

Syllabus • Pharmaceutical Industry Skills Lecture • CHEM 5525 • Fall 2022

Instructor: Mrs. Sharon Ermolowich (Mrs. E), Office: SciTech 343B

Contact Info: **Mrs. E:** Email: ErmolowichS17@ecu.edu Phone: 252-328-9757
Virtual WebEx Office: bit.ly/MrsEOffice
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Office Hours: **Mrs. E:** Wednesdays and Thursdays 9 AM – 12 PM

Course Meetings: **Lecture: Wednesdays 1:00 PM – 1:50 PM in SZ 346**

Pre-Requisites: **None**

Required: Reference documents from Canvas (have internet access and a way to print)

NOTE: Due to the COVID-19 Pandemic and the potential for aerosol and person-to-person transmission through contact with common surfaces, the following Personal Protective Equipment (PPE) and procedures are required for this lecture when meeting face-to-face:

- Conduct a daily health screening using the CDC’s COVID-19 symptoms list. DO NOT attend class if you answer yes to any item on the list or if you are experiencing symptoms of any illness. You must notify Mrs. E by email in the case of such instances.
- In case of a recurrence of COVID-19, we may elect to again go to on-line instruction. Additional information will be provided at that time for how you will receive information from instructors and submit information for subsequent evaluation.

Course Description:

This course is designed to introduce you to cGMPs (current Good Manufacturing Practices) and their impact on the pharmaceutical industry. These FDA required regulations impose strict regimens of process control, validation, procedural methods, training and documentation on both production and the supporting laboratory activities of companies that develop and produce pharmaceuticals, biotechnology products, and other products designed for use in humans or animals. This class will provide an overview of cGMPs and their application to modern analytical techniques.

Expectations:

You are expected to complete each assignment carefully and thoughtfully in the time allotted. Pertinent information will be posted on Canvas. **YOU** are responsible for taking control of your learning experience.

Attendance Policy:

This class is offered both in-person and asynchronous online. If you are late to the in-person lecture, please enter quietly from the rear of the classroom to minimize disturbances.

In case of an outbreak, the class may be moved to an online format for up to two weeks. During this period, you will be expected to participate in online activities as designated by the instructor. If you have poor internet access, contact me within 48 hours of the announcement of the online move to work out a plan for attendance.

Classroom Disruption Policy:

We are here to teach and learn. All members of our classroom are responsible for fostering an environment in which instruction and learning can occur. Please strive to keep classroom discussions civilized and respectful to all parties. If you feel you have had an interaction which is not civil or respectful, please speak to your instructor about it.

Academic Integrity Policy:

All ECU students are expected to complete their academic work honestly. Acts of cheating, plagiarism, falsification, or attempting or assisting with an academic integrity violation will not be tolerated. If I become aware of a potential academic integrity violation, I will meet with you following the procedures specified by the university. Should it be determined that an academic integrity violation has taken place, a grade penalty may be assigned, up to and including an F for the course.

Students with Disabilities:

East Carolina University seeks to comply fully with the Americans with Disabilities Act (ADA). Students requesting accommodations based on a disability must be registered with the Department for Disability Support Services located in Slay 138 (252) 737-1016 (Voice/TTY).

Grading:

Your grade will be based on your participation and performance in lecture, work in your lab notebook, and formal lab report (graduate students). Grades are awarded to individuals, not lab groups. However, if you are a member of a group, you must share the work you have completed with your teammates

Grading Scale: Midterm Exam – 25%, Final Exam – 25%, Homework – 50%

A	≥ 93	B+	≥ 87	C+	≥ 77	D+	≥ 67	F	< 60
A–	≥ 90	B	≥ 83	C	≥ 73	D	≥ 63		
		B–	≥ 80	C–	≥ 70	D–	≥ 60		

Late Penalties: 5 points per day unless previously approved by instructor.
Unexcused work will receive a grade of '0' and will not be accepted more than **5 days** past its due date without prior communication with and direction from instructor.

Homework Assignments:

There will be 5 homework assignments posted on Canvas with due dates.

Tentative Schedule:

Day	Date	Subject	Notes
Wednesday	24 Aug	Lecture 1: Introduction to GMPs/Quality Systems/FDA Enforcement	Ermolowich
Wednesday	31 Aug	Lecture 2: History, Laws, and the FDA	Keith Holmes (Retired, Glaxo Wellcome)
Wednesday	07 Sep	Lecture 3: Compendial Testing	Martina Jones, Thermo Fisher
Wednesday	14 Sep	Lecture 4: Electronic Records – Part 11 Compliance	Tom Wilson, (Retired, Mayne Pharma)
Wednesday	21 Sep	Lecture 5: Drug Development Process	Keith Holmes (Retired, Glaxo Wellcome)
Wednesday	28 Sep	Lecture 6: Stability Testing	John Glennon, Novo Nordisk
		Mid-term Exam (Lectures 1-6)	On Canvas – Lockdown Browser w/Respondus Monitoring Due: 05 Oct
M/T	10-11 Oct	FALL BREAK 2022	
Wednesday	12 Oct	Lecture 7: Pharmaceutical Manufacturing and Development	Mike Ruff, Ruffarma, LLC (Retired, Mayne Pharma)
Wednesday	19 Oct	Lecture 8: Introduction to Validation	Jennifer Popovich, Mayne Pharma
Wednesday	26 Oct	Lecture 9: Investigations	Amy Taylor, Novo Nordisk
Wednesday	02 Nov	Lecture 10: Pharma Career Paths	Nolan Dean, Thermo Fisher
Monday	07 Nov	Tours of Mayne Pharma and Thermo Fisher (Optional But Highly Recommended) 1-5 pm (TBD with Covid)	
Wednesday	09 Nov	Lab Lecture – Notebook Review Activity 2 – Chromatography KF/Disso/HPLC NB Help	Ermolowich
Wednesday	16 Nov	Lecture 11: Biologics and Bioanalytical Methods	Janet Davis/ Brad Joyner Thermo Fisher/ Thermo Fisher
W/Th/F	23-25 Nov	THANKSGIVING BREAK	
Wednesday	30 Nov	Lecture 12: Identification Testing	Martina Jones/ Ricky Davis Thermo Fisher/ Retired, Thermo Fisher
		FINAL EXAM (Lectures 7-12)	On Canvas – Lockdown Browser w/Respondus Monitoring Due: 09 Dec