NJIT New Jersey Institute of Technology

THE COLLEGE OF SCIENCE AND LIBERAL ARTS

THE DEPARTMENT OF CHEMISTRY AND ENVIRONMENTAL SCIENCE

CHEM-714-101: Pharmaceutical Analysis
Fall 2024 Course Syllabus

NJIT Academic Integrity Code: All Students should be aware that the Department of Chemistry & Environmental Science (CES) takes the University Code on Academic Integrity at NJIT very seriously and enforces it strictly. This means that there must not be any forms of plagiarism, i.e., copying of homework, class projects, or lab assignments, or any form of cheating in quizzes and exams. Under the University Code on Academic Integrity, students are obligated to report any such activities to the Instructor.

COURSE INFORMATION

Course Description: The objective of this course is to provide an overview of instrumental techniques and practices used in pharmaceutical analysis. Throughout the drug discovery and manufacturing process, drug materials must be precisely separated, structurally determined, and purified to ensure standardization across batches for human consumption. The focus of this course will be on the instrumentation involved in pharmaceutical analysis including chromatography, mass spectrometry, surface plasmon resonance, and several biochemical validation methods. This course will also cover the rules governing the pharmaceutical industry in the US including current Good Manufacturing Practices (GMP), method validation, and current industry guidance. This course is perfect for those looking to pursue a career in the pharmaceutical research field.

Number of Credits: 3

Prerequisite: CHEM-222

Course-Section and Instructors

Course-Section	Instructor	Time
CHEM-714-101: Pharmaceutical Analysis	Patrick DePaolo, Ph.D	**Wednesday, 6:00 - 8:50 PM TIER LECT 1**

Email: depaolo@njit.edu
Office Hours: ***Wednesday 4PM – 5:30PM and Friday 12PM – 2PM*** *in Tiernan 110* or by appointment
Zoom lecture: https://njit-edu.zoom.us/j/98713005376

University-wide Withdrawal Date: The last day to withdraw with a **W** is Monday, November 11, 2024. It will be strictly enforced.

Textbook (recommended, not required): Method Validation in Pharmaceutical Analysis: A Guide to Best Practice, 2nd Edition By: Joachim Ermer (Editor), Phil W. Nethercote (Editor) ISBN: : 978-3-527-31255-9

POLICIES

All CES students must familiarize themselves with, and adhere to, all official university-wide student policies. CES takes these policies very seriously and enforces them strictly.

Grading Policy: The final grade in this course will be determined as follows:

Homework	15%
Attendance	10%
Midterm Exam	30%
Final Project	10%
Final Exam	35%

Your final letter grade in this course will be based on the following tentative curve:

A	90 – 100	**C**	70 – 75
B+	86 – 89	**D**	60 – 69
B	80 – 85	**F**	<60
C+	76 – 79		

Attendance Policy: Attendance at classes will be recorded and is **mandatory**. Each class is a learning experience that cannot be replicated through simply "getting the notes." This is a converged course, meaning that you may attend virtually on WebEx if you cannot make it. In-person attendance is encouraged and is mandatory on the exam dates.

Homework Policy: Homework is an expectation of the course. The homework problems set by the instructor are to be handed in for grading via canvas and will be used in the determination of the final letter grade as described above. No AI tools are allowed for homework assignments. Any detected AI will result in a zero for the ais

Exams: There will be one midterm exam held in class during the semester and one noncumulative final exam held at the end of the semester. All exams are taken in-person and without notes or computers. Absolutely no electronic devices besides a calculator are allowed on exams. The following exam periods are tentative and therefore possibly subject to change:

Midterm Exam	October 16th, 2024
Final Exam	December 18th, 2024

The final exam will test your knowledge of all the course material taught in the second half of the course.

Makeup Exam Policy: There are no make-up exams without a valid reason. Please let me know if you are planning to miss an exam and the reason why well ahead of time.

Presentation: The final group presentation will consist of a 10-15 minute oral presentation with a group of 2-3 classmates focusing on an important pharmaceutical career of your choice. For those who work, the topic can be your current job, or a title that you strive to reach. It is important to include the pharmaceutical techniques used in this career and give case examples supported by literature of relevant analyzes performed in the lab. A formal rubric will follow.

Cellular Phones: All cellular phones and other electronic devices must be switched off during the exam times. Such devices must be stowed in bags during exams.

ADDITIONAL RESOURCES

Chemistry Tutoring Center: Located in the Central King Building, Lower Level, Rm. G12. Hours of operation are Monday – Friday 10:00 am - 6:00 pm. For further information please click here.

Accommodation of Disabilities: Office of Accessibility Resources and Services (***formerly known as Disability Support Services***) offers long term and temporary accommodations for undergraduate, graduate and visiting students at NJIT.

If you are in need of accommodations due to a disability please contact Chantonette Lyles, Associate Director at the Office of Accessibility Resources and Services at 973-596-5417 or via email at lyles@njit.edu. The office is located in Fenster Hall Room 260. A Letter of Accommodation Eligibility from the Office of Accessibility Resources Services office authorizing your accommodations will be required.

For further information regarding self-identification, the submission of medical documentation and additional support services provided please visit the Accessibility Resources and Services (OARS) website at:

- http://www.njit.edu/studentsuccess/disability-support-services/

Important Dates See: Fall 2024 Academic Calendar, Registrar
https://www.njit.edu/registrar/calendars

Sept	2	Monday	Labor Day. University Closed
Sept	3	Tuesday	First Day of Classes
Sept	9	Monday	Last Day to Add/Drop a Class
Sept	9	Monday	Last Day for 100% Refund, Full or Partial Withdrawal
Sept	10	Tuesday	W Grades Posted for Course Withdrawals
Sept	16	Monday	Last Day for 90% Refund, Full or Partial Withdrawal - No Refund for Partial Withdrawal after this date
Sept	30	Monday	Last Day for 50% Refund, Full Withdrawal
Oct	21	Monday	Last Day for 25% Refund, Full Withdrawal
Nov	11	Monday	Last Day to Withdraw from Classes
Nov	26	Tuesday	Thursday Classes Meet
Nov	27	Wednesday	Friday Classes Meet
Nov	28	Thursday	Thanksgiving Recess Begins. No Classes
Dec	1	Sunday	Thanksgiving Recess Ends

Dec	11	Wednesday	Last Day of Classes
Dec	12	Thursday	Reading Day 1
Dec	13	Friday	Reading Day 2
Dec	14	Saturday	Saturday Classes Meet
Dec	15	Sunday	Final Exams Begin
Dec	21	Saturday	Final Exams End
Dec	23	Monday	Final Grades Due

Course Outline

(Subject to change)

Lecture	Date	Topic	Assignment
1	Sep. 4th	Introduction	Homework 1
2	Sep. 11th	Spectroscopy	Homework 2
3	Sep. 18th	Spectrophotometers	Homework 3
4	Sep. 25th	Liquid Chromatography	Homework 4
5	Oct. 2nd	Gas Chromatography and Other Separation Methods	Homework 5
6	Oct. 9th	Biophysical Methods of Analysis	Homework 6
7	**Oct. 16th**	**Mid-Term Exam (Units 1-6)**	
8	Oct. 23rd	Biochemical Methods of Analysis	Homework 7
9	Oct. 30th	Transfer and Quality Control of Analytical Procedures	Homework 8
10	Nov. 6th	Case Study: Validation of an HPLC-Method for Determination	
11	Nov. 13th	Current Good Manufacturing Practice (GMP)	Homework 9
12	Nov. 27th	Pharmaceutical Analysis in Clinical Trials	Homework 10
13	Dec. 4th	Resume Builder Lecture (SPR, DLS, NanoDSF, MST)	
14	Dec. 11th	Final Project Presentations	Study for Final Exam
15	**Dec. 18th**	**Final Exam (Units 7-12)**	