USC School of Pharmacy

PHRD 663: Pharmaceutical Development

Number of Units: **3** (PharmD)
Term: **Spring 2025**
Day: **Monday**
Time: afternoon (**3-5pm**)
Location: online/in person for one session

Instructor/Course Coordinator: Charles Stark
Office Hours: Monday 5 to 6pm
Contact Info: starkcws@gmail.com and/or cstark@usc.edu
310-310-4060 (office/cell)

Other instructors:
Recent USC graduate guest speakers are invited.

IT Help:
Brightsource is utilized as the learning management system for this course. For help (at any time)
• Call 213-740-5555 and choose Option 2
Brightspace Student Tutorials. Find technical support information below:

Student Guides: Brightspace Student Guides
Brightspace Technical Support Line: 888-895-2812
Brightspace Email Support: usc@d2l.com

Mediasite is used for lecture capture and delivery. For help, send an email to USC School of Pharmacy IT at servicedesk@pharmacy.usc.edu
For other technology-related questions, call USC IT Services at 213-740-5555.

Course Description
This course is for students interested in learning drug development pathways (clinical research) to obtain marketing authorizations in the United States and other regions. It covers a high-level overview of drug discovery and commercialization. Over the past 27 years, school graduates have successfully planned for and attained rewarding jobs in small and large pharmaceutical companies, device industries, and the U.S. Food and Drug Administration.

Program Outcomes
The following School of Pharmacy Ability-Based Outcomes (ABOs) are introduced, practiced and/or achieved in this course.

1. Practice working in teams (about nine individuals are created during the first day of class).
2. Dive deep into a therapeutic area (Sickle Cell Disease) to develop expertise in a rare disease field.
3. Exercise presentation skills when communicating outcomes from assigned readings or literature searches.

4. Learn expected professional behavior in departments such as clinical development, medical affairs, commercialization, and regulatory.
5. Actively participate in an in-person, half-day, competition: Drug Discovery and Development Workshop.

Learning Objectives

Students completing this course will be able to articulate how drugs undergo development (testing) for marketing authorization in the United States and in other countries.

Upon completion of this course, students will be able to:

1. Attain a visceral comprehension of the risks (costs and failure) and benefits (success of obtaining marketing authorization) associated with early to late drug development.
2. Describe internal company planning and communications necessary along with regulatory agency interactions required during the entire development program.
3. Upon marketing authorization, explain the need for continued research, such as post-marketing commitments with regulatory agencies, other sponsored research, and investigator-initiated research.
4. Describe activities related to drug distribution, market access, and strategic engagement and education of HCPs and patients.
5. Describe the variety of roles held and experiences brought forth by PharmDs to the drug development and commercialization field.

Teaching Methods

Teaching methods utilized in this course:
Lecture presentations
Reading (publications)
Guest lecturers and discussions
Team presentations
Short assignments in Brightspace

Course Notes

The course will be letter-graded following two examinations (one workshop exam and an overall final exam) and two PowerPoint presentations by each team on assigned topics. Attendance at each class session is required, and professionalism in class is expected.

Technological Proficiency and Hardware/Software Required:

Learn to operate the software for the 3D workshop (demonstrations and instructions will be provided).

Required Readings and Supplementary Materials

1) Review of the drug development process. https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process
2) Sickle cell disease clinical development readings will be assigned to the teams in Brightspace.
3) Internet review of www.clinicaltrials.gov for various drug trials globally.
4) FDA websites for Code of Federal Regulations (21CFR Parts 50, 56, 312 and 314).
5) FDA Advisory Committee Meetings
6) 3D Workshop eBinder (provided)

Description and Assessment of Assignments

1) Students must learn the Acronyms used in clinical research. Knowledge will be assessed via a quiz (not graded) at the beginning of the third session.
2) Each team will present one presentation, with a Topic TBD. The instructor will assess the content, presentation, and Q&A.
3) The IND, study protocol, investigator's brochure, informed consent, clinical study report, and an NDA will be provided for in-class learning. Knowledge will be assessed via a quiz during a subsequent session.
4) Team colleagues' Sickle Cell Disease journal article review will be evaluated on the selected topic's completeness, quality, clarity, and critical discussion.
5) Drug Discovery and Development Workshop participation: The instructor will assess the level of engagement, understanding, and team presentations made during the workshop.

Grading Breakdown

Assignment	Points	% of Grade
1)	15	15
2)	25	25
3)	15	15
4)	15	15
5)	30	30
Total	**100**	**100**

Assignment Submission Policy

Assignments will be distributed to teams at class sessions as scheduled – please refer to pages 5 and 6.

Additional Policies

Two face-to-face attendances and full completion of each virtual session are required. Professionalism in class is expected, which includes on-screen presence with active engagement. Industry video conferences do not accept off-screen participation (internet failures are understood).

Policy Regarding Missed Examinations

The policy for this course will follow the policy contained in the Academic Policies and Procedures of the University of Southern California School of Pharmacy 2013 Edition. Students who miss an examination are referred to this policy.

Rule on Cell Phones and Other Electronic Equipment during Exams:

Only authorized calculators are allowed during exams. No cell phones are to be in the immediate possession of the student. Cell phones and other electronic equipment not approved for the taking of the exam may be stored in the student's backpack and will be placed in the front of the room during the examination. All cell phones in the student's backpack must be turned off. Any student possessing a cell phone or other unapproved electronic device during an examination will be subject to a failure in that examination and disciplinary action.

Policy on Learning & Assessment Feedback (LAF)

Feedback on examinations will be provided using the following methods.

Method of Providing Feedback on Performance
Other: Written comments on reports and presentations
Zoom meeting if needed

University Policy on Absences

University policy grants students excused absences from class for observance of religious holy days. Faculty are asked to be responsive to requests when students contact them IN ADVANCE to request such an excused absence. The student should be given an opportunity to make up missed work because of religious observance. Students are advised to scan their syllabi at the beginning of each course to detect potential conflicts with their religious observances. Please note that this applies only to the sort of holy day that necessitates absence from class and/or whose religious requirements clearly conflict with aspects of academic performance.

School of Pharmacy policy for written assignments regarding citation style

All written assignments in the course should use the uniform style of the School of Pharmacy for formatting in-text citations and reference lists. This style corresponds to the AMA (American Medical Association) format and can be found in the summary at http://goo.gl/tvNiu2. The complete AMA Manual of Style is also available as an e-book at http://goo.gl/edJfN and print book at the Norris Medical Library.

Statement on Academic Conduct and Support Systems

Academic Conduct

Plagiarism – presenting someone else's ideas as your own, either verbatim or recast in your own words – is a serious academic offense with serious consequences. Please familiarize yourself with the discussion of plagiarism in *SCampus* in Part B, Section 11, "Behavior Violating University Standards" https://policy.usc.edu/student/scampus/part-b. Other forms of academic dishonesty are equally unacceptable. See additional information in *SCampus* and university policies on scientific misconduct: http://policy.usc.edu/scientific-misconduct.

The university does not tolerate discrimination, sexual assault, and harassment. You are encouraged to report any incidents to the *Office of Equity and Diversity* http://equity.usc.edu/ or the *Department of Public Safety* http://dps.usc.edu/contact/report/. This is important for the safety of the whole USC community. Another member of the university community – such as a friend, classmate, advisor, or faculty member – can help initiate the report or can initiate the report on behalf of another person. Relationship and Sexual Violence Prevention and Services (RSVP) https://engemannshc.usc.edu/rsvp/ *(formerly known as 'The Center for Women and Men')* provides 24/7 confidential support, and the sexual assault resource center webpage https://sarc.usc.edu/ describes reporting options and other resources.

Support Systems

Student Complaint Policy

To preserve the significant student-instructor relationship, an attempt to resolve any issues regarding a course should first be addressed with the instructor through direct communication. If the problem cannot be resolved through this dialogue, the issue should move beyond the instructor to the chair of the department and, if needed, a second level of review by the Associate Dean of Student/Faculty Affairs.

Scholarly Writing

Several USC schools provide support for students who need help with scholarly writing. Check with your advisor or program staff to find out more. Students whose primary language is not English should check with the *American Language Institute* http://dornsife.usc.edu/ali, which sponsors courses and workshops for international graduate students.

Course Schedule--A Weekly Breakdown			
	Topics/Daily Activities	**Readings and Homework**	**Deliverable/ Due Dates**
1/13	Overview of the course, address meeting norms, create teams, team representatives, and setting goals and objectives. Establish schedules and expectations	Prepare for a 3-minute interview (each student) on past experiences.	Week1
1/27	Presentation on each of the 4 distinctly different drug approvals in sickle cell disease. Study design, endpoints and statistics used.	Sickle Cell Disease; publications and approvals.	Week 2
2/3	Introduction to Drug Development from a high-level view. Review Sickle Cell Disease publications. The Code of Federal Regulations will be covered.	Readings: Code of Federal Regulations 21 CFR Part 312 (INDs) and 21 CFR Part 314 (NDA).	Week 3
2/10	Drug Discovery and Development Workshop T-shirts will be distributed. .	Noon to 5 pm at CHP G34 (main room and 3 breakout rooms) Lunch will be provided.	Week 4
2/24	Introduction to the Drug Discovery and Development Workshop (3D) a computer-simulated, competitive workshop. Guest lecturer.	Review 3D Workshop synopsis (provided to class) electronically. Roles, responsibilities, and definitions. Readings: Code of Federal Regulations 21 CFR Part 314 (NDA).	Week 5
3/3	Team presentations on drug targets, mTOR inhibitor history, Kaplan-Meier Curve.	Preparation for presentation on various targets (inhibitor of kinases, receptors, growth factors and well as mTOR inhibitor history. Review Kaplan-Meier Curves.	Week 6
3/10	Review of course and team preparation for examination		Week 7
3/24	Final Exam		Week 8

The Office of Disability Services and Programs
http://sait.usc.edu/academicsupport/centerprograms/dsp/home_index.html provides certification for students with disabilities and helps arrange the relevant accommodations. Students requesting test-related accommodation will need to share and discuss their DSP recommended accommodation letter/s with their faculty and/or appropriate departmental contact person at least three weeks before the date the accommodations will be needed. Additional time may be needed for final exams. Reasonable exceptions will be considered during the first three weeks of the semester as well as for temporary injuries and for students recently diagnosed. Please

note that a reasonable period is still required for DSP to review documentation and to make a determination whether requested accommodation will be appropriate.

Stress Management
Students are under a lot of pressure. If you start to feel overwhelmed, it is important that you reach out for help. A good place to start is the Eric Cohen Student Health Center of USC at (323) 442-5631. The service is confidential, and there is no charge.

Emergency Information
If an officially declared emergency makes travel to campus infeasible, *USC Emergency Information* (http://emergency.usc.edu/) will provide safety and other updates, including ways to continue instruction through Brightspace, teleconferencing, and other technology.

About Your Instructor

Charles W. Stark, PharmD, graduated from the USC School of Pharmacy and has been the course coordinator since the curriculum committee approved this class in 1997. He is an Executive Vice President at Emmaus Medical Inc. Before Emmaus, he held roles at immunotherapeutic companies Bavarian Nordic and Dendreon after 11 years at a pharmaceutical company, Pfizer, Inc. He is an adjunct assistant professor and has been an Advanced Pharmacy Practice Experience preceptor since 1991. He has seen over 300 students enter into positions in industry and government.