

BIOL 4450 Bioscience Companies: From Concept to Market
Fall 2016; TuTh 10:50 am – 12:05 pm, BIOS 244

Instructor

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My Moodle course name: FALL 2016 BIOL 4450-01

Prerequisites Completion of first full year of course work in a major in one of the following colleges: College of Natural and Social Sciences; College of Engineering, Computer Science and Technology; College of Business and Economics; College of Health and Human Services.

Course Objectives

Upon completion of this course, the student will be able to:

- Demonstrate mastery of the concept of “unmet need” by, together with his/her teammates, coming up with a concept that fulfills an unmet need and stating orally and in writing a cogent argument for how the concept fulfills an unmet need.
- Apply knowledge of the different aspects of bringing a concept to market in the bioscience industries by incorporating that knowledge into written and oral presentations of a business strategy.
- Recognize successful incorporation of the different aspects of bringing a concept to market into oral presentations as demonstrated by real-time written critiques of final oral presentations given by other teams.
- Demonstrate knowledge of the ethical requirements of clinical trials by participation in class discussion or written analysis of case studies.
- Demonstrate awareness of strategies for establishing a good team by participating in self assessment of expertise, interests, strengths, and weaknesses and subsequent team consensus assignment of responsibility for specific deliverables. Team assignments will be based on the individual attributes of team members.
- Function as a productive member of a team as demonstrated by meeting the requirements of a team assignment and achieving positive confidential peer assessment from fellow team members.
- Represent his/her own expertise and influence the direction and outcome of a development program by clearly stating opinions in a group situation as demonstrated by effectively contributing to an oral wrap up session at the end of a given topic covered in the class lectures.
- Participate actively in a team presentation of a) strategy for bringing a concept to market and b) product advertisement.
- Formulate and present a “targeted” development plan as evidenced by:
 - o developing a team plan for targeted development of oral and written presentations
 - o incorporating into each section of the business strategy a statement of the end goal, the plan for execution as it was developed backward from that goal, and the strategy for execution with a timeline for deliverables.

Required reading:

Handouts from class; materials available on the internet; materials made available through the class Moodle; personal or group research materials.

Required materials:

One 3-ring binder per team; one small blue book per person for quizzes (bring it to each class meeting).

Grading:

Short assignments/pop quizzes/class participation, 5%; Weekly business portfolio, 15%; Midterm, 20%; Written term assignment, 15%; Final presentation, 15%; Comprehensive final, 30%.

Grade assignments: 90-100% = A; 80-89% = B; 65-79% = C; 50-64% = D. +/- grades will be given within these ranges. The highest grade achieved on an exam is taken to be 100%. So, if the highest grade were 92, and you earned 83, your % would be $83/92 \times 100 = 90\%$ and you would be working at the equivalent of "A-".

Short Assignments (in class and homework). Due dates for Short Assignments will be announced in class. Assignments not completed in class are due at the beginning of the period on their due date. They must be typed. You should prepare two copies, one to turn in, and one to keep for class discussion. You may be asked to turn in the copy you kept for class discussion at the end of class. An overall homework and participation grade will be given based on the completeness of the homework and evidence of your preparedness. Take advantage of time, study partners, email, and office hours to study your notes and to complete assignments well.

Quizzes and Exams. Pop quizzes will be at the very beginning of the period. Midterm and Final Exams will have questions of a variety of formats.

Term Assignments (Weekly Business Portfolio; Written Report; PowerPoint Investor Presentation). Teams of three or four will be responsible for developing a plan for a "new" drug or medical device. (Don't panic!). The plan will be based on what you have learned in class. Each team will turn in a developing business portfolio of the plan weekly as we proceed through the different aspects of moving a product from Concept to Market. As you learn more, you will be revising previous parts of the plan. Because this is a group project, you will be asked to numerically grade each other on "contribution" in confidentiality. Your average grade in "contribution," will then be taken into account when the final grades for the term assignments are given. The last time you turn in your business portfolio, it will include an "executive summary," a narrative version of your plan, and you will give a 10 minute presentation of your plan to prospective investors (the class) on one of the last two meetings of the quarter.

Missed exams or assignments. There will be no make-up exams. Late assignments will not be accepted. A missed exam or late assignment will receive no credit. An exception will be made for a documented graduate or professional school interview, hospitalization, or other excuse that can be verified. With a verifiable excuse, the grade on the final will be duplicated for the missed midterm; a missed final will be assigned an incomplete.

General Information

The University Academic Honesty Policy and the Drop/Incomplete Policy explained in the University General Catalogue will be strictly followed. Students are responsible for the prerequisites for this course and are encouraged to discuss any questions regarding the policies and prerequisites with the instructor on the first day of the class. Reasonable accommodation will be provided to any student who is registered with the Office of Students with Disabilities and requests needed accommodation. **Please note Cal State L.A. will be converting from Quarters to Semesters in Fall 2016. Students will be assisted in creating an Individualized Advisement Plan (IAP) that will make seamless their academic transition from the quarter to the semester curriculum.**

CLASS SCHEDULE

Week/Date	Class activity/topic	
1/Aug 23	Overview of the course: class structure, content, assignments and grading policy; Lecture 1: Overview of Concept to Market in Pharmaceutical Industry	
1/Aug 25	Patents and Intellectual Property, guest lecture by Sean Senn and Priti Phukan from Archer Norris	
2/Aug 30	An introduction to Grifols Biologics Inc, guest lecture by Willie Zuniga	
2/Sept 1	Patent Issues in Business	
3/Sept 6	Overview of Concept to Market in Medical Device Industry, guest lecture by Carolyn Schmitz, Medtronic	
3/Sept 8	Technology Transfer, guest lecture by Dr. G. Marie Talnack, Director of Technology Transfer, Cal Poly Pomona	
4/Sept 13	Team formation and team assignments (discuss requirements)	
4/Sept 15	Research in Biotech Industry: what is R & D, guest lecture by Dr. Howard Xu	
5/Sept 20	Entrepreneurship and a personal journey, guest lecture by Barney Santos, Director of The Center for Innovation and Entrepreneurship	
5/Sept 22	Business Development and Networking, guest lecture by Dina Lozofsky, Executive Director, BIOCOM LA	
6/Sept 27	Finance and Economics	
6/Sept 29	Process Development and Manufacturing, guest lecture by Dr. Jeff Silverman, Corporate Vice President, Celgene, Inc.	
7/Oct 4	Introduction to Pasadena Bioscience Collaborative, An Incubator Facility, guest lecture by Dr. Wendie Johnston	
7/Oct 6	MIDTERM	
8/Oct 11	Regulatory Affairs, guest lecture by Dr. Gerard Jensen, Director of Technical Services, Gilead Sciences, Inc.	
8/Oct 13	Ethical Issues in Human Subject Research, guest lecture by Dr. Wendy Kohlhase	
9/Oct 18	Clinical trials and methodology	
9/Oct 20	Synova Life Sciences, guest speaker, CEO John Chi confirmed	
10/Oct 25	TBD	
10/Oct 27	Business Development in Pharmaceutical and Biotechnology Industries, guest lecture by Dr. Ed Baracchini, Chief Business Officer, Xencor.	
11/Nov 1	Anthony Rezavi, Associate Director for Corporate Partnerships, Caltech	
11/Nov 3	Academic-Industry Collaborations, guest lecture by Dr. Jill Adler-Moore	
12/Nov 8	Dr. Hiep-Hoa Nguyen, President, TransMembrane Biosciences	
12/Nov 10	From Concept to Market, A Kite Pharma Perspective, guest lecture by Dr. David Chang, Executive VP of R & D, Kite Pharma	
13/Nov 15	Dr. David Kane: Marketing new technologies for the life sciences: Strategy and tactics, theory and practice	
13/Nov 17	Reserved for team presentations	

14/Nov 22	Reserved for team presentations	
14/Nov 24	Thanksgiving holiday; University closed	
15/Nov 29	Reserved for team presentations	
15/Dec 1	Reserved for team presentations	
Finals wk; Tuesday Dec 6	FINAL EXAM: 11:20 am to 1:20 pm	

