

U80-CRM 529-31: Industry Partnering: Collaborations in Translational Research
Syllabus

Farrell Teaching Center
January 13 – May 5, 2015
Tuesday: 5:30 – 8:00 PM

Instructor: Carl Siekmann, MBA
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I. Course Overview

Innovative new products are the life blood of the biopharmaceutical industry. In the U.S., most discovery research originates at the university level and is transferred via licensing agreements to industry partners or to start-up biotech companies for final development and commercialization. The process of moving this innovation from the lab to industry and then to the patient is the focus of this course. The course examines the market for intellectual property that exists between academic institutions and the private sector and explores commercialization of translational research through collaboration with industry partners. In addition to studying the complex relationship between science and business, the course employs a case study methodology to illustrate specific examples of the translational process from lab to marketed product.

Amongst topics to be explored during the semester will be:

- The history of the biopharmaceutical industry: key scientific, business, public policy events.
- The integration of business and science: inherent conflicts; industrializing science.
- The emergence of the modern biotechnology industry.
- The role of public policy and pharmaceutical industry trends in shaping the funding of university-based research.
- Risk and the development process for therapeutics.
- Financing R&D and the capital markets.
- Fundamentals of Licensing, strategic partnering.
- The scientific entrepreneur and biotech startup companies.
- The rapid cadence of innovation
- The need for greater technological integration.
- Strategic principles and business models for R&D development and commercialization.
- The economics and financing of innovation through capital markets and monetizing intellectual property.
- Technology transfer from universities to the private sector.
- Translational research: funding, developing, and commercializing.
- The interaction of academic institutions and private companies.
- The importance of intellectual property and the market for medical know-how.
- Proof of concept vs. proof of *relevance*

II. Class Schedule

1. **Course Introduction** **Jan 13**
 - Course Policies and Procedures
 - Syllabus review.
 - Biopharma industry Introduction- definitions, overview, industry composition.

2. **Industry Overview and Structure (US)** **Jan 20**
 - Industrializing science
 - History of biopharma to 1976.

Reading: Pisano, preface, Ch.1. Guide to Biotech 2008: *Timeline*, pp. 6-14.

3. **History of Biotech** **Jan 27**
 - 1976 to Present (Science, Public policy, Business)
 - Case Study

Reading: Pisano, Ch 2; Xanadu Case Study: “The Race to Develop Human Insulin”.

4. **Drug R&D and Scientific Breakthroughs** **Feb 3**
 - The early years of drug science.
 - Breakthroughs, key technologies .
 - The drug R&D process

Reading: Pisano, Ch 3; Guide to Biotech 2008: pp. 18-40

5. **Risk and The Drug R&D Process** **Feb 10**
 - Therapeutics, diagnostics, devices.
 - Therapeutics development: risk and reward.
 - Case study: Pharmacocyclics

Reading: Pisano, Ch 4. Case Study: “*Pharmacocyclics*”, Xanadu pack.

6. **Industry Economics and Finance Basics (test)** **Feb 17**
 - History and anatomy of biotech segment of pharmaceutical industry
 - Financing R&D
 - **Take home test**

Reading: Pisano Ch.5. Case Study- “*The Pharma Industry: Challenges in a New Century*”.

- NO CLASS FEBRUARY 24**

7. **Industry Economics: Market for Medical Know-how. Delivery on the Promise** **March 4**
 - Creating the market for medical know how
 - Industry financing and Industry financial performance.

Reading Pisano: Chapter 6; Xanadu: “*Genzyme*” Case Study.

SPRING BREAK

March 10

8. **Patents, Monetizing Intellectual Property** **March 17**
- Definitions, concepts, history, monetizing IP.
- Reading:** Pisano Ch. 7. Xanedu: *Millennium* “Case Study.
9. **University Technology Transfer and translational research** **March 24**
- Guest Lecture: Dr. Brad Castanho, Dir. Washington U. Office of Tech. Mgmt.
 - Case Study Discussion
- Reading:** Xanedu: *Mass General* Case Study.
10. **University Technology Transfer: A Toolkit Company** **March 31**
- Guest lecturer, Dr. John Mc Alister, Former CEO, Tripos.
 - Case Study discussion, *The Langer Lab*
- Reading:** Xanedu: “*The Langer Lab*”
11. **Case Study and Test** **April 7**
- Case study discussion: “Enbrel”
 - **Take home test**
- Reading:** Xanedu: “*Enbrel*” case study.
12. **Strategic Principles and Business Models** **April 14**
- Biopharma business models
 - Case Study
- Reading:** Pisano Ch 8. Xanedu: Case Study: *Vertex and the CFF*’
13. **Future of Biopharma / Healthcare Case Studies - Licensing** **April 21**
- Industry improvements. Do you agree with Pisano? The future of pharma biotech.
 - Case Study
- Reading:** Pisano Ch 9. Xanedu: Case Study: “*Merck Evaluation of a Licensing Candidate*”.
14. **Proof of Relevance vs. Proof of Concept** **April 28**
- Lecture/Discussion.
 - Case Study
- Reading:** Xanedu Case Study:
15. **Student Case Study Presentations (paper due)** **May 5**
- Student presentations
- Reading:** Xanedu Case Studies (TBA)
16. **Final Exam** **Take Home**

III. Required Reading:

Required texts available at the Barnes and Noble Bookstore at the Med School:

1. Pisano, Gary P., *Science Business*, Harvard Business School Press, 2006.
2. *U80-529-31: Industry Partnering*. Case Study Package, Xanadu Publishing, 2015.
3. Students can order texts online at www.wubookstore.com. Books can be shipped.

Required readings on Blackboard:

1. Guide to Biotechnology 2008
Select posted articles and publications.

Suggested Reading Online:

1. Biotechnology Industry Organization (“BIO”) Website:
<http://bio.org>

IV. Grading

One paper with presentation	= 25%
Two tests	= 15% each = 30%
Final exam	= 25%
Classroom participation	= 20%

Pass/Fail

If you are taking the course on a Pass/Fail basis, you must earn a final grade of a C or higher in order to receive a Pass.

Incomplete

Under unusual and unexpected personal or professional circumstances resulting in extended absence in the last several weeks of the semester and inability to complete the final exam, a student may be eligible to receive an Incomplete. The instructor may authorize an Incomplete upon receipt of the University College Incomplete form which must be signed and submitted prior to the end of the semester. Normally, an Incomplete will be changed to a letter grade if warranted, only if all required work is submitted within 60 days after the end of the semester.

V. Written Assignments

One short written paper will be assigned during the semester. This paper will require the student to demonstrate a familiarity with key concepts of the biotech industry and to display an ability to present these concepts in a persuasive argument in support of a specific point of view.

VI. Attendance

Attendance at every class session is required unless unexpected personal or work circumstances prevent you from attending. In case of excused absences, please contact me prior to the class meeting so that we can discuss the situation, including arrangements for obtaining classroom notes and assignments. Two or more unexcused absences will drop the final course grade by at least one full letter grade. Excessive unexcused absences may result in a failing grade. It should be emphasized that each weekly class session in University College is equivalent to three class sessions in the day school program. Students with four or more absences, excused or unexcused, are encouraged to withdraw from the course.

VII. Contact Info

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314-479-7222

Please feel free to contact me by e-mail or phone with quick questions. For longer conversations, please e-mail me to schedule an appointment. I will also be available before and after class.

VIII. Academic Integrity and Plagiarism

Students at Washington University are expected to adhere to the highest standards of behavior. Plagiarism, copying from other students, and other forms of cheating will not be tolerated. It is dishonest and a violation of student academic integrity if you plagiarize, cheat on an examination, copy or collaborate on assignments without permission, fabricate or falsify data or records, or engage in other forms of deceit or dishonesty. Complete information about the University's Academic Integrity Policy may be found at <http://artsci.wustl.edu/~college/Policies/>, click on "Academic Integrity Policy".

All violations of standard rules of academic integrity will be reported to and investigated by the Dean of University College. If it is determined that you have acted dishonestly, or even if you have admitted the charges prior to a formal investigation or hearing, an appropriate sanction will be imposed, including automatic failure of the assignment or course, or in the case of serious or repeat violations, suspension or expulsion from the University. Withdrawing from a course will not prevent the Dean from imposing or recommending sanctions. If you observe another student violating this policy, you have a responsibility to confront the student, report the misconduct to the instructor, and/or seek advice from an appropriate dean or academic integrity officer.

Internet Plagiarism

The Internet makes it easy to cheat, and to detect plagiarism. Additionally, Internet sources, because they are so easily accessed and reproduced, are mistakenly viewed as general or public knowledge, which does not typically require formal attribution. It is important to be absolutely clear that, while the Internet may blur the distinction between public and private, *policies concerning academic integrity, intellectual property, and proper citation apply equally to electronic, online, and conventional print resources*. For information about rules and styles for citing electronic media, including examples, please review the following Websites:

For additional information, definitions of plagiarism, guidelines for writing and research, examples of proper citation, and practical tips on avoiding conventional and Internet plagiarism, please visit the following Web sites:

www.plagiarism.org, click on "Research Resources" and "Citation."

<http://wpacouncil.org>, click on "WPA Guide," then "WPA Position Statements and Resolutions," then "Defining and Avoiding Plagiarism: the WPA Statement on Best Practices."

<http://www.artsci.wustl.edu/~writing/hints>, click on "Helpful Hints," then "Plagiarism: What it is and how do I avoid it?"

<http://www.lib.berkeley.edu/TeachingLib/Guides/Internet/Style.html>

<http://www.apastyle.org/electref.html>

IX. Special Needs and Disabilities

Washington University is committed to providing equal opportunity for students with disabilities. The Disability Resource Center (DRC) assists students with disabilities by providing services and arranging for reasonable accommodations to ensure equal access and equal academic opportunities. Students wishing to request services or accommodations must register and provide appropriate documentation to the DRC. The DRC serves as a resource and advisor to students with disabilities and welcomes opportunities to consult with students, families, faculty, and staff.

Faculty members are responsible for providing to students reasonable accommodations as recommended by the DRC. Faculty members who have questions or concerns about accommodations should contact the director of The Disability Resource Center, located in Cornerstone, Gregg Hall, South 40, (314) 935-4062, or the Dean's office, (314) 935-4806.

X. Notice

This syllabus may be modified during the course of the semester by the instructor to better meet the course goals and the needs of the students. Any revisions will be posted on the course Website and announced in class. It is the responsibility of each student to become aware of any such changes.