

Course title and number: MSCI 689: Special topics in starting a biotechnology company
 Term: Fall 2020
 Meeting times and location: Aug 25 – Nov 3; Tuesdays, 2:00 – 5:00 pm, Virtual by Zoom

Course Description and Prerequisites

The Special topics in starting a biotechnology company course will introduce graduate students to the fundamentals of starting a biotechnology company. The course will provide a framework for evaluating a business idea and outline the considerations that go into starting a biotechnology company.

This is a 10 week graded course worth 2 credit hours.

Prerequisites: Graduate student classification

Learning Outcomes or Course Objectives

After attending the course, graduate students should know the fundamentals of starting a biotechnology company. Graduate students are expected to have a basic understanding of: 1) how to recognize a business idea, 2) what is a business plan, 3) rationale for developing an intellectual property strategy, 4) how to legally form a company, 5) have awareness of funding opportunities for a startup company, 6) regulatory pathways and 7) clinical trial strategy.

Specific learning outcomes for each lecture and team-based learning activities are listed in the course schedule below.

Instructor Information

Name Magnus Hook
 Telephone number 713-677-7551
 Email address mhook@tamu.edu
 Office hours By appointment
 Office location Available via Zoom

Textbook and/or Resource Material

There are no required textbooks for the course. If assigned reading is required for a topic, the instructor will provide the reading material prior to the date of the instructional activity as listed in the course schedule.

Grading Policies

Team assignments, team presentations and quizzes will contribute to the student's final course grade.

The course grade consists of weighted contributions from a student's scores from the following scored elements:

Scored Element	Weighted contribution to course grade
4 Team Assignments (take-home)	30% (7.5% each)

2 Quizzes	20% (10% each)
Final Team presentation	50%
Total	100%

Grading Scale

Grading Scale for the course:

- A = 90-100%
- B = 80-89%
- C = 70-79%
- D = 60-69%
- F = <60%

Attendance / Make-up Work Policies

Attendance in this course is required since there are only 10 classes in 10 weeks. An excused absence must be requested and approved by the instructor in advance. In accordance with Texas A&M attendance and make-up policies, please refer to the website link to Student Rule 7 at <http://student-rules.tamu.edu/rule07>

Late submission of an assignment or quiz is not allowed. A quiz or assignment that is not submitted before the due date receives a grade of zero. The only exception arises when a student has an excused absence. University attendance requirements, make up policies and rules related to excused/unexcused absences are located on-line at <http://student-rules.tamu.edu/rule07>

Course Topics, Calendar of Activities, Major Assignment Dates

Block Number	Topic	Time	Date	Instructor	Learning Outcomes	Assignments Due/Quizzes
1	Opportunity recognition: Needs assessment	1 hour	08/25/20	Rick Silva, Ph.D., MBA Executive Director Clinical Translational Industry Collaborations, Texas A&M Health Science Center	1. Explain opportunity recognition steps and the role of needs assessment in evaluating a company idea 2. Differentiate between a product and a company 3. Describe target product profile	None
	Team based learning	2 hours			Teams will be expected to develop target product profile	
1	Opportunity recognition: Market analysis	1 hour	09/01/20	Omar Hakim, M.S. Professor of Practice (Entrepreneurship & Technology Commercialization), Department of Sociology, Texas A&M	1. Explain market landscape, market segmentation and target market 2. Differentiate total addressable market, serviceable addressable market and serviceable	Team assignment 1: Target product profile

				University	obtainable market. 3. Describe the importance of market analysis during needs screening	
	Team based learning	2 hours			Teams will be expected to do market analysis for their product	
1	Opportunity recognition: Competition analysis	1 hour	09/08/20	Connie Coulomb, MBA Managing Partner and Consultant, Coulomb Strategy Consulting	1. Describe competition analysis and its importance in needs screening. 2 Explain product differentiation.	
	Team based learning	2 hours			Teams will be expected to do competition analysis and product differentiation for their products	
2	Choosing IP strategy	1 hour	09/15/20	Michael Sharer, Ph.D. Associate Vice President for Commercialization, School of Innovation, Texas A&M University	1. Describe different types of patents. 2. Explain the importance of protecting your invention. 3. Identify mistakes that can destroy a company's intellectual property. 4. Describe the process of licensing intellectual property from a university	Quiz 1
	Team based learning	2 hours			Teams will be expected to determine patent landscape around their therapeutic product and whether the patents can be licensed.	
2	Legal considerations for life sciences startups	1 hour	09/22/20	Andrew Strong, J.D. Partner, Pillsbury Winthrop Shaw Pittman LLP	1. Describe the type of entities one can choose from when starting a company. 2. Identify steps to incorporating a company. 3. Describe different types of stocks.	Team assignment 2: Proprietary strategy summary
	Team based learning	2 hours			Teams will be expected to identify value building milestones and the	

					company valuation when those milestones are met	
3	Structures and business models of biotech startups	1 hour	09/29/20	Andrew Strong, J.D. Partner, Pillsbury Winthrop Shaw Pittman LLP	1. Describe the general structure of a startup. 2. Describe the role of founders, employees, board of directors, and scientific board of advisors in a startup.	
	Team based learning	2 hours			Teams will be expected to identify board members, scientific advisors and mentors. Teams will also determine the number of shares for board members and scientific advisors as compensation.	
3	Early stage financing	1 hour	10/06/20	Atul Varadhachary, M.D., Ph.D. Managing Partner, Fannin Innovation Studio	1. Explain different options for funding early stage startups. 2. Differentiate between dilutive and non-dilutive funding. 3. Create a cap-table. 4. Explain pre-VC financing and typical financing terms.	Quiz 2
	Team based learning	2 hours			Teams will be expected to identify government agencies for potential SBIR/STTR funding opportunities relevant to their topic areas. Teams will discuss aims for their SBIR/STTR grants	
3	Writing a business plan	1 hour	10/13/20	Caleb Holt Founder and CEO, Axle Box Innovations	1. Describe a business plan. 2. Identify different elements of a business plan. 2. Describe different exit strategies for a startup.	
	Team based learning	2 hours			Teams will be expected to determine price for their therapeutic products and an exit strategy	

4	Regulatory strategy	1 hour	10/20/20	Sean O'Connor, Ph.D., RAC Director, Investigational New Drug Office, MD Anderson Cancer Center	1. Identify regulatory pathways for drug approval. 2. Describe the process of IND filing. 3. Describe various expedited programs available through FDA for drug approval.	Team assignment 3: Executive summary of a business plan
	Team based learning	2 hours			Teams will be expected to determine a path for FDA approval for their therapeutic products	
4	Clinical trials	1 hour	10/27/20	Rick Silva, Ph.D., MBA Executive Director Clinical Translational Industry Collaborations, Texas A&M Health Science Center	1. Explain the different phases of clinical trials. 2. Describe different designs of a clinical trial. 3. Describe how a wrong clinical trial can derail a company.	Team assignment 4: Describe a regulatory strategy for the teams' product and rationale for the strategy.
	Team based learning	2 hours			Teams will be expected to develop a clinical trial strategy for their products (number of patients, will product be tested with standard of care, clinical trial sites)	
	Team presentations	1-2 hours	11/03/20			

Americans with Disabilities Act (ADA)

Texas A&M University is committed to providing equitable access to learning opportunities for all students. If you experience barriers to your education due to a disability or think you may have a disability, please contact Disability Resources in the Student Services Building or at (979) 845-1637 or visit <http://disability.tamu.edu>. Disabilities may include, but are not limited to attentional, learning, mental health, sensory, physical, or chronic health conditions. All students are encouraged to discuss their disability related needs with Disability Resources and their instructors as soon as possible.

Academic Integrity

For additional information please visit: <http://aggiehonor.tamu.edu>

"An Aggie does not lie, cheat, or steal, or tolerate those who do."