

Bench-to-Market: Regenerative Medicine

Course Syllabus

Honors Course for Undergraduates
IDH3931; 1-2 Credits
1CRE class #27013 Monday 7th period 1:55 - 2:45 PM
2CRE class #27014 Monday 7-8th period 1:55 - 3:50 PM
Honors Village (HVR1) Room 114
Spring 2024

Instructors

Dmitry Traktuev, Ph.D. (dtraktuev@ufl.edu)

Katelyn Bruno, Ph.D., FHFS (katelyn.bruno@medicine.ufl.edu)

Office Hours: Please email Dr. Traktuev to schedule a meeting as needed

Course Description

Regenerative medicine creates an opportunity to lessen pathological processes and repair injured or congenitally defective tissues and organs for patients with conditions that are incompletely addressed. Academic centers and private sectors are trying to address these issues by exploring several complementary approaches, including tissue rejuvenation, tissue or organ replacement, rescue and repair, with the ultimate goal to improve patient health. This course is one of a two-course program (courses can be taken in any sequence) that is focused on evaluating a complex multistage process of conveying innovative ideas that originate in the academic laboratory to regular clinical use. Each week, a different faculty member from the University of Florida or a visiting lecturer from a national regulatory agency, as well as various industrial partners with specific expertise in the field, will give a lecture on topics critical to the regulation, development, financing, and implementation of regenerative medicine technologies. Students enrolled in the 2-credit class will also be required to review appropriate literature prior to each lecture and expected to participate in an interactive discussion during class actively.

Course Objectives

Students will gain a better understanding of each step in the path of product or process development, starting from an initial idea or prototype through the pre-clinical studies and clinical trials to the final approval process for adaptation in standard clinical use. Bringing regenerative therapies into clinical trials, and ultimately into clinical practice, requires significant public-private partnerships and a thorough understanding of the regulatory framework. Therefore, a particular focus will be placed on academic-industry partnerships and navigating the regulatory environment of the Food and Drug Administration.

Target Audience

This course is designed to meet the needs of individuals wanting to pursue a career in medicine or biomedical research. This course will provide a foundation for students who wish to enhance their applications for MD or PhD programs in the medical sciences.

Prerequisite Courses

BSC2010 – Integrated Principles of Biology I

Learning Resources

The course website is found through the University of Florida Canvas (<http://elearning.ufl.edu/>). In-person lectures (50 minutes) with PowerPoint presentations will be given during the first hour of the class. Research papers for each lecture will be provided and are available throughout the entire time the course is open.

Required Materials

There are no required materials for this course.

Course Schedule

CLASS DATE	TOPIC	SPEAKER
01/08/2024 Class #1	Introduction. Process of moving the innovative therapy through clinical trials to the Market	Dmitry Traktuev
01/22/2024 Class #2	Invention Disclosure and Technology Transfer from Academic Center to Industry	Jim O'Connell
01/29/2024 Class #3	Safety and Toxicity Evaluation of Biological Therapies under GLP conditions	Kirsten Coleman
02/05/2024 Class #4	Production of Biological Therapies under GMP Conditions	Eugenio Simon
02/12/2024 Class #5	Regulatory pathways in Reg. Medicine: IDE vs IND. 351 vs 361	Mike Winegar
02/19/2024 Class #6	Designing and navigating Clinical trials. Phase I-IV	Eileen Handberg
02/26/2024 Class #7	Regenerative Medicine from FDA Perspective	Peter Marks
03/04/2024 Class #8	Market research and What it takes to be successful.	Jackson Streeter
03/18/2024 Class #9	Financing product development: Government, Foundations, Angel investments and Venture capital	Maarten Rotman
03/25/2024 Class #10	Product development from the Academic Perspective	Christine Schmidt

CLASS DATE	TOPIC	SPEAKER
04/01/2024 Class #11	Large-Size Biotech: Company Role in Shaping the Market of Devices and Biologics	David Shepard
04/08/2024 Class #12	Challenges of Establishing Small-Size Biotech. Company Culture	Karen Zaderej
04/15/2024 Class #13	Veterinary Regenerative Medicine	Taralyn McCarrel
04/22/2024 Class#14	Prospective of CEO: My lesson with multiple startups in the arena of Regenerative Medicine	Michael Coleman

Evaluation of Grades for 1cr Class

Assignment	Total Points	Percent of Grade
Attendance	39 (3 pts/class)*	30.0%
Online Discussions	91 (7 pts/class) *	70.0%
TOTAL	130	100%

* No assignment will be given after the first class

Evaluation of Grades for 2cr Class

Assignment	Total Points	Percent of Grade
Attendance	39 (3 pts/class)*	18.75%
Speaker Questions Assignment [§]	39 (3 pts/class)*	18.75%
Discussion participation	39 (3 pts/class)*	18.75%
Online Discussions	91 (7 pts/class) *	43.75%
TOTAL	195	100%

* No assignment will be given after the first class

§ for 2 credit class; see below for speaker questions assignment requirements

Speaker Questions Assignment (2-credit hour Only)

Submission of questions for the speaker discussion must be submitted by 1:00 PM on the Monday of class for 2 credit hour students. These questions are based on the required reading publications in the Files section. 5-6 questions must be submitted for full credit. 2-3 questions per paper are suggested.

Online Discussion Criteria

The discussion will open by the Tuesday after that week's class and close at 11:59 PM that Friday. Replies to other students' posts will be due by class time (1:54 PM) on the following Monday. **Late posts/replies will not be accepted.**

	Point Value
Answer the question posted each week with supporting evidence	3
At least 350 words	1
At least 2 references cited APA style (http://www.citationmachine.net/apa)	1
2 replies that will add (agree or disagree and why) to the initial statement of another student. Minimum 100 words each.	2
TOTAL	7

Grading Policy

A numerical grade will be given at the end of the course and will be scored as follows:

Percent	Grade	Grade Points
≥ 93.4	A	4.00
≥ 90.0	A-	3.67
≥ 86.7	B+	3.33
≥ 83.4	B	3.00
≥ 80.0	B-	2.67
≥ 76.7	C+	2.33
≥ 73.4	C	2.00
≥ 70.0	C-	1.67
≥ 66.7	D+	1.33
≥ 63.4	D	1.00
≥ 60.0	D-	0.67
< 59.99	E	0.00

Class Attendance and Make-Up Policy

Class attendance is required. Signing for another student is considered cheating. Each unexcused absence will result in a 3-point reduction in the final grade.

Excused absences are consistent with university policies in the undergraduate catalog (<https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx>) and require appropriate documentation 24 hours in advance.

Students Requiring Accommodations

Students with disabilities requesting accommodations should first register with the Disability Resource Center (352-392-8565, www.dso.ufl.edu/drc/) by providing appropriate documentation. Once registered, students will receive an accommodation letter, which must be presented to the instructor when requesting accommodation. Students with disabilities should follow this procedure as early as possible in the semester.

Course Evaluation

Students are expected to provide feedback on the quality of instruction in this course by completing online evaluations at <https://evaluations.ufl.edu>. Evaluations are typically open during the last two or three weeks of the semester, but students will be given specific times when they are open. Summary results of these assessments are available to students at <https://evaluations.ufl.edu/results/>.

University Honesty Policy

UF students are bound by The Honor Pledge, which states, “We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honor and integrity by abiding by the Honor Code. On all work submitted for credit by students 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.”

The Honor Code (<https://www.dso.ufl.edu/sccr/process/student-conduct-honor-code/>) specifies a number of behaviors that are in violation of this code and possible sanctions. Furthermore, you are obligated to report any condition that facilitates academic misconduct to appropriate personnel. If you have any questions or concerns, please consult with the instructor or TAs in this class.

Honors Program contact information:

- Honors Program, 201 Walker Hall, 352-392-1519
- Quick questions for an Honors advisor? Email advisor@honors.ufl.edu
- Need an Honors advising appointment? Schedule via Microsoft Bookings: <https://bit.ly/ufhonorsadvising>

Counseling and Wellness Center

Counseling and Wellness Center

<http://www.counseling.ufl.edu/cwc/Default.aspx>

352-392-1575

University Police Department

352-392-1111

9-1-1 for emergencies