

# USC Mann

Alfred E. Mann School of Pharmacy  
and Pharmaceutical Sciences

## Fall 2024 - BPSI 410: Biopharmaceutical Product Development and Brand Planning

*Updated: July 1, 2024*

### Instructors:

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**Course Weight:** 4 units

**Days/Time:** Tuesday, Thursday: 2:00pm to 3:20 p,

**Location:** WPH B36

**Catalogue Description:** *Introduces critical financial decisions and development milestones in biopharmaceutical drug product development and commercialization. Learn to align business strategies with decisions supporting a product lifecycle.*

### **Introduction**

Financial stakes in bringing a new drug to market are high. Over \$75 billion is spent annually by drug manufacturers on pharmaceutical research and development in the United States yet only 1 in 10,000 compounds in drug discovery find its way to the commercial market and patients. This course introduces students to critical financial decisions and development milestones in new drug product development and commercialization. Students will learn how to align business strategies

and tactics into each go or no-go decision in the product development lifecycle to support the commercial and financial success of a product.

## Objectives

This course is designed for undergraduates of both scientific and non-scientific majors with an interest in learning about economic principles and concepts underlying the pharmaceutical and health care industries. Chapters from the textbook will be supplemented with journal articles and other timely materials such as policy white papers and newspaper articles. Students will critically evaluate and debate policy positions and emerging “hot” topics will be discussed.

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

- Define the importance of business planning and product strategy for new products
- Describe essential clinical development and regulatory requirements for new products.
- Describe the role of marketing throughout the product development process to optimize commercial success of new products.
- Explain how products are measured against an unmet need and clinical value.
- Evaluate critical milestones and go/no go decision mapping throughout the product development process.
- Analyze marketing and value strategies from clinical development to commercial product launch.
- Discuss pricing mechanisms and assumptions used in establishing a price of a biopharmaceutical product.
- Develop brand management strategies and plans critical to building the commercial foundation of a product.
- Devise product life cycle management strategies to maximize asset value of a biopharmaceutical product.
- Develop a launch readiness plan to support the launch of a new product
- Develop a sales forecast to plan and manage a new product launch

## Assignments and Grading

Assignment	Points	Percent
3 Assignments (10 points, 10% each)	30	30%
3 Reaction papers (5 points, 5% each)	15	15%
Group Project & Presentation	15	15%
Midterm Exam	35	15%
Final Exam	50	25%

**Assignments (10 points, 10% each)**

**Submitted on Brightspace by on the deadline date by 11:59 pm**

- **Assignment 1: Thursday, September 5, 2024**
- **Assignment 2: Tuesday, October 15, 2024**
- **Assignment 3: Thursday, November 26, 2024**

### **Reaction papers (5 points, 5% each)**

These reports will be related to the weekly topics and students will sign-up for their topics via Brightspace. Students will prepare a one-page reaction paper. Students will need to research their topic based on materials presented and outside reading that will be suggested during the lectures and updated on Brightspace. This can include journal articles, news report, legal case, ethical issue, or policy review. Students should then be prepared to lead class discussion on the topic that week. Students are encouraged to sign-up early as it is first come, first served – once a topic week has passed, no additional reactions will be accepted for that week. You are expected to cite at least two sources (class books and articles, articles from journals, books, etc.) per essay. You will be penalized -5 points for each missing resource. The reference page does not count toward the total paper length. You should NOT use Wikipedia or any other similar form of wiki to write these essays.

**Submitted on Brightspace by on the deadline date by 11:59 pm**

- **Reaction Paper 1: Thursday, September 19, 2024**
- **Reaction Paper 2: Tuesday, October 22, 2024.**
- **Reaction Paper 3: Thursday, November. 7, 2024**

**Capstone project and presentation (15%):** Student teams will be assigned a group project in which they will be assigned a drug under clinical development to take through product development to product launch. Student teams utilize information and skill learned from the class lectures, readings, and student's individual research. Student teams will present their project to the class at the end of the semester.

**Midterm (15%) and final (25%) exams:** Exams will be a combination of true/false, short-response, and problem-solving questions. There will be one midterm and one final exam. The final exam is cumulative.

**Midterm Date:** Tuesday, Oct 8

**Final Exam Date:** Thurs. Dec. 12 – 2 to 4 pm

**Note: Exam dates must be taken in person (no remote option) and cannot be changed due to travel.**

**No late essays will be accepted for any reason short of a serious, documented emergency.** An official note explaining why you were unable to write the essay will be required for an extension. All other late submissions will incur a penalty.

**There are no make-up exams.** If exceptional circumstances prevent you from attending an exam, your reason for missing it must be accompanied by a written statement from a third party (e.g., a note from a medical doctor). Subject to verification.

## ***Course Readings***

Course readings are posted on the course website (<http://brightspace.usc.edu>). These readings have been compiled from a variety of source materials to provide you with current evidence-based practices from the field of pharmacology and augment lecture materials. Selected chapters from the textbook and supplemental readings should be read according to the course outline below; these materials are relevant for group presentations, quizzes, and exams. Other topical materials including but not limited to the syllabus, supplemental reading assignments and additional handouts will be posted.

## **Class Policies Regarding Class Discussions and Etiquette**

An overview of the class policies and how they relate to the discussions and interactions that will occur in this class can be found below. We expect each student to review, understand and adhere to these policies.

### **Respect**

- Listen actively and attentively
- No name calling or other character attacks
- Always use a respectful tone
- Know tone of voice and body language are powerful communicators. Some postures or facial expressions can silence, intimidate, or hurt your classmates (e.g., crossed arms, eye rolls). Other postures or facial expressions can show you are listening respectfully (e.g., making eye contact, staying quiet, nodding).

### **Constructiveness**

- If you wish to challenge something that has been said, challenge the idea not the individual sharing it
- Ask for clarification if you are confused
- Commit to learning, not debating

### **Inclusivity**

- Try not to silence yourself out of concern for what others will think about what you say
- Try not to let your question (or answer) run on. Give others the chance to speak, too.
- Do not remain silent. Make sure to contribute to the discussion
- Take responsibility for the quality of the discussion

## **Course Evaluations**

Course evaluation occurs at the end of the semester university wide. It is an important review of students' experience in the class.

## **Course Outline**

This course will be in the format of a directed lecture under the guidance of the instructor for this specific session. During each biweekly session, the instructor will engage the students with questions and draw comments or interpretations primarily based on the

assigned reading. Students are expected to ask questions and participate in an interactive fashion. Because this is an area of rapid change in policies, the readings may vary from one term to the next.

The course schedule is as follows:

Week	Topics	Assigned Reading
<p><b>Week 1</b></p> <p>Tues. Aug. 27</p> <p>Thurs. Aug. 29</p>	<p><b>Introduction: Expectations and Goals of Class</b></p> <p><b>Dr. Daryl Davies</b></p> <p><b>Why Drugs work – or Don't.</b></p> <ul style="list-style-type: none"> <li>• Introduction and expectations for the class</li> <li>• Overview of Drug Discovery Process</li> <li>• Presentation of several drug successes and failures</li> </ul>	<p><i>Assigned and Supplemental Reading (View YoutubeLinks below)</i></p> <ul style="list-style-type: none"> <li>• <a href="#">What is Pharmacology and Pharmacodynamics</a></li> <li>• <a href="#">Basics on PK: what the body does to a drug</a></li> </ul>
<p><b>Week 2</b></p> <p>Tues. Sept. 3</p> <p><b>Assignment #1</b></p> <p>Thurs. Sept. 5</p>	<p><b>Overview of Biopharmaceutical Marketplace and Industry Landscape</b></p> <p><b>Defining a Market</b></p> <p><b>Dr. Daryl Davies</b></p> <p>Overview of healthcare, pharmaceutical commercial landscape</p> <ul style="list-style-type: none"> <li>• Trends in capitalization and R&amp;D</li> <li>• Impact of health policy landscape on R&amp;D</li> <li>• Factors driving success vs. failure in new product development</li> </ul> <p><b>Dr. Jesse Hong</b></p> <ul style="list-style-type: none"> <li>• Overview of healthcare, pharmaceutical commercial landscape</li> <li>• Trends in capitalization and R&amp;D</li> <li>• Impact of health policy landscape on R&amp;D</li> <li>• Factors driving success vs. failure in new product development</li> <li>• Reimbursement and payment of biopharmaceuticals</li> </ul>	
<p><b>Week 3</b></p> <p>Tues. Sept. 10</p> <p>Thur. Sept. 12</p>	<p><b>Introduction to Clinical Drug Development and Research</b></p> <p><b>Dr. Larissa Yedigarova</b></p> <ul style="list-style-type: none"> <li>• Drug discovery, pre-clinical trials, and clinical research</li> <li>• Clinical trials development planning and critical endpoints</li> <li>• Pharmacovigilance</li> <li>• Patient reported outcomes</li> <li>• R&amp;D and regulatory probability of success, risk assessment</li> </ul>	

<p><b>Week 4</b></p> <p>Tues. Sept. 17</p> <p><b>Reaction Paper #1</b></p> <p>Thur. Sept. 19</p>	<p><b>Business Strategy in Clinical Development</b></p> <p><b>Dr. Ed Lieskovan</b></p> <ul style="list-style-type: none"> <li>• Business decisions to product investments and strategies</li> <li>• Evaluating unmet market needs, idea generation</li> <li>• Determining a "go - no go" plan and key measures</li> <li>• Intellectual property</li> <li>• R&amp;D and regulatory probability of success, risk assessment</li> </ul> <p><b>Field Medical Affairs Strategy</b></p> <p><b>Dr. Jesse Hong</b></p> <ul style="list-style-type: none"> <li>• Publication plan and strategy</li> <li>• Medical congress</li> <li>• Research and Development and regulatory probability of success, risk assessment</li> </ul>	
<p><b>Week 5</b></p> <p>Tues. Sept. 24</p> <p>Thurs. Sept. 26</p>	<p><b>Regulation of Biopharmaceuticals</b></p> <p><b>Dr. Larissa Yedigrova</b></p> <ul style="list-style-type: none"> <li>• Applications and Agencies: FDA, EMEA, NMPA, PDMA</li> <li>• Labeling and filings: IND, NDA, BLA</li> <li>• Approval pathways</li> <li>• Managing the regulatory process</li> <li>• Market authorization</li> </ul>	





<p><b>Week 9</b></p> <p>Tues. Oct. 22</p> <p><b>Reaction Paper #2</b></p> <p>Thurs. Oct. 24</p>	<p><b>Market Access, Coverage and Reimbursement, Payer and Stakeholder Requirements and Stratification, Health Outcomes (HERO)</b></p> <p><b>Dr. Jesse Hong</b></p> <ul style="list-style-type: none"> <li>• Commercial payers</li> <li>• Government payers</li> <li>• Hospitals</li> <li>• Providers (in-office, outpatient administration)</li> <li>• Pharmacies (retail, specialty)</li> <li>• PBM</li> </ul> <p><b>Dr. Larissa Yedigrova</b></p> <ul style="list-style-type: none"> <li>• Principles of product evaluations in healthcare payers</li> <li>• HERO</li> </ul>	
<p><b>Week 10</b></p> <p>Tues. Oct. 29</p> <p>Thurs. Oct. 31</p>	<p><b>Launch planning and execution, Managed care</b></p> <p><b>Dr. Jesse Hong</b></p> <ul style="list-style-type: none"> <li>• Market access strategy assessment by customer</li> <li>• Evidence generation plan</li> <li>• Setting foundation of successful launch</li> <li>• Life-cycle management</li> <li>• Strategies to maximize asset value</li> <li>• Marketing, market access strategies</li> <li>• Patient support programs</li> </ul>	
<p><b>Week 11</b></p> <p>Tues. Nov. 5</p> <p>Thurs. Nov. 7</p> <p><b>Reaction Paper #3</b></p>	<p><b>Post Marketing Surveillance and Pharmacovigilance</b></p> <p><b>Dr. Jesse Hong</b></p> <ul style="list-style-type: none"> <li>• Market access strategy assessment by customer</li> <li>• Evidence generation plan</li> <li>• Setting foundation of successful launch</li> </ul>	

<p><b>Week 12</b></p> <p>Tues. Nov. 12</p> <p>Thurs. Nov. 14</p>	<p><b>Lifecycle Management</b></p> <p><b>Dr. Larissa Yedigarova (Medical)</b></p> <ul style="list-style-type: none"> <li>• Medical affairs strategies</li> <li>• Digital strategies</li> </ul> <p><b>Dr. Ed Lieskovan (Commercial)</b></p> <ul style="list-style-type: none"> <li>• Sales and account management</li> <li>• Marketing, market access strategies</li> <li>• Patient support programs</li> <li>• Commercial financial budget and planning</li> </ul>	
<p><b>Week 13</b></p> <p>Tues. Nov. 19</p> <p>Thurs. Nov. 21</p>	<p><b>Future Industry Trends &amp; Case Studies</b></p> <p><b>Dr. Larissa Yedigarova</b></p> <ul style="list-style-type: none"> <li>• Global clinical trials, regulations and post-approval activities</li> </ul> <p><b>Dr. Ed Lieskovan</b></p> <ul style="list-style-type: none"> <li>• AI in research and development</li> </ul>	
<p><b>Week 14</b></p> <p>Tues. Nov. 26</p> <p><b>Assignment #3</b></p>	<p><b>Future Industry Trends &amp; Case Studies</b></p> <p><b>Dr. Jesse Hong</b></p> <ul style="list-style-type: none"> <li>• Gene Transfer for Hemophiliac B</li> <li>• Alzheimer treatment controversy</li> </ul>	
<p><b>Thanksgiving Holiday, Wednesday, Nov. 27 to Sunday, Dec. 01, 2024</b></p>		
<p><b>Week 15</b></p> <p>Tues. Dec. 3</p> <p>Thurs. Dec. 5</p>	<ul style="list-style-type: none"> <li>• <b>Capstone Presentations</b></li> <li>• <b>Final Exam Review</b></li> </ul>	
<p><b>In class Final Exam: Thursday, December 12, 2024 2 pm-4 pm</b></p> <p>Final Exam Policy: <a href="https://classes.usc.edu/term-20243/finals/">https://classes.usc.edu/term-20243/finals/</a></p> <p><b>Final exam cannot be changed due to travel, nor can the final exam be administered remotely.</b></p>		

## Academic Integrity

The University of Southern California is foremost a learning community committed to fostering successful scholars and researchers dedicated to the pursuit of knowledge and the transmission of ideas. Academic misconduct is in contrast to the university's mission to educate students through a broad array of first-rank academic, professional, and extracurricular programs and includes any act of dishonesty in the submission of academic work (either in draft or final form).

This course will follow the expectations for academic integrity as stated in the [USC Student Handbook](#). All students are expected to submit assignments that are original work and prepared specifically for the course/section in this academic term. You may not submit work written by others or "recycle" work prepared for other courses without obtaining written permission from the instructor(s). Students suspected of engaging in academic misconduct will be reported to the Office of Academic Integrity.

Other violations of academic misconduct include, but are not limited to, cheating, plagiarism, fabrication (e.g., falsifying data), knowingly assisting others in acts of academic dishonesty, and any act that gains or is intended to gain an unfair academic advantage.

Academic dishonesty has a far-reaching impact and is considered a serious offense against the university. Violations will result in a grade penalty, such as a failing grade on the assignment or in the course, and disciplinary action from the university itself, such as suspension or even expulsion.

For more information about academic integrity see the [student handbook](#) or the [Office of Academic Integrity's website](#), and university policies on [Research and Scholarship Misconduct](#).

Please ask your instructor if you are unsure what constitutes unauthorized assistance on an exam or assignment or what information requires citation and/or attribution.

## Course Content Distribution and Synchronous Session Recordings Policies

USC has policies that prohibit recording and distribution of any synchronous and asynchronous course content outside of the learning environment.

Recording a university class without the express permission of the instructor and announcement to the class, or unless conducted pursuant to an Office of Student Accessibility Services (OSAS) accommodation. Recording can inhibit free discussion in the future, and thus infringe on the academic freedom of other students as well as the instructor. ([Living our Unifying Values: The USC Student Handbook](#), page 13).

Distribution or use of notes, recordings, exams, or other intellectual property, based on university classes or lectures without the express permission of the instructor for purposes other than individual or group study. This includes but is not limited to providing materials for distribution by services publishing course materials. This restriction on unauthorized use also applies to all information, which had been distributed to students or in any way had been displayed for use in relation to the class, whether obtained in class, via email, on the internet, or via any other media. Distributing course material without the instructor's permission will be presumed to be an

intentional act to facilitate or enable academic dishonesty and is strictly prohibited. ([Living our Unifying Values: The USC Student Handbook](#), page 13).

## **Statement on University Academic and Support Systems**

### **Students and Disability Accommodations:**

USC welcomes students with disabilities into all of the University's educational programs. [The Office of Student Accessibility Services \(OSAS\)](#) is responsible for the determination of appropriate accommodations for students who encounter disability-related barriers. Once a student has completed the OSAS process (registration, initial appointment, and submitted documentation) and accommodations are determined to be reasonable and appropriate, a Letter of Accommodation (LOA) will be available to generate for each course. The LOA must be given to each course instructor by the student and followed up with a discussion. This should be done as early in the semester as possible as accommodations are not retroactive. More information can be found at [osas.usc.edu](http://osas.usc.edu). You may contact OSAS at (213) 740-0776 or via email at [osasfrontdesk@usc.edu](mailto:osasfrontdesk@usc.edu).

### **Student Financial Aid and Satisfactory Academic Progress:**

To be eligible for certain kinds of financial aid, students are required to maintain Satisfactory Academic Progress (SAP) toward their degree objectives. Visit the [Financial Aid Office webpage](#) for [undergraduate](#)- and [graduate-level](#) SAP eligibility requirements and the appeals process.

### **Support Systems:**

[Counseling and Mental Health](#) - (213) 740-9355 – 24/7 on call

Free and confidential mental health treatment for students, including short-term psychotherapy, group counseling, stress fitness workshops, and crisis intervention.

[988 Suicide and Crisis Lifeline](#) - 988 for both calls and text messages – 24/7 on call

The 988 Suicide and Crisis Lifeline (formerly known as the National Suicide Prevention Lifeline) provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week, across the United States. The Lifeline consists of a national network of over 200 local crisis centers, combining custom local care and resources with national standards and best practices. The new, shorter phone number makes it easier for people to remember and access mental health crisis services (though the previous 1 (800) 273-8255 number will continue to function indefinitely) and represents a continued commitment to those in crisis.

[Relationship and Sexual Violence Prevention Services \(RSVP\)](#) - (213) 740-9355(WELL) – 24/7 on call

Free and confidential therapy services, workshops, and training for situations related to gender- and power-based harm (including sexual assault, intimate partner violence, and stalking).

[Office for Equity, Equal Opportunity, and Title IX \(EEO-TIX\)](#) - (213) 740-5086

Information about how to get help or help someone affected by harassment or discrimination, rights of protected classes, reporting options, and additional resources for students, faculty, staff, visitors, and applicants.

[Reporting Incidents of Bias or Harassment](#) - (213) 740-2500

Avenue to report incidents of bias, hate crimes, and microaggressions to the Office for Equity, Equal Opportunity, and Title for appropriate investigation, supportive measures, and response.

[The Office of Student Accessibility Services \(OSAS\)](#) - (213) 740-0776

OSAS ensures equal access for students with disabilities through providing academic accommodations and auxiliary aids in accordance with federal laws and university policy.

[USC Campus Support and Intervention](#) - (213) 740-0411

Assists students and families in resolving complex personal, financial, and academic issues adversely affecting their success as a student.

[Diversity, Equity and Inclusion](#) - (213) 740-2101

Information on events, programs and training, the Provost's Diversity and Inclusion Council, Diversity Liaisons for each academic school, chronology, participation, and various resources for students.

[USC Emergency](#) - UPC: (213) 740-4321, HSC: (323) 442-1000 – 24/7 on call

Emergency assistance and avenue to report a crime. Latest updates regarding safety, including ways in which instruction will be continued if an officially declared emergency makes travel to campus infeasible.

[USC Department of Public Safety](#) - UPC: (213) 740-6000, HSC: (323) 442-1200 – 24/7 on call

Non-emergency assistance or information.

[Office of the Ombuds](#) - (213) 821-9556 (UPC) / (323-442-0382 (HSC)

A safe and confidential place to share your USC-related issues with a University Ombuds who will work with you to explore options or paths to manage your concern.

[Occupational Therapy Faculty Practice](#) - (323) 442-2850 or [otfp@med.usc.edu](mailto:otfp@med.usc.edu)

Confidential Lifestyle Redesign services for USC students to support health promoting habits and routines that enhance quality of life and academic performance.