WELCOME!

YOU ARE ADVISED TO READ THIS SYLLABUS VERY CAREFULLY. NOTE ALL PENALTIES FOR MISSING DEADLINES AND FOR NOT FOLLOWING THE RULES.

Times and Rooms

Section 011 Class: Monday and Wednesday: 3:00-3:50 pm (Room-CC118)

Lab: Tuesday: 11:00 am-12:50 pm (Room-CC259)

Section 012 Class: Monday and Wednesday: 3:00-3:50 pm (Room-CC118)

Lab: Thursday: 11:00 am-12:50 pm (Room-CC259)

INSTRUCTOR: Dr. Wujie Zhang

Office: CC-250

414-277-7438 (voice mail)

zhang@msoe.edu

OFFICE HOURS: Tuesday & Thursday, 9-10 am and 1-3 pm; Wednesday, noon – 3 pm

(Or by appointment) All office hours are held in CC-250

REQUIRED TEXTS: 1. Design of Controlled Release Drug Delivery Systems

(McGraw-Hill) by Xiaoling Li and Bhaskara R. Jasti

2. Engineering Controlled Drug Delivery Laboratory Manual by Wujie Zhang

and Gul Afshan

ACCESSORIES: Calculator

PRE-REOS: EB-3570 Kinetics and Bioreactors

EB-4510 Proc Design and Control EB-4300 Metabolic Eng Synthetic Bio

IMPORTANT DATES:

Exam-I 20% Week 4 (Wednesday, April 2nd) Exam-II 20% Week 7 (Wednesday, April 23rd)

FINAL EXAM 25% TBA

<u>Drop Deadline: Monday of the 8th week.</u> <u>Withdrawal Deadline: Friday of the 10th week</u>

Learning Outcomes of EB-4520:

Course Description: Engineering of Controlled Drug Delivery

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This course addresses the engineering principles behind the development and understanding of controlled drug delivery systems. This course focuses on analysis of the regulation of the drug delivery process and industrial-relevant techniques used for the preparation of specific formulations. The topics range from general biological barriers to drug delivery and drug pharmacokinetics to synthetic gene delivery vectors and the use of antibodies for organ/tissue selective drug delivery.

Upon successful completion of this course, the student will:

- be able to discuss basic pharmacology, pharmacokinetics and pharmacodynamics
- be able to discuss the principles of prodrug design and design prodrugs as drug delivery systems
- be able to discuss physiological and chemical barriers for drug delivery
- be able to discuss and design the carriers for drug delivery
- be able to discuss different controlled drug delivery systems and understand the FDA requirements for controlled release systems; and, be able to design controlled drug delivery systems under the FDA requirements
- be able to discuss targeted drug delivery, especially to the brain and tumor; and, be able to design targeted drug delivery systems

| Program | a | b | c | d | Е | f | g | h | i | j | k | 1 |
|---------|---|---|---|---|---|---|---|---|---|---|---|---|
| Outcome | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| EB-4520 | R | Α | R | | R | | | | | | R | R |
| | | | | | | | | | | | | |

BioE Program Outcomes to be met in EB-4520 Program Outcomes: a, c, e, k, and l will be reinforced, while b and j are going to be assessed.

- a) apply knowledge of basic sciences, including physics, mathematics, biology, systemic chemistry, biochemistry, molecular biology and biomolecular engineering.
- b) perform biomolecular engineering experimentation, including hypothesis formulation, model development, measurements with positive and negative controls, data analysis and data interpretation.
- c) apply acquired knowledge especially for the integration of molecular information into analysis and design of chemical and biological processes and products.
- e) develop criteria by which to rank the merits of feasible solutions. Identify, devise and solve biomolecular engineering problems.
- j) exhibit knowledge of contemporary issues.
- k) demonstrate the use of technical skills, tools, equipment and safety rules associated with biomolecular engineering practice.
- l) display a thorough foundation in the basic sciences and sufficient knowledge in the concepts and skills required to design, analyze and control physical, chemical and biological processes in the field of biomolecular engineering.

Rules of the Road:

- a) All students should attend classes and lab sessions according to their schedule. **One point per absence will be deducted from the final grade for each class or lab session absence beyond 1.** The reason(s) for the absences need to be reported to instructor within 24 hours of the absence. It is your responsibility to sign the attendance sheet when provided. When absent or late for any class or lab session, you still are responsible for the entire material of that class or lab session -- including announcements, handouts, board work, lectures (**also posted online before or after each class**) etc. that was covered or distributed during your absence. It is your responsibility to find out what was covered during your absence.
- b) **No make-up exams and labs are arranged**. Don't ask for one! Please provide a written notification if you miss an exam or a lab session due to illness (or a similar serious concern). Final exam counts **45%** of the total grade, if exam I or II are missed (NOT RECOMMENDED!). If the final exam is missed it counts as zero. The reason for an absence with proper documents needs to be submitted within 24 hours of absence. No extra time will be offered to students who arrive late for any exam. You will turn in the exam at the same time as those who came to the exam on time.

While doing a numerical problem in an exam or a lab report you are required to use all appropriate units and show all calculations line by line in a systematic order. Failing to use appropriate units or not showing clean and correct calculations will cost you 75% of the total points assigned for the problem.

When exams are returned, please check the total on every page, check the overall total also. Instructors will either provide you a hard or e-copy of the exam key or post it outside their offices. Write inquiries about grade, exam clearly on a sheet of paper and attach the sheet to your original exam and either slip (inquiries and full exam) under instructor's office door or hand it in after the class. Your entire exam will be looked at again and returned to you with a reply to your inquiries. It is a good idea to tally your exam with the key before writing your inquiries!

- c) It is expected that you will have to study at least 2 or more hours for every in class lecture. Lecture slides for students will be accessible at mymsoe.edu. or blackboard. Lectures, all exercises done on the board in class, projects, and all homework assignments are included in material for exams.
- d) Keep a calculator and blue or black pen on you for every class, exam and lab session. Pencil is not allowed for every exam and lab report, otherwise a penalty of 5 points each for an exam or a lab report will be charged.
- e) Keep your cell phone off in class -- ABSOLUTELY no calls and no texting. You can take/make your emergency (only) calls by stepping out of the classroom. **If your phone rings in class after the first week of the quarter, you lose 5 points on the next exam.** Cell phone, ipod, and ipad cannot be used as a calculator during exams under any circumstances!
- g) Closed-toe and closed-heel shoes must always be worn in the lab. Long hair should be bound back neatly, away from the shoulders. Jewelry should be minimal and should not dangle. Avoid rings that

can puncture gloves. A clean lab coat and gloves should be worn at all times in the lab. Goggles can provide extra protection; bring your own and use them if they make you feel safer. Do not eat, drink, or chew anything in the lab. Do not bring food or drink into the lab. Never place any objects in your mouth while in lab, even if they belong to you. Wash your hands thoroughly with soap and hot water before and after every lab session at minimum and during lab as necessary. Wipe down your lab tabletop with disinfectant before and after every lab session. DO NOT begin work until your instructor tells you it is time to begin. No chatting, no running and chasing, and no offensive actions during lab session. Share the lab resources with the others. Not following lab rules can result in the following consequences: your instructor can deduct points from your lab session grade (**up to 100%**) and/or any open lab privileges can be revoked and/or your instructor can eject you from the lab permanently.

f) Late assignments (such as homework and lab reports) will be penalized 10% per day up to a maximum of 50%.

Details of grading:

| Homework | 10% |
|--------------|-----|
| Exam I | 20% |
| Exam II | 20% |
| Final Exam | 25% |
| Lab sessions | 25% |

To earn an A in this class a score of 93 or higher needs to be acquired. An overall score of 54 or lower will acquire a letter grade F. Extra credit points offered in an exam will only be added to your score if you already have acquired a BC or better grade in the exam without the inclusion of extra credit points.

The grade scale for this course and MSOE definitions of grades is as follows:

93 and Higher-A Student has performed outstandingly in all regards and is clearly exceptional.

92-88-AB Student has performed with excellence.

87-80-B Student has shown very high command of course content.

79-75-BC *Student has done a commendable job dealing with course content.*

74-65-C Student has an adequate grasp of course content.

64-59-CD *Student has met fair expectations.*

58-55-D *Student has attained minimal expectations in the course.*

54 and lower-F *Student has not attained minimal expectations in the course.*

Tentative Lecture and Reading Assignment Schedule

| <u>Class</u> | Topic and Reading Assignment | Week |
|--------------|---|------|
| I | Syllabus, Introduction to drug delivery | 1 |
| II | Pharmacology, pharmacokinetics and pharmacodynamics | |
| | | |
| I | Pharmacology, pharmacokinetics and pharmacodynamics (continued) | 2 |
| II | Pharmacology, pharmacokinetics and pharmacodynamics (continued) | |

| | FINAL EXAM | <u>11</u> |
|--------------------------|--|-----------|
| I II | Market and FDA requirements for controlled release products Review | 10 |
| I II | Site-specific drug delivery Bioconjugates and chemical drug delivery | 9 |
| I II | Oral controlled-release delivery Targeting approaches to drug delivery | 8 |
| I II | Osmotic-controlled drug delivery systems EXAM-II | 7 |
| I II | Dissolution-controlled drug delivery systems Erodible drug delivery systems | 6 |
| I II | Engineered carriers and vectors in drug delivery Diffusion-controlled drug delivery systems | 5 |
| I II | Prodrugs as drug delivery systems EXAM-I | 4 |
| I | Physiological and biochemical barriers to drug delivery Physiological and biochemical barriers to drug delivery (continued) | 3 |
| EB-4520 Eng Control I | Prof. Zhang Spring-2014 | |

Lab Topics and Schedule

| <u>Lab session</u> I | Topic and Reading Assignment Biopolymer purification to achieve pharmaceutical grade | Weeks 1 & 2 |
|-------------------------|--|--------------------|
| II | Drug stability | 3 & 4 |
| III | Novel drug delivery systems/carriers | 5 & 6 |
| IV | Release profiles of encapsulated drugs | 7 & 8 |
| V | Lab Exam | 9 |
| | | |

All students are expected to abide by MSOE's policy on student integrity. In cases of alleged academic dishonesty, procedures involving the student, the instructor, the department chair, and a Board of Review have been established to assess the facts and determine the appropriate penalties. If you are found directly or indirectly involved in any attempt of cheating or aiding others in cheating, you will be immediately reported to the chairman of the department and other MSOE administrators. The final decision on such cases will be made at the discretion of the instructor, department head and

other MSOE administrators. Please read MSOE's Policy on Student Integrity. Check it out in the Undergraduate Academic Catalog found at http://www.msoe.edu/admiss/catalog.shtml (page 21-23).

Tips for your success:

Attendance is highly recommended -- if you want an 'A'; Don't waste your time memorizing -- STUDY, ANALYZE & LEARN; Hard work pays off -- and you feel wonderful afterwards; Set goals -- and schedule dates for accomplishment.

Respect yourself and others.

We wish you a very happy and productive quarter!