

MCB6937 Special topics: Regulatory aspects of microbiome research (1 credit hour)

Summer C 2025

Course Description: MCB6937 will cover basic aspects of pre-clinical and clinical research on microbiome research for the use of microbiome-derived species to modulate the health status in the host. The course will discuss the requirements and guidelines published by the Food and Drug Administration as well as other regulatory agencies.

Prerequisite Knowledge and Skills: Basic microbiology or biology. Basic understanding of statistics is expected.

Goals of the Course: The goal of this course is to guide students on the requirements and steps needed to translate the laboratory findings on beneficial microbial strains into therapeutics. Students will gain knowledge on the methodology used for pre-clinical and clinical assessment of microorganisms for their use as probiotic and / or live biotherapeutic products. Students will explore the current regulatory paths for live biotherapeutic products.

Student Learning outcomes – After successful completion of this course, students will be able to:

- Explain the roles of the microbiome in human health.
- Define prebiotics, probiotic, symbiotic, live biotherapeutic product and postbiotic.
- Compare the characteristics of prebiotics, probiotic, symbiotic, live biotherapeutic product and postbiotic.
- Explain the methods used for preclinical testing of microorganisms and their interactions with the host.
- Describe differences between preclinical experiments and clinical phases.
- Define the role and requirements of institutional review board on clinical research.
- Compare and contrast food supplements, medical foods and biologics.
- Select appropriate regulatory pathway for live biotherapeutic product.
- Apply the FDA/CBER guidelines for the development and testing of live biotherapeutic product.

INSTRUCTOR:

Graciela L Lorca, PhD

Professor

Department of Microbiology and Cell Science

College of Agricultural and Life Sciences

WebPage: Canvas (<https://ufl.instructure.com/>). Please select MCB6937 Special topics: Regulatory aspects of microbiome research.

Online help with classroom technology: <http://helpdesk.ufl.edu/>

Communication: for questions regarding class and paper assignments use the Discussion Board, for issues on Homework Assignments, class organization check first the syllabus, the announcements and calendar on Canvas, then post your questions on the discussion board. For all other issues contact the instructors through CANVAS email ONLY.

VIRTUAL OFFICE HOURS: are available on demand through Zoom Conferences in Canvas. To request an appointment, send an e-mail with three suggested times and I will choose one for us to meet.

Contact Information: Use TEACHER in your emails through Canvas ONLY (personal emails should only be used in a case of emergency only)

Dr. Graciela L Lorca:

Email (the most efficient): ONLY use Canvas e-mail (If you do not have access to the e-learning platform and need to contact me for an **emergency**, use glorca@ufl.edu)

Phone: 273 8090 (please leave a message).

- **General Content Discussion Boards:** A discussion board is available in Canvas. It is very useful, please post and answer your questions on class content and organization there. Postings and answers are monitored by the instructor to make sure no mistakes get propagated. There are several discussion themes. Please post your questions in the adequate section.

Required Text: There is no assigned textbook. Assigned research publications will be posted on the course web page.

Material: This course is based on peer reviewed papers either available for free through the links provided or through the UF library (ejournals). **Remember** to connect to [UF through VPN](#) (if outside campus) before accessing the journals. See here how to see [papers on mobile devices](#).

Assessment of learning

Assignments (500 points): Activities will be assigned by module. The activities include short online research activities and graded discussion boards. The goal of these assignments is that the student keep-up with reading of the material on weekly basis. **The activities are mandatory and count towards the final grade. They should be completed by the deadline indicated on Canvas.**

Graded quizzes (500 points): Two graded quizzes (250 points each). Each of the proctored mid-term exams will be 50 minutes long with multiple choice, match and or true/false type of questions. The student will be given the option to take a final cumulative exam to improve the grade obtained through the mid-term exams.

Make-Up policy: Make-up assignments will ONLY be allowed with a VALID justification. If one assignment is missed, it will result in a score of 0 (see below for “Excused absences”).

Excused absences:

Documentation MUST be provided for absences caused by serious illness, accident, jury duty, or death in the immediate family. You must contact the instructor **as soon as possible** of the missed assignment and I will arrange an alternative time for the submission.

Requirements for class attendance and make-up assignments and other work are consistent with university policies that can be found at: <https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx>.

Grades and Grade Points

For information on current UF policies for assigning grade points, see <https://catalog.ufl.edu/UGRD/academic-regulations/grades-grading-policies/>

Grading: Straight scale

Grading Scale

A	900 or above
A-	860-899
B+	830-859
B	790-829
B-	750-789
C+	720-749
C	690-719
C-	660-689
D+	630-659
D	600-629
D-	570-599
E	560 or below

COURSE CONTENT

Unit	Topic
Unit 1	Definitions, Classifications and Beneficial properties of Microorganisms
	1. The role of the microbiota in human health
	2. Prebiotics, probiotic, symbiotic, live biotherapeutic product and postbiotic
Unit 2	Approaches used to study microbiome and host interactions
	3. Preclinical models for microbial interventions
	4. Clinical research: Protocols and IRB
	Test 1
Unit 3	Regulatory framework
	5. Choosing the best regulatory pathway: Dietary supplements, medical foods, Biologics
	6. FDA/CBER guidelines for live biotherapeutics, Case studies
	Test 2
	OPTIONAL CUMMULATIVE FINAL

University of Florida Policies

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Attendance and Make-Up Work

Requirements for class attendance and make-up exams, assignments and other work are consistent with university policies that can be found at: <https://catalog.ufl.edu/UGRD/academic-regulations/attendance-policies/>

Services for Students with Disabilities

Students with disabilities who experience learning barriers and would like to request academic accommodations should connect with the disability Resource Center (<https://disability.ufl.edu/get-started/>). 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.

Campus Helping Resources

Health and Wellness

- U Matter, We Care: If you or someone you know is in distress, please contact umatter@ufl.edu, 352-392-1575, or visit U Matter, We Care website (<https://umatter.ufl.edu/>) to refer or report a concern and a team member will reach out to the student in distress.
- Counseling and Wellness Center: Visit the Counseling and Wellness Center website (<https://counseling.ufl.edu/>) or call 352-392-1575 for information on crisis services as well as non-crisis services.
- Student Health Care Center: Call 352-392-1161 for 24/7 information to help you find the care you need, or visit the Student Health Care Center website (<https://shcc.ufl.edu/>).
- University Police Department: Visit UF Police Department website (<https://police.ufl.edu/>) or call 352-392-1111 (or 9-1-1 for emergencies).
UF Health Shands Emergency Room / Trauma Center: For immediate medical care call 352-733-0111 or go to the emergency room at 1515 SW Archer Road, Gainesville, FL 32608; Visit the UF Health Emergency Room and Trauma Center website (<https://ufhealth.org/emergency-room-trauma-center>).
- GatorWell Health Promotion Services: For prevention services focused on optimal wellbeing, including Wellness Coaching for Academic Success, visit the GatorWell website (<https://gatorwell.ufsa.ufl.edu/>) or call 352-273-4450.

Academic Resources

- E-learning technical support: Contact the UF Computing Help Desk at 352-392-4357 or via e-mail at helpdesk@ufl.edu.
- Career Connections Center: Reitz Union Suite 1300, 352-392-1601. Career assistance and counseling services (<https://career.ufl.edu/>).

- Library Support: Various ways to receive assistance with respect to using the libraries or finding resources (<https://uflib.ufl.edu/>).
- Teaching Center: Broward Hall, 352-392-2010 or to make an appointment 352-392-6420. General study skills and tutoring (<https://teachingcenter.ufl.edu/>).
- Writing Studio: 2215 Turlington Hall, 352-846-1138. Help brainstorming, formatting, and writing papers (<https://writing.ufl.edu/writing-studio/>).
- Student Complaints On-Campus: Visit the Student Honor Code and Student Conduct Code webpage for more information (<https://sccr.dso.ufl.edu/policies/student-honor-%20code-student-conduct-code/>).
On-Line Students Complaints: View the Distance Learning Student Complaint Process (<https://distance.ufl.edu/state-authorization-status/#student-complaint>).

Course Evaluation

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.ua.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.bluer.com/ufl/>. Summaries of course evaluation results are available to students at <https://gatorevals.ua.ufl.edu/public-results/>.

Class demeanor

Opinions held by other students should be respected in discussion, and conversations that do not contribute to the discussion should be held at minimum, if at all.

Netiquette guide for online courses

It is important to recognize that the online classroom is in fact a classroom, and certain behaviors are expected when you communicate with both your peers and your instructors. These guidelines for online behavior and interaction are known as netiquette.

<http://teach.ufl.edu/wp-content/uploads/2012/08/NetiquetteGuideforOnlineCourses.pdf>

Academic Honesty

As a student at the University of Florida, you have committed yourself to uphold the Honor Code, which includes the following pledge: *"We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honesty and integrity."* You are expected to exhibit behavior consistent with this commitment to the UF academic community, and on all work submitted for credit at the University of Florida, the following pledge is either required or implied: *"On my honor, I have neither given nor received unauthorized aid in doing this assignment."*

It is assumed that you will complete all work independently in each course unless the instructor provides explicit permission for you to collaborate on course tasks (e.g. assignments, papers,

quizzes, exams). Furthermore, as part of your obligation to uphold the Honor Code, you should report any condition that facilitates academic misconduct to appropriate personnel. It is your individual responsibility to know and comply with all university policies and procedures regarding academic integrity and the Student Honor Code. Violations of the Honor Code at the University of Florida will not be tolerated. Violations will be reported to the Dean of Students Office for consideration of disciplinary action. For more information regarding the Student Honor Code, please see: <http://www.dso.ufl.edu/sccr/process/student-conduct-honor-code>.

Additional comments regarding academic integrity:

Students are encouraged to discuss material with each other from the course, help each other understand concepts, study together, and even discuss assessment questions with each other once the quiz window is closed. However, the following is considered academic dishonesty, and I expect that no student will ever do any of the following:

- Have another person complete a quiz in this course
- Copy another student's quiz in this course
- Collaborate with anyone during a quiz in this course
- Discuss the questions and answers of a quiz with other students while the quiz window is still open
- Manipulate and/or distribute any materials provided in this course for any purpose (including course lecture slides).
- Use any materials provided by a previous student in the course

Use of Artificial Intelligence In academic work

AI-powered tools, such as language generators and citation managers, may be useful for creating outlines for literature reviews. However, AI should be used as a supplement to, not a replacement for, human critical thinking and analysis. ***Make sure you always cite and acknowledge AI-generated content properly.***

Prohibited Use Cases:

- Using AI to complete assignments or projects without human critical analysis.
- Relying solely on AI-generated content for research or analysis.
- Presenting AI-generated content as original work without proper citation.

Software Use

All faculty, staff and students of the university are required and expected to obey the laws and legal agreements governing software use. Failure to do so can lead to monetary damages and/or criminal penalties for the individual violator. Because such violations are also against university policies and rules, disciplinary action will be taken as appropriate.

Microsoft Office 365 Software is free for UF students

<http://www.it.ufl.edu/gatorcloud/free-office-365-downloads/>

Other free software is available at:

<http://www.software.ufl.edu/>

To check for availability of the media and technical requirements, contact the UF Computing Help Desk at (352)392-HELP(4357).

University of Florida Complaints Policy and Student Complaint Process

Most problems, questions and concerns about the course will be resolved by professionally communicating with the instructors.

The University of Florida believes strongly in the ability of students to express concerns regarding their experiences at the University. The University encourages its students who wish to file a written complaint to submit that complaint directly to the department that manages that policy. If a problem really cannot be resolved by communicating with the instructor or the TAs you can contact

- Residential Course: <https://sccr.dso.ufl.edu/policies/student-honor-code-student-conduct-code/>.
- Online Course: <http://www.distance.ufl.edu/student-complaint-process>.

This said, professionalism is a two-way-street. Unprofessional behavior of students includes, among other things: lack of communication, blaming other people or external factors, lying, affecting others negatively in a group or in the class, not accepting criticism and not being proactive in solving problems or seeking help. Furthermore, faculty often have family and other obligations to tend to. Over the weekend, replies to your inquiries or questions maybe delayed. If a student is lacking professionalism repeatedly, the instructor has the rights to file formal complaint against the student through the Dean of Student office.