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 2023 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.

Number of Credits: 3

Prerequisite: CHEM-222

Course-Section and Instructors

Course-Section	Instructor
CHEM-714 Section 101	Patrick DePaolo, Ph.D

Email: depaolo@njit.edu

Office Hours: ***Wednesday 10AM – 1 PM & 3PM -4PM*** or by appointment

Webex meeting room: https://njit.webex.com/meet/depaolo

University-wide Withdrawal Date: The last day to withdraw with a **W** is Monday, November 13, 2023. 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	20%
Attendance	15%
Midterm Exam	30%
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.

Homework Policy: Homework is an expectation of the course. The homework problems set by the instructor are to be handed in for grading and will be used in the determination of the final letter grade as described above.

Exams: There will be two midterm exams held in class during the semester and one comprehensive final exam. The following exam periods are tentative and therefore possibly subject to change:

Midterm Exam	October 18th
Final Exam	December 17th

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

Makeup Exam Policy: There will normally be **NO MAKE-UP QUIZZES OR EXAMS** during the semester. In the event that a student has a legitimate reason for missing a quiz or exam, the student should contact the Dean of Students office and present written verifiable proof of the reason for missing the exam, e.g., a doctor's note, police report, court notice, etc. clearly stating the date AND time of the mitigating problem. The student must also notify the CES Department Office/Instructor that the exam will be missed so that appropriate steps can be taken to make up the grade.

Cellular Phones: All cellular phones and other electronic devices must be switched off during all class times. Such devices must be stowed in bags during exams or quizzes.

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 2023 Academic Calendar, Registrar
https://www.njit.edu/registrar/fall-2023-academic-calendar

Date	Day	Event
September 4		Labor Day, University Closed
September 5		First Day of Class
September 11		Last Day to Add/Drop a Class
September 11		Last Day for 100% Refund, Full or Partial Withdrawal
September 12		W Grades Posted for Course Withdrawals
September 18		Last Day for 90% Refund, Full or Partial Withdrawal – Not Refund for Partial Withdrawal after this date
October 2		Last Day for 50% Refund, Full Withdrawal
October 23		Last Day for 25% Refund, Full Withdrawal
November 13		Last Day to Withdraw
November 21		Thursday Classes Meet
November 22		Friday Classes Meet
November 23		Thanksgiving Recess Begins
November 26		Thanksgiving Recess Ends
December 13		Last Day of Classes
December 14		Reading Day 1
December 15		Reading Day 2
December 17		Final Exams Begin
December 23		Final Exams End

Course Outline

(Subject to change)

Lecture	Date	Topic	Assignment
1	Sep. 6	Introduction	Homework 1
2	Sep. 13	Spectroscopy	Homework 2
3	Sep. 20	Spectrophotometers	Homework 3
4	Sep. 27	Gas and Liquid Chromatography	Homework 4
5	Oct. 4	IR and Raman Spectroscopy	Homework 5
6	Oct. 11	Biophysical Methods of Analysis	Homework 6
7	**Oct. 18**	**Mid-Term Exam (Units 1-6)**	
8	Oct. 25	Biochemical Methods of Analysis	Homework 7
9	Nov. 1	Transfer and Quality Control of Analytical Procedures	Homework 8
10	Nov. 8	Case Study: Validation of an HPLC-Method for Determination	
11	Nov. 15	Current Good Manufacturing Practice (GMP)	Homework 9
12	Nov. 29	Pharmaceutical Analysis in Clinical Trials	Homework 10
13	Dec. 3	Critical Review of Literature Paper 1	
14	Dec. 10	Critical Review of Literature Paper 2	
15	Dec. 17	**Final Exam (Units 8-12)**	