PhEN 601

Syllabus Fall 2022

Location: Faculty Memorial Hall 412

Canvas: https://canvas.njit.edu/

Accessibility: The canvas accessibility statement is https://www.instructure.com/canvas/accessibility

Time: Tuesdays from 6:00 PM to 8:50 PM

Calendar: Below.

Instructor: Marc Bernhardt

Instructor Contact: mjb27@njit.edu

Instructor Feedback: Questions, comments and feedback to the instructor can be submitted in class, posted online in Canvas or via email. The instructor's goal is to respond to all feedback within 2 business days, usually within 24 hours.

Office Hours: There are no office hours; contact with the instructor is via email.

Prerequisites: An undergraduate degree in chemical engineering or mechanical engineering. Students who have not completed such a degree may be enrolled on a case-by-case basis. See the NJIT Course Catalog and your academic advisor for more details.

Course Description: This course provides an overview of the pharmaceutical industry, including basic information about drug discovery and development, FDA requirements and approval processes, drug dosage forms, and the role of key operational units in drug manufacturing processes. This course enables the students to: understand the role of the pharmaceutical industry in the global market and its implications; learn the fundamentals of the drug development cycle and the investment required to bring a drug to market; learn the most important drug manufacturing processes and the key elements of dosage formulation.

Learning Objectives:

- Explain the role of the pharmaceutical industry in the global market and its implications.
- Apply the fundamentals of the drug development cycle.
- Compare and contrast the investment required to bring different drugs to market.
- Describe the most important drug manufacturing processes.
- Evaluate the pros and cons of different dosage forms.
- Create a strategy for designing a new drug.
- Document the role of the FDA in law enforcement, the legal requirements for marketing pharmaceuticals and the current the regulatory environment in which manufacturers and distributors function. By the end of this course the student will:
- Understand all of the key topics discussed.
- Be able to clearly integrate these topics into their total understanding of the pharmaceutical industry.
- Be familiar with and be able to effectively communicate using the specialized terminology (jargon) of the pharmaceutical industry.

- Apply their understanding of pharmaceutical engineering to analyze, evaluate and create drugs and medical devices.

Textbook: Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems 12th edition by Loyd. V. Allen, Jr. and Timothy B. McPherson

Navigating the course: Each week the student is expected to:

Attend class as scheduled.
Read the assigned chapter(s) of the textbook.
Participate in discussions.
Stay current with the course materials and integrate new materials into their overall understanding of pharmaceutical engineering.
Prepare for the midterm exam and the final exam.

What is expected from Students:

The course format was selected to facilitate learning in a with in class and online information.
The course includes several opportunities for students to demonstrate their mastery of the key topics.
Students are expected to dedicate at least 7.5 hours per week to the course during the semester.
Estimates:
Attend class & take notes…….. 3 hours/week
Read Textbook & take notes…… 3 hours/week
Study for exams……. 1.5 hour/week

Grade Calculation:

Participation and Homework	15%
Midterm exam	35%
Final exam	50%

Grade Policies:

"D" Is not assigned in Graduate courses.
Each student must pass BOTH the midterm exam and the final exam with 70%, minimum.
If a student fails either the midterm or the final exam, the student will likely fail the course.
Exams will be administered in class using Canvas. Exams will be graded and the grades will be sent to students as soon as possible, typically within 2 weeks.

Participation Requirements:

Students are expected to participate in discussions in class or online.
During the first two weeks of the course each student is required to upload a short (1 – 2 minute) video introducing themselves to the class and stating the reason that they are taking the course.

Exam Policies:

2 HOURS, MAXIMUM.
EXAMS ARE CLOSED BOOK
No books, No computers, No phones, No notes
The instructor will grade the exams.

Policy for Make-Up Exams: Pre-Approval by the instructor is REQUIRED.

Academic Integrity

ACADEMIC HONESTY AND INTEGRITY ARE PARAMOUNT AT NJIT.
THE NJIT HONOR CODE WILL BE UPHELD.

ALL VIOLATIONS WILL IMMEDIATELY BE BROUGHT TO THE ATTENTION OF THE DEAN OF STUDENTS.
DON'T CHEAT.
DON'T COPY.
DON'T PLAGIARIZE.

Student Resources:

The instructor.
The Teaching Assistant.
FDA.GOV
IST service desk for computer or connectivity issues: 973-596-2900
Academic Advising
Canvas student orientation.
Center for Counseling and Psychological Services (C-CAPS): (973) 596-3414

Calendar:

Fall 2024

Date	Topics	Ansel Chapter (12th edition)	Notes
3 September	Introduction Value Proposition Grade Policies	N/A	1
	Syllabus FDA.gov	N/A	2
	Product Classification	1	3
	Medical Devices Cosmetics Dietary Supplements	1	4
	Snake Oil Homeopathy Counterfeit Drugs	1	5
10 September	Pharmaceutical History U.S. Pharmacopeia The Future?	1	6
	COVID Vaccines	N/A	7
	Drug Development Funnel and Contract Organizations	2	8
	"New" Drugs	2	9
	Pre-Clinical Tests	2	10
	Clinical Trials	2	11
17 September	New Drug Applications	2	12
	Biological Drugs Prodrugs	2	13
	Patents Copyrights Trademarks	N/A	14
	Receptors Side Effects Drug Interactions	2	15

24 September	FDA Organization History of Regulations	2	16
	GMP	3	17
	FDA Investigations	N/A	18
	Controlled Substances Act	N/A	19
	Packaging	N/A	20
	Labeling	3	21
	Advertising	N/A	22
1 October	Medication Errors Risk	N/A	23
	Drug Types / OTC	3	24
	Goal Drug	2	25
	ADME First Pass Effect	2	26
	Serum Concentration Curves	5	27
8 October	Placebo Logical Fallacies	5	28
	Drug Discovery Drug Analogues	2	29
	DPP-4 Discovery Example Drug Names	N/A	30
	Dosage Form Purpose Dosage Form Issues	4	31
	Preformulation Concerns	4	32
	Stability / Preservatives / Shelf Life Excipients	4	33
15 October	Absorption Transport Phenomena Compartmental Analysis	N/A	34
	Bioavailability	5	35
	Generics	N/A	36
	Clearance	5	37
	Powders	6	38
	Capsules	7	39
	Tablets	8	40
	Granulation	6	41
	Tablet Coating	8	42
	Oral Solid Dosage	9	43
	Modified Release	9	44
22 October	Midterm Exam	N/A	N/A
29 October	Ointments, Creams, Gels	10	45
	Transdermal Drug Delivery	11	46
	TDDS Advantages & Disadvantages	11	47
	Sanitary Equipment Design	N/A	48
	Stainless Steel	N/A	49
	Welding	N/A	50
5 November	No Class in person – Videos will be assigned.		

12 November	Water Purification	N/A	51
	Water Regulations	N/A	52
	Water Purification Technologies	N/A	53
	RO, DI, Distillation	N/A	54
	Suppositories	12	55
	Phrma	N/A	56
	Solutions	13	57
19 November	Validation	N/A	58
	Validation of Sterilization	N/A	59
	Disperse Systems	14	60
	Aerosols	14	61
	Parenterals	15	62
	Parenteral Packaging Infusion Pumps	15	63
26 November	Sterilization	15	64
	Biologicals rDNA	16	65
	Monoclonal Antibodies	19	66
	Diabetes	N/A	67
	Research Project 2 groups and objective will be assigned.	N/A	N/A
	Follow On Biologicals	19	68
	Vaccines	16	69
3 December	Cancer Vaccines Cold Chain	N/A	70
	Facilities	N/A	71
	Utilities Process Gases	N/A	72
	Cleanroom Design	N/A	73
	Cleanroom Regulations	N/A	74
10 December	Ophthalmics	17	75
	Radiopharmaceuticals	18	76
	Novel Drug Delivery Ideas	20	77
	Quality	21	78
17 December	Final Exam	N/A	N/A