

2016 REVISED v1.2 – 2016 SYLLABUS

USCMarshall

School of Business
*Lloyd Greif Center for
Entrepreneurial Studies*

BAEP 561:

Entrepreneurship in Innovative Industries: Life Sciences

Syllabus, Spring 2016

Thursdays 6:30p - 9:20p, Room JKP204

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Office Hours: By appointment.

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I. COURSE OVERVIEW AND LEARNING OBJECTIVES

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.

Learning Objectives

The general goal of the course is to gain an understanding of the unique aspects of the life science industry ecosystem, and of the importance of entrepreneurship to the vitality of the industry. Specific learning objectives to achieve this goal include:

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.

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II. COURSE MATERIALS AND COMMUNICATION

Required Course Reader

Required cases are available through Harvard Business School Publications:
<https://cb.hbsp.harvard.edu/cbmp/access/47887033>

Other Required readings are posted on Blackboard.

Supplementary Materials

Supplementary reading materials are provided for future reference, for those interested, and for possible use in your written assignments or final project. You may find additional insights from reading the experiences of other life science entrepreneurs. 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 list will be continually up-dated.

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.

III. ASSIGNMENTS AND GRADING

<u>Assignments</u> - details for the Memo Assignments will be provided	<u>Points</u>	<u>% of Grade</u>
QUIZZES – in class, testing your understanding of key aspects of specific knowledge	300	30%
WRITTEN ASSIGNMENT – you are to choose ONE of these ALTERNATIVE assignments – Memo A OR Memo B OR Memo C OR Memo D. Each assignment is due on a different day. This is an INDIVIDUAL assignment.	200	20%

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FINAL 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%), presentation (10%), and team participation (10%)	400	40%
CLASS PARTICIPATION	100	10%
TOTAL	1000	100%

Assignment Submission Policy

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 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 it to be delivered to the classroom or to my box 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 and for the Final Project.

Evaluation of Your Work

There will be four basic types of evaluation in this course:

QUIZZES (30%) – There is certain knowledge that you would be well-served to know as you engage in life science entrepreneurship. The quizzes are intended to test your acquisition of that knowledge from the readings and the first half of the class. In general, the quizzes will be short – 5-10 questions, straightforward, fact-based, and multiple-choice or very short answer.

WRITTEN ASSIGNMENT (20%) – Each student is to choose ONE of the ALTERNATIVE assignments – either Memo A (Intellectual Property), Memo B (Clinical/Regulatory Affairs) or Memo C (Student Choice). Each assignment is due on a different day:

Memo A – Intellectual Property – due before start of class: March 31, 2016

Memo B – Clinical/Regulatory Affairs – due before start of class: April 14, 2016

Memo C – Market Assessment – due before start of class: April 21, 2016

Memo D – Student Choice – due before start of class: April 28, 2016

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

FINAL PROJECT (40%) – The final project is a team project, with multiple parts: Written plan (20%) is due by 5pm, May 5, 2016; presentation: each team is assigned a due date (10%); team participation (10%). Teams are assigned, with an attempt to balance business and technical expertise of the team members.

CLASS PARTICIPATION (10%) – This is a combination of your attendance, and your self-evaluation of your participation in class discussions. Participation is evaluated based on your level of involvement in class discussions – both the quality (relevance and insightfulness) and quantity (frequency) of your participation. At the end of the semester you will be asked to complete a self-assessment of your participation. See Appendix 2 of this Syllabus for the grading scale and self-assessment form.

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I will do my best to make my expectations for the various assignments clear and to evaluate them as fairly and objectively as I can. If you feel that an error has occurred in the grading of any assignment, you may, within one week of the date the assignment is returned to you, write me a memo in which you request that I re-evaluate the assignment. Attach the original assignment to the memo and explain fully and carefully why you think the assignment should be re-graded. Be aware that the re-evaluation process can result in three types of grade adjustments: positive, none, or negative.

Grading

Final grades represent how you perform in the class relative to other students. Your grade will not be based on a mandated target, but on your performance. 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!

IV. COURSE POLICIES

Classroom policies

- Class seating and name cards. Please sit in the same seat throughout the course and display your name card at every class meeting. (I will have name cards available.)
- Please be prompt. Arriving late or leaving early from class meetings is not acceptable, as it disrupts the learning experience for other students.
- On days when we have a guest speaker, dress code is **business casual** (no hats, shorts, etc.).
- No eating during class.
- 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 experience in class.

Add/Drop Process

We can drop you from our class if you don't attend the first meeting of a class that meets once per week or first two meetings of a class that meets twice per week. If you are dropped from the class you risk not being able to add yourself to another section this semester. Please visit www.usc.edu/soc and note the final deadlines to add/drop.

Greif Center for Entrepreneurial Studies Confidentiality Policy

Throughout The Entrepreneur Program's classes and events, students will be exposed to proprietary information from other students, guest lecturers, and faculty. It is the policy of The Entrepreneur Program that all such information be treated as confidential.

By enrolling in and taking part in The Entrepreneur Program'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 Program.

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Any breach of this policy may subject a student to academic integrity proceedings as described in the University of Southern California "University Governance Policies and Procedures" as outlined in *SCampus* and to any remedies that may be available at law.

The Entrepreneur Program, the Marshall School of Business and the University of Southern California disclaim any responsibility for the protection of intellectual property of students, guest lecturers or faculty who are involved in The Entrepreneur Program classes or events. Receipt of this policy and registration in our classes is evidence that you understand this policy and will abide by it.

Retention of Graded Coursework

Final exams and all other graded work which affected the course grade will be retained for one year after the end of the course *if* the graded work has not been returned to the student (i.e., if I returned a graded paper to you, it is your responsibility to file it, not mine).

Technology Policy

Laptop and Internet usage is not permitted during academic or professional sessions unless otherwise stated by the respective professor and/or staff. Use of other personal communication devices, such as cell phones, is considered unprofessional and is not permitted during academic or professional sessions. ANY e-devices (cell phones, PDAs, I-Phones, Blackberries, other texting devices, laptops, I-pods) must be completely turned off during class time. Upon request, you must comply and put your device on the table in off mode and FACE DOWN. You might also be asked to deposit your devices in a designated area in the classroom. Videotaping faculty lectures is not permitted due to copyright infringement regulations. Audiotaping may be permitted if approved by the professor. Use of any recorded or distributed material is reserved exclusively for the USC students registered in this class.

Academic Conduct

Plagiarism – presenting someone else's ideas as your own, either verbatim or recast in your own words – is a serious academic offense with serious consequences. Please familiarize yourself with the discussion of plagiarism in *SCampus* in Section 11, *Behavior Violating University Standards* <https://scampus.usc.edu/1100-behavior-violating-university-standards-and-appropriate-sanctions/>. Other forms of academic dishonesty are equally unacceptable. See additional information in *SCampus* and university policies on scientific misconduct, <http://policy.usc.edu/scientific-misconduct/>.

Discrimination, sexual assault, and harassment are not tolerated by the university. You are encouraged to report any incidents to the *Office of Equity and Diversity* <http://equity.usc.edu/> or to the *Department of Public Safety* <http://capsnet.usc.edu/department/departement-public-safety/online-forms/contact-us>. This is important for the safety of the whole USC community. Another member of the university community – such as a friend, classmate, advisor, or faculty member – can help initiate the report or can initiate the report on behalf of another person. *The Center for Women and Men* <http://www.usc.edu/student-affairs/cwm/> provides 24/7 confidential support, and the sexual assault resource center webpage <https://sarc.usc.edu/reporting-options/> describes reporting options and other resources.

Academic Integrity

USC seeks to maintain an optimal learning environment. General principles of academic honesty include the concept of respect for the intellectual property of others, the expectation that individual work will be submitted unless otherwise allowed by an instructor, and the obligations both to protect one's own academic work from misuse by others as well as to avoid using another's work as one's own. All students

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are expected to understand and abide by these principles. *SCampus*, the Student Guidebook, (www.usc.edu/scampus or <http://scampus.usc.edu>) contains the University Student Conduct Code (see University Governance, Section 11.00), while the recommended sanctions are located in Appendix A.

Students will be referred to the Office of Student Judicial Affairs and Community Standards for further review, should there be any suspicion of academic dishonesty. The Review process can be found at: <http://www.usc.edu/student-affairs/SJACS/>. Failure to adhere to the academic conduct standards set forth by these guidelines and our programs will not be tolerated by the USC Marshall community and can lead to dismissal.

Support Systems

Students whose primary language is not English should check with the *American Language Institute* <http://dornsife.usc.edu/ali>, which sponsors courses and workshops specifically for international graduate students. *The Office of Disability Services and Programs* http://sait.usc.edu/academicsupport/centerprograms/dsp/home_index.html provides certification for students with disabilities and helps arrange the relevant accommodations. If an officially declared emergency makes travel to campus infeasible, *USC Emergency Information* <http://emergency.usc.edu/> will provide safety and other updates, including ways in which instruction will be continued by means of blackboard, teleconferencing, and other technology.

Students with Disabilities

The Office of Disability Services and Programs (www.usc.edu/disability) 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 STU 301 and is open 8:30 a.m.–5:00 p.m., Monday through Friday. The phone number for DSP is (213) 740-0776. For more information visit.

Emergency Preparedness/Course Continuity

In case of a declared emergency if travel to campus is not feasible, the *USC Emergency Information* web site (<http://emergency.usc.edu/>) will provide safety and other information, including electronic means by which instructors will conduct class using a combination of Blackboard, teleconferencing, and other technologies.

V. COURSE SCHEDULE

This schedule may change due to changes in guests' schedules, and additional readings may be distributed during the semester.

CR = course reader (available electronically through Harvard Business School Publishing - <https://cb.hbsp.harvard.edu/cbmp/access/47887033>)

BB = Readings available on Blackboard.

	Topics/ Daily Activities/Guest Lecturers	Required Readings	Deliverables & Due Dates
Week 1 Thu, Mar 10, 2016	Analysis of the Life Science Industry; Key points: Where the money flows; regulation; how to characterize the industry; unique, common features of	BB: Battelle_Bio_2014; BB: EvaluatePharma World Preview 2015, Outlook to 2020. CR: Stan Lapidus: Profile of a	

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	different biotech industry segments.	Medical Entrepreneur (9-805-087);	
Week 2 Thu, Mar 24, 2016	Timelines, Costs Risks, and Regulation of life science products	BB: DiMasi JA, Hansen RW, Grabowski HG. The price of innovation: new estimates of drug development costs. <i>J Health Econ.</i> 2003 Mar;22(2):151-85. BB: Russell (2015) Investor Drought and Regulatory Headwinds Slow Device Innovation <i>Health Affairs</i> , 34:199-202. BB: DiMasi, JA Cost of Developing a New Drug (2014) BB: Witten, et al. (2008) Overview of FDA Regulatory Process. Ch. 81 <i>in: Principles of Regenerative Medicine</i> . Pp. 1366-1385. CR: Targanta	Team 5 Presentation
Week 3 Mar 31, 2016	Follow the money (1) - M/A, spinouts, corporate partnerships	BB: Celgene GlobalData 2014; BB: Celgene_Nogra License Agreement (2014)	Memo A Due - start of class <i>If you selected Memo A, it is due.</i> Team 6 Presentation
Week 4 Apr 7, 2016	Intellectual Property basics; strategic decisions; when problems occur Ms. Kari Barnes , Senior Counsel, Intellectual Property Practice Group, Buchalter Nemer	CR: Technical Note: Innovation and Invention--A Patent Guide for Inventors and Managers. James G. Conley; David Orozco M. CR: Evaluate Commercial Viability R. Herzlinger (2015) TARGANTA CASE	Team 7 Presentation
Week 5 Apr 14, 2016	Technology ecosystem - Academic research, technology transfer, and the "Valley of Death" Jonathan Lasch, PhD , Executive Director, Alfred E. Mann Institute for Biomedical Engineering at USC (AMI-USC)	CR: U.S. Universities and Technology Transfer. Richard G. Hamermesh; Josh Lerner; Phillip Andrews. (2011) CR: Syndexa and Tech Transfer Harvard (2009)	Memo B Due - start of class <i>If you selected Memo B, it is due.</i> Team 8 Presentation
Week 6 Apr 21, 2016	Follow the money (2) - grants, insurers, physicians, corporate partners, patients; who is the customer? IPO's	BB: Targanta S1 Document (2007)	Memo C Due - start of class <i>If you selected Memo B, it is due.</i>

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			Team 9 Presentation
Week 7 April 28, 2016	Teams 1-4 Final Presentations Mr. Gary Hutchinson , Entrepreneur- in-Residence, AMI@USC		Memo D Due - start of class <i>If you have not submitted Memo A or Memo B or Memo C, you must select Memo D and it is due at the start of this class.</i>
May 5	Final Project due by 5pm May 5, 2016		

APPENDIX 1

**BAEP 561:
Entrepreneurship in Innovative Industries: Life Sciences
Spring 2016
Professor Schmid**

List of Required Materials

Electronic course reader on Harvard website:

<https://cb.hbsp.harvard.edu/cbmp/access/47887033>

- Stan Lapidus: Profile of a Medical Entrepreneur
- Technical Note: Innovation and Invention--A Patent Guide for Inventors and Managers.
- Evaluate Commercial Viability
- U.S. Universities and Technology Transfer
- Syndexa and Tech Transfer at Harvard
- Targanta

To be distributed through Blackboard:

- Battelle_Bio_2014
- EvaluatePharma Pharmaceutical & Biotech Half-Year Review 2014
- EvaluatePharma World Preview 2015
- Witten, et al. (2008) Overview of FDA Regulatory Process. Ch. 81 in: Principles of Regenerative Medicine. Pp. 1366-1385.
- Celgene GlobalData 2014;
- Celgene_Nogra License Agreement (2014)
- Targanta S1 Document (2007)
- DiMasi JA, Hansen RW, Grabowski HG. The price of innovation: new estimates of drug development costs. J Health Econ. 2003 Mar;22(2):151-85.
- DiMasi, JA (2014) Cost of Developing a New Drug
- Russell (2016) Investor Drought and Regulatory Headwinds Slow Device Innovation Health Affairs, 34:199-202

Additional supplementary readings will be supplied through the course and posted on Blackboard

APPENDIX 2

BAEP 561:

ENTREPRENEURSHIP IN INNOVATIVE INDUSTRIES: LIFE SCIENCES

Your name: _____

Your signature: _____

SELF-EVALUATION OF YOUR PARTICIPATION IN THE COURSE DURING THE SEMESTER

IMPORTANT:

- Please consider how frequently and insightfully you have participated in class and whether you have been well-prepared on readings and cases.
- Do not take into account your number of missed classes or volunteering for presentations; I will adjust for those separately.

PARTICIPATION COUNTS FOR 100 POINTS OUT OF 1,000 IN THE OVERALL COURSE EVALUATION.

Mark an "X" for the category you think you belong in	Description	Explanation
	<i>Top participation (100 points) Grade equivalent: A</i>	<i>You are in the top 5-10% of participating students, i.e., there are only a few other students in the class who have participated more actively or equally actively. You have been well prepared for class discussions in every class. Your comments have usually been insightful.</i>
	<i>Very good participation (90 points) Grade: A-</i>	<i>You have tended to offer frequent comments or questions in every class. You have been well prepared for class discussions in nearly every class. If cold-called, you have been able to provide an insightful, well-prepared comment.</i>
	<i>Good participation (80 points) Grade: B+</i>	<i>You have offered at least one comment or question in almost every class, and have been well prepared for discussions most of the time. If cold-called, you have been able to provide a well-prepared comment.</i>
	<i>Low participation (70 points) Grade: B</i>	<i>In general, you have spoken up only when cold-called, but have occasionally offered a comment or question proactively. If cold-called, you have not always been able to provide a well-prepared comment.</i>
	<i>Lowest participation (60 points) Grade: B-</i>	<i>There are only a few other students in the class who have participated less actively. In general, you have spoken up only when cold-called and have not been prepared.</i>

YOU MAY USE THE SPACE BELOW AND THE REVERSE SIDE OF THIS FORM TO ADD ANY COMMENTS ON YOUR PARTICIPATION PERFORMANCE OR TO EXPLAIN YOUR CHOICE OF CATEGORY ABOVE.