Stevens Institute of Technology
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Syllabus

PME 530/MGT 683/CHE 530/ME 530: Introduction to Pharmaceutical Manufacturing

Semesters taught: Fall, Spring	**Start and end date of the semester:**
Professor Name: Professor Elaine Lehecka Pratt (elaine.pratt@stevens.edu)	
	Course Web Address:

Overview

Pharmaceutical manufacturing is vital to the success of the technical operations of a pharmaceutical company. This course is approached from the need to balance company economic considerations with the regulatory compliance requirements of safety, effectiveness, identity, strength, quality, and purity of the products manufactured for distribution and sale by the company.

Topics covered include:

- overview of chemical and biotech process technology and equipment,
- dosage forms and finishing systems,
- facility engineering, including health, safety, & environmental aspects,
- quality assurance and regulatory issues in pharmaceutical manufacturing.

Prerequisites

None

Cross-listed as PME 530/MGT 683/CHE 530/ME 530

Learning Goals

After taking this course, the student will be able:

- To review the regulatory requirements governing pharmaceutical manufacturing
- To cover representative pharmaceutical dosage forms, and general issues of formulation, production, quality requirements, validation and uses
- To gain an understanding of the challenges associated with quality pharmaceutical manufacturing

Pedagogy

The course employs lectures, class discussions, in-class assignments, homeworks, and projects. Students make at least one presentation during the class, via the Discussion Board.

Required Text(s)

Pharmaceutical Dosage Forms and Drug Delivery Systems, **8th edition**, Loyd V. Allen, Nicholas G. Popovich, and Howard C. Ansel, Lippincott Williams & Wilkins, 2005, 738 pp, ISBN 0781746124.

Required Readings

Readings will be assigned for each week. These will be found on the course website.

Assignments

The course will emphasize class discussion postings and the analysis of the assigned readings. The primary assignment is to prepare to discuss the readings and cases each week and comment on other students' postings.

Tests help to reinforce the material covered in the lectures, and 2 short answer tests may be given during the course.

The final grade will be based on various components as shown below, such as weekly assignments and discussions, quizzes, midterm and final examinations, and the term paper and its presentation.

Grade is calculated out of 1000 total available points as follows:

Discussion postings: best 10 postings x 30 points each = 300 possible total points
Self-check quizzes: best 10 quizzes x 10 points each = 100 possible total points
Midterm exam = 150 possible total points
Term paper = 200 possible total points
Term paper PowerPoint presentation posting = 100 possible total points
Final exam = 150 possible total points

Please note that assignments in this class may be submitted to www.turnitin.com, a web-based anti-plagiarism system, for an evaluation of their originality.

Course Schedule (Sample)

Week	Subject	Assignment Due
1	Introduction to pharmaceutical manufacturing industry, including regulatory compliance, GMP, QA, CFR Part 11, validation issues, and FDA inspections	Assigned reading Discussion posting Quiz
2	Active pharmaceutical ingredients (API), chemical process technology	Assigned reading Discussion posting Quiz
3	Biochemical process technology	Assigned reading Discussion posting Quiz
4	Aseptic pharmaceutical manufacture	Assigned reading Discussion posting Quiz
5	Simple solution systems	Assigned reading Discussion posting Quiz
6	Semi-solid dispersed systems	Assigned reading Discussion posting Quiz
7	Midterm exam, assignment of term paper project	Midterm exam Submission of term paper topic for approval
8	Pharmaceutical powders and encapsulation operations	Assigned reading Discussion posting Quiz
9	Pharmaceutical granulation and compression operations	Assigned reading Discussion posting Quiz
10	Pharmaceutical coating operations	Assigned reading Discussion posting Quiz
11	Aerosols and transdermal drug delivery systems	Assigned reading Discussion posting Quiz
12	Pharmaceutical packaging operations	Assigned reading Discussion posting Quiz
13	Pharmaceutical facilities, posting of term paper presentations	Assigned reading Discussion posting Quiz PowerPoint term paper summary posting Term paper due
14	Final exam	Final exam