

BME 4931/6938: Bench to Bedside Clinical Translation

Fall 2024 Course Syllabus

University of Florida

Days, Times, and Locations:

T, period 9, 4:05 pm - 4:55 pm, Black Hall Room 315

Th, periods 9 & 10, 4:05 pm - 6:00 pm, Black Hall Room 415

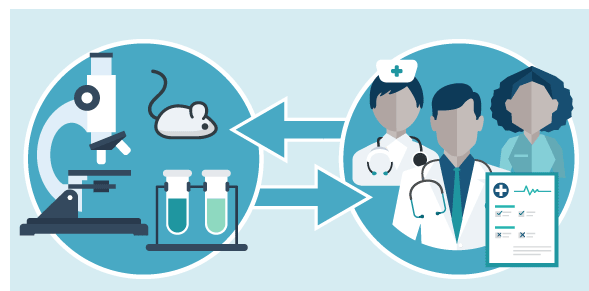
Instructor and Office Hours:

Dr. Christine E. Schmidt (schmidt@bme.ufl.edu)

Office Hours: Wednesdays, 1:30 pm - 2:30 pm (via Zoom),

or in person, by appointment. Other days/times by appointment.

Note: Any changes to office hours will be announced in class and/or via Canvas.



Course Development Collaborators:

- *Intellectual Property and Licensing:* Anita Rao, Pathways Program Director, UF Innovate, arao@ufl.edu
- *Customer Discovery and Entrepreneurship:* Richard Berman, Center for Entrepreneurship, University of South Florida (USF), richardberman12345@gmail.com
- *Healthcare Reimbursement and Finance:* Traci S. d'Auguste, CCO for Shands Hospital, traci@shands.ufl.edu; Assistant: Esther Portalatin-Ramos, epor0001@shands.ufl.edu

Target Audience and Prerequisites:

This is a junior/senior undergraduate and graduate level BME elective course, which is open to any UF student interested in biomedical innovation and commercialization. This course is designed to meet the needs of individuals wanting to pursue a career in biomedical research, industry, and/or entrepreneurship. General biomedical/life science background knowledge is instrumental. Speak with instructor if not sure.

Course Description and Objectives:

This course will provide a basic roadmap for the process of translating innovative ideas that originate in the academic laboratory to clinical use. We will explore concepts related to biomedical technology development, invention disclosures, technology licensing, the Food and Drug Administration (FDA) regulatory pathways, customer discovery, and approaches for commercialization. Class will consist of lectures by the professor, guest lectures, in-class discussions, quizzes, in-class presentations, and team projects.

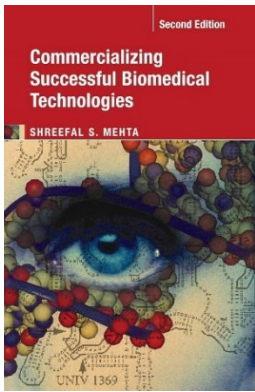
By the end of this course, students will be able to:

- describe the process for protecting intellectual property
- describe the main requirements for technology licensing
- understand and describe the basic FDA approval processes for biomedical products (medical devices)
- describe the process for market analysis and customer discovery
- describe the essential steps needed for successful product development
- understand and describe some of the challenges and pitfalls to commercialization
- formulate a pitch presentation to potential "investors" for an idea/invention

Course Learning Resources:

The course website is found through the University of Florida Canvas (<http://elearning.ufl.edu>). All necessary materials and communications will occur via Canvas.

Text/Materials:



There are no required texts.

The following book is recommended: “Commercializing successful biomedical technologies”, 2nd Edition, Shreefal S. Mehta, Cambridge University Press, ISBN # 9781316510063.

This book is available via the UF Catalog (UF VPN login required to access):
https://ufl-flvc.primo.exlibrisgroup.com/permalink/01FALSC_UFL/6ad6fc/alma99384238528406597

Copies of chapters from the text will be made available on Canvas as needed. Other course materials will also be posted on Canvas.

Grading Criteria:

In-Class Participation	10%
Speaker Questions	10%
Quizzes (lowest quiz grade dropped)	20%
Interim Project Presentations	15%
Project (Pitch) Written Report	20%
<u>Project (Pitch) Slides, Presentation, Q&A</u>	<u>25%</u>
	100%

Grading Scale:

Grade	Percentage
A	90.00-100%
B+	87.50-89.99%
B	80.00-87.49%
C+	77.50-79.99%
C	70.00-77.49%
D+	67.50-69.99%
D	60.00-67.49%
F	< 60.00%

Speaker Questions:

Submission of questions for the speaker discussion must be submitted by 1:00 PM on the day of class for each guest speaker. Questions should be based on topic of discussion, including online resources for speaker/topic and related posted reading materials. At least 3 distinct, thoughtful questions must be submitted for full credit.

Quizzes:

Short 10-minute quizzes will be given each Thursday (unless otherwise indicated) at the beginning of class, before the lecture, guest speaker, or class activities. Quizzes will cover the material discussed in classes since the prior quiz. Students must be in attendance to take quizzes. No make-up quizzes are given. If a student has an excused absence (notification in advance), then that quiz grade will be dropped. The lowest quiz grade will also be dropped to calculate final course grade.

Extra Credit (Optional):

Any student can receive extra credit that will be applied to any quiz score (up to 5 total points per quiz; extra credit applies to all quizzes). To receive extra credit, a student must submit a sample quiz problem(s) with solution by 12 noon the day prior to a quiz. The number of points credited for a problem will depend on originality, applicability (does it test what we learned in class?), detail, and accuracy of the solution. Also, your sample problem may be selected for the quiz, making the quiz easier! A student may turn in more than one sample problem per quiz, but only the grade for the best problem will count for extra credit. However, all submissions will be considered as possible problems for the quiz.

Project:

A project (small groups or individual) will be assigned, with more details to come. The project will require independent research outside of class and three in-class interim oral project presentations to the class. A final written report is required, as well as an oral final “pitch” presentation to the class and external guest judges (i.e., “investors”). The final oral presentation will be graded based on presentation skills, quality of slides (content choice, layout), and ability to answer questions. Input from the judges will be factored into the final oral grade.

Class Attendance and Excused Absences Policy:

Attendance is required for quizzes and in-class presentations and is also key for mastery of subject material. In-class participation is factored into the course final grade. Excused absences must be consistent with UF policies: <https://catalog.ufl.edu/UGRD/academic-regulations/attendance-policies> and approval needs to be obtained prior to missed class (except for documented emergencies). Students are responsible for content covered during a missed class (i.e., responsible for securing notes from classmates and any documents from Canvas).

Grading Disputes:

Requests for regrading must be submitted to the professor within 1 week after the graded assignment has been returned. If regrading is desired, then the entire assignment is subject to regrading. If your work is not clear or the specific question involves subjectivity, then there is no justification for regrading.

In-Class Recording:

Students are allowed to record video or audio of class lectures provided by the professor; however, guest speakers cannot be recorded unless students seek explicit permission from the guest in advance. Also, the purposes for which any recordings may be used are strictly controlled. The only allowable purposes are (1) for personal educational use, (2) in connection with a complaint to the university, or (3) as evidence in, or in preparation for, a criminal or civil proceeding. All other purposes are prohibited.

A “class lecture” is an educational presentation intended to inform or teach enrolled students about a particular subject, including any instructor-led discussions that form part of the presentation, and delivered by any instructor hired or appointed by the University, or by a guest instructor, as part of a course. A class lecture does not include student presentations, academic exercises involving solely student participation, assessments (quizzes), private conversations between students or between a student and the faculty or lecturer during class.

Publication without written permission of the instructor or guest speaker is prohibited. To “publish” means to share, transmit, circulate, distribute, or provide access to a recording, regardless of format or medium, to another person (or persons), including but not limited to another student within the same class section. Additionally, a recording, or transcript of a recording, is considered published if it is posted on or uploaded to, in whole or in part, any media platform, including but not limited to social media, book, magazine, newspaper, leaflet, or third-party note/tutoring services. A student who publishes a recording without written consent may be subject to a civil cause of action instituted by a person injured by the publication and/or discipline under UF Regulation 4.040 Student Honor Code and Student Conduct Code.

Use of ChatGPT or Other AI Tools:

AI tools can be used as a resource; if they are used, then the tool must be cited as a reference. In addition to citing the tool as a resource, students are required to provide a short description as to how the tool was used and how you validated accuracy of the information secured from the AI resource.

Software Use:

All faculty, staff, and students at 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 UF policies and rules, disciplinary action will be taken as appropriate. We, the members of the University of Florida community, pledge to uphold ourselves and our peers to the highest standards of honesty and integrity.

Student Privacy:

There are federal laws protecting your privacy with regards to grades earned in courses and on individual assignments. For more information, please see: <https://registrar.ufl.edu/ferpa.html>.

Students Requiring Accommodations:

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

Course Evaluations:

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. 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://sccr.dso.ufl.edu/policies/student-honor-code-student-conduct-code>) specifies a number of behaviors that are in violation of this code and possible sanctions. The first student to email the professor with the subject line 'I read the syllabus' will receive five bonus points on the first quiz. 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.

Commitment to a Safe and Inclusive Learning Environment:

The Herbert Wertheim College of Engineering (HWCOE) values broad diversity within our community and is committed to individual and group empowerment, inclusion, and the elimination of discrimination. It is expected that every person in this class will treat one another with dignity and respect regardless of gender, sexuality, disability, age, socioeconomic status, ethnicity, race, and culture.

If you feel like your performance in class is being impacted by discrimination or harassment of any kind, please contact your instructor or any of the following:

- Your academic advisor or Graduate Program Coordinator
- Dr. Pamela Dickrell, HWCOE Associate Dean for Student Affairs, 352-392-4524, pld@ufl.edu
- Dr. Toshikazu Nishida, HWCOE Associate Dean for Academic Affairs, 352-392-0943, nishida@eng.ufl.edu

Counseling and Wellness:

U Matter, We Care:

Your well-being is important to the University of Florida. The U Matter, We Care initiative is committed to creating a culture of care on our campus by encouraging members of our community to look out for one another and to reach out for help if a member of our community is in need. If you or a friend is in distress, please contact umatter@ufl.edu so that the U Matter, We Care Team can reach out to the student in distress. A nighttime and weekend crisis counselor is available by phone at 352-392-1575. The U Matter, We Care Team can help connect students to the many other helping resources available including, but not limited to, Victim Advocates, Housing staff, and the Counseling and Wellness Center. Please remember that asking for help is a sign of strength. In case of emergency, call 9-1-1.

Counseling and Wellness Center: <https://counseling.ufl.edu> and 392-1575.

Sexual Discrimination, Harassment, Assault, or Violence:

If you or a friend has been subjected to sexual discrimination, sexual harassment, sexual assault, or violence contact the **Office of Title IX Compliance**, located at Yon Hall Room 427, 1908 Stadium Road, (352) 273-1094, titleix@ufl.edu

Sexual Assault Recovery Services (SARS): Student Health Care Center, 392-1161.

University Police Department at 392-1111 (or 9-1-1 for emergencies), or <http://www.police.ufl.edu/>.

Academic Resources:

E-learning technical support, 352-392-4357 (select option 2) or e-mail to Learning-support@ufl.edu; <https://elearning.ufl.edu/student-help/>.

Career Connections Center, Reitz Union, 392-1601. Career assistance and counseling; <https://career.ufl.edu>.

Library Support, <http://cms.uflib.ufl.edu/ask>. Various ways to receive assistance with respect to using the libraries or finding resources.

Teaching Center, Broward Hall, 392-2010 or 392-6420. General study skills and tutoring. <https://teachingcenter.ufl.edu/>.

Writing Studio, 302 Tigert Hall, 846-1138. Help brainstorming, formatting, and writing papers. <https://writing.ufl.edu/writing-studio/>.

Student Complaints Campus: <https://sccr.dso.ufl.edu/policies/student-honor-code-student-conductcode/>; <https://care.dso.ufl.edu>.

On-Line Students Complaints: <https://distance.ufl.edu/getting-help>; <https://distance.ufl.edu/state-authorizationstatus/#student-complaint>.

Last up-dated: August 6, 2024

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Dr. Christine Schmidt; Fall 2024

T, 4:05 pm - 4:55 pm, Black Hall 315; Th, 4:05 pm - 6:00 pm, Black Hall 415

Dept. of Biomedical Engineering

University of Florida

Schedule of Lectures, Quizzes, and Project Due-Dates:

Wk	Date	Class	Lecture Topic	Speaker	Notes
1	8/22	1	Introduction to class	Dr. Christine Schmidt & Anita Rao , UF Innovate	
2	8/27	2	Academic innovator perspective	Dr. Schmidt	
	8/28	n/a	<i>UF Innovate: "Innovation Hour" at the Hub, 4:30-6:00 pm Optional (free, but need to register***)</i>	n/a	
	8/29	3	Bench-to-bedside start-up company experience (Sharma)* Project overview; Communication tips (Schmidt)	Dr. Blanka Sharma , UF & Dr. Schmidt	Quiz #1** <i>Project assigned</i>
3	9/3	4	Commercializing medical devices and prototyping*	Dr. Frank Bova , UF	
	9/5	5	UF Shands Hospital (d'Auguste) Unmet needs and customer discovery (Berman)*	Traci d'Auguste , Shands & Richard Berman , USF	
4	9/10	–	No class – Work on inventor & customer interviews	–	NO CLASS
	9/12	6	Intellectual property basics; Licensing IP; Innovation resources at UF*	Anita Rao , UF Innovate & Dr. Kevin McDonald , Wolf Greenfield	Quiz #2**
5	9/17	7	Commercializing digital health technologies*	Dr. David Vaillancourt , UF	
	9/19	8	<i>1st Interim Project Presentations & Class Feedback – IP Overview & Customer Discovery Feedback</i>	All Students	Interim #1
6	9/24	9	Overview of FDA regulatory processes*	Dr. Aarti Urs , Zimmer-Biomet	
	9/26	10	Overview of commercializing therapeutics*	Dr. Pravin Chaturvedi , Oceanyx Pharmaceuticals	Quiz #3**
7	10/1	–	No class – Work on project & customer interviews	–	NO CLASS
	10/3	11	Milestones and funding for product development*	John Engels	Quiz #4**
8	10/8	12	Entrepreneurial strategies and lessons learned*	Dr. Jackson Streeter , UF Innovate	
	10/10	–	No class – Work on project & customer interviews	–	NO CLASS
9	10/15	13	Bench to bedside start-up company experience*	Dr. Sarah Mayes , Alafair, Inc.	
	10/17	14	<i>2nd Interim Project Presentations & Class Feedback – Competing Tech & Customer Discovery Feedback</i>	All Students	Interim #2

Schedule of Lectures, Quizzes, and Project Due-Dates:

Wk	Date	Class	Lecture Topic	Speaker	Notes
10	10/22	15	Biomanufacturing: A critical checkpoint in biopharmaceutical translation*	Dr. Greg Hudalla , UF	
	10/24	–	No class – Annual BMES Meeting in Baltimore, MD	–	NO CLASS
11	10/29	16	Bench to Bedside - well, not quite...*	Dr. Jamal Lewis , UF	
	10/30	n/a	UF Innovate: “Standing Innovation” at the Hub, times TBA Optional (free, but need to register***)	n/a	
	10/31	17	Pitch presentation tips: Do’s and don’ts	UF Innovate Staff	Quiz #5**
12	11/5	18	How industry interacts with the FDA*	Dr. Ben Spearman , Axogen, Inc.	
	11/7	19	3rd Interim Project Presentations & Class Feedback – Regulatory & Customer Discovery Feedback	All Students	Interim #3
13	11/12	20	In class project work period	All Students	
	11/14	21	In class project work period and report finalization	All Students	Written Reports Due 11:59 pm
14	11/19	22	Final Student Pitch Presentations to Class & Guests	Assigned Students	Pitch Talks
	11/21	23	Final Student Pitch Presentations to Class & Guests	Assigned Students	Pitch Talks
15	11/26	–	No class – Thanksgiving Holiday	–	NO CLASS
	11/28	–	No class – Thanksgiving Holiday	–	NO CLASS
16	12/3	24	Final Student Pitch Presentations to Class & Guests	Assigned Students	Pitch Talks Last Class Day!

* Required: Speaker Questions are due by 1 pm on the same day of guest lecture.

** Optional: Students can receive up to 5 extra credit bonus points per quiz. To receive extra credit, a student must submit a sample quiz problem(s) with solution by 12 noon the day prior to quiz.

*** Optional: Reach out to Dr. Schmidt or Anita Rao for UF Innovate Program registration information; need to register 3-5 days in advance for the August 28 event and 1 month in advance for the October 30 event. Food provided at events for those registered.

Note: As a result of guest schedules and unforeseen circumstances, it may be necessary to make changes to the course schedule. Students will be informed in class, and/or via Canvas, of any changes made to the lecture or assignment schedule. Students are responsible for any announced changes (i.e., absence from the class in which the announcement is made is not an excuse).