Drug Discovery and Drug Development (MMD-893)

Credit Hours 3 (3-0)

Course Description

This course will explore the process of drug development, from target identification to final drug registration. It will present drug development as a process involving target selection, lead discovery using computer-based methods and combinatorial chemistry/high-throughput screening. Safety evaluation, bioavailability, clinical trials, and the essentials of patent law will also be discussed. Along the way the students will learn about molecular recognition, computer aided drug design, and toxicology as applied to the development of new medicines.

Educational Objectives

- Understand the different stages of the process of drug discovery and development
- Identify the role played by different disciplines in preclinical drug development
- Appreciate the interplay between business and science in drug discovery
- Be aware of the legal regulations to be thought through to get a drug commercialized
- Analyze case studies that exemplify the modern drug discovery and preclinical processes

Course Outcomes

- Compare and understand common natural sources of drugs and contemporary approaches to drug design and development.
- Demonstrate an understanding of the timelines and resources required to discover and develop new drugs in a preclinical setting.
- Demonstrate an understanding of the critical features of each stage of the preclinical drug development process.
- Utilize *in silico* approaches to critically evaluate the pharmacophore for ligand-protein binding.

- Work in small groups to design a novel drug binding to a protein target at a molecular level.
- Demonstrate an understanding of the environment and drivers of drug discovery and commercialization of research .

Course Contents

1. Basic concepts in pharmacology
2. Pharmacodynamics and pharmacokinetics
3. Concepts of dose response curves and therapeutic index
4. Drug targets, mechanisms and target identification
5. Target based drug design and modeling
6. Lead generation and optimization
7. Cell and animal experimentation
8. Absorption distribution metabolism and elimination.
9. Toxicity, drug safety pharmacology
10. Utilization of *In vitro* Cytochrome P450 Inhibition Data for Projecting Clinical Drug-Drug Interactions
11. *In vitro* Evaluation of Metabolic Drug–Drug Interactions
12. Concepts of half-life and dosing
13. Formulations
14. Bioavailability and Bioequivalence Studies
15. Regulatory Considerations and Filing Investigational New Drug (IND) filings.
16. Clinical trials

    - Clinical Trials: Phase 1
    - Clinical Trials: Phase 2
    - Industry Considerations with Phase III Clinical Trials

17. New Drug Application, Filing, Product Labeling,
18. FDA processing

Recommended Books

1. Gad, S. C. (Ed.). (2008). *Preclinical development handbook: toxicology* (Vol. 4). John Wiley & Sons.
2. Strømgaard, K., Krogsgaard-Larsen, P., & Madsen, U. (Eds.). (2017). *Textbook of drug design and discovery*. CRC press.
3. Shargel, L., Andrew, B. C., & Wu-Pong, S. (1999). *Applied biopharmaceutics & pharmacokinetics* (pp. 32-35). Stamford: Appleton & Lange.
4. Steffansen, B., Brodin, B., & Nielsen, C. U. (Eds.). (2009). *Molecular Biopharmaceutics*. Pharmaceutical Press.
5. Krishna, R., & Yu, L. (Eds.). (2007). *Biopharmaceutics applications in drug development*. Springer Science & Business Media.
6. Katzung, B. G. (2017). *Basic and Clinical Pharmacology 14th Edition*. McGraw Hill Professional.
7. Brunton, L., Chabner, B. A., & Knollmann, B. C. (2011). Goodman and Gilman's the pharmacological basis of therapeutics. Twelfth.