Fall 2018

PHEN 602 - Pharmaceutical Facilities Design

Robert Lechich

Robert R. Lechich New Jersey Institute of Technology
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Pharmaceutical Facilities Design
PhEn 602

Syllabus

Term: 2018 Fall Semester

NJIT Course Title: Pharmaceutical Facilities Design

NJIT Course Number: PhEn 602

Course Instructor:

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Students are strongly encouraged to contact the instructor via e-mail to arrange for a meeting. Please note use the email above not the NJIT email for quickest response.

Course Day and Time: Friday 6-9 pm

Classroom: TBD

Course Notes, Textbooks, and Other Reference Materials

- **Class Slides/Notes:** The slides and notes published in the class Moodle area are duplications of the overheads used in class.
- **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 hardback and online)
  - ISPE, Baseline Pharmaceutical Engineering Guides for New and Renovated Facilities, Volume 3, Sterile Manufacturing Facilities, 2011

- **References:** The following books are suggested references (not required):
  - "Sterile Product Facility Design and Project Management", 2nd Edition, Jeffrey N. Odum, CRC Press.
  - Cole, G., Pharmaceutical Production Facilities: Design and Applications, Informa Healthcare; 2nd edition, 1998
  - "Aseptic Pharmaceutical Manufacturing, Applications for the 1990's", Groves and Murty, Interpharm Press
  - "Validation of Pharmaceutical Processes", Carlton and Agalloco, Marcel Dekker, Inc.
  - "Cleanroom Technology, Fundamentals of Design, Testing and Operation", Whyte, John Wiley.
  - "Cleanroom Microbiology for the non-Microbiologist", Carlberg, CRC Press.
  - ISPE, Baseline Pharmaceutical Engineering Guides for New and Renovated Facilities, Volume 4 "Water and Steam Systems".
  - ISPE, Baseline Pharmaceutical Engineering Guides for New and Renovated Facilities, Volume 5 "Commissioning and Qualification".

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

- The *Course Slides/Notes* 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 Moodle. Students can **either** access Moodle directly (http://moodle.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 Moodle Rooms: Click here to access our course in Moodle"
  4. You will automatically be logged into NJIT's new Moodle 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 Moodle.
- Additional material (reading material, etc.) will be post in Moodle as required. For additional information, please contact one of the instructor.
- Most additional references (not required as textbooks) as well as the textbooks are available in most university libraries, including the NJIT library.

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.

Course Objectives: The main objective of the course is to provide and 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 regulations, types of facilities including laboratories, pilot plants, manufacturing, warehousing and distribution facilities as well as site considerations for new and existing plants. The course will cover process architecture of material and personnel flow, equipment layout, and the facility architecture including room finishes currently used in industry. Further the course will review room class specifications, controlled environments 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:

• 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:

Cumulative Points	Overall Grade
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. The instructors will feel free to change the grading scale (both ways) when assigning the final grades.

Important Remark: Each exam (midterm and final) will be graded on a point scale from 0 to 100 (100 points in an exam = 25% of the final grade, see above).
Exams:

- A calendar of exams is 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 others arrangements. In fairness to others, grades for late work will be penalized 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	TBD	Introduction, cGMPs, Facility Project Lifecycle	• Readings: FDA 21 CFR 210 and 211 Jacobs Chapter 1, 2, 8, 14 • Internet Research • Case Study Aseptic Processing
2	TBD	Process Architecture	• Readings: Jacobs Chapter 4, 9 19 ISPE Guidance Chapter 2,3 and 4 Excerpts supplied by Professor • Internet Research • Case Study: Bulgarian Facility
3	TBD	Facility Architecture	• Readings: Jacobs Chapter 10, 11, 12 ISPE Guidance Chapter 9 Excerpts supplied by Professor • Internet Research
4	TBD	Room Classification and Controlled Environments	• Readings: Jacobs Chapter 10, 11, 12 Excerpts supplied by Professor • Homework Problem
5	TBD	Environmental , Safety and Health Considerations	• Readings: Jacobs Chapter 15,16 18 ISPE Guidance Chapter 10 Excerpts supplied by Professor • Study for Exam
6	TBD	In Class Midterm	
7	TBD	HVAC/Barrier Technology/Isolators	• Readings: Jacobs Chapter 10, 11, 12, 15 ISPE Guidance Chapter 5,9 and 11

			Excerpts supplied by Professor • Case Study
8	TBD	Plant Utilities	• Readings: Jacobs Chapter 5 ISPE Guidance Chapter 6,7 Excerpts supplied by Professor
9	TBD	Critical Process Utilities	• Readings: Jacobs Chapter 5 ISPE Guidance Chapter 6 and 7 Excerpts supplied by Professor
10	TBD	Pure Water Systems/Clean Steam	• Readings: Jacobs Chapter 6 Excerpts supplied by Professor • Case Study
11	TBD	Site Selection Planning	• Readings: Jacobs Chapter 3 Excerpts supplied by Professor
12	TBD	Project Presentations	• Submit Presentation and Present in class
13	TBD	No Class	• Hand in Take Home Final Exam

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.