PHA6797: APPLIED PHARMACEUTICAL RESEARCH COMMUNICATIONS
3 credit hours

Note: The final syllabus posted in the Course Canvas site is the most current and supersedes this syllabus.

Class Meeting Times
Thursdays, 8:00-10:00 pm Eastern when the course is in session.
Should any class be scheduled on a University of Florida holiday, it will be recorded and will be available after the next scheduled class. All classes are via the Internet through the University of Florida's Canvas system. Our class sessions may be audio visually recorded for students in the class to refer back and for enrolled students who are unable to attend live. Students who participate with their camera engaged or 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. As in all courses, unauthorized recording and unauthorized sharing of recorded materials is prohibited.

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 DESS@ahc.ufl.edu.

Instructor
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Phone/Text: 412.657.1410 (cell)
Office Hours: By appointment, before, or after class meetings
Office Location: via Zoom or phone

Course Description
Research should be the foundation of all pharmaceutical decisions in today's health care system— from treatment choices to product approval and formulary decisions. A prerequisite to using pharmaceutical research is communicating that research. Pharmaceutical research must be communicated in a way that effectively translates value to the intended audience. Yet, the very definition of value may vary for different

audiences, such as health care providers, payers, and consumers. Dissemination vehicles for communicating pharmaceutical research also vary by audience and are often governed by different rules and regulations. This course will describe the concept of pharmaceutical value from the viewpoint of the health care provider, the consumer, and the payer. Students will learn about various types of research communications for each audience and their applicable rules and regulations. This is an applied class where students will critically evaluate a variety of pharmaceutical research communications, such as peer-reviewed journal articles, conference presentations, and health care provider and payer communications. Over the course of the semester, students will be expected to develop payer and health care provider focused pharmaceutical research communications that incorporate value messaging and other important concepts learned throughout the semester. Upon completion of the course, students will be able to understand the various considerations when developing research communications that incorporate value messaging and apply the applicable rules and regulations for each audience.

The course will emphasize giving and receiving feedback and incorporation of value messaging into all pharmaceutical research communications.

Course Objectives

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

1. Understand the definition of value in pharmaceuticals from the perspectives of the healthcare provider, the payer, and the consumer
2. Apply best practices to develop pharmaceutical research communications that incorporate value messaging for three distinct audiences: health care provider, payer, and consumer.
3. Apply the key rules and regulations governing how pharmaceutical manufacturers can communicate to each of health care providers, payers, and consumers in the development of pharmaceutical research communications.
4. Collaborate with classmates to give and receive peer reviews of communications that meet quality control standards.
5. Select appropriate and targeted dissemination venues for research, including scientific conferences and peer-reviewed journals.
6. Prepare study materials for presentation at a scientific conference, including an abstract and poster, in compliance with guidelines.
7. Create tables and figures that convey study results accurately and effectively.
8. Describe the steps of publication planning to support a pharmaceutical product.
9. Describe general considerations when preparing regulatory materials.

Relationship to Program Outcomes
This course pertains to the following program outcomes:

1. Assess the value of a pharmaceutical product using systematic reviews, meta-analyses, and value messaging practices
2. Create evidence-based communications that are compliant with regulations and convey the value story of a pharmaceutical product that uses data-driven visuals.

Required Textbooks and/or Software

There is no textbook required for this course. Rather, required readings will be assigned for each module. Additional readings can be added to the below list throughout the semester; please check the Canvas site for each weeks' assigned readings.

- (Week 1) BCG Market Access Roundtable Working Group. A multi-stakeholder perspective on assessing drug value. Pharmaceutical Executive. 2019;39(12). Available at: https://www.pharmexec.com/view/multi-stakeholder-perspective-assessing-drug-value-0
- (Week 2) FDA Guidance for Industry: Drug and device manufacturer communications with payors, formulary committees, and similar entities- questions and answers. June 2018. Available at: https://www.fda.gov/media/133620/download
- (Week 2) Neumann PJ, Weissman H. The FDA's new guidance on payer communications: Implications for real-world data and value-based contracts. Health Affairs Blog. July 17, 2018. Available at: https://www.healthaffairs.org/do/10.1377/hblog20180712.816686/full/
- (Week 2) AMCP Format for Formulary Submissions, version 4.1 Available at: http://www.amcp.org/sites/default/files/2019-12/AMCP_Format%204.1_1219_final.pdf
- (Week 3) Continuity and decline of the pharma value proposition. Pharmaceutical Executive. October 29, 2020. Available at: https://www.pharmexec.com/view/continuity-and-decline-of-the-pharma-value-proposition
- (Week 4) FDA Guidance for Industry: Distributing scientific and medical publications on risk information for approved prescription drugs and biological products. June 2014. Available at: https://www.fda.gov/media/88674/download
- (Week 4) FDA Guidance for Industry: Distributing scientific and medical publications on unapproved new uses – recommended practices. February 2014. Available at: https://www.fda.gov/media/88031/download
- (Week 5) FDA Guidance for Industry: Presenting risk information in prescription drug and medical device promotion. May 2009. Available at: https://www.fda.gov/media/76269/download
- (Week 7) McQuarrie G. Components of a strategic and tactical publication plan. International Society for Medical Publication Professionals. Available at: https://www.ismpp.org/assets/docs/Certification/StudyMaterials/3.mcquarrie.pdf
- (Week 8) Archer R, Johnson MR, Chipps E. Evaluating the role of the regulatory writer. 2019;33(9). Available at: https://acrpnet.org/2019/11/12/evaluating-the-role-of-the-regulatory-writer/

Recommended Materials
None

Course Pre-Requisites
None

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
1	Thursday, January 18	Course Overview and Value in Pharmaceuticals	• 2 lectures • Discussion board • Required readings • Assignment
2	Thursday, January 25	Payer Communications	• 2 lectures • Discussion board • Required readings • Assignment
3	Thursday, February 1 ***no live class, pre-recorded***	Value Messaging	• 2 lectures • Discussion board • Required readings • Assignment
4	Thursday, February 8	Healthcare Provider Communications	• 2 lectures • Discussion board • Required readings • Assignment
5	Thursday, February 15	Direct-to-consumer Communications	• 2 lectures • Discussion board • Required readings • Assignment

6	Thursday, February 22	Data Visualization	• 2 lectures • Discussion board • Required readings • Assignment
7	Thursday, February 29 ***May be changed to Monday, February 20***	Scientific Conferences	• 2 lectures • Discussion board • Required readings • Assignment
8	***Sunday March 3rd***	Regulatory Writing and Final Presentations	• Final presentation due

Evaluation Methods

Assignments (50%):

Each module will have one or more assignments for the student to complete. Some assignments will be completed individually and others will be group assignments. Each assignment is weighted equally.

Discussion Board and Class Participation (30%):

Students are expected to actively contribute to discussions both in the synchronous class meetings and through online discussion boards in Canvas. Participation points will be awarded for each of the modules. **Students are expected to post at least one substantive comment to the Canvas discussion board each week.** The post can be an original/new post or a comment on another post.

Substantive posts are characterized by the following: demonstrates understanding significant ideas relevant to the issue, elaborates with accurate explanations or evidence, provides accurate information, distinguishes fact from opinion, stimulates inquiry through thoughtful posts, asks clarifying questions, synthesizes points of agreement or disagreement, attempts to motivate the group discussion, presents creative approaches to the topic. Posts should include citations when appropriate. All citations should be in AMA format.

Students are expected to contribute to the 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.

Final Presentation (20%):

Students will submit a final paper in this course.

Timeline for instructor feedback:

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

UF

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

Unexcused absences from a class carry a 5-point (1/2 letter grade) penalty taken off the final grade.

Excused absences require a make-up reflection paper on the module topic 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). 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. Two or more excused absences will be addressed by the instructor and 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.

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%

UF | **College of Pharmacy**
Department of Pharmaceutical
Outcomes and Policy
UNIVERSITY *of* **FLORIDA**

Online Graduate Program
onlinepop.pharmacy.ufl.edu

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/.

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." <u>The Honor Code</u> 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

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 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 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**