BMED 8813 CM – Special Topics: Engineering concepts in Therapeutic Cell Manufacturing
Running Title: Cell Manufacturing
Spring 2024

Tues and Thurs 2:00 – 3.15 PM EST / 1:00 – 2:15 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. Co-Director CMaT ERC Engineering Workforce Development 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. Associate Professor Regenerative Bioscience Center School of Chemical, Materials, and Biomedical Engineering University of Georgia	By Appointment luke.mortensen@uga.edu
Madeline Torres-Lugo, Ph.D. Professor Department of Chemical Engineering University of Puerto Rico Mayaguez	By Appointment madeline.torres6@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	BMED 8813 CM
UGA	Remote	BIOE 8980
UPRM	Remote	BING 8995
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, industry, and government agencies experts in the field of therapeutic cell manufacturing.

Grading:

Participation	20%
Assignments	30%
Project Presentation	20%
Project Report	30%

Homework Assignments: Homework assignments will be posted on the course website and the due date will be indicated on the assignments. Assignments will be completed by the students in pairs where each student will be paired with their peer from another institution. Student pairs will be assigned by the instructors for each assignment. **A 10% deduction will be taken for each day of late homework.** Answers will not be posted.

Group 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 a project presentation to the class followed by a 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 homework assignments and 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 teammates
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.

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: Shalu Suri is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
https://gatech.zoom.us/j/96210811639

Meeting ID: 962 1081 1639

One tap mobile
+16892781000,,96210811639# US
+17193594580,,96210811639# US

Dial by your location
• +1 689 278 1000 US
• +1 719 359 4580 US
• +1 929 205 6099 US (New York)
• +1 253 205 0468 US
• +1 253 215 8782 US (Tacoma)
• +1 301 715 8592 US (Washington DC)
• +1 305 224 1968 US
• +1 309 205 3325 US
• +1 312 626 6799 US (Chicago)
• +1 346 248 7799 US (Houston)
• +1 360 209 5623 US
• +1 386 347 5053 US
• +1 507 473 4847 US
• +1 564 217 2000 US
• +1 646 931 3860 US
• +1 669 444 9171 US
• +1 669 900 6833 US (San Jose)
Meeting ID: 962 1081 1639

Date	Topic	Lecturer
Tues 1/09, week 1	Course overview	All instructors
Thurs 1/11, week 1	Scalable Cell Manufacturing	Suri
Tues 1/16, week 2	Quality by design	Suri
Thurs 1/18, week 2	Cellular reprogramming	Palecek
Tues 1/23, week 3	Stem cells	Mortensen
Thurs 1/25, week 3	Concepts of MSC Cell Manufacturing	Johnna Temenoff
Tues 1/30, week 4	Organoid engineering	Palecek
Thurs 2/01, week 4	Culture substrates	Madeline
Tues 2/06, week 5	Grant writing	Madeline
Thurs 2/08, week 5	Sensors in Cell Manufacturing	Andrei Federov
Tues 2/13, week 6	Industry Perspective - Century Therapeutics	Greg Russotti
Thurs 2/15, week 6	Experimental Design	Mauricio
Tues 2/20, week 7	Cell Surface Engineering	Luke Mortensen
Thurs 2/22, week 7	3 D printing of stem cell engineered tissue constructs	Martin Tomov
Tues 2/27, week 8	Metabolic Quality Attributes in Therapeutic Cells	Melissa Skala
Thurs 2/29, week 8	Gene editing – Science and Technology	Kris Saha
Tues 3/05, week 9	Microfluidics Technologies in cells Manufacturing	Todd Sulchek
Thurs 03/07, week 9	Industry Perspective	Taby Ahsan
Tues 3/12, week 10	Guest lecture	Cheryl Gomillion
Thurs 3/14, week 10	Industry Perspective – AxionBio	Stacie Chvatal
Week of 3/18 - 3/22	**Spring Break**	
Tues 3/26, week 11	The role of standards in cell/bio manufacturing	Lin-Gibson (NIST)
Thurs 3/28, week 11	Industry Perspective	Eli Fine
Tues 4/02, week 12	Supply chain management and logistics	White/Wang
Thurs 4/04, week 12	Industry Perspective - JnJ	Chris Kloss
Tues 4/09, week 13	Tentative NSF site visit	
Thurs 4/11 week 13	MSC phenotype	Marklein
Tues 4/16 week 14	Robotics and Automation	Balakirsky
Thurs 4/18 week 14	**Student Presentations**	
Tues 4/23 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.