

Pharmaceutical Facilities Design
PhEn 602

Syllabus

Term: 2025 Fall Semester

NJIT Course Title: Pharmaceutical Facilities Design

NJIT Course Number: PhEn 602

Course Instructor:

Robert Lechich
Adjunct Professor
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Students are strongly encouraged to contact the Professor via e-mail to arrange for a meeting.

Course Day and Time: Friday 6:00 - 8:30 pm

Classroom: Tiernan Hall 108

Course Textbooks, and Other Reference Materials

- **Textbook:** The following books are required as Textbooks:
 - “Good Design Practices for GMP Pharmaceutical Facilities”, Terry Jacobs and Andrew Signore, 2nd Edition, CRC Press Taylor and Francis (available in hardcover and online)
 - ISPE, Baseline Pharmaceutical Engineering Guides for New and Renovated Facilities, Volume 3, Sterile Manufacturing Facilities, 3rd Edition, 2018 (paperback and online) **Provided by Professor**

- **References:** The following books are suggested references (not required):
 - J. Odum and M. Flickinger, Process Architecture in Biomanufacturing Facility Design, 1st Edition, 2017.
 - Cole, G., Pharmaceutical Production Facilities: Design and Applications, Informa Healthcare; 2nd edition, 1998

- Carlton and J. Agalloco, Validation of Pharmaceutical Processes, Marcel Dekker, Inc., 3rd Edition, 2003
- ISPE, Baseline Pharmaceutical Engineering Guides for New and Renovated Facilities, Volume 4 “Water and Steam Systems, 2011

Availability of Course Slides/Notes, Homework Assignments, Textbook and References:

- The course material will be posted as PPT or PDF files (i.e., you will need Adobe Acrobat to read and print them). The Course Notes can be downloaded from the NJIT website using Canvas. Students can **either** access Canvas directly (<http://canvas.njit.edu/>) and follow the instructions there, **or** go through Highlander Pipeline as follows:
 1. Go to <http://my.njit.edu> and log in using your UCID.
 2. Click on the “My Courses” tab.
 3. Click on the link towards the bottom of the screen for “NJIT Canvas Rooms: Click here to access our course in Canvas”
 4. You will automatically be logged into NJIT’s new Canvas server.
 5. Locate your course and click on the link with the course title.
 6. If at any time you are experiencing problems and are unable to log in, please let the helpdesk know at 973-596-2900
- The homework is also posted weekly through Canvas.
- Additional material (reading material, etc.) will be posted in Canvas as required. For additional information, please contact the professor.

Course Prerequisites: PhEn 601, **and** successful completion of the bridge program (PhEn 500 PhEn 501 and PhEn 502) **if required in the student’s admission conditions**, as well as any other undergraduate-level courses. However, students who have taken PhEn 500 and PhEn 501 and are currently enrolled in PhEn 502 can take PhEn 602. Depending upon advisor, possible exceptions can be made.

Course Objectives: The main objective of the course is to provide an overview of the concepts needed to design, construct and maintain pharmaceutical facilities.

Course Description: The course covers the basic principles that are used in pharmaceutical facility design and application. The student will be exposed to a variety of topics including cGMPs and other global quality regulations, project management methodologies, types of facilities including laboratories, pilot plants, manufacturing and warehousing facilities as well as site considerations for new and existing plants. The course will also cover process architecture with material flow, personnel flow and equipment layout approaches. In addition, the course will cover facility architecture including room class specifications, controlled environments, room design and HVAC systems. Finally, critical utilities including pure water systems and plant utilities/support services and general

environmental, safety and health and site planning considerations will be discussed.

Course Requirements:

- Examinations: Two exams, i.e., a midterm exam and a final exam
- Term Project: Each student will develop a facility design based upon information given to them. Project presentation will also be required to present to class. Project instructions will be issued by the professor.

Grading Policy:

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|--------------------------------|------|
| • Midterm: | 30% |
| • Final exam: | 30% |
| • Term Project | 30% |
| • Homework/Class Participation | 10% |
| Total | 100% |

Course Final Grade: a tentative guideline for the assignment of final grades is the following:

<u>Cumulative Points</u>	<u>Overall Grade</u>
90 to 100%	A
88-89	B+
80-87	B
78-79%	C+
70-77	C
<69	F

The grade of “D” is not assigned to students taking graduate courses. Students could receive either a C or an F, depending on their overall performance. Please remember that this is only a guideline designed to help the students understand how they are performing in the course.

Important Remark: Each exam (midterm and final) will be graded on a point scale from 0 to 100 (100 points in an exam = 30% of the final grade, see above).

Exams:

- Exams are included in the Course Outline given below.
- All exams are typically 3 hours long unless otherwise stated.
- The final exam will be on all the material covered throughout the course. Although emphasis of the exam will be on the material covered after the midterm exam.
- Make-up exams will only be given to students who cannot attend the regular exam time, and only under documented and extraordinary circumstances. No student will be allowed to take a make-up exam unless he/she has the prior consent of the instructor. If a student will simply not come to the exam, the exam grade will automatically be zero.

Homework and Class Assignments: will be assigned as required. Class participation is extremely important to your learning experience and its contribution to your final grade.

All assignments are due as noted. If the student cannot complete the assignments by the due date, it is their responsibility to contact the professor and make other arrangements. In fairness to others, grades for late work will be penalized by 10%.

- **Readings, Class Participation and Homework**

Each class will have assigned readings and homework assignments. It is imperative that the student maintain the pace on the assigned readings. The professor is providing you PowerPoint slides to provide additional support of the key concepts and topics found in the readings. Utilizing the assigned readings, the discussions will provide opportunities for students to apply what they have learned from the module as well as challenge each other with varying views and opportunities to debate. There is an expectation that all students will participate on a weekly basis both with the initial response to the questions but also critiquing each other's comments. The professor will also provide guidance on particular comments.

- **Case Study Critiques**

The course will also involve case studies to help students gain a more in-depth appreciation for relevant topics, and students are expected to read and provide a one-page written critique of each case study including the following:

- Critique the Author(s) Conclusions or Propositions (Agree or Disagree)
- Highlight the Key Lessons Learned
- Suggestions on How to Improve the Author(s) Point
- If possible, suggest alternative rationale in the case study
- If possible, broaden or expand their key points with other examples, personal or work related.

The critiques will be due as per the class schedule. The professor will also grade and provide comments on a timely basis to ensure the student for guidance and additional clarifications.

Class Attendance: As for all graduate courses at NJIT, attendance is not mandatory, but **strongly** recommended. Experience shows that students who do not regularly attend class typically perform poorly in the course. In addition, examples are worked out during the lectures. These examples are not in the Class Notes. Students are responsible for all material covered in class.

NJIT Honor Code: The NJIT honor code is being upheld on all issues related to the course. Students are expected to be familiar with the code and conduct themselves accordingly.

Course Outline

Week	Date	Topic	Assignments
1	Sep 5	Introduction, cGMPs, Facility Project Lifecycle	<ul style="list-style-type: none"> • Readings: FDA 21 CFR 210 and 211 Jacobs Chapters 1, 2, 8 • Home Assignment
2	Sep 12	Process Architecture	<ul style="list-style-type: none"> • Readings: Jacobs Chapters 4, 9, 10, 11, 12, 20 ISPE Guidance Chapters 2,3,4 Excerpts supplied by Professor Rethinking Product Lifecycle Management Process Architecture Article • Homework Assignment:
3	Sep 19	Facility Architecture	<ul style="list-style-type: none"> • Readings: Jacobs Chapters 10, 11, 12, 15, 19, 20 ISPE Guidance Chapters 4, 9, Excerpts supplied by Professor • Homework Assignment
4	Sep 26	Room Classification and Controlled Environments	<ul style="list-style-type: none"> • Readings: Jacobs Chapters 10, 11, 12, 15 ISPE Guidance Chapters 9, 11 Excerpts supplied by Professor • Homework Assignment
5	Oct 3	Environmental, Safety and Health Considerations	<ul style="list-style-type: none"> • Readings: Jacobs Chapters 15, 16, 18 ISPE Guidance Chapter 10 Excerpts supplied by Professor • Homework Assignment
6	Oct 10	HVAC/Barrier Technology/Isolators	<ul style="list-style-type: none"> • Readings: Jacobs Chapters 5, 15 ISPE Guidance Chapters 5, 8, 9, 11 Excerpts supplied by Professor • Homework Assignment
7	Oct 17	In Class Midterm	
8	Oct 24	Plant Utilities	<ul style="list-style-type: none"> • Readings: Jacobs Chapter 5 ISPE Guidance Chapters 6, 7 Excerpts supplied by Professor • Homework Assignment

9	Oct 31	Critical Process Utilities	<ul style="list-style-type: none"> • Readings: Jacobs Chapter 5 ISPE Guidance Chapters 6, 7, 8 Excerpts supplied by Professor • Homework Assignment
10	Nov 7	Pure Water Systems/Clean Steam	<ul style="list-style-type: none"> • Readings: Jacobs Chapter 6 Excerpts supplied by Professor • Homework Assignment
11	Nov 14	Automation/Information Systems	<ul style="list-style-type: none"> • Readings: • Excerpts supplied by Professor
12	Nov 21	Site Selection Planning	<ul style="list-style-type: none"> • Readings: Jacobs Chapter 3 Excerpts supplied by Professor
13	Dec 5	Project Presentations	<ul style="list-style-type: none"> • Submit Term Project and Presentation
14	Dec 12	In Class Final Exam	<ul style="list-style-type: none"> • None

Important: It is conceivable that some changes in the above outline will take place, depending on the overall performance of the class and the time actually required to present the material