Course Syllabus

Jump to Today

Building Biotechnology

Syllabus

ENTP 6801/BSBT 7301

Spring, 2016

University of Colorado Denver Business School Jabs Center for Entrepreneurship

Course Director: Arlen D. Meyers, MD, MBA

Emeritus Professor of Otolaryngology, Engineering and Dentistry, University of Colorado at Denver and Health Sciences Center

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Professional Experience

Arlen D. Meyers, MD, MBA is Emeritus Professor of Otolaryngology, Dentistry and Engineering at the University of Colorado at Denver. He is the CEO and President of the Society of Physician Entrepreneurs at www.sopenet.org

Educational Background

Dr. Meyers received his B.S. degree from Dickinson College, his M. D. from Jefferson Medical College and did his residency in Otolaryngology-Head and Neck Surgery at the University of Pennsylvania. His received his MBA from the University of Colorado and is a former Harvard-Macy fellow and a Fulbright Scholar.

Text books and Supplementary Readings

The Life Science Innovation Roadmap, Meyers A and Price C.

I would also recommend that you subscribe to the Wall Street Journal.

Finally, you will be given a set of supplementary readings that will help you understand the context of technology transfer and bioscience business in the present environment. Please read the appropriate sections before each class and prepared to discuss them.

Course Structure

The course is divided into 15 sessions incorporating the essential elements of bioscience and health innovation and entrepreneurship. For each module, you will be asked to:
1. Read a case study (if assigned) by the instructor and be prepared to discuss it.
2. Read supplementary readings relevant to the module
3. Read the relevant chapter materials in Meyers/Price
4. Check and review the e-links on Canvas
5. Miscellaneous tasks to be determined by each lecturer.
6. Participate in the weekly online Canvas chat room for each module moderated by the instructor

Target Audience

Biomedical and business graduate students, faculty and professional research associates with an interest in biomedical technology transfer and commercialization. It is designed for students who are interested in:

a) learning how to commercialize a life science idea, discovery or invention
b) pursuing a career outside of academic life science research
c) learning the technology transfer issues involved in commercializing life science discoveries or inventions

Prerequisites

An undergraduate degree in science, technology, business, engineering or math. You do not need to be admitted to the business school or have any previous business experience.

The course is a 3-credit course. Students cannot audit any of the sessions or the course.

Course Objectives

This course is designed to familiarize biomedical scientists and those interested in the business of science with the basic fundamentals of biomedical and health innovation and entrepreneurship. The emphasis of the course will be on how technology transfer occurs, different technology transfer models, early stage technology finance, basics of intellectual property, and the regulatory and reimbursement environment for commercializing drugs, devices, diagnostic tests and health information software.

Bioentrepreneurship Learning Objectives

Bioentrepreneurship requires an extensive repertoire of knowledge, skills and attitudes. Following completion of the introductory course in bioscience technology transfer and the four short courses in bioscience finance, marketing, product development and regulatory affairs/reimbursement, attendees should:

Legal environment

https://ucdenver.instructure.com/courses/339391/assignments/syllabus
- understand the basics of intellectual property
- be able to create a plan to protect their ideas
- understand basic licensing terms
- be able to interpret a term sheet
- understand the legal implications of creating and distributing a private placement memorandum

Marketing

- be able to write a market analysis
- be able to perform a SWOT analysis
- be able to perform a consumer analysis
- be able to write a competitive analysis
- be able to identify important market segments
- be able to validate marketing assumptions using primary research techniques
- be able to describe their distribution and sales plan
- be able to describe their pricing strategies
- be able to describe their promotional strategies: public relations, advertising, point or sale, etc

International Bioentrepreneurship

- understand the regulatory and reimbursement environment in international markets
- determine whether they want to engage foreign resources or markets in the development of their product or service

Regulatory environment

- understands how to get FDA approval for their product or service
- understands how to get reimbursement for their product or service
- understands how their product or service needs to be manufactured to be within regulatory compliance guidelines

New Product Development

- understands the stages of new product development
- understands how to manage an R & D portfolio
Business Development and Planning

- can write an innovation plan
- can decide whether to proceed with, modify, or abandon a new idea early in its development
- can write a business development plan

Manufacturing

- be able to describe how the product will be manufactured

Finance

- be able to secure capital in each stage of development
- be able to construct and interpret a capitalization table
- be able to create and interpret basic financial statements
- be able to describe an exit strategy

Leading Bioscience Ventures

- be able to demonstrate managerial skills like team building, project management, conflict resolution, budgeting and negotiation and persuasion
- be able to demonstrate leadership ability like inspiring employees, articulating a vision and providing direction

Clinical Trials and Clinical Validation

- understand the regulatory requirements for clinical trials
- understand potential legal and ethical risks involved in performing clinical trials
- Become familiar with and apply the basic ethical principles of biomedical research

Communication Skills

- be able to effectively network and connect to the value chain
be able to convincingly present their innovation plans to stakeholders

Technology Development, Management and Commercialization

- Understands the basics of technology transfer in the academic, industrial and government laboratory setting
- Understands different mechanisms for technology transfer such as licenses, in-licensing and outlicensing, spin out formation and other mechanisms.

Faculty

The faculty for this course includes members from academia, industry and local government labs. They are all accomplished practitioners of life science technology transfer and commercialization and bring real world, relevant experiences and skills to the class.

Faculty for the Spring, 2016

Course Director: Arlen D. Meyers, MD, MBA

Rob Traver (Intellectual Property): IP attorney with Sheridan Ross

Dan Kramer (Technology Transfer): Attorney at University of Colorado Office of Technology Transfer

Tim Bates (product development): Product development and marketing consultant

David Davis (reimbursement): Reimbursement specialist with Spectranetics

Evan Husney (Biobusiness Law): Attorney at Foster Graham

John Kelley (Putting Together the Team): CEO of www.cerescan.co  (http://www.cerescan.com)


Jason Sapsin(FDA and regulatory affairs): FDA lawyer with FaegreBD

Karl Dakin (Finance): Serial entrepreneur and angel advisor

Mark Burgeson (Sales and Marketing): Career medical device exec and sales trainer

Mike Biselli (digital health): Serial entrepreneur and developer of Catalyze


Course Description
There are multiple definitions of technology transfer. Here are a few:

- The process of converting scientific findings from research laboratories into useful products by the commercial sector. [www.onli.gov/sci/techresources/Human_Genome/publicat/97pr/09gloss.html](http://www.google.com/url?sa=X&start=0&oq=http://www.onli.gov/sci/techresources/Human_Genome/publicat/97pr/09gloss.html)

- The diffusion of practical knowledge from one enterprise, institution or country to another. Technology may be transferred by giving it away (eg, through technical journals or conferences); by theft (eg, industrial espionage); or by commercial transactions (eg, patents for industrial processes) as well as through cross-national exchanges among components of multinational enterprises. ... [www.itcsonline.com/introduction/glossary2_g-z.html](http://www.google.com/url?sa=X&start=1&oq=http://www.itcsonline.com/introduction/glossary2_g-z.html)


- The ability to take a concept from outside the organization (typically from a government or university research programs) and create a product from it. (Process) [ccs.mit.edu/21c/iokey.html](http://www.google.com/url?sa=X&start=3&oq=http://ccs.mit.edu/21c/iokey.html)

- The communication or transmission of a technology from one country to another. This may be accomplished in a variety of ways, ranging from deliberate licensing to reverse engineering. [www-personal.umich.edu/~alandear/glossary/t.html](http://www.google.com/url?sa=X&start=4&oq=http://www-personal.umich.edu/~alandear/glossary/t.html)

Fundamentally, the term describes the process of transferring an idea to another person, organization or market usually via development and commercialization. Bioentrepreneurship is the pursuit of opportunity with uncontrolled resources with the goal of creating user/customer/patient defined value by deploying bioscience or health innovation. The innovation can be in the area of bioscience or health and included not just products and services, but systems and platform/process innovation as well.

New product development takes place in definable stages. The model developed by Robert Cooper, shown below, defines the different gates and stages.

This course examines the process of technology transfer and bioentrepreneurship in the academic, government laboratory and corporate setting. The focus of the course, from the discovery stage to building the business case, will be on the process of creating innovation from inventions, protecting the innovation and intellectual property and deciding whether to proceed with commercialization. The focus of this course is on managing and leading early stage technology development and deciding whether to proceed with commercializing a technology and technology transfer, i.e. packaging and preparing the intellectual property and prototypes for the next stage of business development

The course will consist of both lectures and case studies. Student groups will present an innovation plan incorporating elements of the course during the final weeks of the class.

**Notes on Extensions, Late Work, and Missed Classes**
Unless you have a valid medical or compassionate reason for needing an extension, all assignments are due by the stated deadline. Assignments not turned in on time will be marked down. You are required to attend class and participate fully. If you have to miss a class, contact arlen.meyers@ucdenver or call 303-724-1952 in advance. You will receive zero for the class participation grade that session. If you miss three or more classes without discussing your situation with me, you will fail. All students who take the class must register as regular students and pay the required fees. **No students will be permitted to audit the course.** Students may audit individual sessions with the permission of the instructors.

**Grading**

**Final case presentation and Simulated Business Plan Competition**

At the end of the course, each group is required to submit their final written innovation plan. Remember, the purpose of the innovation/commercialization plan is to a) identify those things that could potentially cause failure of the venture b) address those factors that are not fatal, and c) decide whether to abandon the project, work on the project some more or move on to writing a more formal business case or plan. Be sure to include a “Risks and Mitigation Plan” at the end of your document, identifying those elements that will place your idea at risk and how you intend to address them.

In addition, each group will pitch their idea to a panel of experts. Use 10 slides, twenty minutes, 30 point Powerpoint slides

Ten Slides for your pitch:

1. 1. Title slide
2. 2. Problem description
3. 3. Solution
4. 4. Business model
5. 5. Underlying Magic
6. 6. Marketing and Sales
7. 7. Competition
8. 8. Management team
9. 9. Financial Projections and Key Metrics
10. Current Status, timelines, benchmarks, use of funds

Following the presentation, there will be a 5 minute Q/A session. Your presentation will be judged by an experience panel of judges on its funding potential assessing the following:

**IP risk: Is there sufficient freedom to operate?**

https://ucdenver.instructure.com/courses/339391/assignments/sylabus
Market risk: Is there a big enough and growing market with lots of pain?

Technical risk: Will your solution work?

Financial risk: Is there a big enough potential return on investment?

Business risk: Does the plan make sense and attainable?

Implementation risk: Do you have the people to pull it off?

Course presentations and exercises: During the course, students will be asked to participate in exercises involving various skills required for leading technology transfer and new venture creation.

SYLLABUS

If I had asked my customers what they wanted, they'd have said a faster horse

-Henry Ford


Reading: Read "The Life Science Innovation Roadmap"

Instructor: Arlen Meyers, MD, MBA, is Professor of Otolaryngology, Engineering and Dentistry and Director of the course in bioinnovation and entrepreneurship at the University of Colorado Denver. A Fulbright Scholar, Dr Meyers is the founding CEO and President of the Society of Physician Entrepreneurs and cofounding President of www.medvoy.com

Discussion topics:

Truths and myths of bioentrepreneurship

Over view of the new product development process

What is life science and health entrepreneurship?

What are value factors and why are they important?

What are the key challenges in getting an idea, product or service to patients and markets?

What are the key elements of life science technology commercialization and how are they different for drugs, devices and digital health products and services?

Online Module: Business Model Generation and Testing

Faculty: Arlen Meyers, MD, MBA
Leave the beaten track occasionally and dive into the woods. Every time you do so, you will be certain to find something that you have never seen before.

-Alexander Graham Bell

2. Week of Jan 25th:

Basics of Technology Transfer (Wed night lecture)

Reading:

Instructor: Dan Kramer

Discussion topics:

What are intellectual assets
Why are they important
What is intellectual property
How if it formed and protected

Online module: New product development (Bates)

Theodore Levitt Creativity is thinking up new things. Innovation is doing new things.

3. Week of Feb 1st: Basics of Intellectual Property (Wed night lecture)

Reading:

Instructor: Rob Traver

Discussion topics:

1. What is intellectual capital and intellectual property
2. Why is it necessary to protect your idea? When does it not matter?
3. Who owns your ideas?

Online module: Sales and Marketing (Mark Burgeson)

4. Week of Feb 8th: FDA law (Wed night lecture)
Instructor: Jason Sapsin

Discussion topics:
1. What is the purpose of the FDA
2. How is it organized?
3. How should you interact with the FDA?
4. How has FDA administrative law evolved?

Online Module: Digital Health Entrepreneurship (Mike Biselli and Yaniv Kanfi)

Plato The beginning is the most important part of the work.

5. Week of Feb 15th: Legal Environment (Wed night lecture)

Reading:
Instructor: Evan Husney

Discussion topics:
1. How to choose the right business entity
2. Principles of organizational governance and procedure
3. Legal and regulatory environment of raising private money

Online module: Reimbursement principles (Dave Davis)

Innovation is ultimately a team sport
-Tom Kelley, IDEO

6. Week of Feb 22th: Financing your new venture (Wed night lecture)

Reading:
Instructor: Karl Dakin

Discussion topics:

1. How to create a funding plan
2. Where to go to find money
3. How to approach investors

Online module: Drug Discovery and Development (Rick Duke)

Andrew Carnegie No person will make a great business who wants to do it all himself or get all the credit.

7. Week of Feb 29th: How to build and lead high performance teams (Wed night lecture)

Reading:
Instructor: John Kelley

Discussion topics:

1. Leading high performance teams
2. Personal leadership development
3. How to make yourself obsolete

Online module: Commercial Feasibility Testing and Risk Evaluation and Mitigation

8. March 8th: Final Team Project Presentations at Jabs Center

Suggested reading: The Art of the Start, Guy Kawasaki, Portfolio, 2004

Presentations of innovation plans

Go/No Go decision and why

If you want to know about the water, don’t ask the fish.

Anonymous
Innovation Plan due

Textbooks:
Friedman, Y: Building Biotechnology, (4th edition), Logos Press

Optional Supplementary Readings
Blank S and Dorf, B: The Startup Owner's Manual, K& S Ranch, Inc

Tech-Transfer Strategy. Lindsay Moore, PhD
http://www.klinc.com/strategic_thinking/tech-transfer.html

Fueling Innovation, Courtney Price and Mack Davis

Venture Quest Ltd., LLC

The New Business Road Test

John Mullins, Prentice Hall

CU Technology Transfer Office Annual Report and Startup Chart
http://www.cusys.edu/techtransfer/downloads/Annual%20Report%202005.pdf
http://www.cusys.edu/techtransfer/downloads/Startup%20Chart%202005.pdf

Colorado Bioscience Strategic Plan Update

Colorado Bioscience Strategic Plan 2003
http://www.oit.state.co.us/resources/docs/Colorado_Final_Report_04-03-01.pdf
What's the best job for your personality?


**Strategic Management of Technological Innovation**
Melissa Schilling, McGraw-Hill Irwin, 2005

**Diffusion of Innovations, 4th ed.**
E. Rogers, Free Press, 1995

**Clusters and the New Economics of Competition**

**The Wall Street Journal Center for Entrepreneurs**

**The Ten Faces of Innovation**
Tom Kelley, Currency Doubleday, 2005

**The Art of Innovation**
Tom Kelley, Currency Doubleday, 2004

**Crossing the Chasm**
Geoffrey Moore, Collins Business Essentials, 2002

**The Art of the Start**
Guy Kawasaki, Portfolio, 2004

**Innovation and Entrepreneurship**
Peter Drucker, 1985

Medicine by Design: The Practice and Promise of Biomedical Engineering
Fen Montaigne, Johns Hopkins, 2006

The Business of Healthcare Innovation
Lawton Burns, Cambridge University Press, 2005

Course Summary:

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<tr>
<td>Mon Jan 18, 2016</td>
<td><a href="https://ucdenver.instructure.com/courses/339391/assignments/235376">Entrepreneurial trait self assessment</a> due by 11:59pm</td>
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<td>Mon Jan 25, 2016</td>
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<td>Wed Feb 10, 2016</td>
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|      | Biselli Talk on Digital Health Clusters  
(https://ucdenver.instructure.com/courses/333931/assignments/270677)  
(ENTP 6801 H50) |
|      | Dakin lecture assignment for Wed night, Feb 3  
(https://ucdenver.instructure.com/courses/333931/assignments/269812) |
|      | Davis lecture  
(https://ucdenver.instructure.com/courses/333931/assignments/235372) |
|      | Dempsey Lecture  
(https://ucdenver.instructure.com/courses/333931/assignments/235373) |
|      | Duke Reading Materials  
(https://ucdenver.instructure.com/courses/333931/assignments/235374) |
|      | Entity formation and securities law  
(https://ucdenver.instructure.com/courses/333931/assignments/235375) |
|      | For Traver class, read Chapter 7 in the Life Science Innovation Roadmap (LSIR)  
(https://ucdenver.instructure.com/courses/333931/assignments/235378) |
|      | Identifying a problem and creating a solution  
(https://ucdenver.instructure.com/courses/333931/assignments/235379) |
|      | Kelley Lecture  
(https://ucdenver.instructure.com/courses/333931/assignments/235381) |
|      | Lecture 15  
(https://ucdenver.instructure.com/courses/333931/assignments/235382) |
|      | Next steps  
(https://ucdenver.instructure.com/courses/333931/assignments/266375) |
|      | Price lecture  
(https://ucdenver.instructure.com/courses/333931/assignments/235385) |
|      | Read case prior to Sapsin lecture  
(https://ucdenver.instructure.com/courses/333931/assignments/271362) |
|      | Read The Life Science Innovation Roadmap 1  
(https://ucdenver.instructure.com/courses/333931/assignments/235387) |
|      | Readings for Duke lecture  
(https://ucdenver.instructure.com/courses/333931/assignments/235386) |
|      | Roll Call Attendance  
(https://ucdenver.instructure.com/courses/333931/assignments/235392) |
|      | Silva assignment  
(https://ucdenver.instructure.com/courses/333931/assignments/235393) |
|      | View the YouTube Video I posted on "How to read financial statements"  
(https://ucdenver.instructure.com/courses/333931/assignments/235397) |
|      | View this talk  
(https://ucdenver.instructure.com/courses/333931/assignments/252970) |
|      | Week 2 assignment (Dan Kramer lecture)  
(https://ucdenver.instructure.com/courses/333931/assignments/268313)  
(ENTP 6801 H50) |
|      | Write a concept statement for your project  
(https://ucdenver.instructure.com/courses/333931/assignments/235399) |
|      | Write a concept statement for your team project and post it under discussion section  
(https://ucdenver.instructure.com/courses/333931/assignments/235400) |