Drug and Device Development FA2015 (U80-518-01; M17-518)
Fall Semester, 2016

This course will provide an overview of the commercial development pathways for both pharmaceuticals and medical devices, from inception to market. Class topics will include preclinical, clinical, regulatory, and marketing factors which influence discovery and development of new medicinal products. Through lectures and discussions, students will gain an appreciation for the role clinical study programs play in the broader scope of product development. Additionally, each student will prepare a report on a medication or medical device of their personal interest, for an in-depth project.

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Class Schedule

Date	Topics	Quiz?	Chapter readings
9/1/2016	Class Orientation and Organization #1: Introduction to Medical Device Development • History and Background • Regulation • Acronyms, terms, definitions • Information resources		Chpts 4 & 16
9/8/2016	#2: Device Design and Development Process • Design Controls • Failure Mode and Effects Analysis • Risk Assessments: clinical & design	Yes	Chpts 6 & 12; Chpt 7: 7.4.3, 7.6-7.9, 7.11-7.16
9/15/2016	#3: Clinical Trials • Device trial design • Human factors • Difference between device and drug trials • Clinical compliance	Yes	Chapter 9
9/22/2016	#4: Mid-Class Exam – Devices Regulatory Processes • United States • European Union Asia & Pacific Rim		Chpt 19
9/29/2016	#5: Non-clinical testing • Good Laboratory Practices (GLP) • Animal studies Manufacturing • Good Manufacturing Practices (cGMP) • Pilot and Scale-up Marketing & Reimbursement • Labeling • Claims	Yes	Chpts 11, 13, & 21

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10/6/2016	#6: Post-Marketing • Requirements • Studies • Complaints • Continuous Improvement • Sponsored research	Yes	None
10/13/2016	Class Exam - Devices final		None
10/20/2016	Introduction to medicinal products • Drug Development Thought Process • Regulatory History		None
10/27/2016	Drug Development Process - overview • Identifying therapeutic targets • Drug Discovery • Preclinical Development	Yes	None
11/3/2016	Drug Development – Clinical Development • Clinical Trials • Manufacturing	Yes	None
11/10/2016	Mid-class exam – Pharmaceuticals • Clinical trial metrics • 2012 FDA initiatives: PDUFA		None
11/17/2016	R&D Portfolio Management Vertex Case Study	Yes	None
11/24/2016	NO CLASS – HAPPY THANKSGIVING!!		
12/1/2016	Generic Drug Development • Hatch Waxman Act 1984 Teva Case Study	Yes	None
12/8/2016	Class Exam - Pharmaceuticals final		None
12/15/2016	Individual Project Reports • Written - discussions Oral Presentations		
	No final exam		

Textbook (devices section):
King, PH, RC Fries, and AT Johnson. *Design of Biomedical Devices and Systems, 3rd Edition*. CRC Press, 2015.

The Device section utilizes textbook and supplemental readings provided by the instructor. There is no specific textbook for the Drug section; supplemental readings will be provided by the instructor.

As a guide, the grading scale is based on total points across all 4 exams, 8 quizzes, and the final project, which is 100 points:

Letter Grade	Total Points	Percentage
A+	601-620	96.9-100%
A	577-600	93-96.8%
A-	558-576	90-92.9%
B+	539-557	87-89.9%
B	515-538	83-86.9%
B-	496-514	80-82.9%
C+	477-495	77-79.9%
C	434-476	70-76.9%
F	<434	<70.0%