PhEn-601
NOTES 0

SYLLABUS & POLICIES
DISTANCE LEARNING COURSE

Marc Bernhardt

Spring 2016
WELCOME!!

NO SMOKING

FASTEN SEATBELTS
FULL DISCLOSURE

THE OPINIONS EXPRESSED BY ME ARE NOT NECESSARILY THE OPINIONS OF THESE ORGANIZATIONS.
THE COURSE NOTES ARE AVAILABLE AT NJIT’S MOODLE 2 WEBSITE:

http://njit2.mrooms.net/
Check the NJIT Calendar!

www.njit.edu/registrar
PhEn 601
VALUE PROPOSITION

• EXPAND YOUR HORIZON

• MANDATORY
  – CERTIFICATE PROGRAMS
  – DEGREE PROGRAMS

• GET YOU THROUGH THE INTERVIEW
OUR TIME HAS VALUE
THE PRODUCTS HAVE VALUE

At a retail pharmacy, this product costs more than gold!
LIVES HAVE VALUE
OUR PRODUCTS SAVE LIVES
YOU and PhEn 601

- REGULATIONS
- HISTORY
- CLINICAL TRIALS
- PLACEBO
- WATER
- EQUIPMENT
- UTILITIES
- CLEANROOMS
- FACILITIES
- YOU
- PK & PD
- S.A.R.
- BIOLOGY
- SERUM CONC.
- DOSAGE
- FORMS
- TABLETS
- CAPSULES
- O.C.G.
- TDDS
DISTANCE LEARNING

THE FOLLOWING SLIDES (WHICH ARE LABELED “DISTANCE LEARNING”) APPLY ONLY TO THE DISTANCE LEARNING CLASSES:

- PhEn-601-851
- PhEn-601-852
DISTANCE LEARNING

PROS

• LESS TRAVEL TIME.
• STUDENTS CAN LIVE ANYWHERE OR TRAVEL DURING THE SEMESTER.
• STUDENTS CAN LEARN AT THEIR OWN PACE.
• STUDENTS CAN TIME-SHIFT, FF, REWIND & PAUSE LECTURES.
DISTANCE LEARNING

CONS

• NO FACE-TO-FACE TIME WITH INSTRUCTORS OR PEERS.
• STUDENTS MUST CONFORM TO A SELF-IMPOSED SCHEDULE.
• STUDENTS MUST IGNORE NUMEROUS DISTRACTIONS (e.g. FACEBOOK, EMAIL, SOCIAL MEDIA, etc.)
• GENERALLY LESS LEARNING DUE TO ALL OF THE ABOVE.
• PROVING COMPREHENSION IS DIFFICULT
DISTANCE LEARNING

HARDWARE REQUIREMENTS

NJIT COMPUTER REQUIREMENTS:

• A computer with internet access, possibly wired as opposed to connected via Wi-Fi (to retrieve course material, WebEx access, etc.)

• Microphone (for WebEx access)

• Camera (optional)

• Scanner or access to scanner (to e-mail homework as attachments).
NJIT COMPUTER REQUIREMENTS:

- NJIT E-mail account, including UCID and password (to access Moodle)
- Web browser (Internet Explorer, Safari, etc.)
- Adobe Acrobat, Microsoft Word, or whatever software is needed to access the teaching material
- WebEx (freely available; please visit http://www.webex.com/).
- Remark: students do not need to open an account to attend a WebEx meeting.
DISTANCE LEARNING
SCHEDULE

• THE LECTURES WILL BE POSTED ON MOODLE WITH AUDIO-VISUAL FILES.
• LECTURES WILL BE POSTED EACH WEEK.
• A WEBEX MEETING TIME AND DAY WILL BE ARRANGED BY AGREEMENT WITH THE MAJORITY OF THE CLASS FOR ONLINE INTERACTION.
DISTANCE LEARNING
NJIT EXAM POLICY

• Exams will be administered either at NJIT or at testing centers, as described below.
• Exams and Quizzes will be given on the dates specified in the syllabus at 6PM on the NJIT Newark campus.
• The specific room on campus will be announced on Moodle prior to the test day.
DISTANCE LEARNING

NJIT POLICY

FOR EXAMS ADMINISTERED AT LOCATIONS OTHER THAN NJIT, THE POLICY IS AS FOLLOWS:

• According to NJIT policy, all students taking DL classes but living within 50 miles of NJIT must take the required exams at the NJIT main campus in Newark, NJ.

• Students living outside this area can take exams at predefined testing locations. The National College Testing Association (NCTA) lists the participating institutions nationwide (http://www.ncta-testing.org/cctc/find.php) where students can take proctored tests according to the rules set up by the NJIT course instructor (e.g., closed-book). Students should visit this website, identify the testing location where they plan to take the exams, and inform the course instructor within two weeks from the beginning of classes of which testing location they have selected.
DISTANCE LEARNING

NJIT POLICY

Students should be aware that they will be required to pay a fee to the chosen testing center for each exam that they take there. Such a fee is typically on the order of $25-$50 per exam, depending on the testing center. Prior to each exam, students should make arrangements with the selected testing center to ensure that they can take the exam at the predefined location at a given day and time.
THE TEXTBOOK: READ IT

The 10th edition.
A WORD ABOUT ANSEL

• THE TEXTBOOK WAS DESIGNED TO TRAIN PHARMACISTS, NOT PHARMACEUTICAL ENGINEERS.

• SOME TOPICS ARE NOT COVERED IN ENOUGH DEPTH (e.g. CLINICAL TRIALS, WATER PURIFICATION, VALIDATION, SANITARY EQUIPMENT DESIGN, MANUFACTURING FACILITY DESIGN).

• WE WILL ADDRESS THIS BY DIVING MORE DEEPLY INTO THESE TOPICS IN THE NOTES AND LECTURES.
HOW TO BOMB THIS CLASS

• DON’T PAY ATTENTION TO LECTURES.
• DON’T READ THE TEXTBOOK.
• DON’T STUDY FOR EXAMS.
CAUTION!

• SOME STUDENTS DO NOT BUY THE BOOK.
• THIS IS A MISTAKE.
THE TEACHING METHOD

- REPETITION
- MULTIPLE PERSPECTIVES
- INTEGRATION OF IDEAS
- REPETITION
HOW ENGINEERS THINK

• LOGIC
• PROS & CONS
• COST
HOW ENGINEERS TEND TO COMMUNICATE
IMPORTANT INFORMATION MAY BE UNCLEAR INITIALLY
TRY A DIFFERENT PERSPECTIVE

Photo: NASA
ALWAYS REMEMBER **THE PATIENT**
HOUSEKEEPING

I WILL USE YOUR @NJIT.EDU EMAIL ADDRESS

30 MINUTE POLICY FOR INSTRUCTOR ABSENCE IN NEWARK OR ONLINE.
ATTENDANCE

ATTENDANCE IS AT YOUR DISCRETION, WHETHER IN NEWARK OR DISTANCE LEARNING.

CLASS PARTICIPATION MIGHT HELP WITH BORDERLINE GRADES

NOTES & LECTURES COVER MATERIAL THAT IS NOT IN THE TEXTBOOK

YOU ARE A GROWN-UP.
GRADE CALCULATION

- Quiz 1: 15%
- Midterm exam: 35%
- Quiz 2: 15%
- Final exam: 35%
QUIZ AND EXAMS

• THE QUIZZES AND EXAMS WILL OCCUR IN THE CLASSROOM IN NEWARK.

• QUIZZES MAY BE REPLACED BY HOMEWORK AT THE INSTRUCTOR’S DISCRETION.

• EXCEPTIONS WILL BE CONSIDERED.
EXAMS & QUIZZES

• EXAMS ARE 3 HOURS
• QUIZZES ARE 90 MINUTES
• BOTH ARE CUMULATIVE
• CLOSED BOOK
  – No books
  – No computers*
  – No telephones
  – No notes

* WITH THE WRITTEN PERMISSION OF THE INSTRUCTOR, DISTANCE LEARNING STUDENTS MAY USE A COMPUTER TO WRITE AND EMAIL THE QUIZ AND MIDTERM. NO OTHER INTERNET ACCESS IS PERMITTED.
MAKE-UP EXAMS & QUIZ

• VERY UNDESIRABLE
• TIME-CONSUMING
• LOGISTICALLY COMPLEX
• PRE-APPROVAL IS REQUIRED
ABOUT “D” AND “F”

“D” IS NOT ASSIGNED IN GRADUATE COURSES

Important Notes:

• The average of the midterm and the final exam grades must be >70% in order to receive a passing grade for the course.

• If a student fails either the midterm or the final exam, the student will likely fail the course.
CHEATING

• ACADEMIC HONESTY AND INTEGRITY ARE PARAMOUNT AT NJIT.
• THE NJIT HONOR CODE WILL BE UPHELD.
• ALL VIOLATIONS WILL IMMEDIATELY BE BROUGHT TO THE ATTENTION OF THE DEAN OF STUDENTS.
CHEATING

• DON’T DO IT.
• DON’T COPY.
• DON’T PLAGIARIZE.
• TURNITIN.com WILL BE USED.

Photo: letsgotribe.mlblogs.com
CHEATING
SYLLABUS

TENTATIVE
SYLLABUS.

CHANGES MAY OCCUR AND WILL BE ANNOUNCED IN CLASS OR VIA MOODLE.
<table>
<thead>
<tr>
<th>Session</th>
<th>Week of</th>
<th>Topics</th>
<th>Ansel Chapter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>January 17</td>
<td>Introduction, History, Law</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>January 24</td>
<td>Drug Development, Clinical Trials, Placebo</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>January 31</td>
<td>Receptors, FDA, cGMP, Controlled Substances</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>February 7</td>
<td>Packaging, Labeling, Advertising, Goal Drug, ADME, Drug Discovery, Drug Names</td>
<td>4</td>
</tr>
</tbody>
</table>
## SYLLABUS

<table>
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<th>Ansel Chapter(s)</th>
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<tbody>
<tr>
<td>5</td>
<td>February 14</td>
<td>Quality Assurance, Focus on a Disease, QUIZ 1 or HOMEWORK</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>February 21</td>
<td>Dosage Forms &amp; Physics</td>
<td>5,6,7,</td>
</tr>
<tr>
<td>7</td>
<td>February 28</td>
<td>Stability, Absorption, Clearance, Solid Dosage Forms</td>
<td>8,9</td>
</tr>
<tr>
<td>8</td>
<td>March 6</td>
<td>MIDTERM</td>
<td></td>
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</tbody>
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Spring Recess is March 13 to March 20.
<table>
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<tr>
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</tr>
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<tbody>
<tr>
<td>9</td>
<td>March 20</td>
<td>Ointment, Creams, Gels TDDS, Pharma</td>
<td>10 11</td>
</tr>
<tr>
<td>10</td>
<td>March 27</td>
<td>Sanitary design, Water purification, Reverse Osmosis, Distillation</td>
<td>12 13</td>
</tr>
<tr>
<td>11</td>
<td>April 3</td>
<td>Suppositories, Solutions, QUIZ 2 or HOMEWORK</td>
<td>14</td>
</tr>
<tr>
<td>12</td>
<td>April 10</td>
<td>Validation, Disperse Systems.</td>
<td></td>
</tr>
</tbody>
</table>
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<th>Week of</th>
<th>Topics</th>
<th>Ansel Chapter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>April 17</td>
<td>Parenterals, Biologicals, Risk</td>
<td>15 16</td>
</tr>
<tr>
<td>14</td>
<td>April 24</td>
<td>Facility design, Ophthalmics, Radiopharmacy, Biotechnology, Novel drug delivery</td>
<td>17 18 19 20</td>
</tr>
<tr>
<td>15</td>
<td>May 9</td>
<td>Final Exam IN NEWARK on Monday, May 9, 2016</td>
<td></td>
</tr>
</tbody>
</table>

**May 1:** Reading Days, No class
ANSEL CHAPTERS
PRE-MIDTERM vs. POST-MIDTERM

1, 2, 3, 4, 5

6, 7, 8, 9, 10
11, 12, 13, 14, 15,
16, 17, 18, 19, 20

1, 2, 3, 4, 5
FDA.GOV

• WEALTH OF INFORMATION
  – GENERAL PUBLIC
  – SPECIAL GROUPS
    • CONSUMERS & PATIENTS
    • HEALTH PROFESSIONALS
    • SCIENTISTS & RESEARCHERS
    • INDUSTRY
FDA.GOV

• GIVES INSIGHTS
• CURRENT ACTIONS
• PRIORITIES
• THOUGHT PROCESSES
The Meat Inspection Act
The Pure Food and Drug Act of 1906
The Bureau of Chemistry (became FDA)
www.interphex.com

Jacob K. Javits Convention Center, NYC

April 26 – 28, 2016
FINANCIAL STUFF
Atenolol, for hypertension!

FINANCIAL STUFF

THIS IS THE STUFF THAT I WISH THAT I HAD UNDERSTOOD AT THE BEGINNING OF MY CAREER

DISCLAIMER:
I AM NOT AN ACCOUNTING PROFESSIONAL, CPA OR CFP

Photo: Dailymail.co.uk
FINANCIAL STUFF

KNOW HOW TO READ A BALANCE SHEET.

ALWAYS CONSIDER THE TAX IMPLICATIONS
PARTIAL LIST OF TAXES IN NEW JERSEY

FEDERAL INCOME TAX (BY BRACKETS)
NJ STATE INCOME TAX (BY BRACKETS)
SOCIAL SECURITY TAX (6.2%, UP TO A LIMIT)
MEDICARE TAX (1.45%)
UNEMPLOYMENT TAX (~$115)
FAMILY LEAVE TAX (~$36)
WORKFORCE DEVELOPMENT TAX (~$13)
REAL ESTATE TAX: TOWN, COUNTY AND STATE
SALES TAX (7%)
OTHERS (FUEL TAX $0.145/GALLON, MOTOR VEHICLE FEES, TOLLS ON ROADS, TELEPHONE TAX, CIGARETTE TAX $2.70/PACK)
FINANCIAL TERMS

- CAPITAL
- ROI (RETURN ON INVESTMENT)
- DEPRECIATION
- REVENUE (vs. INCOME)
- DIRECT LABOR
- OVERHEAD
- OIBT (OPERATING INCOME BEFORE TAXES)
- EPS (EARNINGS PER SHARE)
- VALUE ADDED ACTIVITY
- LEADING INDICATOR (vs. LAGGING INDICATOR)
- CURRENCY-NEUTRAL
- SOX (SARBANES-OXLEY)
- GAAP (GENERALLY ACCEPTED ACCOUNTING PRACTICES)
BACKUP SLIDES
EXPLANATION

• SOME LECTURE NOTES WILL INCLUDE INFORMATION IN **BACKUP SLIDES**.

• THIS IS DONE IN ORDER TO:
  – EASE LEARNING
  – REDUCE THE WORDINESS OF THE LECTURE SLIDES

• STUDENTS ARE RESPONSIBLE FOR READING AND UNDERSTANDING THE BACKUP SLIDES.
“This course provides an overview of the pharmaceutical industry, including basic information about drug discovery and development, FDA requirements and approval processes, drug dosage forms, and the role of key operational units in drug manufacturing processes. This course enables the students to: understand the role of the pharmaceutical industry in the global market and its implications; learn the fundamentals of the drug development cycle and the investment required to bring a drug to market; learn the most important drug manufacturing processes and the key elements of dosage formulation.”
ADDITIONAL REFERENCES

- THE PRINCESS BRIDE
- MONTY PYTHON AND THE HOLY GRAIL
- YOUNG FRANKENSTEIN
- THE SIMPSONS
- FERRIS BUELLER’S DAY OFF
- THE HITCHHIKER’S GUIDE TO THE GALAXY
- ANY PODCAST BY MARK CRISLIP, M.D.
- ANY PODCAST BY STEVEN NOVELLA, M.D.
PhEn601

• INSTRUCTOR’S TELEPHONE: 201.847.6310
• INSTRUCTOR’S E-MAIL ADDRESS: MJB27@NJIT.EDU
• INSTRUCTOR’S OFFICE HOURS: NJIT DOES NOT PROVIDE OFFICE SPACE FOR ADJUNCT PROFESSORS. THE INSTRUCTOR MAY BE AVAILABLE BEFORE EACH CLASS BY APPOINTMENT.
• STUDENTS MAY EMAIL AT ANY TIME OR PHONE DURING REGULAR BUSINESS HOURS. RESPONSES WILL BE HANDLED AS QUICKLY AS POSSIBLE, SUBJECT TO SCHEDULING, TRAVEL AND OTHER PRIOR COMMITMENTS.

• COURSE DAY AND TIME:
  MONDAY 6:00 – 9:05 P.M.
COURSE FINAL GRADE (NJIT GUIDELINE):
A TENTATIVE GUIDELINE FOR THE ASSIGNMENT OF FINAL GRADES IS PROVIDED BELOW:

<table>
<thead>
<tr>
<th>CUMULATIVE GRADE</th>
<th>OVERALL GRADE</th>
<th>UNIVERSITY LEGEND</th>
</tr>
</thead>
<tbody>
<tr>
<td>90 - 100%</td>
<td>A</td>
<td>EXCELLENT</td>
</tr>
<tr>
<td>88 - 89%</td>
<td>B+</td>
<td>GOOD</td>
</tr>
<tr>
<td>80 - 87%</td>
<td>B</td>
<td>ACCEPTABLE</td>
</tr>
<tr>
<td>78 - 79%</td>
<td>C+</td>
<td>MARGINAL PERFORMANCE</td>
</tr>
<tr>
<td>70 - 77%</td>
<td>C</td>
<td>MINIMUM PERFORMANCE</td>
</tr>
<tr>
<td>&lt; 69%</td>
<td>F</td>
<td>FAILURE</td>
</tr>
</tbody>
</table>
GRADES

• Make-up exams will only be given to students who cannot attend the regular exam time, and only under documented and extraordinary circumstances. In any case, no student will be allowed to take a make-up exam unless he/she has the prior consent of the instructor.

• If a student fails to take a quiz or an exam as scheduled, the grade will automatically be zero.