

Pharmaceutical Drug Discovery and Development Course:

Dr. Kevin J. Scanlon

First Semester:

Drug Discovery (lecture-90 minutes/ discussion of the articles-45 minutes)

1. Introduction to the Health Care Industry, the Pharmaceutical Pipeline and course outline/objectives.
2. Pre-Clinical and Clinical Drug Development.
3. Therapeutics; Filling an Unmet Medical Need.
4. Why do drugs work (ADME) and the role of a Therapeutic Index (TI).
5. Drug Design for a specific human disease: a new chemical entity (NCE) or a biological product (DNA, RNA or protein).
6. Mechanisms of drug resistance and strategies circumventing drug resistance.
7. Preclinical Animal Model Testing: pharmacology, toxicology, bioavailability, biodistribution, animal models as predictors for human disease.
8. Drug Discovery (genomics): concept, bioinformatics, database mining, gene discovery, and target identification/validation.
9. Introduction to vaccines
10. Immunology of vaccinations
11. IDEC-Rituxan, a new biological product- Case Study
12. Gene Therapy Companies: targets, therapeutic genes, delivery systems, stem cells and disease targets.
13. Onyx Case Study; A Gene Therapy Company
14. Onyx Case study; A NCE Company
15. Analysis of the case study.

Recommend Reference Books:

Goodman and Gilman's "The Pharmacological Basis of Therapeutics" Tenth Edition (2001), McGraw-Hill Publishers, New York

Lippincott's

"Illustrated Review of Pharmacology" (Harvey and Champe), 2nd edition, \$39.95.

Stringers

"Basic Concepts in Pharmacology - A Student's Survival Guide" for \$29.95

Supplemental Reading:

Selected scientific articles for each lecture

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Second Semester:

Drug Development (lecture-90 minutes/ discussion of the articles-45 minutes)

1. Introduction; goals, outline and evaluation
2. Case Study – Bristol-Meyers-Squibb
3. Case Study – ImClone
4. Clinical Pharmacology
5. Medical Devices
6. Regulatory, testing and safety of vaccines
7. Clinical Trials – Academic
8. Clinical Trials – Industry
9. Case study - Amylin
10. Marketing and Sales
11. Case study - Biogen/IDEC
12. Case study - Chiron/Berlex
13. Case study- Biogen
14. Case study- Soreno
15. Analysis and Course Summary

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