Syllabus for Biotechnology Industry Immersion Course

MGT 290-1 (CRN# 65031)

Winter 2020 (Fridays, Jan 10- Feb 7)
1302 Gallagher Hall (Dorf Classroom)
Graduate School of Management

Instructor of Record

Judith A. Kjelstrom, PhD, Director Emerita, UC Davis Biotechnology Program and Academic Coordinator, GSM, UC Davis
Email: jakjelstrom@ucdavis.edu
Cell phone: 916-812-0938

Course Description

This course introduces students to the many facets of the biotechnology industry and provides a framework for understanding the complex forces that shape and drive it. Drawing upon the deep expertise of UC Davis as well as connections to industry experts, each session will take a deep dive into a challenging issue. General Topics to be covered include:

1. An Introduction to biotech drug development – from the view point of the scientist, the company, the consumer, the physician, and the regulator
2. Access to Capital – how to raise money
3. The FDA approval process
4. Scaling – what does it take to grow a small company
5. Manufacturing Network (Contract manufacturing vs. In-house)
6. Supply Chain Management (Accountability in patient care, moving sensitive materials across countries)
7. Marketing and Commercialization of drugs/technologies
8. Innovations in the future – examples: Precision Medicine, Cell Therapy, Gene Therapy, Big Data Analytics

Drawing on background readings, speakers' presentation and other information, students will learn about a topic or case study, discuss it in class, tackle a specific problem in small groups of MBA students and PhD students in STEM disciplines, then present their findings. Students will be given opportunities to develop cross-functional solutions to problems facing the industry.

Learning Objective

Biotechnology has been a disruptive technology in the life sciences industry, especially in biomedical therapeutics and diagnostics. Continued success in the biotechnology industry requires the application of extraordinary leadership and management skills in addition to the scientific innovations. The objective of this course is to increase the student's practical knowledge of the operations and sustainable practices in the biotechnology industry and gain hands-on experience in solving industry-

specific problems. Introducing students to academic and industry experts will help them to develop their problem-solving skills in a team environment.

Course Structure

The course will meet for 10 sessions (2 speakers per week). Students will prepare for each session by reviewing reading materials related to the topic. During the class meeting time, a biotech expert will provide background and context to lead the discussion. At the end of the discussion, students will break up into small groups to tackle a specific industry challenge or opportunity related to the topic and develop a solution to deal with the issue. Each group will present their recommendation and receive feedback on their proposed solution.

Code of Academic Conduct See http://sja.ucdavis.edu/files/cac.pdf

Assignments

Participation in each session's discussion, small work group and submission or papers (weekly and final)
Five two-page papers consisting of:

a. A brief summary of what the speakers discussed.
b. The managerial problem that was discussed in class.
c. The different solutions you heard from your classmates.
d. The solution that appealed to you and the reason why.
e. This assignment is due on the following Wednesday by 5PM (post on Canvas as well as email to Dr. Kjelstrom at jakjelstrom@ucdavis.com.
f. 5 points will be deducted for each day late.

An 8-10 page final synthesis paper that includes the following:

a. What are the important lessons you learned from the various speakers? You can categorize the problems discussed by various speakers any way you want to and explain the types of solutions that were discussed in class for each category of problems. For example, if the problem dealt with supply chains, you should discuss solutions that were presented with respect to supply chains (e.g., usage of technology, supplier contracting processes, building redundancy into the supply system).
b. Select one speaker who made the most impact on you. What part of the material covered by the speaker affected you? Explain why.
c. How does this course affect what you do (or plan to do) in the future? Be specific in your response.
d. **This final paper is due on Friday, March 13, 2020 by 5 PM. Post to Canvas and email to Dr. Kjelstrom.**

Grading (letter grade (MBA students); letter grade or S/U for PhD students)
40% Class Participation
30% Five 2-page Papers
30% Final Paper

Recommended Textbook (for deeper understanding of the subject matter) [Not Required]

Check to see if new edition is out, by December 30, 2019

Biotechnology Entrepreneurship (Starting, Managing, and Leading Biotech Companies)

Edited by Craig Shimasaki, PhD, MBA, President and CEO, Moleculera Labs and BioSource Consulting Group. 2014. Elsevier, Inc. ISBN: 978-0-12-404730-3. *"Biotechnology Entrepreneurship: Starting, Managing and Leading Biotech Companies"*

"Biotechnology entrepreneurship is the sum of all the activities necessary to build an enterprise through the melding of both scientific and business disciplines." (Craig Shimasaki, Chapter 4, pg 45)

Jan 2020

MGT 290-1(CRN#65031) TEAM PROJECT WITH GSM (BIOTECH INDUSTRY IMMERSION)

- UC DAVIS PERSONNEL

Dr. Judy Kjelstrom, director emerita, UC Davis Biotechnology Program is the lead for the 5 week course in winter 2020 (Fridays) -3 unit class. In partnership with Dean Rao Unnava and his executive assistant, Stephanie Young-Birkle, MBA students will receive a letter grade, PhD students may take as S/U.

2020 Dates: Jan 10, Jan17, Jan 24, Jan 31, and Feb 7. Room 1302 Gallagher Hall (Dorf Classroom)

- Format (all day Program: AM session/PM session) - the instructors will send materials to class before the session. Need two instructors per week. The speaker may bring colleagues to observe or assist in the case study.
  - Morning (9-11:45am)- Case Study by Guest Instructor (leader in Biotech Industry). Students are a mix of UCD MBA students and 10-15 STEM PhD students (DEB students preferably). - After a 45 minute presentation (overview plus the case study (**'the problem**") by the instructor, the students will work in groups (MBA/PhD) to discuss solutions to the problem presented (~50 minutes). Wrap up with Instructor at the end of the session**.**
  - Lunch provided as a box lunch (afternoon speaker is invited too) – 6-7 students will join instructor(s) (students may join the speaker twice in the course). The rest of the class will lunch with each other …. Network with peers.
  - Afternoon Session 1:15-4pm Case Study by Guest Instructor (leader in Biotech Industry). Students are a mix of UCD MBA students and 10-15 STEM PhD students (DEB students preferably). - After a 45minute presentation (overview plus the case study **('the problem**") by the instructor, the students will work in groups (MBA/PhD) to discuss solutions to the problem presented (~50 minutes). Wrap up with Instructor at the end of the session**.**
  - **Assessment: the students will answer a series of questions about each session (due by the following Thursday). The Final Project is an 8-10 page summary due at the end of the quarter (see syllabus)**

- INDUSTRY INSTRUCTORS (FOCUS ON BIOMEDICAL)
  - 9-10 biotech industry leaders will share case studies with graduate students from business, science and engineering. Lunch will be provided.

- POSSIBLE TOPICS

9. An Introduction to drug development – from the viewpoint of the scientist, the company, the consumer, the physician, and the regulator
10. Cell Therapy and Gene Therapy – the new Frontiers
11. Access to Capital – how to raise money
12. The FDA approval process
13. Business Development/Data Analytics
14. Scaling – what does it take to grow a small company
15. Manufacturing Network (Contract manufacturing vs. In-house)
16. Supply Chain Management (Accountability in patient care, moving sensitive materials across countries)
17. Marketing and Commercialization of drugs
18. Innovations in the Future – what to look for and prepare for

- SCHEDULE (ROOM1302 GALLAGHER HALL, GSM)

Week 1: Friday, January 10, 2020
Morning Session (9AM-11:45PM):
9am -**Welcome and Orientation** (Class logistics by Dr. Kjelstrom). Self-introductions by students. **Need each class member to submit a resume/CV before start of class. Form teams of MBA and PhD students (3-4 per team)**

10:30AM-11:45AM **An Introduction to Drug Development** (focus on biologics versus small molecule drugs. Biotechnology was revolutionary; It created unique challenges in drug development, drug delivery and regulatory from the viewpoint of the scientist, the company, the consumer, the physician, the investor and the regulator.
Confirmed Speaker: **Lonnie Bookbinder, PhD, MBA, Founder and CEO, ARIZ Precision Medicine, Davis, CA.**

Lunch Noon -1PM

Afternoon Session (1:15-4 PM) **Case Study 1: Issues in growing a small company** presented by **Lonnie Bookbinder.**

Week 2: Friday, January 17, 2019
Morning Session (9AM-11:45PM): **Case Study 2: Supply Chain Issues**
Invited Speaker: **Charles "Chuck" Calderaro III, Senior VP, Global Manufacturing, Biomarin Pharmaceutical, Novato, CA.**

Lunch Noon-1PM

Afternoon Session (1:15-4PM): **Case Study 3: What does it take to grow a small company and bring a product to market? - Access to Financial and Human Capital (access to talent, promotion of diversity, creation of a corporate culture, etc.)**
Invited Speaker: **Seema Kantak, PhD, Executive Director, Biologics & Biotherapeutics, Exelixis, South San Francisco, CA.**

Week 3: Friday, January 24, 2020
Morning Session (9AM-11:45PM): **Case Study 4: Product Development using Data Informatics (exact title TBA)**
Invited Speaker: **Kimberly Barnholt, PhD, Global Program Lead, Genentech, Inc., south San Francisco, CA.**

Lunch Noon-1PM

Afternoon session (1:15-4PM): **Case Study 5**: **Tips for Entrepreneurs** (**exact topic TBA; based on new article; Moleculera Labs Story: Lessons in a Capital Efficient Start-Up**)
Confirmed Speaker: **Craig Shimasaki, PhD, MBA, President and CEO, Moleculera Labs and BioSource Consulting, Oklahoma City, OK.**

Week 4: Friday, Jan31,2020
Morning Session (9AM-11:45PM)**: Case Study 6: Marketing and Commercialization of Drugs and Products**
Invited Speaker: **Omead Ostadan, MBA, SVP of Products, Marketing and Strategic Planning, Illumina, Inc**.

Lunch

Afternoon Session (1:15-4PM)**: Case Study 7: Case Study on Growing a Company - Developing a Biopharmaceutical Product (exact topic TBA).**
Confirmed Speaker: **Steve Chamow, PhD, Principal, Chamow and Associates, San Mateo, CA**.

Week 5: Friday, Feb 7, 2020
Morning Session (9AM-11:45PM)**: Case Study 8: Innovations in the Future – Big Data Analytics in the Life Sciences.**
Confirmed Speakers: **Kristen Beck, PhD, Staff Scientist, Research Staff Member, Industrial and Applied Genomics and a colleague (TBA), IBM Research-Almaden, San Jose, CA.**

Lunch Noon-1PM

Afternoon session (1:15-4PM)**: Case Study 9: Innovations in the Future – Immunotherapeutics: Cancer Therapy Modalities that Leverage the Immune System**
Confirmed Speaker**: Vivien Chan, PhD, COO, Eureka Therapeutics, Inc., Emeryville, CA**.