Proposed Syllabus for MBS Students (2 credits) and MSCTS Students (3 credits)

Course Title: MBS-5120S: Clinical Drug Development; MSCTS: Perspectives in Translational Pharmacology

Fall Semester 2018

Time and location: Mondays @ 5:00 – 7:30PM; V12B in Research Tower (ground floor)

Instructor: William J. Welsh, PhD
Email: welshwj@rwjms.rutgers.edu

Overview

This course provides a detailed overview of the drug and biologics development process from discovery through regulatory approval and beyond to marketing strategy. Special attention is given to the roles, functions and significance of the various disciplines involved in the Research & Development (R&D) process, their interactions with each other, and the strategic management of these functions. Attention will also be given to key technologies used throughout the R&D process, specifically: biomarker development, imaging, computer-aided drug design and examples of their application. The economics of pharmaceutical R&D as well as topics in licensing, legal and ethical issues, generic and biosimilars, outsourcing and partnerships will be covered. The student will gain an understanding of R&D strategy and the relationship between R&D and overall organizational success.

Among its many highlights, the course features guest lectures by leaders in the biopharmaceutical industry on current developments in drug discovery & development, clinical trials, drug safety, drug regulatory approval, and career opportunities. The course and guest lectures will cover the latest exciting developments in medicine and patient care, and offers networking opportunities with professionals in the field.

Pedagogy

The course will employ lectures given by the instructor Dr. Welsh, assigned readings, case analyses, and a final report. Each student will analyze two cases (MBS students) or three cases (MSCTS students) involving health care, translational medicine, and drug development, and corporate structure and culture of biopharmaceutical companies. The final report (required by the MSCTS students) will be a written paper of 4-6 pages touching on some aspect of pharmaceutical R&D. In all cases, students may choose from among topics and reading materials provided by Dr. Welsh. Importantly, the classroom atmosphere is relaxed, open, and highly interactive.

Learning Goals

After taking this course, the student will be able to:

- Understand the entire drug development process, from the discovery stage, to clinical trials, and beyond to product market launch and post-marketing surveillance
- Gain appreciation of the many technical, financial, business, legal and ethical issues in drug development and marketing
- Understand the interaction of risk, reward, and strategy in drug development
- Learn about career opportunities in the biopharmaceutical industry

Required Text
No text is required.

**Recommended Text**

**Class Notes**
Class lectures will be given except for classes reserved for guest lectures and student presentations. On these weeks, students will work on the assigned Case Studies (three cases for MCTS students and two cases for MBS students).

**Assignments**

**Case Studies**
The MSCTS students will analyze three case studies in their 15-week curriculum; the MBS students will analyze two case studies in their 10-week curriculum. Cases are set at a point in time and describe a real problem or situation faced by the subject organization. As noted above, students may choose a specific topic of interest to them for each case study. Alternatively, Dr. Welsh will provide (post on AMP) ample reading materials in the form of published articles, editorials, reports, etc., that students may select as topics for each of their case studies. The case studies provide an extraordinary opportunity for the students in the course to learn from each other. They are intended to promote classroom discussion beyond the class lecture materials.

**Deliverables from Case Studies**
Each student will prepare and deliver i) a 3-5 page Case Analysis Report and ii) a Powerpoint presentation (10 slides max) on the Case Study. The Report is submitted in Microsoft Word or PDF format to Dr. Welsh within a reasonable time format (2-3 weeks following topic selection).

**Final Report (MSCTS students only)**
The MSCTS students will be required a final report consisting of a paper on a specific topic of interest to the student. Some topics you might choose to write about could be a key function, process or strategy in drug development; an emerging technology used in the drug discovery and/or development process; or a current problem or challenge in the R&D area. By Week 13 of the course, Dr. Welsh will need from each MSCTS student the title or general topic of your final report. The final report will be due Week 14 (or by the final class).

**Final Paper: Suggested Table of Contents**
1. Title page
2. Background
3. Discussion of the problem or situation and opportunities presented in the reading material (article, etc.) selected for the report.
4. Specific recommendations or lessons learned from the reading material.
6. References (if needed)
7. Appendix (if needed)
Basis for Grade Assignments

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<tr>
<td>Attendance</td>
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<td>Classroom Participation</td>
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<td>Final Project</td>
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Course Schedule (tentative, subject to modification)

**Week 1** Introduction to Pharmaceutical Research & Development
Recommended Reading: Ng - Chapter 1

**Week 2** Drug Discovery
Recommended Reading: Ng - Chapters 2

**Week 3** Small Molecule & Large Molecule Drugs
Recommended Reading: Ng - Chapters 3-4

**Week 4** Preclinical Development
Recommended Reading: Ng - Chapter 5

**Week 5: Case Study 1**
Student presentations (10-15 minutes per student or group of students)

**Week 6:** Clinical Trials
Recommended Reading: Ng - Chapter 6

**Week 7** Regulatory Affairs
Recommended Reading: Ng - Chapters 7, 8, and 9

**Week 8:** R&D Organizations, Strategy, and Future Perspectives
Recommended Reading: Ng – Chapter 11

**Week 9:** Pharmaceutical Industry in the 21st Century
Recommended Reading: Ng - Chapter 11

**Week 10: Case Study 2**
Student presentations (10-15 minutes per student or group of students)

REQUIREMENTS FOR MBS STUDENTS STOP HERE (MSCTS CONTINUE)
Week 11: Pharmaceutical Formulation & Good Manufacturing Practices (GMP)
Recommended Reading: Ng – Chapter 9 and 10

Week 12: Case Study 3
MSCTC students inform Dr. Welsh on the title or topic of their final report

Week 13: Project Discussions: Students discuss their final projects

Week 14: FINAL PROJECT DUE