

Pharmaceutics Delivery in Biological Systems
Summer 2008
BIOL 2930Z

Course leader: Beth Zielinski, Ph.D.
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Course days and times: Tuesdays and Thursdays: 3:00-6:15PM
(3:00-4:00PM, break, 4:10-5:00PM, break, 5:10-6:15PM)
Course location: Pfizer, Inc. (on-site)

Required readings:

Text: Drug Delivery: Principles and Applications, Binghe Wang; Gene Therapy: Treating Disease by Repairing Genes, Joseph Panno

Journals and lay-press: Journal of Controlled Release, Journal of Advanced Drug Delivery Reviews, New York Times, Washington Post

Course description:

Pharmaceuticals have traditionally been administered to patients via oral routes that rely on ingestion of tablets, appropriate degradation absorption in the gastrointestinal tract and transport to target tissues. Many drugs are chemically unstable and are significantly degraded during the digestion and absorption processes. Furthermore, once in the circulatory system, these drugs do not necessarily reach their intended physiological sites and are distributed throughout the entire body. Advances in the formulations of chemical and protein-based therapeutic molecules and site-specific delivery systems have allowed for the development of targeted drug and protein therapies. The emergence of advanced delivery technologies for drugs and most recently genes, for gene therapy, has catapulted site-specific drug, protein and gene therapies into the forefront of pharmaceutical and biopharmaceutical research, process development and manufacturing.

Drug and Gene Delivery will address the historical perspectives and the science and technologies that form the basis of drug, protein and gene delivery systems. Presentations and interpretations of these advances in the lay press will also be reviewed and discussed. The therapeutic systems will be presented in the context of specific organ systems and associated pathophysiologies. Topics for discussion will include drug and gene therapies for cardiovascular disease, hormone therapies, bone and cartilage related therapies and genetically-based vaccines. The emerging areas of in utero and embryonic gene therapies will also be discussed.

Course goals and objectives:

The goals of this course are to provide students with a knowledge base in the most recent advances in drug and gene delivery. Lectures focusing on various therapeutic modalities to treat specific organ-related and genetically-based diseases will allow students to gain comprehensive views of the disciplines of drug and gene delivery. In addition, students will be able to compare and contrast different therapies and critically

analyze the interpretations of these developments in the lay press. For each therapeutic delivery system presented, following questions will be addressed:

How are drug and gene delivery systems used to treat disease?

How are drug and gene delivery systems designed and optimized for use in these applications?

How are these systems designed and fabricated?

What are the pro's and con's of each system as compared to traditional modes of therapy?

How are developments in drug and gene delivery presented in the high-end lay press and how have these presentations affected their integration into mainstream medicine?

Student Assessment:

Reading selections will be assigned on a weekly basis.

Students will be required to read assigned text chapters (per week) that pertain to the weekly topics. In addition, reading assignments from the primary journals listed above will be required on a weekly basis. Number of pages per week may vary depending upon topic (80-100 pages).

Students will be evaluated based upon two in class exams, and a final exam. Exams will be comprised of both multiple choice and short answer questions.

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| Exam 1 | 30% |
| Exam 2 | 30% |
| Final Exam | 40% |

Prerequisites:

Drug and Gene Delivery is designed for post-baccalaureate level students who are professionals in the pharmaceutical industry. Students are expected to have diverse backgrounds and varying levels of knowledge in Biology, Chemistry and Biochemistry. Previous undergraduate education in the Life Sciences that are equivalent to such courses as BIOL020, BIOL028 and CHEM 0035 are acceptable.

Topics

Module 1:

May 15:

Course Mechanics
Introduction to Drug Delivery Systems
Introduction to Gene Therapy

Module 2:

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| May 20 and May 22: | Drug and Gene Delivery for cardiovascular disorders |
| Module 3: | |
| May 27: | Drug and Gene Delivery for pulmonary disorders |
| May 29: | Exam 1 |
| Module 4: | |
| June 3: | Drug and Gene Delivery to the CNS |
| June 5: | Drug and Gene Delivery for diseases of bone and cartilage |
| Module 5: | |
| June 10 and June 12: | Drug and Gene Delivery for Endocrine Disorders |
| Module 6: | |
| June 17: | Exam 2 |
| Module 7: | |
| June 19: | Gene therapy for cancer |
| June 26: | Gene therapy for site-specific mutations |
| Module 8: | |
| July 1: | Gene therapy for the embryo and fetus |
| Final Exam: July 8 | |