



**BMED 8813 CM – Special Topics: Engineering
concepts in Therapeutic Cell Manufacturing
Running Title: Cell Manufacturing
Fall 2020**

Tues and Thurs 3:00 – 4.15 PM EST / 2:00 – 3:15 CST

This multi-institution course is intended to provide graduate level foundation in the biology of therapeutic cells, especially stem and progenitor cells, stromal cells, and immune cells - and the engineering and manufacturing approaches to developing scalable manufacturing platforms with these cells and their derivatives. Emphasis will be on application of analytical engineering approaches for the quantitative study of stem/immune cell biology and effective translation of cells into industrial scale therapies and diagnostics. The progression of the course content is intended to lead students through the conceptual process of identifying an appropriate type of therapeutic cell, based on functional attributes for a desired application. In the second half of the course, we will examine various aspects of cell manufacturing as well as industrial translation and regulatory processes that should be considered to bring the concept to clinical application.

Graduate students at Georgia Institute of Technology (GT), University of Georgia (UGA), University of Puerto Rico – Mayagüez (UPRM) and University of Wisconsin – Madison (UW) who are participating in the NSF Center for Cell Manufacturing Technologies (CMaT) are expected to take it as part of their graduate programs. The course is open to other interested graduate students at each institution and, with permission, advanced undergraduates.

Instructors	Office Hours/Contact information
Shalu Suri, Ph.D. Associate Director CMaT ERC Engineering Workforce Development and Diversity & Inclusion Georgia Institute of Technology	By Appointment shalu.suri@bme.gatech.edu
Sean Palecek, Ph.D. Professor Dept of Chemical and Biological Engineering University of Wisconsin-Madison	By Appointment sppalecek@wisc.edu
Luke Mortensen, Ph.D. Assistant Professor Regenerative Bioscience Center University of Georgia	By Appointment luke.mortensen@uga.edu
Wandaliz Torres-Garcia, Ph.D. Associate Professor Industrial Engineering Department University of Puerto Rico Mayaguez	By Appointment wandaliz.torres@upr.edu

Learning Objectives:

1. Provide graduate-level foundation on principles governing therapeutic cell manufacturing
2. Discuss the elements of quality control, quality by design, cell manufacturing unit operations, and the relationship between process development, critical quality attributes (CQAs), and critical process parameters (CPPs).
3. Develop an understanding of bioprocessing approaches for the effective translation of cells into industrial scale therapies
4. Discuss the importance of standards in cell manufacturing, and learn about regulatory issues in cell therapy translation.
5. Enable graduate students with the necessary biological and engineering background to successfully conduct research with therapeutic cells and lay the foundation for a potential professional career in cell manufacturing.

Campus-Specific Details:

Campus	Instruction mode	Course Number
GT	Remote/ EBB 4029	BMED 8813 CM
UGA	Remote	BIOE 8980
UPRM	Remote	BING 8995-086
UW	Remote	CBE 562

Readings: Recommended reading materials will be chosen from a combination of book chapters, review articles and current research papers which will provide the necessary supporting information or topical examples of principles of the course. Related reading material items will be posted on the course web site. There is no required textbook.

Instructional Mode: The course combines lecture and discussion. This includes live, real-time interaction with students from other campuses via videoconferencing. Lectures will be delivered by multiple instructors including academia and industry experts in the field of therapeutic cell manufacturing.

Grading:

Attendance and in-class participations	20%
Assignments	30%
Project Presentation	20%
Project Report	30%

Project: A cell-manufacturing research proposal in the format and style of an NIH R21. Due before the last day of class. More details will be discussed in the class. There will be 10-15 minute project presentation to the class followed by a 5-minute Q&A. Guidelines for the final oral presentations and complete written proposal will be distributed in lecture.

Peer Evaluations: Peer evaluation questionnaires will be handed out for group projects and ask about how you and each of your teammates contributed to the team's work. Specific aspects to be evaluated will be:

1. Contribution to team's work
2. Interacting with team mates
3. Keeping the team on track
4. Expecting quality

Participation: Students are expected to proactively participate in synchronous in-class discussions. Participation is designed to help students engage with students and faculty from other U.S. universities in real-time. Participation will be evaluated on the quality and frequency of insightful questions and comments contributed to in-class discussions.

Re-grading: Requests for regrading of a homework assignment or an exam may be submitted in writing within one week of the day the homework or exam is handed back to the class (regardless of whether or not you attend class that day). You must justify in writing the technical basis for the regrade. If the regarding request is accepted, your entire homework or exam may be regarded (your grade may decrease after regarding). Please do not assume that your grade will always go up after regrading.

Honor Code: Students are expected to abide by the Honor Code of their respective institutions, e.g. at Georgia Tech please see www.honor.gatech.edu. The objective of the honor code is "to prevent any students from gaining an unfair advantage over other students through academic misconduct". Any violations will be reported to the respective Deans of Students, or otherwise appropriate entity, on the first offense.

Accommodations: Students seeking an academic or employment accommodation (including graduate teaching and research assistants) should start by contacting the appropriate office at their respective institutions, e.g. at Georgia Tech please contact the Office of Disability Services (ODS). Registering with ODS is a 3-step process that includes completing an application, uploading documentation related to the accommodation request, and scheduling an appointment for an “intake meeting” (either in person or via phone or video conference) with a disability coordinator. Students who work as undergraduate or graduate teaching assistants and graduate research assistants seeking an employment accommodation should also complete the Georgia Tech Covid-19 Higher Risk Alternative Work Arrangement Request Form.

Mask policy: Anyone attending in-person class sessions is **required** to wear masks during the entire duration of the class.

Emergencies: In the event of a major campus emergency like a COVID or flu outbreak, course requirements, deadlines, and grading percentages are subject to changes that may be necessitated by a revised semester calendar or other circumstances. The course website will be used to provide information about changes in this course.

Schedule: Please see the following page for detailed course schedule. Please note: The schedule is subject to change and lecture orders could be reorganized based on changes in availability of guest instructors. Students will be informed well in advance if such changes are necessary.

Joining Details:

Meeting URL

https://bluejeans.com/692140726?src=join_info

Meeting ID

692 140 726

Want to dial in from a phone?

Dial one of the following numbers:

+1.408.419.1715 (United States(San Jose))

+1.408.915.6290 (United States(San Jose))

(see all numbers - <https://www.bluejeans.com/numbers>)

Enter the meeting ID and passcode followed by #

Connecting from a room system?

Dial: bjn.vc or 199.48.152.152 and enter your meeting ID & passcode

Date	Topic	Lecturer
Tues 8/18, week 1	Course overview	All instructors
Thurs 8/20, week 1	Introduction to Cell therapy – Promises and Challenges	Suri
Tues 8/25, week 2	Stem cells	Mortensen
Thurs 8/27, week 2	Bioreactors	Suri
Tues 9/1, week 3	Quality by design	Suri
Thurs 9/3, week 3	Cellular reprogramming	Palecek
Tues 9/8, week 4	Engineering tissues from iPSCs	Palecek
Thurs 9/10, week 4	Data Analytics	Torres-Garcia
Tues 9/15, week 5	AI in cell manufacturing confirmed	Chuck Zhang
Thurs 9/17, week 5	Data Analytics/Grant writing	Torres-Garcia
Tues 9/22, week 6	Concepts in scalable bioprocessing of cells	Mantalaris
Thurs 9/24, week 6	Concepts in scalable bioprocessing of cells	Mantalaris
Tues 9/29, week 7	No Class –Full day CMA_T retreat	
Thurs 10/1, week 7	Cell Surface Engineering	Mortensen
Tues 10/6, week 8	Immune cells Manufacturing	Roy
Thurs 10/8, week 8	Gene editing – Science and Technology	Saha
Tues 10/13, week 9	Regulatory issues in cell therapy translation	Iris Marklein
Thurs 10/15, week 9	The role of standards in cell/bio manufacturing	Lin-Gibson/NIST
Tues 10/20, week 10	3D printing of stem cell engineered tissue constructs	Serpooshan
Thurs 10/22, week 10	Industry Perspective - Century Therapeutics	Russotti
Tues 10/27, week 11	Supply chain management and logistics	White/Wang
Thurs 10/29, week 11	Industry Perspective - Rooster bio	Ehsan
Tues 11/03, week 12	Industry Perspective - Vicapsys	Chavan
Thurs 11/05, week 12	Analytical tools in cell manufacturing	Ross Marklein
Tues 11/10, week 13	Industry Perspective - Lonza	Eytan
Thurs 11/12 week 13	Multiscale engineering of immune cells and organs	Singh
Tues 11/17 week 14	Multiscale engineering of Immune cells and organs	Singh
Thurs 11/19 week 14	Student Presentations	
Tues 11/24 week 15	Student Presentations	

Note: As a result of unforeseen circumstances, it may be necessary to make changes to the course schedule. Students will be informed during lecture and/or via e-mail of any changes made to the lecture or assignment schedule.