PHA 6797 Applied Pharmaceutical Research Communications

3 Semester Credit Hours

Course Purpose

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, consumers, and payers. 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 produce portions of a variety of pharmaceutical research communications, such as peer-reviewed journal articles, clinical study reports, formulary dossiers, publication plans, and conference presentations. Upon completion of the course, students will have a portfolio of their work suitable for sharing in a job interview.

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

Prerequisites:

None

Course Faculty and Office Hours

Course Coordinator:
TBD

Place and Time of Synchronous Online Class Sessions

Classes are XX-XX Eastern Time. All times are given as Eastern Time unless explicitly stated otherwise. 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.

Course Objectives:

Upon completion of this course, the student will:

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

Course Structure & Outline

Course Structure.

Learning activities

a) Video Lectures
b) Mandatory readings
c) Web-based learning
d) Preparation for weekly readiness assessments
e) Participation in live weekly discussions during class
f) Participation in discussion board activities
g) An individual written paper on a topic approved by the course coordinator

Course Outline/Activities.

See the course outline in Appendix B. All assignments and topics are subject to change as posted on Canvas to include current issues regarding the issues of discussion.

Most classes will involve discussions. Students are expected to come to class prepared to discuss the readings and other assignments.

Textbook:

There is no textbook required for this course. Rather, required readings will be assigned for each module.

- 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/reimbursement-benchmark-share-an-objective-measure-of-the-impact-of-product-reimbursement-on
- 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
- 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
- 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
- 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/
- 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
- 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/
- 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

Active Learning Requirements

Participation in the live online classroom sessions is mandatory. These sessions are an essential part of this course. Students may be permitted to submit a make-up assignment for up to two excused absences. (See Class Attendance Policy)

Student Evaluation & Grading

Evaluation Methods

Online quizzes (15% of course grade): Each week, student preparedness for the synchronous class meeting will be assessed through an online quiz. The quiz will cover the assigned readings and pre-recorded lectures. The lowest quiz grade will be dropped.

Weekly assignments (70%): Each week, students will prepare pharmaceutical research communications relevant to the weekly topic. The purpose of these assignments is for students to apply what they have learned in the modules and produce pharmaceutical research communications that can ultimately be used in a portfolio or job interview.

The weekly topics and corresponding assignments are shown in Appendix B. Schedule of Course Activities/Topics. Each assignment will be graded using a rubric, provided in Appendix C. No weekly assignment grades will be dropped.

The assignments are described below:

1. **Tables and Figures:** Students will be provided with pharmaceutical data and asked to produce a variety of tables and figures displaying the data. The tables and figures should be developed in accordance with best practices for data visualization and should be appropriate to support a pharmaceutical regulatory submission.
2. **Value Messages:** Students will be provided with clinical, economic, and humanistic information on a pharmaceutical product. They will be asked to interpret these data to craft value messages for different audiences including payers and health care providers. The value messages must be compliant with regulatory requirements and can be used to support other communications.
3. **Study Reprint Cover Sheet:** Students will produce a study reprint cover sheet compliant with FDA guidance on distributing scientific and pharmaceutical publications on risk information for approved prescription drugs and biological products.
4. **Plain Language Summary:** Students will write a plain language summary of a pharmaceutical research study at an appropriate reading level that can be used by lay audiences, including patients, media, and policy-makers.
5. **Unbranded Website Analysis:** Students will identify an unbranded website produced by a pharmaceutical company. They will analyze the website against regulation for unbranded materials, identify the underlying value messages, and make recommendations for enhancement.

6. **Study Summary:** Students will prepare a study summary of an economic or outcomes study on a pharmaceutical product. The study summary will be prepared in compliance with the AMCP Format for Formulary Submissions, which standardizes the format of information passed from pharmaceutical companies to members of formulary committees.
7. **Abstract:** Students will identify a scientific conference and research the specifications for abstract submissions. Then, given a pharmaceutical research study report, they will prepare an abstract that is compliant with meeting guidelines.
8. **Poster:** Students will identify a scientific conference and research the specifications for poster presentations. Then, given a pharmaceutical research study report, they will prepare a poster that is compliant with meeting guidelines.
9. **Publication Plan Summary:** Students will prepare a publication plan summary for a pharmaceutical product with multiple research studies ongoing. The summary will include target journals, reasonably planned timelines, and visual presentation of the publication plan.

Peer critiques (15%): Students will provide feedback on a classmate's work on a weekly basis. The purpose of these critiques is to develop the skill of providing feedback on pharmaceutical research communications as well as the ability to receive such feedback. Both skills are essential in the workplace. Two peer-critiques will be selected at random throughout the semester and graded according to the rubric provided in Appendix D.

Grading	**% of grade**
Online quizzes *To assess preparedness for synchronous class meeting* *Lowest quiz grade will be dropped*	15%
Weekly assignments* *To apply learnings and produce a portfolio of work* *Listed in Appendix B. Schedule of Course Activities/Topics* *Grading based on rubric in Appendix C*	70%
Peer critiques *To simulate the feedback cycle in pharmaceutical communications* *Completed weekly – two selected at random for grading*	15%

Grading Scale

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

Note: this scale already reflects a rounding of grades. A grade of 92.4 is not 0.1 from an A; it is 0.6 points from an A. There will be no additional rounding or awarding of "extra" points because a grade is close to the cut-off. This course's rounding policy already considers these issues.

Class Attendance Policy

Unexcused absences from the online group discussions carry a 4-point (~1/2 letter grade) reduction in the final grade. Absences due to illness, job conflicts, and other emergencies must be conveyed by e-mail (preferred) or phone/text to the course coordinator before the group discussion begins. Messages from friends or classmates will not be accepted, except under exceptional circumstances. When a student has an excused absence, they will receive no deduction for participation. Excused absences will require a make-up reflection paper within 2 weeks of the missed class to obtain your participation points. This paper requires you to listen to the recorded class session and write a reflection paper on the content covered during the missed classed.

The course coordinator will address more than two excused absences; an incomplete grade (i.e., I grade) is a strong possibility.

Quiz/Exam Policy

Make-up Quiz/Exam Policy

The course coordinator will handle make-up quizzes on a case-by-case basis. Usually, these will be considered a zero score and be the dropped quiz grade. If more than two quizzes are missed for a valid reason (i.e., medical excuse), the course coordinator will make accommodations on a case-by-case basis.

Policy on Old Quizzes and Assignments
No old quizzes, exams, or assignment examples will be provided.

Assignment Deadlines

Assignments will be posted with precise due dates. Students are responsible for complying with these deadlines. Late assignments will not be graded (0 points). Delays due to unforeseen and/or distressing events will be treated on a case-by-case basis by the course coordinator.

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

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. Guidance on how to give feedback in a professional and respectful manner is available at https://gatorevals.aa.ufl.edu/students/. 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 https://ufl.bluera.com/ufl/. Summaries of course evaluation results are available to students at https://gatorevals.aa.ufl.edu/public-results/.

Complaints

Should you have any complaints about your experience in this course or suggestions for improvement, please visit:

http://www.distancelearning.ufl.edu/student-complaints

Session Recording

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.

Students Requiring 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 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. Guidance on how to give feedback in a professional and respectful manner is available at https://gatorevals.aa.ufl.edu/students/. 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 https://ufl.bluera.com/ufl/. Summaries of course evaluation results are available to students at https://gatorevals.aa.ufl.edu/public-results/.

Appendix A: Directions for Contacting Faculty and Technical Support

Directions for Contacting Course Faculty

Canvas will be used for most communications between the faculty and students. Check for new announcements at least once a day for any course updates. 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.

General questions about course content (e.g., assignments or lectures) or policies should be posted to the 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 clear subjects for your post topics to make it clear to all what your post pertains to.

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 the Course Coordinator. Be sure to include in your subject line the course listing and then a quick subject (i.e., PHA6935 – Your Name -). This will allow coordinators to quickly identify emails related to the course amongst the plethora of junk and other 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. If you have any issues with the course site, please email Justin DeLeo (jdeleo1970@ufl.edu).

Directions for Contacting Technical Support

Should you experience any technical issues with course media or content, email Pharmaceutical Outcomes & Policy Support: **popsupport@ahc.ufl.edu**.

Appendix B. Schedule of Course Activities/Topics

Week and Date	Learning Activities/Topic
Course Overview	
<date>	Introduction to course
	What is value in pharmaceuticals?
	Quality control in research communications
	Giving and receiving feedback
Module 1: Regulatory Writing	
Week 1 <date>	Study protocols – formats, best practices
	Clinical study reports
	Other regulatory writing: informed consent, risk evaluation mitigation strategy (REMS), investigator resources
	Assignment: Tables and Figures
	Synchronous meeting: Discussion of best practices for tables and graphs
	Required readings: 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/
Module 2: Value Messaging	
Week 2 <date>	Value assessment frameworks – ICER, NCCN, etc.
	Value messages by audience – payer and health care provider
	Approaches to developing value messages
	Assignment: Value Messages
	Synchronous meeting: Exercise in prioritizing value messages
	Required readings: 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/reimbursement-benchmark-share-an-objective-measure-of-the-impact-of-product-reimbursement-on
Module 3: Health Care Provider Communications	
Week 3 <date>	Promotional vs non-promotional communications
	Fair balance, off-label uses, and pre-launch communications
	Scientific communications: peer-reviewed publications (primary and secondary), abstracts and posters for scientific conferences
	Other provider communications: continuing education, medical science liaison (MSL) slide decks (proactive and reactive), symposium (live and web-based)
	Assignment: Study Reprint Cover Sheet
	Synchronous meeting: Discuss the peer-review publication process from start to finish
	Required readings: 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 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
Module 4: Direct-to-Consumer Communications	
Week 4 <date>	Role of Federal Trade Commission (FTC) and FDA
	Guidance for communication print and non-print (TV, audio recordings, videos) vehicles
	Branded vs unbranded materials – and the role of unbranded communications
	Advocacy groups for rare diseases

Week and Date	Learning Activities/Topic
	Translating research for consumers
	Assignment: Plain Language Summary and Analysis of Unbranded Website
	Synchronous meeting: Discuss compliant and non-compliant examples from FDA guidance on presenting risk information in prescription drug and medical device promotion
	Required readings: 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
Module 5: Payer Communications	
Week 5 <date>	Section 114, Section 3037, and the Pharmaceutical Information Exchange Act
	HEOR and budget impact evidence
	AMCP dossiers
	Payer value decks
	Assignment: Study Summary
	Synchronous meeting: Demo and discussion of example payer value deck(s) – mock P&T vote
	Required readings: 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 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/
Module 6: Scientific Conferences	
Week 6 <date>	Selecting a meeting
	Developing an abstract – written and visual
	Developing a poster – written and digital with audio
	Assignment: Abstract and Poster
	Synchronous meeting: Presentation of abstracts and poster materials
	Required readings: None
Module 7: Publication Planning	
Week 7 <date>	Situation analysis
	Target audience and value messages
	Publication strategy
	Tactical recommendations
	Visual presentation of publication timing
	Assignment: Publication Plan Summary
	Synchronous meeting: Interactive analysis of identifying target journals
	Required readings: 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

*Specific notations about a week's class (i.e., voluntary participation on a holiday weekend).

Appendix C: Rubric for Assignments

Criteria	Excellent (90%-100%)	Good (80%-89%)	Unsatisfactory (<80%)	Score
Basic requirements (10%)	Submission meets all the requirements described in the instructions.	Submission meets ≥80% of the requirements described in the instructions.	Submission meets <80% of the requirements described in the instructions	
Ideas and Insights (20%)	Submissions makes clear, compelling points derived from the source data that is at an appropriate level for the target audience.	Submission is reasonably clear, compelling, and at an appropriate level but could be improved.	The insights and ideas are not clear and/or are poorly presented.	
Visual elements (10%)	Visual data displays are used appropriately, are accurate, and follow best practices.	Visual data displays are used appropriately in part, are somewhat accurate, and/or follow only some best practices.	Visual data displays are not used appropriately, are not accurate, and/or do not follow best practices.	
Value messages (10%)	Superior incorporation of value messages.	Basic incorporation of value messages but could be improved.	No incorporation of value messages.	
Presentation (10%)	Submission is prepared with the highest level of professionalism.	Submission is reasonably professional but could be improved.	Submission lacks key elements of professionalism.	
Navigation (10%)	Superior use of navigational cues to guide the reader.	Reasonable use of navigational cues to guide the reader but could be improved.	Inadequate use of navigational cues to guide the reader.	
Accuracy of information (10%)	Submission contains no noticeable errors or omissions in the data.	Submission contains 1-2 noticeable errors or omissions in the data.	Submission contains >2 noticeable errors or omissions in the data.	
Grammar and syntax (10%)	Precise syntax and superior use of grammar, punctuation and spelling.	Syntax is clear and the relatively few grammar, punctuation, and spelling errors do not impede understanding.	Syntax is sometimes garbled and errors in grammar, punctuation and spelling disrupt understanding.	
References (10%)	All necessary statements and data are appropriately cited.	There are minimal errors in citations and references.	Missing references and errors in citations are extensive.	