



**Lloyd Greif Center**  
for Entrepreneurial Studies

**USC Marshall**  
School of Business

**BAEP-561: ENTREPRENEURSHIP IN INNOVATIVE INDUSTRIES: LIFE SCIENCE  
Spring 2018**

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**COURSE DESCRIPTION**

This course focuses on new venture creation in the life science industry. The course will provide an overview of the breadth and makeup of the industry, the challenges that new entrants into this industry face and their opportunities for successful new venture creation. This is a business course that examines entrepreneurship in an industry that creates technical goods and services, as well as consumer products and services, based on innovations in the biological sciences.

While an understanding of the underlying biological sciences can be extremely valuable in this industry, it is not required for this course. Nonetheless, you will be encouraged to begin learning the language and fundamental concepts of the biological sciences. To be successful in this industry, especially in entrepreneurship in the life sciences, you must have some degree of fluency in the language of the life scientist.

Many new products based on innovations in the life sciences have long, risky, and expensive product development cycles, rely heavily on intellectual property protection to create competitive barriers, may be regulated by governmental agencies, and/or have very large product revenue expectations. These distinguishing features of the products create unique challenges and opportunities for life science entrepreneurial ventures.

This is a lecture and case-based course with guest speakers to highlight aspects of the curriculum.

**COURSE OBJECTIVES**

1. Understand the typical timelines, risks, and costs for the development of new products in the life science industry. Apply this knowledge to create plans for new life science ventures, based on early stage life science technologies.
2. Understand the importance of intellectual property protection in creating barriers that allow new ventures to fend off competitors. Also understand the importance of other's intellectual property, and how that intellectual property may influence business decisions of the new life science venture.

3. Understand the role of governmental agencies in regulating certain types of life science products. Apply this knowledge in formulating strategic plans about how to build a new life science venture based on early stage life science technologies.
4. Understand the options for financing the life science venture. Apply this knowledge in assessing the financial decisions made by life science companies at various stages of their corporate maturation.
5. Recognize the multiple types of customers for the products of a new life science venture, and how a new venture may change its product offerings to increase its value as it grows and matures.
6. Understand the range of skills and knowledge that are needed for a life science venture to succeed over time.

## COURSE MATERIALS

### **Required Course Reader**

Required cases are available through Harvard Business School Publications:

<http://cb.hbsp.harvard.edu/cbmp/access/77454735> Other Required and Supplementary readings are posted on Blackboard, organized by week. PLEASE SEE THE CLASS SCHEDULE, and READ REQUIRED MATERIALS BEFORE CLASS. BE PREPARED FOR DISCUSSION.

Note below that CR indicates course readings that are found in the HBS Publications website at the link shown above. BB indicates readings that are found in folders on the BAEP561 BlackBoard website.

Week 1: CASE (CR) Stan Lapidus: Profile of a Medical Entrepreneur (2004; 9-805-087)

Week 2: CASE (CR) Syndexa and Tech Transfer Harvard (2009; 9-808-073)

Week 3:

BB: General information concerning patents (2015) USPTO;

Patent process overview (USPTO, downloaded 2018,

<https://www.uspto.gov/patents-getting-started/patent-process-overview> )

BB: General Navigation Guide for Manufacturers of FDA-Regulated Products and Startups (US FDA, downloaded 2018,

<https://www.fda.gov/downloads/ForIndustry/FDABasicsforIndustry/UCM239011.pdf>

Week 4: CASE (BB) Theranos readings: Fortune (2014) and several WSJ articles (2015-2017)

Week 5: CASE: (CR) Proteus Biomedical: Making Pigs Fly Hamermesh, Barley, Graham (2010; 9-809-051)

Week 6: CASE (CR) CV Ingenuity (A) Herzlinger, Otazo (2017; 9-315-045); (CR) Evaluate Commercial Viability Herzlinger (2015; 9-313-070) – *this reading may be valuable for your final project, and you might want to read it much earlier in the course*

### **Supplementary Materials**

Supplementary reading materials are provided for future reference, for those interested, and for possible use in your written assignments or final project. These materials are all posted on Blackboard, and are either public domain, or available through the USC libraries. Note that many of these materials are copyright protected.

There is also a list of useful databases for evaluating life science ventures that is posted on Blackboard. This Supplementary list will be continually updated.

## Course Notes

Lecture notes and slides will be posted on Blackboard. Faculty slides will be available prior to class, and guest lecture slides may be available after the guest lecture, at the discretion of our guest.

## Course Communication

Course communication will take place through announcements in class, emails, and on Blackboard (blackboard.usc.edu). Many of the emails I send will go through Blackboard; therefore it is imperative that you have a fully operational Blackboard account with a current and correct email address posted. By default, Blackboard uses your USC email address (username@usc.edu). If this is not your primary email account, please make sure to forward your USC email to the primary email account that you use. You are responsible for ensuring that you receive email messages, including assuring that messages will not bounce back due to your storage quota being full.

*If you have any questions or need assistance with the Blackboard Course Pages, please contact the Marshall HelpDesk at 213-740-3000 or HelpDesk@marshall.usc.edu.*

## **CLASSROOM POLICIES**

**Class name cards.** Please display your name card at every class meeting. (I will have name cards available - but you will need to remember to bring it with you to each class. If you forget your name card, please make a substitute.)

**Please be prompt.** Arriving late or leaving early from class meetings can disrupt the learning experience for other students.

**Dress code for class is "student formal"** ☺ We will have a guest speaker on most class days, so please, no hats, shorts, etc. in class.

**Please take advantage of the guest speakers we will have.** They have volunteered to give lectures and to meet with you. Please interact with them by asking questions during class, and chatting with them after their presentation, typically at the mid-class break.

**No eating during class.** Please eat before, after, or during the 10 min break we will have.

**Remember to turn off cell phones.** Laptop computers/tablets are to remain closed (unless otherwise instructed), as I have found that laptop use distracts from the learning experiences of others in class.

## **GRADING**

Final grades represent how you perform in the class relative to other students. Your final grade will be assigned based on your total points from the various assignments and other course evaluation components (listed in the table on page 2), the overall average points within the class, and your ranking among all students in the class.

If you have any questions about your grade during the semester, please make an appointment to see me to discuss your concerns. Do not wait until the end of the semester to do so!

*The target course GPA for this elective graduate course is 3.5.*

<b><u>Assignments</u></b> - details for the assignments are provided in the Appendix	<b><u>Points</u></b>	<b><u>% of Grade</u></b>
CLASS PARTICIPATION	100	10%

INDIVIDUAL WRITTEN ASSIGNMENT - you are to choose ONE memo as your individual written assignment - Memo A OR Memo B OR Memo C OR Memo D. Each assignment is due on a different day. This is an INDIVIDUAL assignment, but there can be team input. <b>Please note that for some memos, only one or two team members can undertake the assignment.</b>	200	20%
FINAL TEAM PROJECT - a team project to formulate the initial plans for commercializing a USC life science technology. There are multiple parts to the final project: Written plan (20%, 200 points), presentation (10%, 100 points), and team participation (10%, 100 points)	400	40%
QUIZZES - in class, testing your understanding of key aspects of specific knowledge. The quizzes will be given on March 22, April 5, April 12, and April 19. The top three scores will count in your final grade.	300	30%
<b>TOTAL</b>	1000	100%

### CLASS PARTICIPATION (10%)

Class participation is an extremely important part of the learning experience in this course as the richness of the learning experience will be largely dependent upon the degree of preparation by *all* students prior to each class session.

A course that incorporates the frequent use of case analyses to illustrate the practical application of concepts and practices requires the student to diligently and thoroughly prepare cases and actively offer the results of the analyses and conclusions derived as well as recommendations during each class session. My expectation and that of your classmates are that you are prepared for *all* classes and will actively participate in and meaningfully contribute to class discussions.

If you have not previously participated in case discussions in class, please find one or more of the excellent guides to student preparation for case discussions online, such as: <https://www.youtube.com/watch?v=tauV48IEcgc> (very short, very basic);

In-class participation is also a critical part of this course's learning experience. Cold calling may take place to encourage active participation and to gain multiple perspectives and points of view, thus lending itself to the richness of the learning experience. In-class participation grading will be based on students' demonstrated willingness to participate and the quality of the comments expressed, rather than quantity. While some students are far more comfortable than others with class participation, *all* students should make an effort to contribute meaningfully.

Students will offer their opinions in group settings many times in their careers; thus, class participation serves to prepare students for this business experience.

The evaluating of in-class participation is based on the following:

- *Relevance* – Does the comment or question meaningfully bear on the subject at hand? Irrelevant or inappropriate comments can detract from the learning experience.
- *Responsiveness* – Does the comment or question connect to what someone else has said?

- *Analysis* – Is the reasoning employed consistent and logical? Has data from course materials, personal experience, or general knowledge been employed to support the assertions/findings?
- *Value* – Does the contribution further the understanding of the issues at hand?
- *Clarity* – Is the comment concise and understandable?

During class sessions, I frequently assume the role of a facilitator to encourage a discussion that includes perspectives from a variety of viewpoints and, secondly, to help pull together prevailing analyses and recommendations. The direction and quality of a discussion is the *collective responsibility of the class*.

For each in-class session twenty (20) points will be awarded to a student for relevant and meaningful participation, ten (10) point for modest contributions to the class and zero (0) points for no participation or absence.

To underscore the importance of participation, overall, 10 percent of the course grade or 100 of 1000 points are allocated to class participation.

To provide clarity on the expectations for class participation, the following behavioral rating scale is provided

#### Excellent Performance

- Initiates information relative to topics discussed
- Accurately exhibits knowledge of assignment content
- Clarifies points that others may not understand
- Shares personal experiences or opinions related to topic
- Offers relevant / succinct input to class
- Actively participates in class exercises
- Demonstrates ability to apply, analyze, evaluate & synthesize course material.
- Demonstrates willingness to attempt to answer unpopular questions
- Builds on other students' contributions

#### Average Performance

- Participates in group discussions when asked
- Demonstrates knowledge of course material
- Offers clear, concise, “good” information on class assignments
- Offers input, but tends to reiterate the intuitive
- Attends class regularly

#### Unacceptable Performance

- Fails to participate even when directly asked
- Gives no input to discussions
- Does not demonstrate knowledge of the readings
- Shows up to class: does nothing
- Distracts group / class
- Irrelevant discussion

## INDIVIDUAL WRITTEN ASSIGNMENT (20%)

Each student is to choose ONE of the ALTERNATIVE assignments – either Memo A (Intellectual Property), Memo B (Clinical/Regulatory Affairs), Memo C (Market Assessment) or Memo D (Student Choice). This is an INDIVIDUAL assignment, but there can be team input. Each assignment is due on a different day:

- *Memo A* – Intellectual Property – due before start of class: *March 29, 2018* – only one student from each team can select Memo A.
- *Memo B* – Clinical/Regulatory Affairs – due before start of class: *April 5, 2018* – only one student from each team can select Memo B.
- *Memo C* – Market Assessment – due before start of class: *April 12, 2018* – up to three students from each team can select Memo C. If more than one student chooses this memo, each memo should address a different market, or a different aspect of the market, e.g., “customers”, “competitors”, etc.
- *Memo D* – Student Choice – due before start of class: *April 19, 2018* – any number of students on the team can select Memo D.

Assignments must be turned in before the due date/time electronically via Blackboard. Any assignment turned in late, even if by only a few minutes, will receive a full grade deduction (for example, if your work is a B+ grade, you will be given a C+ grade). If your internet breaks down on the due date, you must deliver a hard copy at the beginning of class on that day. If you are unable to attend class on that day, make arrangements for the assignment to be turned in by the start of class.

Late or not, however, you must complete all required assignments to pass this course.

- Separate detailed instructions will be given out for each of the major assignments.
- A single PDF file should be submitted to Blackboard for the written assignment.

***Please do not submit the written assignment after the due date. You must select only ONE of the memo assignments.***

## FINAL TEAM PROJECT (40%)

Team members are assigned, with an attempt to balance business and technical expertise of the team members.

The final project is a team project, with multiple parts:

- Written plan (20%) is due by 5pm, May 3, 2018;
- Presentation: in class, April 26 (10%);
- Team participation (10%).

Assignments must be turned in before the due date/time electronically via Blackboard. Any assignment turned in late, even if by only a few minutes, will receive a full grade deduction (for example, if your work is a B+ grade, you will be given a C+ grade). For the Final Team Project, a SINGLE PDF file should be submitted via BlackBoard for the entire team. Team members names should be listed on the first page, along with a clear description of the USC technology that the Final Project is based upon.

After the final presentation and written plan are completed, each individual will provide input for the Team participation score by evaluating each of the team members (including yourself) for their contributions to the final project deliverables. Each individual will have 100 points that will be distributed amongst the team members. The final points granted for each individual on each aspect of the final team project are the sole responsibility of the instructor, after assessing all of the deliverables, including the team participation scores.

## QUIZZES AND EXAMS (30%)

There is certain knowledge that you would be well-served to know as you engage in life science entrepreneurship.

There will be four closed-book quizzes given in-class that are intended to test your acquisition of knowledge from the readings, the class sessions and guest lectures. In general, the quizzes will be short – 5-10 questions, 10-15 minutes, straightforward, fact-based, and multiple-choice or very short answer. Quizzes may cover any material up to that point in the course, including material based on readings for class on the day of the quiz.

The quizzes will be given on March 22, April 5, April 12, and April 19. Your top three quiz scores will be counted, allowing you to miss or skip one quiz. There will not be any make-up quizzes.

Your top three quizzes will comprise 30% of your final grade, or 300 total points.

## THE IMPORTANCE OF COURSE EVALUATIONS

The student course evaluations are valuable. This course is continuously improved, based on feedback from students and instructor observations. Please make sure to provide constructive feedback – including topics that you would like to see added to the course - in the electronic course evaluation.

## **LLOYD GREIF CENTER FOR ENTREPRENEURIAL STUDIES' CONFIDENTIALITY POLICY**

Throughout the classes and events of the Lloyd Greif Center for Entrepreneurial Studies (“the Greif Center”), students will be exposed to proprietary information from other students, guest lecturers, and faculty. It is the policy of the Greif Center that all such information be treated as confidential.

By enrolling in and taking part in the Greif Center’s classes and activities, students agree not to disclose this information to any third parties without specific written permission from students, guest lecturers or faculty, as applicable. Students further agree not to use any such proprietary information for their own personal commercial advantage or for the commercial advantage of any third party.

In addition, students agree that any legal or consulting advice provided without direct fee and in an academic setting will not be relied upon without the enlisted opinion of an outside attorney or consultant without affiliation to the Greif Center.

Any breach of this policy may subject a student to academic integrity proceedings as described in the University of Southern California Student Handbook SCampus and to any remedies that may be available at law.

The Lloyd Greif Center for Entrepreneurial Studies, the Marshall School of Business, and the University of Southern California disclaim any responsibility for the protection of intellectual property of students, guest lecturers, faculty or staff who are involved in our classes or events.

Receipt of this policy and registration in our classes is evidence that you understand this policy and will abide by it.

## **STATEMENT OF ACADEMIC CONDUCT AND SUPPORT SYSTEMS**

USC seeks to maintain an optimal learning environment. Students are expected to submit original work. They have an obligation both to protect their own work from misuse and to avoid using

another's work as their own. All students are expected to understand and abide by the principles of academic honesty outlined in the University Student Conduct Code (see University Governance, Section 11.00) of SCampus ([www.usc.edu/scampus](http://www.usc.edu/scampus) or <http://scampus.usc.edu>). The recommended sanctions for academic integrity violations can be found in Appendix A of the Student Conduct Code.

### **Students with Disabilities:**

USC is committed to making reasonable accommodations to assist individuals with disabilities in reaching their academic potential. If you have a disability which may impact your performance, attendance, or grades in this course and require accommodations, you must first register with the Office of Disability Services and Programs ([www.usc.edu/disability](http://www.usc.edu/disability)). DSP provides certification for students with disabilities and helps arrange the relevant accommodations. Any student requesting academic accommodations based on a disability is required to register with Disability Services and Programs (DSP) each semester. A letter of verification for approved accommodations can be obtained from DSP. Please be sure the letter is delivered to me (or to your TA) as early in the semester as possible. DSP is located in GFS (Grace Ford Salvatori Hall) 120 and is open 8:30 a.m.– 5:00 p.m., Monday through Friday. The phone number for DSP is (213) 740-0776. Email: [ability@usc.edu](mailto:ability@usc.edu).

### **Support Systems:**

*Student Counseling Services (SCS) - (213) 740-7711 – 24/7 on call*

Free and confidential mental health treatment for students, including short-term psychotherapy, group counseling, stress fitness workshops, and crisis intervention. <https://engemannshc.usc.edu/counseling/>

*National Suicide Prevention Lifeline - 1-800-273-8255*

Provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week. <http://www.suicidepreventionlifeline.org>

*Relationship & Sexual Violence Prevention Services (RSVP) - (213) 740-4900 - 24/7 on call*

Free and confidential therapy services, workshops, and training for situations related to gender-based harm. <https://engemannshc.usc.edu/rsvp/>

*Sexual Assault Resource Center*

For more information about how to get help or help a survivor, rights, reporting options, and additional resources, visit the website: <http://sarc.usc.edu/>

*Office of Equity and Diversity (OED)/Title IX compliance – (213) 740-5086*

Works with faculty, staff, visitors, applicants, and students around issues of protected class. <https://equity.usc.edu/>

*Bias Assessment Response and Support*

Incidents of bias, hate crimes and microaggressions need to be reported allowing for appropriate investigation and response. <https://studentaffairs.usc.edu/bias-assessment-response-support/>

*Student Support & Advocacy – (213) 821-4710*

Assists students and families in resolving complex issues adversely affecting their success as a student EX: personal, financial, and academic. <https://studentaffairs.usc.edu/ssa/>

*Diversity at USC – <https://diversity.usc.edu/>*

Tab for Events, Programs and Training, Task Force (including representatives for each school), Chronology, Participate, Resources for Students



*Emergency Preparations*

*In case of an emergency if travel to campus is not feasible, the USC Emergency Information web site (<http://emergency.usc.edu/>) will provide relevant information, such as the electronic means the instructors might use to conduct their lectures through a combination of USC's Blackboard learning management system ([blackboard.usc.edu](http://blackboard.usc.edu)), teleconferencing, and other technologies.*

<b>COURSE OUTLINE AND ASSIGNMENTS</b>
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	<b>Topics/ Daily Activities</b>	<b>Readings and Homework</b>	<b>Deliverables with Due Dates</b>
<b>Week 1</b> Thu, March 8, 2018	<b>Life Science Industry Overview</b> Key points that differentiate life science entrepreneurship  <b>Guest lecturer:</b> <b>Milton L. Greenberg, Ph.D.</b> <b>President &amp; Co-founder</b> Vivreon Biosciences, LLC	<b>CASE (CR):</b> <i>Stan Lapidus: Profile of a Medical Entrepreneur (9-805-087);</i>	
<b>Week 2</b> Thu, March 22, 2018	<b>Technology ecosystem -</b> Academic research, technology transfer, and the "Valley of Death" <b>Guest lecturer: Daniel Fullerton,</b> <b>Patent and Corporate Counsel,</b> <b>Alfred E. Mann Institute for</b> <b>Biomedical Engineering at USC</b>	<b>CASE (CR):</b> <i>Syndexa and Tech Transfer Harvard (2009)</i>  <b>BB:</b> "Inventor's Guide"	<b>QUIZ #1</b>
<b>Week 3</b> Thu March 29, 2018	<b>Intellectual Property basics;</b> timelines, costs, process  <b>Regulation basics</b> – devices, diagnostics & drugs  <b>Guest lecturer: Prof. Susan Bain</b> <b>DRSc, Dept. of Regulatory &amp;</b> <b>Quality Science, USC School of</b> <b>Pharmacy</b>	<b>BB:</b> General information concerning patents (2015) USPTO <b>BB:</b> Patent process overview (USPTO, downloaded 2018, <a href="https://www.uspto.gov/patents-getting-started/patent-process-overview">https://www.uspto.gov/patents- getting-started/patent-process-overview</a> ) <b>BB:</b> General Navigation Guide for Manufacturers of FDA-Regulated Products and Startups (US FDA, downloaded 2018, <a href="https://www.fda.gov/downloads/ForIndustry/FDABasicsforIndustry/UCM239011.pdf">https://www.fda.gov/downloads/ForIndustry/FDABasicsfo rIndustry/UCM239011.pdf</a> ) <b>BB: ***PLEASE ALSO READ</b> <b>ARTICLE POSTED IN WEEK 3</b> <b>REQUIRED READING ON THERANOS</b> <b>CASE</b>	<b>In class:</b> IP activity; Regulatory activity  <b>MEMO A Due</b>
<b>Week 4</b> Thu April 5, 2018	<b>Follow the money (1) – M&amp;A,</b> corporate partnerships, IPO's  <b>Guest lecturer: Erik Schuchard,</b> <b>Director, Lazard</b>	<b>CR:</b> <i>Proteus Biomedical: Making Pigs Fly</i> Hamermesh, Barley, Graham (2010; 9- 809-051)	<b>QUIZ #2</b>  <b>MEMO B Due</b>
<b>Week 5</b> April 12, 2018	<b>Regulation, Ethics, Leadership</b>  <b>Guest lecturer: Gary Hutchinson,</b> <b>Entrepreneur-in-Residence,</b> <b>AMI@USC</b>	<b>CASE (BB) Theranos readings:</b> Fortune (2014) and several WSJ articles (2016,- 2017)	<b>QUIZ #3</b>  <b>MEMO C Due</b>
<b>Week 6</b> Thu April 19, 2018	<b>Follow the money (2) – grants,</b> venture funding	<b>CR:</b> <i>CV Ingenuity (A)</i> (2017) – Herzlinger, Otazo <b>CR:</b> Evaluate Commercial Viability Herzlinger (2015) – <i>this may be valuable for your final project, and you might want to read this much earlier in the course</i>	<b>QUIZ #4</b>  <b>MEMO D Due</b>
<b>Week 7</b>			Final Presentations

Thu April 26, 2018			
<b>Week 8</b> Thurs May 3, 2018	Final Project due before: 5pm May 3, 2018		

**This outline will be updated with additional guest lecturers, information as they are confirmed.**