



PSCI 513: Drugs: Biologics and Specialty Pharmaceuticals

2 units

Fall 2022—Tue—1:00 PM-3:00 PM

Location: PSC B13

Course Coordinator(s):

Jennica Zaro: zaro@usc.edu

Office: PSC 404B Phone: (323) 442-1429

Office Hours:

By email appointment

Instructors:

Amanda Burkhardt: aburkhar@usc.edu

Zhipeng Lu: zhipengl@usc.edu

Eunjoo Pacifici: epacific@usc.edu

John Stofko: johnstofko@usc.edu

Jianming Xie: jianminx@usc.edu

IT Help:

Blackboard is the Learning Management System (LMS) used at the USC School of Pharmacy. For 24/7 help with Blackboard:

- Call (213) 740-5555 and choose Option 2.
- Send an e-mail to blackboard@usc.edu.
- Visit USC's Blackboard Online Help site for how-to videos and guides.
- Access additional Blackboard training videos on LinkedIn Learning at <https://itservices.usc.edu/linkedin-learning/>.
- **Zoom and Panopto may be used for lecture capture and delivery, Zoom and Poll Everywhere may be used as an audience response system, and Blackboard and ExamSoft may be used to administer quizzes and examinations.**
- For help with Zoom, visit <https://itservices.usc.edu/zoom/>.
- For help with Panopto, call the 24/7 Panopto support team at (855) 765-2341 or e-mail support@panopto.com
- For help with ExamSoft, call the 24/7 ExamSoft support team at (866) 429-8889, e-mail support@examsoft.com , or visit <https://help.examsoft.com/>.
- You may also visit our Technical Support Specialists in PSC 102, M-F from 8:00 AM-5:00 PM, call (323) 442-0002, or e-mail pharmit@usc.edu.
- **For all other technology-related questions, call USC Information Technology Services at (213) 740-5555.**

Course Description

Biologics, including recombinant proteins, oligonucleotides, whole cell therapies, and vaccines, represent a rapidly growing class of therapeutic compounds for treatment of many major diseases. This course focuses on common therapeutic targets and pathways, drug development, formulations and delivery, fundamental pharmacokinetics/pharmacodynamics, and regulatory considerations of currently marketed biologic drugs. The course material will be delivered via didactic lectures, as well as student-led journal club-style presentations involving a critical analysis of the supporting evidence and main conclusions of primary research articles. Grades are based on the presentation and written assignments, and the course is open to PharmD, PhD and MS students.

Learning Objectives

- Describe the challenges associated with the production, formulation, and administration/delivery of biologics.
- Discuss the hypothesis, results, and conclusions of primary research articles.
- Analyze the main conclusions and supporting evidence of primary research articles.

Course Notes

Required Readings and Supplementary Materials

- All required materials be posted on Blackboard.

Description and Assessment of Assignments

Assignments for this course include an Oral Project Presentation, a term paper/report, and Short writing assignments.

Please refer to Blackboard under the "Assignments" section for more detailed information regarding the course assignments, including the deadlines, how to submit, and grading rubrics.

Methods

Teaching Methods

Before Event

- Assigned reading/writing (texts)
- Assigned reading (journal or papers)

During Event

- Classroom lecture
- Student presentation

After Event

- Reflection

Assessment Methods

In Class

- Oral presentation

Longer term

- Reflective writing
- Observation

Other

- Other Assessment Methods

Grading Breakdown

Assignment	Percent
Oral Presentation Project (Group Assignment)	45
Journal Club Written Report (Individual Assignment)	45
Peer Feedback Written Assignments (Individual Assignment)	10

Grading Scale

A	95-100
A-	90-94
B+	87-89
B	83-86
B-	80-82
C+	77-79
C	73-76
C-	70-72
D+	67-69
D	63-66
D-	60-62
F	59 and below

Additional Policies

Policy Regarding Class Recordings

All class recordings (Zoom, Panopto, etc.) are accessible only to students currently enrolled in the class, instructors, and TAs. These recordings may not be shared or used for purposes outside of this course. Students are also not permitted to record or distribute any course materials or activities on their own without the instructor's permission.

Policy Regarding Assignments and Examinations

The following actions are all violations of academic integrity and subject to disciplinary action:

- Any use or attempted use of external assistance in the completion of an academic assignment and/or during an examination, or any behavior that defeats the intent of an examination or other classwork or assignment, unless expressly permitted by the instructor.
- The following are examples of unacceptable behaviors: communicating with fellow students during an exam, copying or attempting to copy material from another student's exam; allowing another student to copy from an exam or assignment; possession or use of unauthorized notes, calculator, or other materials during exams and/or unauthorized removal of exam materials.
- Other examples of academic misconduct have been and will be considered.

Policy Regarding Missed Examinations

The policy for this course will follow the policy contained within the Academic Policies and Procedures section of the Student Handbook located on the [USC School of Pharmacy Intranet](#). Students who miss an examination are referred to this policy.

Technological Requirements and Software Updates

Students may be required to bring an internet-enabled device with browser capabilities, such as a cell phone, tablet, or laptop to class. During class time, it is expected that students will use their devices only to participate in activities guided by the instructor. Use of devices for other purposes is not permitted during class time.

The USC School of Pharmacy recommends that students purchase a computer that meets, at minimum, the “medium” level hardware requirements that are also recommended for faculty and staff:

<https://itservices.usc.edu/recommendations/>.

Students who use Zoom should be running the latest version of Zoom available at <https://zoom.us/download>.

Students who use ExamSoft will also be required to have the latest version of Examplify installed on their laptops at all times compatible with their operating system. Occasional updates to the software may be asked of you throughout the year. It is your responsibility to read your USC e-mails regarding Examplify and follow the instructions as listed.

Policy on Learning & Assessment Feedback (LAF)

Feedback on examinations/assessments will be provided using the following methods.

- Written/verbal feedback will be given for all assignments
- Assignments will be graded with a rubric, which will be provided to students

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. For additional program-specific absence policies, please refer to the Student Handbook on the [USC School of Pharmacy Intranet](#).

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 through this following guide <https://libguides.usc.edu/ama11> and handout https://libguides.usc.edu/ld.php?content_id=54130825. The complete AMA Manual of Style is also available as an e-book at tinyurl.com/bdh8amka.

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. Other forms of academic dishonesty are equally unacceptable. See additional information and university policies on [Research and Scholarship Misconduct](#).

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. You may contact OSAS at (213) 740-0776 or via email at osasfrontdesk@usc.edu.

Support Systems

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

studenthealth.usc.edu/counseling

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

National Suicide Prevention Lifeline - 1 (800) 273-8255 – 24/7 on call

suicidepreventionlifeline.org

Free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week.

Relationship and Sexual Violence Prevention and Services (RSVP) - (213) 740-9355(WELL), press "0" after hours – 24/7 on call

studenthealth.usc.edu/sexual-assault

Free and confidential therapy services, workshops, and training for situations related to gender-based harm.

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

eotix.usc.edu

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) 740-5086 or (213) 821-8298

usc-advocate.symplcity.com/care_report

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.usc.edu

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) 821-4710

campussupport.usc.edu

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

diversity.usc.edu

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

dps.usc.edu, emergency.usc.edu

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) 442-120 – 24/7 on call

dps.usc.edu

Non-emergency assistance or information.

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

ombuds.usc.edu

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) 442-3340 or otfp@med.usc.edu
chan.usc.edu/otfp

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

Expanded Course Schedule

Date	Lecturer	Event
Tue 08/23/22 01:00p - 02:00p	Jennica Zaro	Course Introduction/Overview
Tue 08/23/22 02:00p - 03:00p	Jennica Zaro	Introduction to Biologics
Tue 08/30/22 01:00p - 03:00p	Jennica Zaro	Protein Drugs: Production, Formulations, and Drug Development Group project time: Students will be assigned their drugs for their written report and the groups for the oral presentation.
Tue 09/06/22 01:00p - 03:00p	Jennica Zaro	Protein Drugs: Administration Routes, Advanced Delivery Systems, and Categories Individual/Group Project time: Groups will work together to finalize a theme for their Oral Presentations and select their research articles for the Written Journal Club Report.
Tue 09/13/22 01:00p - 03:00p	Amanda Burkhardt	Vaccine technologies (whole cell, inactivated, subunit, nucleic acid)
Tue 09/20/22 01:00p - 03:00p	Jianming Xie	CAR T-cell therapy for Cancer
Tue 09/27/22 01:00p - 03:00p	Zhipeng Lu	Aptamers/Antisense Drugs (Part 1)
Tue 10/04/22 01:00p - 03:00p	Zhipeng Lu	Aptamers/Antisense Drugs (Part 2)
Tue 10/11/22 01:00p - 03:00p	Eunjoo Pacifici	Regulation of Biologics and Biosimilars
Tue 10/18/22 01:00p - 03:00p	John Stofko	Biopharmaceutical Market Access
Tue 10/25/22 01:00p - 03:00p	Jennica Zaro	Guest Lecture: Aligning Process Development, Process Capability, and Analytical Development to enable Deliverable Biologics Guest Lecturer: Adam Widera, Ph.D., Senior Director, Quality Control, Kite Pharma
Tue 11/01/22 01:00p - 03:00p	Jennica Zaro	Student Presentations
Tue 11/08/22 01:00p - 03:00p	Jennica Zaro	Student Presentations

Date	Lecturer	Event
Tue 11/15/22 01:00p - 03:00p	Jennica Zaro	Student Presentations
Tue 11/22/22 01:00p - 03:00p	Jennica Zaro	Student Presentations
Tue 11/29/22 01:00p - 03:00p	Jennica Zaro	Student Presentations