

## BPSI 408: Vaccines & Biologics Spring 2024

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Office Hours:  
Fridays 4-5:30pm (weekly zoom ID 456 782 6834)

**Course Weight:** 4 Units

**Office Hours:** Additional announcements on course Blackboard.

**Day/Time/Location:** Tuesday & Thursday 2:00p-3:20p, KAP 141

### Catalogue Description

This course will provide students and in-depth understanding of how biologics and vaccines are researched and developed and why they have become a significant focus of the current day therapeutic development pipelines. Vaccine development possesses unique challenges relevant not only to an economic and patient compliance perspective, but the wide range in patient age and health status directly impacts the variability in immune response, making the prediction and assessment of effectiveness particularly difficult. Despite these challenges, vaccines are considered among the greatest advancements in the history of medicine. A central theme of this course will focus on the varying technologies used to develop these therapeutics and the many diseases and conditions they can be used to manage or completely prevent. In this context the course will provide relevant insight and practical suggestions for a common sense, cost-effective, risk-managed approaches to meeting the Chemistry,

Manufacturing and Controls (CMC) requirements and expectations for biopharmaceuticals as human medicinal products.

### Learning Objectives

- Describe and define what is a biologic and its basic mechanism of action
- Summarize the basic mechanism of action for the biologics covered in class
- Explain the connection between biologic development and immunology
- Describe and define what is a vaccine and its basic mechanism of action
- Describe the ethical issues surrounding biologic and vaccine deployment in humans
- Describe the regulatory issues associated with biologic and vaccine research, development, clinical trials and deployment as FDA approved therapeutics
- Compare and contrast the differences between a biologic and a vaccine
- Understand biosimilars and complex drug products
- Understand current vaccine types, their mechanism of action, benefits, drawbacks, and examples (e.g. live-attenuated, inactivated, subunit, toxoid, nucleic acid, and viral vectors)
- Analyze a scientific study on a biologic or vaccine related to course material

### Evaluation and Grading

Evaluation will be based on 12 Journal Club presentations and contribution to the Journal Club Paper Selection activity.

<i>Description</i>	<i>Points</i>	<i>Weight</i>
<i>Journal Club Presentations (12 at 20 points each)</i>	240 pts	92%
<i>Journal Club Paper Selection Participation</i>	20 pts	8%
<b>Total</b>	<b>260 pts</b>	<b>100%</b>

### Assignments

**Journal Club Presentations:** Students will participate in 12 Journal Club presentations throughout the course of the semester. Students will be expected to read, synthesize and present the findings from primary research articles related to course material on vaccines and biologics in small group settings. This assignment will help students understand how to read and extract information from primary research articles, analyze reported research and clinical trial results, and allow them to hone their presentation and public speaking skills. An assignment description and rubric for this assignment can be found on Blackboard under the Assignments tab.

### Journal Club Paper Selection

In Week 2 of the course students will be guided through how to select primary literature (papers) for journal clubs and then provided the opportunity to select the papers that will be discussed in future Journal Clubs within the class. Additional information about this assignment will be provided on the day of the in-class activity (see course schedule below).

### Grading Scale

93% to 100%: A	79% to 81%: B-	65% to 67%: D+
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90% to 92%: A-	76% to 78%: C+	62% to 64%: D
87% to 89%: B+	71% to 75%: C	55% to 61%: D-
82% to 86%: B	68% to 70%: C-	0% to 54%: F

## Course Readings

Links or PDFs of the Journal Club articles for each week will be provided to students on Blackboard.

Practical Aspects of Vaccine Development Book • 2021 Edited by: Parag Kolhe and Satoshi Ohtake DOI <https://doi.org/10.1016/C2017-0-01489-1>

The Challenge of CMC Regulatory Compliance for Biopharmaceuticals • 2021 Edited by: John Geigert DOI <https://doi.org/10.1007/978-3-031-31909-9>

## Course Attendance

Attendance at all classes is expected. Due to the unpredictability of technology, it cannot be guaranteed that a Zoom recording will be available for each class meeting.

Students who are unable to attend class on Journal Club presentation days will complete an Alternative Assignment (see assignment description on Blackboard).

## Late Assignment Policy

Assignments that are submitted past the due date/time will be eligible for a maximum of 80% credit in the first 24 hours that they are late. For each subsequent week, an additional 5% credit will be deducted from the possible score (i.e. an assignment that is submitted 2 weeks late will be worth a maximum of 75% total points, an assignment that is submitted 3 weeks late will be worth a maximum of 70% total points, etc).

## Course Outline

Week	Date	Lecture	Deliverable
Week 1	Tues. Jan. 09	Introduction to course, immunology introduction	
	Thur. Jan. 11	Immunology introduction, cont.	
Week 2	Tues. Jan. 16	How to select articles for journal club	
	Thur. Jan. 18	In class journal selection workshop	Student selected manuscripts
Week 3	Tues. Jan. 23	Immunology of vaccines and biologics	
	Thur. Jan. 25	How to give a journal club presentation	
Week 4	Tues. Jan. 30	Vaccine technologies	
	Thur. Feb. 01	Journal Club	Student presentation
Week 5	Tues. Feb. 06	Vaccines for non-infectious diseases	
	Thur. Feb. 08	Journal Club	Student presentation
Week 6	Tues. Feb. 13	Vaccine design and delivery considerations	
	Thur. Feb. 15	Journal Club	Student presentation
Week 7	Tues. Feb. 20	Ethical considerations of vaccines	
	Thur. Feb. 22	Journal Club	Student presentation
Week 8	Tues. Feb. 27	Guest lecturer	
	Thurs. Feb. 29	Journal Club	Student presentation
Week 9	Tues. Mach 05	Introduction to vaccine/biologic Development †	
	Thurs. March 07	Journal Club	Student Presentation
Week 10	Tues. March 12	<b>SPRING BREAK</b>	
	Thurs. March 14	<b>SPRING BREAK</b>	
Week 11	Tues. March 19	Overview of vaccine adjuvants †	
	Thurs. March 21	Journal Club	Student presentation
Week 12	Tues. March 26	Formulation design considerations and good practice for live attenuated vaccine development†	
	Thurs. March 28	Journal Club	Student presentation
Week 13	Tues. April 02	pDNA and mRNA vaccines†	

	Thurs. April 04	Journal Club	Student presentation
<b>Week 14</b>	Tues. April 09	Conventional and nontraditional delivery methods and routes of vaccine/biologic administration‡	
	Thurs. April 11	Journal Club	Student presentation
<b>Week 15</b>	Tues. April 16	Manufacturing the Biopharmaceutical Drug Product‡	
	Thurs. April 18	Journal Club	Student presentation
<b>Week 16</b>	Tues. April 23	The Challenge of Demonstrating Biopharmaceutical Product Comparability‡	
	Thurs. April 25	Journal Club	Student presentation
<b>April 27, 2024 to April 30, 2023 – Study Days</b>			
<b>FINAL EXAM: THURSDAY 05/02/24 2:00PM-4:00PM</b>			

‡Professor HJG lectures, topics locked in however professor may bring in or remotely connect (all synchronous) potential invited speakers from biopharmaceutical industry

## 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 relationship to the class, whether obtained in class, via email, on the internet, or via any other media. ([Living our Unifying Values: The USC Student Handbook](#), page 13).

### 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.

The impact of academic dishonesty is far-reaching and is considered a serious offense against the university and could result in outcomes such as failure on the assignment, failure in the course, suspension, or even expulsion from the university.

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](#).

## Statement on Academic Conduct and Support Systems

### Academic Integrity:

The University of Southern California is a learning community committed to developing successful scholars and researchers dedicated to the pursuit of knowledge and the dissemination of ideas. Academic misconduct, which includes any act of dishonesty in the production or submission of academic work, comprises the integrity of the person who commits the act and can impugn the perceived integrity of the entire university community. It stands in opposition to the university's mission to research, educate, and contribute productively to our community and the world.

All students are expected to submit assignments that represent their own original work, and that have been prepared specifically for the course or section for which they have been submitted. You may not submit work written by others or "recycle" work prepared for other courses without obtaining written permission from the instructor(s).

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

The impact of academic dishonesty is far-reaching and is considered a serious offense against the university. All incidences of academic misconduct will be reported to the Office of Academic Integrity and could result in outcomes such as failure on the assignment, failure in the course, suspension, or even expulsion from the university.

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.

### 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](https://osas.usc.edu). You may contact OSAS at (213) 740-0776 or via email at [osasfrontdesk@usc.edu](mailto:osasfrontdesk@usc.edu).

### 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 is comprised 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) 740-5086 or (213) 821-8298

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.