

## **Bench to Market Regenerative Medicine**

Honors Course for Undergraduates

IDH3931; 1-2 Credits; 3:00 PM – 4:55 PM

1CRE class #27013 Tuesday's 8<sup>th</sup>; Weimer 1084

2CRE class #27014 Tuesday's 8-9<sup>th</sup>; Weimer 1084

Spring 2023

### **Instructors**

Dmitry Traktuev, PhD (dtraktuev@ufl.edu)

Katelyn Bruno, PhD (katelyn.bruno@ufl.edu)

Keith March, MD, PhD (kmarch@ufl.edu)

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

### **Course Description**

Regenerative medicine creates an opportunity to lessen pathological processes, 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 actively participate in an interactive discussion during class.

### **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 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.

### **Prerequisite Courses**

BSC2010 – Integrated Principles of Biology I

BSC2011 – Integrated Principles of Biology II

## Required Materials

There are no required materials for this course.

## Course Schedule

DATE	SPEAKER	TOPIC
<b>01/10/2023</b> Class #1	Dmitry Traktuev	Introduction. Process of moving the innovative therapy through clinical trials to the Market
<b>01/17/2023</b> Class #2	Jim O'Connell	Invention Disclosure and Technology Transfer from Academic Center to Industry
<b>01/24/2023</b> Class #3	Kirsten Coleman	Safety and Toxicity Evaluation of Biological Therapies under GLP conditions
<b>01/31/2023</b> Class #4	Eugenio Simon	Production of Biological Therapies under GMP Conditions
<b>02/07/2023</b> Class #5	Keith March	Test models for new therapies: in vitro and animal models
<b>02/14/2023</b> Class #6	Ian McNiece & Mike Winegar	Regulatory pathways in Reg. Medicine: IDE vs IND. 351 vs 361
<b>02/21/2023</b> Class #7	Eileen Handberg	Designing and navigating Clinical trials. Phase I-IV
<b>02/28/2023</b> Class #8	Jackson Streeter	Assessment of the market size and "financing" product development
<b>03/07/2023</b> Class #9	Maarten Rotman	Financing product development: Government, Foundations, Angel investments and Venture capital
<b>03/21/2023</b> Class #10	Peter Marks	Regenerative Medicine from FDA Perspective
<b>03/28/2023</b> Class #11	Christine Schmidt	Product development from the Academic Perspective
<b>04/04/2023</b> Class #12	David Shepard	Large-Size Biotech: Company Role in Shaping the Market of Devices and Biologics
<b>04/11/2023</b> Class #13	Karen Zaderej	Challenges of Establishing Small-Size Biotech. Company Culture
<b>04/18/2023</b> Class#14	Taralyn McCarrel	Veterinary Regenerative Medicine
<b>04/25/2023</b> Class#15	Michael Coleman	Prospective of CEO: My lesson with multiple startups in the arena of Regenerative Medicine

## Evaluation of Grades

Assignment	Total Points	Percent of Grade
Attendance on	42 (3 pts/class)*	30.0%
Online Discussions	98 (7 pts/class)*	70.0%
<b>TOTAL</b>	<b>140</b>	<b>100%</b>

## Online Discussion Criteria

The discussion will open at 5:00 PM every Wednesday and close at 11:59 PM the following Sunday. **Late posts/replies will not be accepted.**

	Point Value
Answer the question that is posted each week with supporting evidence At least 350 words (1 point will be subtracted if less)	4
At least 2 references cited APA style ( <a href="http://www.citationmachine.net/apa">http://www.citationmachine.net/apa</a> )	1
2 replies that will add (agree or disagree and why) to the initial statement of the other student. Minimum 100 words each.	2
<b>TOTAL</b>	<b>7</b>

## Grading Policy

Percent	Grade	Grade Points
≥ 90.00	A	4.00
≥ 86.66	A-	3.67
≥ 83.33	B+	3.33
≥ 80.00	B	3.00
≥ 76.66	B-	2.67
≥ 73.33	C+	2.33
≥ 70.00	C	2.00
≥ 66.66	C-	1.67
≥ 63.33	D+	1.33
≥ 60.00	D	1.00
≥ 56.66	D-	0.67
< 56.66	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/](http://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 the 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.

## **Counseling and Wellness Center**

Contact information for the Counseling and Wellness Center: <http://www.counseling.ufl.edu/cwc/Default.aspx>, 392-1575; and the University Police Department: 392-1111 or 9-1-1 for emergencies.