Rutgers School of Graduate Studies, Newark Health Science Campus Rutgers Biomedical and Health Science (RBHS) PATH N5209: Molecules to Medicines (M2M) Fall 2025

The course is taught online through live lectures. Students' participation and attendance is required. Students are required to keep their camera on. During the fall 2025 semester, students will also have the option to attend lectures in-person.

Course director: Dr. Doreen Badheka, Assistant Dean, School of Graduate Studies (SGS), Rutgers University.

Contact information: doreen.badheka@rutgers.edu | 973-972-0908

About the course: There are a myriad of research and non-research departments in the biopharma industry. All of these work together to help launch a treatment (new drug) and continue its safety monitoring. The objective of this course is to provide students a deep insight into the drug development and commercialization process. Lecture topics are designed for those who may be interested in a career in a pharmaceutical company, biotech company, consulting firms or medical communication agencies. The course will give students an opportunity to interact with professionals from these areas.

Structure of the class: Classes are held on Mondays from 6:00 PM to 9:00 PM. A majority of the sessions involve 1.5 hours of lectures and 1.5 hours of individual or group activities. Students will be sent relevant reading material which they are expected to read before class.

Technological considerations: Students will receive lecture materials through a Canvas course site. The take-home exam and all in-class exercises will be conducted through the Canvas course site. The lectures will be conducted through Zoom. Students will be required to keep their video ON during all the lectures. Prior to the course start date, students are recommended to visit and understand the information available on these two pages: <u>Canvas for students</u> and <u>Create your Zoom account</u>.

Expectations and Student Profile: This is an advanced, graduate-level course and students can register only by permission of the Course Directors. As such, we have the following expectations of the students who take this course:

- 1. **Pre-class reading assignments:** Students are expected to read all the materials emailed to them
- In-class participation: Students are expected to participate in all in-class
 discussions and activities. Unless approved on an earlier date and time,
 students are not allowed to leave the class early. During the remote virtual
 teaching sessions and group discussion, students will be expected to keep their
 video on.

- 3. **Class attendance:** Class attendance will be taken twice during each class. If a student has to leave early or miss a lecture, they should **email** Dr. Badheka in-advance. A student is allowed to miss a maximum of two classes.
- 4. Communication style and professionalism: Students will be given basic guidance to improve their communication skills and enhance their professionalism. These will not be considered in the grading directly but will be an added value to students taking this course. Students are required to maintain highest level of professionalism during live lectures, this includes but is not limited to paying attention to the lectures, participating in the class, not engaging in other activities parallel to the class time, and more. Students are required to keep their camera on during the class time. Under specific circumstances, and with permission from the course director, students will be allowed to keep their camera off.
- 5. **Group Work:** Group work is the foundation of this course. You will be assigned to a groups. We are aware that working in a group is challenging, but this skill is absolutely required in the Pharma industry and most other professions.
- 6. **Critical Thinking:** Industry professionals are expected to be skilled in critical thinking and able to work independently. While we will provide guidance and examples of what we expect you to deliver, much of the "practicality" of this course requires you to figure out (on your own, within your group) how to apply the concepts you learn in a way that enables a business/management decision for your project.

Grading: Students will be graded on the following course elements:

Attendance and participation through in-class quizzes: 20%

Exam 1: 20% Exam 2:20%

Exam 3: 20%

Exam 4: 20%

Final grading will be calculated as

follows:

A: 90 - 100

B+: 86 - 89.9

B: 80 - 85.9

C+:76-79.9

C: 70 – 75.9

Absence from course quizzes and exams: SGS has issued a **MISSED EXAM POLICY** for students enrolled in their programs. Below are the valid excuses for missing a quiz or exam in this course (verbatim from the SGS Exam Policy):

1) Significant illness, with official note by doctor, which must include a valid reason for missing the exam. The doctor's note cannot result from a remote (online) diagnosis. NOTE: Illness prior to the exam ("didn't have time to study") does not constitute a valid

- excuse, although exceptions can be given by the SGS Associate Dean of Student Affairs if the prior illness has been severe or lengthy.
- 2) Death in the immediate family (parents, siblings, children, grandparents, aunts/uncles, niece or nephew, sister-in-law or brother-in-law, parents-in-law, first-cousins).
 Verification, with dates, is required, but this can be a newspaper announcement, event (e.g. wake) announcement, etc.
- 3) Medical/dental school interview, in which the interview or unavoidable travel overlaps with the exam. Copy of the invitation letter.
- 4) Presentation at a meeting. Proof of attendance required.
- 5) More than two final exams on the same day. (NOTE: An exam should not be rescheduled for an individual with two exams on the same day). If a student has more than two exams on the same day, they will need to contact the SGS Associate Dean of Student Affairs, who will contact the course directors about allowing the student to take one of the exams on a different day. The vast majority of schools across the country, including Rutgers New Brunswick, allow up to two final exam in the same day.
- 6) Permission of SGS Associate Dean of Students Affairs, with consultation of coursedirector. This will be rare, but is meant to account for valid, but unforeseen circumstances.

Each of these reasons will require some form of documentation to be submitted to verify the absence. For the full policy, please follow this link:

http://njms.rutgers.edu/sgs/current_students/docs/new/ExamPolicy.pdf

Code of professional conduct (course examinations): All students have a fundamental responsibility for maintaining academic integrity and intellectual honesty in their academic and professional endeavors. They are expected to observe generally accepted principles of scholarly work, to submit their own rather than another's work, to refrain from falsifying data, to acknowledge the published work of others in an appropriate manner, and to refrain from receiving or giving aid during examinations or other work requiring independent effort. When submitting written material, students take full responsibility for the originality of all work not otherwise identified by appropriate acknowledgments and imply that both the ideas and words used are their own. All students are expected to respect the property of faculty and other students, and not use research equipment or laboratory supplies of others without permission.

Specific examples of appropriate behavior in examinations exams are given below:

Examinations: The purpose of an examination is to assess a student's knowledge of a topic defined within a course or courses. **Unless given explicit written instructions to the contrary, a student must work without assistance on an examination.**

- Classroom examination: Each student will provide answers to questions as directed.
 Unless otherwise stated, no material (books, calculators, computers, communication devices) of any kind can be used during an examination.
- Take-home examination: Each student will provide answers as directed. Unless otherwise stated, research and writing must be done individually without assistance or exchange of information with others. The ability to use source material in the research of answers will be defined for each examination. But, unless stated otherwise, all source material should be cited appropriately as outlined below.

NOTE: THESE POLICIES ALSO HOLD TRUE FOR ALL EXAMS ADMINISTERED REMOTELY.

To view the full policy for the Code of Professional Conduct in the School of Graduate studies regarding examinations, research and oral presentations follow this link: http://njms.rutgers.edu/sgs/current students/ac integ.php

ACADEMIC WARNING POLICY:

http://njms.rutgers.edu/sgs/documents/policys/SGS Academic Warning Policy.pdf

Each program shall clearly inform students of the criteria for satisfactory academic performance. Academic standing will be reviewed each semester by the Program's Academic Standing Committee. Students who receive less than an average grade of "B" in the designated Core course(s) or have a GPA less than 3.0 will receive an academic warning notice. Students performing below satisfactory levels of proficiency as outlined by the program may also receive a written warning notice. The written warning states the problem(s), outlines those measures needed for improvement and sets a deadline for compliance. Letters informing students of an academic warning will be sent within 30 calendar days of the end of the semester. A request will be made to students receiving academic warning letters to meet with the Program Director and/or the Academic Standing Committee.

COURSE ADD/DROP POLICY:

Policy for the Addition of a Course:

Students may add courses with the approval of the instructor (when required) and the program director. A student wishing to add a course after the general registration period has closed, must complete the "Add/Drop/Withdraw" form and have appropriate approval of the course instructor (when required) and program director prior to the start of the course. Registration will not be permitted beyond the first week of a course. Credit will not be given for courses in which the student was not registered.

Add Course Form Link:

https://na2.docusign.net/Member/PowerFormSigning.aspx?PowerFormId=96fcae95-bc67-45fb-8da3-11300ded2e99

Policy for Dropping a Course:

Students may drop courses with approval of the instructor (when required) and the program director. Students submitting a completed "Add/Drop/withdraw" form to the SGS Registrar's office within 10 academic days of the start of the course will receive a full tuition refund and the course will not appear on their official transcript. The drop period of 1-10 *academic days, is distinguishable from the withdrawal period in that the drop period is without penalty. A completed and approved Add/Drop/Withdraw" form(s) must be received by the Registrar's office within the time periods set forth above in order for a course(s) to be "dropped".

Drop Course Form Link:

https://na2.docusign.net/Member/PowerFormSigning.aspx?PowerFormId=c45635ca-6a1e-4936-b436-337b211b8433

*An academic day is defined as a day that the SGS campus at which the student is enrolled is open for business.

Reasonable accommodations at Rutgers School of Graduate Studies: Rutgers School of Graduate Studies is committed to providing equitable access to learning opportunities to students with documented disabilities (e.g. mental health, attentional, learning, chronic health, sensory, or physical). To ensure access to this please contact Student Affairs, to engage in a confidential conversation about the process for requesting reasonable accommodations in the classroom setting. Students are encouraged to register with the Office of Student Affairs as soon as they begin their program. Accommodations are not provided retroactively. Rutgers School of Graduate Studies encourages students to access all resources available through the School for consistent support and access to their program.

More information can be found online at

http://nims.rutgers.edu/education/student affairs/student support/disability services.cfm .

Rutgers University welcomes students with disabilities into all of the University's educational programs. In order to receive consideration for reasonable accommodations, a student with a disability must complete the ODS registration form: https://webapps.rutgers.edu/student-ods/forms/registration and contact the RBHS Office of Disability Services at 973-972-5396 or cindy.poorepariseau@rutgers.edu to make an appointment for an intake interview. You will also be asked to provide documentation of your disability:

https://ods.rutgers.edu/students/documentation-guidelines .

If_the documentation supports your request for reasonable accommodations, the Office of Disability Services will provide you with a Letter of Accommodations. This Letter will be used to notify appropriate school personnel about the accommodations you are qualified to receive. To

begin this process, please complete the Registration form on the ODS web site at:_ https://webapps.rutgers.edu/student-ods/forms/registration.

Teacher-learner policy: The Rutgers SGS Newark Health Science Campus strongly believes that teaching and learning should take place in a climate of mutual respect where students and faculty are equally responsible for maintaining a professional and collegial environment. An environment where students are evaluated based upon accomplishment, professionalism and academic performance. We are committed to maintaining a positive learning environment and the highest standards of behavior in the teacher-student relationship.

To view the full Teacher-Learner policy for the School of Graduate studies, please follow this link: https://njms.rutgers.edu/sgs/current students/docs/Teacher%20Learner%20Policy.pdf

Fall 2025 Schedule

The dates of some lectures might interchange depending on speaker's availability

Exams 1-4 are take home exams. Unless notified students are expected to work on exams independently. Failure to upload exams in a timely manner will lead to zero grade for that specific exam.

Attendance is required for all classes. Two absences are allowed. Please read the <u>Expectations and Student Profile</u> above carefully.

Lecture No.	Date	Lecture topic
1	9/03/2025	The evolution of biopharma industry
2	9/10/2025	Introduction to the FDA and regulatory affairs
3	9/17/2025 Exam 1 released	Drug development to clinical success: Session 1
4	10/24/2025	Drug development to clinical success: Session 2
5	10/01/2025	Drug development to clinical success: Session 3
6	10/08/2025 Exam 2 released	Drug development to clinical success: Session 4
7	10/15/2025	Biomarkers and companion diagnostics
8	10/22/2025	Alectinib case study
9	10/29/2025	Bispecific antibodies
10	11/5/2025 Exam 3 released	Cell therapies: introduction, current state, and the future. QC in cell therapy
11	11/12/2025	Intellectual Property Law
12	11/26/2025	No class – thanksgiving
13	12/03/2025	Bioinformatics in pharmaceutical drug

		discovery
14	12/10/2025 Exam 4 released	Pricing and market access
15	12/17/2025	Lecture : TBD

Grading: Students will be graded on the following course elements:

Attendance and participation through in-class quizzes: 20%

Exam 1: 20%

Exam 2:20%

Exam 3: 20%

Exam 4: 20%

Final grading will be calculated as

follows:

A: 90 – 100

B+: 86 - 89.9

B: 80 – 85.9

C+:76 - 79.9

C: 70 – 75.9