Dole Act</li> <li>The Cost of Discovery, Development, and Approval</li> <li>Types of Drugs</li> </ul>             |

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|   |                    |   |   |
|---|--------------------|---|---|
| 3 | September 17, 2023 | The FDA Approval Process                      | <ul style="list-style-type: none"> <li>Expanded Access and Right to Try</li> <li>Emergency Use Authorizations</li> <li>Phases of Drug Approvals</li> <li>Drug Names</li> </ul>  |
| 4 | September 24, 2023 | The FDA Approval Process (continued)          | <ul style="list-style-type: none"> <li>Biological Approvals</li> <li>ANDAs for Generics</li> <li>505(b)(2) NDAs</li> <li>Biosimilar Approvals</li> <li>Expedited Drug Approvals</li> </ul>                                  |
| 5 | October 1, 2023    | Pharmaceutical Manufacturing                  | <ul style="list-style-type: none"> <li>Manufacturers</li> <li>Sources of Raw Materials</li> <li>Making Finished Drug Products</li> <li>FDA Oversight of Drug Production</li> <li>Stability and Expiration Dating</li> </ul> |
| 6 | October 8, 2023    | Marketed Products & Other "Drugs"             | <ul style="list-style-type: none"> <li>Labeling</li> <li>Nonprescription Drugs</li> <li>Vitamins and Minerals</li> <li>Dietary Supplements</li> </ul>   |
| 7 | October 15, 2023   | Marketed Products & Other "Drugs" (continued) | <ul style="list-style-type: none"> <li>Homeopathic Remedies</li> <li>Medical Foods</li> <li>Devices that "Look-Like" Drugs</li> <li>Unapproved Drugs</li> <li>Approval of Controlled Substances</li> </ul>                  |

\*Attendance is optional for this session since it is a holiday weekend. Please watch the recording of the class.

## Evaluation Methods

### Online quizzes:

This course will involve mandatory readings, online assignments, and pre-recorded lectures that must be reviewed before each weekly quiz. Weekly quizzes will be available for at least 3 days before each class. Quizzes will include 10 multiple-choice or short-answer questions over 15 minutes. There will be eight quizzes [including the syllabus quiz], and the lowest quiz grade will be dropped. The purpose of the quizzes will be to assess readiness for the weekly discussions and understanding of the course materials. The quiz average will contribute 49% towards the final grade in this course (i.e., each quiz will contribute 7% towards your final grade).

### Class participation:

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Class participation is mandatory. Discussion board participation, class attendance, and class participation will award 32% of the final grade. There are eight participation grades (seven weeks plus the introductory session); thus, each week will contribute 4% towards your final grade. Each student is expected to post one substantial post to the discussion board weekly. What constitutes a “substantial post” and how posts will be graded is described in the Introductory class session. The discussion board post may offer an opinion regarding one of the topics covered, a thoughtful reaction to another student's post, an extension of the concepts covered in readings or lectures, or an addition to the general theme of the week (e.g., Drug Discovery and Development). Characteristics of a substantial post include the following: demonstrates understanding of the issue, elaborates with accurate explanations and evidence, provides accurate information, distinguishes fact from opinion, synthesizes points of agreement or disagreement, attempts to stimulate discussion, and presents a creative approach to the topic. Each post must include a unique citation that is not class material or that another student has used.

## Final Paper:

Students will identify a topic for a paper and submit it to the course coordinator for approval. Approval must occur before the class session for Week 3. Students are encouraged to pick a subject for in-depth evaluation consistent with the topics listed in the Course Schedule. The paper's content must be more extensive than the materials covered in class. The report should be a maximum of 10 pages and follow the *POP Online Graduate Program: Style Guide for Writing Assignments*. Proper attribution is mandatory; plagiarism will be assessed using Turnitin. References should be sequentially numbered and cited as a superscript at the end of a sentence and consecutively listed at the end of the paper. All students must watch and follow the instructions in the pre-recorded lectures, *Tips for Writing Your Paper*, and *Using Turnitin to Assess Similarity*, and *POP/AMA Referencing*. All papers will be due on October 16, 2022, by 4:00 PM Eastern Time. The final paper will determine 20% of your final grade. Refer to the grading rubric.

## Timeline for instructor feedback:

Grades and feedback from the instructor will be posted within seven calendar days.

## Diversity, Equity, and Inclusion

“An inclusive classroom climate refers to an environment where all students feel supported intellectually and academically and are extended a sense of belonging in the classroom regardless of identity, learning preferences, or education.” -*Yale Center for Teaching and Learning*

The online Pharmaceutical Outcomes and Policy (POP) graduate program embraces the idea that we all benefit from our individual differences and that our collected diversity is a source of strength. Additionally, as

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members of the health care community, improving health equity for our patients or others whom we serve, begins with us.

Our instructors are committed to creating course environments that celebrate diversity, honor inclusivity, and ensure equity for all students. It is important that all class-related interactions feel like a safe space for students of all backgrounds and learning styles to feel welcome, heard, and supported.

And, as this is your learning experience, your suggestions to ensure this commitment is fulfilled are encouraged and appreciated. Interactions that do not honor the spirit of this commitment will be addressed as they arise on an as needed basis.

## Attendance Policy for this Course

Students are expected to attend synchronous class meetings. Students who miss 15 minutes or more of the synchronous class meeting are considered absent.

**Unexcused absences** from a class carry a 1/2 letter grade (e.g., from an A to an A- or B+ to a B) penalty taken off the final grade.

**Excused absences** require a makeup reflection paper on the module topic to be submitted within two weeks of the missed class (unless the class is near the end of the semester and a shorter timeline will be required). Absences are 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 will address two or more excused absences which may result in an incomplete final grade for the course.

## Attendance Policy for Online POP

Students are expected to formally [drop or withdraw](#) from the course if they no longer wish to participate. See the program's [Academic Calendar](#) for applicable deadlines. In some cases, the University may automatically drop students for inactivity and/or for failure to pay tuition. It is crucial for students to communicate with the DESS (DESS@ahc.ufl.edu) about their status in the course, and about any tuition deferments or other special conditions related to their tuition payment. Any student who remains enrolled in the course after the drop/add deadline is considered tuition-liable, unless exempted by University petition. The official UF Attendance Policy can be found [here](#).

## Makeup Policy:

Each assignment is posted with an exact due date. **Assignments not submitted by the due date will be given a zero.** The instructor will consider extenuating circumstances on a case-by-case basis – if the student contacts him before the due date. No other makeup assignments are offered. Contact the instructor for any concerns.

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## 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%       |

## 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](mailto:DESS@ahc.ufl.edu)

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- **IT Support:** Contact UF Computing Help Desk at 352-392-HELP (4357) or [helpdesk@ufl.edu](mailto: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/](http://ufl.bluera.com/ufl/).

## 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.



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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.

The University policy on use of ChatGPT is available [here](#).

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](#)

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.

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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 48 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 48 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.

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

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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](mailto: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](http://police.ufl.edu)
- [E-learning technical support](#): 352-392-4357 (select option 2) or e-mail to [Learning-support@ufl.edu](mailto: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](#)