16:125:584 *INTEGRATIVE MOLECULAR AND CELLULAR BIOENGINEERING*

Spring 2025

I. PLACE, TIME, CREDITS

Location: BME116
Time: Wednesday 12:10 -3:10 PM, on scheduled dates shown on next pages
Credits: 3

II. INSTRUCTORS

Professor Biju Parekkadan, PhD and Guest Lecturers
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III. COURSE DESCRIPTION

Integration of engineering and mathematical principles with molecular and cell biology for the development of bioprocesses involved in the manufacture and use of human cell and gene therapeutics. This course will emphasize a quantitative understanding of large-scale human cell culture, cell separations, viral/non-viral gene manufacture, cell purification, combination cell-device products, cell formulation/preservation, clinical trials and more. There will be a balanced contribution from both academic and industry experts around the country as guest lecturers. The course is taught "inside-out" whereby students are expected to review the lecture video prior to class and arrive for in-person assessment and discussion about a debate topic. Upon course completion, students will have a modern view of an emerging new class of cell and genetic medicines with cutting-edge applications of bioprocess tools and practical insights from industry. Furthermore, it will offer students examples of career opportunities in the future. Undergraduates with advanced standing (completion of transport and kinetics required) may enroll with instructor permission.

IV. COURSE STRUCTURE

(A) Textual Materials

All information will be posted on the course Canvas website. Pre-reading for every class will be assigned.

(B) Learning Objectives

Upon completion of this course, students should:

1. Understand the emerging industry considerations for translating a cell/gene therapeutic.
2. Learn of the major unit operations to create cell and gene therapeutics and their bottlenecks.
3. Challenges and directions of bioengineering in the development of new cell/gene therapy products, manufacturing tools, and service-based platforms.

4. Be aware of significant research problems in cell/gene therapy and biomanufacturing with the ability to specify biological and engineering science approaches towards addressing these problems.
5. Be familiar with various laboratories, companies, and facilities that are dedicated to the cell/gene therapy field.
6. Be familiar with the regulation of cell/gene therapy products.

(C) Assessment

Class Attendance, Participation in Class Discussions, and Weekly Quiz: 30%

One absence is permitted; two absences will require make-up work. Three+ absences will result in a failing grade.

Quiz Assessments: The intent of the quiz is to help students develop intuitive skills and concepts outside of lecture and recitation after viewing the lecture video prior to class. This semester, skills development will be assessed via in class quiz rather than by traditional at-home problems. A 5-min, multiple choice set of quiz questions related to the video lectures will be administered at the beginning of selected classes. Quizzes will be submitted electronically using the Canvas system. Each HW is an individual assignment, closed book, with no partial credit. No makeup HW will be given.

Oral Presentations: 20%

For most class periods, the class will read and discuss one journal article addressing a specific molecular or cellular engineering topic. All readings are posted on the Canvas course site.

First, on most weeks the instructor will lead a brief, ~5 min discussion of the topic at hand. Then two teams will critique and debate current research articles on the topic. Two teams of 3-4 students will be responsible for making detailed presentations of the paper to the class and leading the discussion. Each team will be assigned at least 2 oral presentations for the semester.

For a given topic, after the instructor's presentation, the two groups assigned that topic will present back-to-back. Then, for the remainder of that class period, we will have an open debate and formal vote about which of the two approaches that were presented hold more promise for clinical translation. The presentations should be approximately 15-20 minutes long, leaving ample time for discussion.

All students are expected to read the papers before class and to participate in the in-class discussion.

Term Project: 50% (total)

The project will be carried out in two phases. ***The first phase is a team business plan for a new technology for cell/gene therapy product (Video): 20%.*** A general set of content to consider is as follows: title, market focus, significance/background, current product(s), novel biological/engineering approach, key proof of concept data, regulatory plan, and execution plan.

Students will identify the business opportunity, major risks, and appropriate ways to mitigate those risks to develop a viable business plan.

(DUE APRIL 1) Students will break into small groups of 2-4 and work together to 'pitch' an idea for a new cell product, manufacturing tool, or service/IT solution to benefit the cell/gene therapy industry. Be prepared to present your idea as a video for submission. The following categories are examples of areas that can be the core focus of the group project:

- A new cell/gene therapeutic or combination product: With this focus, students will identify the 'therapeutic problem' as a disease indication, epidemiology, market potential, and existing approaches of care to make the case for a cell/gene therapeutic intervention. Teams must provide an example of major steps needed to manufacture a product and what target specifications are of interest. A regulatory plan including major pre-clinical and Phase I-III trial studies will be included.
- A new manufacturing technology: With this focus, students will identify the 'manufacturing problem' as a unit operation, market size, and existing approaches of manufacturing to make the case for a new tool
- intervention. Teams must provide an example of the prototype device and what target specifications are of interest. A regulatory plan including pre-clinical and Phase I-III trial validation (if necessary) will be included.

- A new service tool: With this focus, students will identify the 'supply chain/logistical problem'. Teams must provide an example of the prototype service and what target specifications are of interest. A sales/marketing plan including customer discovery, engagement, and retainment plan will be submitted.

(D) Schedule

Classes will start promptly at 12:10pm in person. The course instructor will begin with any pertinent announcements followed by administration of the weekly quiz regarding the video lecture. There will then be a 15-20 minute presentation by the debate teams followed by a group discussion about the pre-reading to answer any open questions and/or expand on topics of interest to the students in an open dialogue.

Course policy on Generative AI resources

You may use generative AI as a tool to assist your learning and coursework, but you **may not** directly use the output of a large language model and represent this output as your own work. The accuracy of generative AI outputs (e.g. ChatGPT) are uneven and require independent verification. When you use language-based generative AI, you should:

- independently investigate all pieces of information and claims in the response.
- rewrite the text to improve accuracy or the response based on your knowledge and additional trusted sources.
- rewrite the text to generate concise communication that prioritizes the most important elements of your response.
- ensure that your submitted work is written in your voice and is consistent with your ideas and values

- cite which generative AI tools helped you create an answer (even if only ideas were contributed, and the text is entirely yours).

Intellectual Property: The contents of this course including, but not limited to, lecture slides, syllabi, solutions, quizzes, homework, exams, and any written materials is property of Rutgers University and is intended only for the designated recipient(s). It is not to be reproduced or shared publicly on the internet without written consent and may contain confidential or proprietary information that is subject to confidentiality protections. By registering and attending this course, you automatically self-attest to the protection of this copyrighted material under penalty of intellectual property laws of the state of NJ.

Student Wellness: Below are links to services for health and wellness. Students are encouraged to use these services should you need them – or share the links with a friend who may need them. Rutgers is a community that cares.

- Food Pantry - http://ruoffcampus.rutgers.edu/food/
- Title IX – Report of Sexual Misconduct by a student - https://cm.maxient.com/reportingform.php?RutgersUniv&layout_id=69
- VPVA (violence prevention and victim assistance – 848-932-1181 - http://vpva.rutgers.edu/
- CAPS – 848-932-7884 - http://health.rutgers.edu/medical-counseling-services/counseling/
- Dean of Students -Student Support – https://studentsupport.rutgers.edu
- Community Concern Reporting - http://health.rutgers.edu/do-something-to-help/

Let's Talk is a confidential consult space for students to discuss anything they are struggling with in a given moment without the documentation of a therapy session. It also creates an opportunity for students to identify if they would be interested in therapy, as many people are skeptical due to the stigma surrounding mental health. Let's Talk sessions are available in person or by phone. Walk-ins are welcome, however, appointments are highly recommended. Please note that appointments will be prioritized before walk-ins. In order to schedule an appointment for Let's Talk, students can call CAPS at 848-932-7884 and select option 2.

This semester, Dana Simons will hold Let's Talk drop-in hours on Tuesdays between 10am and 12pm in BME-130, however, appointments can be made for other days and times by request. Additionally, students are welcome to see another Community Based Counselor for a Let's Talk session.

Other **Community Based Counseling** options are available.
See https://health.rutgers.edu/medical-and-counseling-services/counseling-services/community-based-counseling for details.

In addition to the services listed above, CAPS also offers ADAP (Alcohol and Other Drug Assistance Program) services for students who are concerned about their drinking or use of other drugs, or those of a friend or family member; psychiatric care (including medication management); group therapy; crisis intervention and consultation; and community referrals.
Any individual services provided to students are all confidential and guarded by HIPAA, which prohibits mental health clinicians from sharing any information with staff and faculty that may refer a student to services.

Academic Integrity: Cheating of any kind will result in course de-registration and/or disciplinary action within the School of Engineering. Students are expected to adhere to university policy on academic integrity, available at http://cat.rutgers.edu/integrity/policy.html#Integrity

Course Policy: The following is an anticipated course syllabus. The instructor reserves the right to modify course material as needed to aid student preparation and retention of technical concepts.

Date	Speaker	Affiliation	Topic/Title of talk
January 22 (Intro Talks)	Biju Parekkadan	Rutgers	Course Intro
	Robert Preti	Minaris	History of the Cell Therapy Industry
	John Lucas	N/A	Patient Experience
January 29 (Pharmacology)	Charlie Roth	Rutgers	Introduction to Genetic and Cell Engineering
	Hardik Mody	Janssen	Pharmacology of Cell/Gene Therapy
February 5 (Gene Editing)	Peter Romanieski	Rutgers	Gene editing
February 12 (CAR-T)	Andrew Fesnak	UPenn	CAR T cell biology
	Tom Brieva	Tmunity	CAR-T manufacturing
February 19 (HSCs)	Biju Parekkadan	Rutgers	Overview of hematopoietic stem cell biology
	Matt Li	Vor	HSC engineering
February 26 (NK Cells)	Dongfang Lu	Rutgers	Engineered NK cell therapy
	Swapna Panuganti	Adicet Bio	gdNKT cell therapy
March 5 (MSC/CR-M)	Biju Parekkadan	Sentien	Ex Vivo Mesenchymal Stem Cell Therapy
	Martin Heidecker	AMR Action Fund	How to Pitch a Start-Up
March 12 (iPSCs)	Jen Moore	Rutgers	Stem Cells in Human Disease Modeling
	Bruno Marques	Century	Bioprocessing of Hypoimmune iPSCs
	Mark Tomishima	BlueRock	Machine learning and synthetic approaches to cell therapies
March 19	**NO CLASS; HAPPY SPRING BREAK!**		
March 26 (FDA/PM)	Joyce Frey-Vasconcells	Ex-FDA	Regulatory Transitioning from Research to the Clinic
	Sascha Abramson	Carisma Therapeutics	CAR Macrophages: Pioneering the Development of Engineered Macrophages
April 2 (Analytics)	Elina Tzatzalos	Minaris	Quality Target Product Profiles
April 9 (Viral Mfg)	Johannes van der Loo	UPenn	Manufacturing of Viral Vectors- General Principles and Approaches
April 16 (Separations)	Haoran Zhang	Rutgers	Bioseparation operations and process design
	Mehmet Toner	Harvard Med	Microfluidic Cell Isolation
April 23 (Poration)	Jeff Zahn	Rutgers	Principles of Electroporation
	Jim Brady	MaxCyte	Clinical Electroporation for Non-viral Cell Engineering
April 30 (Advanced BioMaterials)	Adam Gormley	Rutgers	Design, Development and Manufacturing of Polymeric Biomaterials
	Jonathan Thon	STRM.BIO	Platelet Generating Bioreactor
May 7	**FINAL PAPERS DUE**		