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Expanded Course Description UC Berkeley:
Bioengineering: Graduate Students and Upper Division Undergraduates
Spring 2021

Biotechnology Entrepreneurship: Impact, History, Therapeutics R&D, Entrepreneurship & Careers

Course Number: BioE 253 grad; BioE 153 undergrad
Course Title: Biotechnology Entrepreneurship: Impact, History, Therapeutics R&D, Entrepreneurship & Careers
Instructor: David Kirn, MD (Adjunct Professor)
Offered: Spring (Tuesday 5-7 PM – virtual class)
Duration of Course for Summer Session: n/a
Units: 2 units
GSI/TA: Sydnee Ruff

Estimated total number of hours of student work per week: 6 hours total (2 hours in class, including lectures and group projects; 4 hours reading, homework).

Course Format: 2 hours per week in one class session. Sessions include 1) lectures followed by 2) team activities focused on developing new company business models and therapeutic product design and development plans.
May be repeated for credit? No
Courses that restrict credit and how much? None

Prerequisites (BioE 253): None
Prerequisites (BioE 153): Upper Division Undergraduates or Consent of Instructor

Grading (BioE 253): Letter, Pass/No Pass, S/U (grad courses only), breakdown grading %

Class Participation - 50%

- *Participation will be graded both quantitatively and qualitatively.*
- *Attendance will be graded quantitatively (two or more unexcused absences may decrease the student's grade).*
- *Class participation will be assessed qualitatively based on participation in class discussions, question and answer sessions following lectures, and question and answer sessions following student teams' presentations.*
- *Weekly quizzes may be given on the recommended weekly readings*

Start-Up Company Projects - 50%

- *Start-Up Company Business Plan and Presentations: Business Model Canvas, Therapeutic Product Design and Development Plan (25%)*
- *Start-Up Company Pitch Slide Deck and Presentation (25%)*

Grading (BioE 153): Letter grade only, breakdown grading %

Class Participation - 75%

- *Participation will be graded both quantitatively and qualitatively.*

- *Attendance will be graded quantitatively (two or more unexcused absences may decrease the student's grade).*
- *Class participation will be assessed qualitatively based on participation in class discussions, question and answer sessions following lectures, and question and answer sessions following student teams' presentations.*
- *Weekly quizzes may be given on the recommended weekly readings*

Start-Up Company Projects - 25%

- *Start-Up Company Business Plan and Presentations: Business Model Canvas, Therapeutic Product Design and Development Plan (10%)*
- *Start-Up Company Pitch Slide Deck and Presentation (15%)*

Room share and graduate content: BioE 153 and BioE 253 will share the same lectures, but the two cohorts will be graded separately from one another. The graduate students will have two projects, while the undergraduates will have only one. The graduate students will be expected to develop and lead their teams, and they will give a final presentation with the rest of their team. The undergraduate students will have the option to participate in the presentations by their teams.

Overall, the undergraduate grading will depend more on the shared homework, while the graduate grading will depend more on project work and presentations. The expectations for the development and depth of the project work will be higher for the graduate students.

Brief Course Description for catalog: (one paragraph)

This course is designed for students interested in an introduction to the biotechnology, entrepreneurship, therapeutics research and development, and careers in the biopharmaceutical/ biotech industry. Students should be interested in the impact of biotechnology on medicine and society, the history of the field (including individual scientists, entrepreneurs and companies), key methodologies, therapeutic product classes, entrepreneurship and innovation within the life sciences. Students will learn principles of drug and biologics design, discovery, and development. Students will also be exposed to the range of careers in the biopharmaceutical/ biotechnology industry. Students should be considering careers in the biopharmaceutical and biotech fields, and/or considering the application of life sciences to novel therapeutic products and companies. The curriculum will include lectures by the course instructor, presentations and discussion sessions with outside experts (including biotech entrepreneurs, developers, executives and innovators). In addition, case studies will be presented and discussed, including those of historically impactful scientists, entrepreneurs, therapeutics/ medicines and biotherapeutics companies. Finally, students will work in cross-functional teams to create and develop biopharmaceutical product development plans and start-up company business models and pitch decks.

The course is divided into five modules:

1. **The Biopharmaceutical Industry**: Introduction, Overview and Impact on Medicine & Society
2. **Innovation in Biotechnology**: Disruptive Technologies, Product Classes & Inventors
3. **Entrepreneurship in Biotechnology**: Vision, Business Models, Product Design & Development
4. **Case Studies**: Innovative Products, Companies & Business Models
5. **Team Presentations**: Product Design & Development Plans; Business Model Canvases & Company Pitch Decks

Course Objectives:

(1) To foster understanding and appreciation for the medical and societal impact of the biopharmaceutical field and industry;
(2) To educate students on the history of the field and industry, including key methodologies, technologies, product classes, scientists, entrepreneurs, and companies;
(3) To introduce the key steps in the process of discovery, development and commercialization of novel therapeutics;
(4) To educate students on careers in the biopharmaceutical industry;
(5) To educate students on biopharmaceutical company entrepreneurship and innovation through team-based hands on virtual company creation

Desired Course Outcomes:
Students will understand the following: (1) the impact of the biopharmaceutical industry on medicine and society, (2) the history of the biotech industry, (3) the methods, product classes/ technologies and development methodologies that have driven the evolution of the field, (4) the nature of the ecosystem and specific careers in the biopharmaceutical industry, (5) the product design and development process (with a focus on biotherapeutics), including opportunities and challenges, (6) entrepreneurship principles, including those defined by the Lean Launchpad approach (including the Business Model Canvas, the Minimum Viable Product and Customer Discovery).

Room Share:
Yes

Course Books: recommended reading

- **Biotechnology Overviews: Technical**
  - The BioTech Primer (2019) – BioTech Primer Inc (https://biotechprimer.com/):
    - Burke, Emily. *The Biotech Primer*. BioTech Primer Inc., 2019.
  - Biotech Primer's Quinquennial Weekly Compendium 2015-2020 eBook
  - Biotechnology (Cell Press; 2nd Edition; 2016) – David Clark, Nanette Pazdernik
    - Clark, David P., and Nanette Jean. Pazdernik. *Biotechnology*. 2nd ed., Academic Cell, 2016.
- **Innovation Overviews: History**
  - The Innovators: How a Group of Hackers, Geniuses and Geeks Created the Digital Revolution (2014) – Walter Isaacson: Chapter 12
    - Isaacscon, Walter. The Innovators: How a Group of Hackers, Geniuses and Geeks Created the Digital Revolution. Simon & Schuster, 2012.
- **Entrepreneurship Overviews:**
  - The Lean Startup (2011) – Eric Ries: Foreword, Introduction, Chapt 8
    - Ries, Eric. The Lean Startup. The Crown Publishing Group, 2011.
- **Personal Management & Leadership**
  - Primal Leadership: Unleashing the Power of Emotional Intelligence (2013) - Daniel Goleman, Richard Boyatzis: Preface, Chapt 1, Chapt 4, Appendix B
    - Goleman, Daniel, et al. Primal Leadership: Unleashing the Power of Emotional Intelligence. Harvard Business Review Press, 2013.

Course Podcasts: recommended listening

- **Entrepreneurship: Case Studies with Entrepreneurs**
  - How I Built This with Guy Raz:
    - Michael Dell – Dell Computers
    - Jenn Hyman – Rent the Runway

Course Outline

I. The Biopharmaceutical Industry: Introduction, Overview and Impact on Medicine & Society

1. Introduction & Industry Overview: Course & Module Overview; Definitions & sectors in the industry; Impact on medicine and society; Understanding the biotechnology industry ecosystem (key positions, organizations & relationships)
2. Biotechnologies Overview: Key enabling methodologies, technologies and therapeutic classes; Understanding the innovators and companies behind key methods and therapeutics

II. Innovation in Biotech: Overview of the Therapeutics Design, Discovery & Development Process

3. Therapeutics Design & Development Process 1: Module Overview; Product design, non-clinical & clinical development
4. Therapeutics Design & Development Process 2: Regulatory affairs; Intellectual property
5. Therapeutics Design & Development Process 3: Manufacturing, CMC & related tech

III. Entrepreneurship in Biotechnology:

6. Entrepreneurship 1: Module Overview; Lean Launchpad Approach, Minimum Viable Product; Business Models, Vision setting
7. Entrepreneurship 2: Mergers & Acquisitions
8. Entrepreneurship 3: Business Development
9. Entrepreneurship 4: Finance

IV. Case Studies

10. Case Studies 1
11. Case Studies 2

V. Final Team Presentations: Company Pitch Decks

12. Company Pitch Deck Presentations
13. Company Pitch Deck Presentations
14. Company Pitch Deck Presentations

Course Outline: Details by Week

Week	Topic		Speakers *(invited external speakers)*	Virtual Company Team Activities in Class; Suggested Reading for Following Week
Module 1: The Biotechnology Industry: Introduction, Overview and Impact on Medicine & Society				
1 (1/19)	Introduction & Industry Overview: Course & Module Overview; Definitions & sectors in the industry; Impact on medicine and society; Understanding the biotechnology industry ecosystem (key positions, organizations & relationships); overview of R&D process		▪ D Kirn, MD	Biotech Primer: Chapters 1 (What the Heck is Biotech) & 9 (Lab to Marketplace) Biotech Primer Compendium: 303 Plants That Heal; 413 The Medicine Machine; 432 The Science Behind The Nobel Prize (Avermectin, Artemisinim); 26 DNA Structure; 149 Immune System – Friend and Foe; 155 Pills, Peptides, Proteins; 182 Immune System for Good; 236, 272 CRISPR/Cas9
2 (1/26)	Biotechnologies Overview: Key enabling methodologies, technologies and therapeutic classes; Understanding the innovators and companies behind key methods and therapeutics; basics of R&D; basics of entrepreneurship		▪ D Kirn, MD	Virtual Company: Team Formation, Selection of a Therapeutic Area, Product & Company Work Biotech Primer: Chapters 2 (Putting the Bio in Biotech) & 3 (Life's Blueprint) Chapter 8 (The Science of Discovery) Biotech Primer Compendium: 228, 151-154, 251 Antibody Therapeutics: Monoclonal, Bi-Specific, ADC Ab-Drug Conjugates, Nanobodies; 172 Immune Checkpoint Inhibitors
Module 2: Innovation in Biotechnology: Overview of the Therapeutics Design, Discovery & Development Process				
3 (2/2)	Therapeutics Design & Development Process I		▪ D Kirn, MD ▪ *Outside Speaker: Terry Hermiston (Bayer) – "Engineered protein and virus-based therapeutics"*	Virtual Company: Team Formation, Selection of a Therapeutic Area, Product & Company Work Biotech Primer:

				Chapters 4 (From Gene to Protein); Chapt 6 (The Technology That Created an Industry) Biotech Primer Compendium: 96 Next-Gen Protein Therapeutics; 128, 249 Oncolytic Viruses; 240-243 RNA Therapeutics; 401 Proteome Discovery
4 (2/9)	Therapeutics Design & Development Process 2		▪ D Kirn, MD ▪ *Outside Speaker(s): David Schaffer, PhD (UCB BioE, ChemE; 4DMT) – "Transformative biotechnology methods and gene therapeutics"*	Virtual Company: Team Formation, Selection of a Therapeutic Area, Product & Company Work Biotech Primer: Chapter 7 (Immune Response: Defender Extraordinaire); Chapter 10 (Putting the Bio in Biomanufacturing) Biotech Primer Compendium: 309 Gene Therapy; 88 Zolgensma Gene Therapy for SMA; 371 Gene Therapy for Hemophilia
5 (2/16)	Therapeutics Design & Development Process 3		▪ D Kirn, MD ▪ *Outside Speaker(s): Fred Kamal PhD, Katy Barglow PhD, Kevin Whittlesey PhD (4DMT) - "Manufacturing/CMC, Regulatory Affairs"*	Virtual Company: Product Design & Development Plan Biotech Primer Compendium: 184-187 BioManufacturing; 71-74 Drug Discovery; 47 Small Molecules for Cystic Fibrosis; 268 Small Molecule Chaperones
Module 3: Entrepreneurship in Biotechnology				
6 (2/23)	Entrepreneurship 1: Module Overview; Lean Launchpad Approach, Minimum Viable Product; Business Models, Vision setting, Business Model Canvas		▪ D Kirn, MD ▪ *Outside Speaker(s): Gideon Bollag PhD (Plexxicon, Onyx) – "Small molecule therapeutics discovery and development"*	Virtual Company: Business Model Canvas Work The Lean Startup: Foreword & Introduction Biotech Primer Compendium: 65-70 Drug Development Ph 1-4; 319 Market Access
7 (3/2)	Entrepreneurship 2: Mergers & Acquisitions		▪ D Kirn, MD ▪ *Outside Speaker(s): Mark Robinson, MBA (Centerview Partners) – "The life sciences industry business models, mergers & acquisitions"*	Virtual Company: Business Model Canvas Work The Lean Startup: Chapt 8 Biotech Primer Compendium: 322 Drug Development to Approval Recap; 351 Post-

				Translational Modification Therapeutics; 476 Blockbuster Medicines
8 (3/9)	Entrepreneurship 3: Business Development		▪ D Kirn, MD ▪ *Outside Speaker(s): John Bishai, PhD (Bank of America) – "Life sciences investment banking"*	Virtual Company: Business Model Canvas Work The Innovators: Chapt 12
9 (3/16)	Entrepreneurship 4: Finance (Venture Capital, Investment Banking) Legal (Corporate, Intellectual Property)		▪ D Kirn, MD ▪ *Outside Speaker(s): Kole Roybal, PhD (UCSF, PICI) – "Next-generation CAR-T cells"* ▪ *Outside Speaker(s): Camille Landis, MBA (T-knife) – "Business development life sciences"*	Virtual Company: Business Model Canvas Work & Pitch Deck Work Primal Leadership: Chapt 4, Appendix B Biotech Primer Compendium: 22, 24, 116, 270, 280, 383 (CAR-T Next Gen, CAR-NK)
10 (3/23)	No class - SPRING BREAK		▪ n/a	**Mid-Term Due:** Virtual Company: Business Model Canvas Slide Deck Complete & Submitted
Module 4: Case Studies				
11 (3/30)	Case Studies - 1		▪ D Kirn, MD ▪ *Outside Speaker(s): Rajeev Shah (RA Capital) – "Venture capital in the life sciences"* ▪ *Outside Speaker: Ed Penhoet, PhD (Chiron; UCB) – "Case report: Chiron Corp"*	Virtual Company: Pitch Deck Work
12 (4/6)	Case Studies - 2		▪ D Kirn, MD ▪ *Outside Speaker(s): Entrepreneurship Panel – 4D Molecular Therapeutics, Ignite Immunotherapy, Plexxicon, Onyx*	Virtual Company: Pitch Deck Work
Module 5: Final Team Presentations: Company Pitch Decks				
13 (4/13)	Virtual Company Presentations - 1		▪ D Kirn, MD	**Final Presentations** - Virtual Company Pitch Deck: Teams 1-5
14 (4/20)	Virtual Company Presentations - 2		▪ D Kirn, MD	**Final Presentations** - Virtual Company Pitch Deck: Teams 6-10
15 (4/27)	Virtual Company Presentations - 3		▪ D Kirn, MD	**Final Presentations** - Virtual Company Pitch Deck: Teams 11-15