FLORIDA ATLANTIC UNIVERSITY™

Graduate Programs—NEW COURSE PROPOSAL

UGPC APPROVAL _____
UFS APPROVAL _____
SCNS SUBMITTAL _____
CONFIRMED _____
BANNER POSTED _____
ONLINE _____
MISC _____

DEPARTMENT NAME: MANAGEMENT PROGRAMS | **COLLEGE OF: BUSINESS**

RECOMMENDED COURSE IDENTIFICATION:

PREFIX _____ENT_____ **COURSE NUMBER** ____6188____ **LAB CODE** (L or C) _____

(*TO OBTAIN A COURSE NUMBER, CONTACT ERUDOLPH@FAU.EDU*)

COMPLETE COURSE TITLE: BIOTECHNOLOGY BUSINESS DEVELOPMENT

EFFECTIVE DATE
(first term course will be offered)

_____**FALL 2010**_____

CREDITS: 3

TEXTBOOK INFORMATION: ***SCIENCE BUSINESS: THE PROMISE, THE REALITY, AND THE FUTURE OF BIOTECH,*** **FIRST EDITION BY GARY P. PISANO (HARVARD BUSINESS SCHOOL PRESS, ISBN 1-59139-840-1)**

GRADING (*SELECT ONLY ONE GRADING OPTION*): **REGULAR** ___X___ **PASS/FAIL** _____ **SATISFACTORY/UNSATISFACTORY** _____

COURSE DESCRIPTION: BIOTECHNOLOGY IS THE APPLICATION OF BASIC SCIENCE DISCOVERIES TO MEDICINE, AGRICULTURE, AMD THE ENVIRONMENT. BIOTECH COMPANIES ARE FORMED AROUND BIOTECHNOLOGY APPLICATIONS AND THESE COMPANIES INVOLVE BOTH SCIENCE AND BUSINESS. THE GOAL OF THIS COURSE IS TO UNDERSTAND THE RELATIONSHIP BETWEEN BIOTECH BUSINESS AND BIOTECH SCIENCE.

PREREQUISITES W/MINIMUM GRADE:*	**COREQUISITES:**	**OTHER REGISTRATION CONTROLS (MAJOR, COLLEGE, LEVEL):**
NONE	**NONE**	**GRADUATE STANDING**

PREREQUISITES, COREQUISITES & REGISTRATION CONTROLS SHOWN ABOVE WILL BE ENFORCED FOR ALL COURSE SECTIONS.

**DEFAULT MINIMUM GRADE IS D-.*

MINIMUM QUALIFICATIONS NEEDED TO TEACH THIS COURSE: PH.D. IN SCIENCE OR EQUIVALENT AND BUSINESS EXPERIENCE

Other departments, colleges that might be affected by the new course must be consulted. List entities that have been consulted and attach written comments from each.

Gary Castrogiovanni, castrogi@fau.edu, (561) 297-2523_____
Faculty Contact, Email, Complete Phone Number

SIGNATURES

Approved by:	***Date:***
Department Chair: _____	_____
College Curriculum Chair: _____	_____
College Dean: _____	_____
UGPC Chair: _____	_____
Dean of the Graduate College: _____	_____

SUPPORTING MATERIALS

Syllabus—must include all details as shown in the UGPC Guidelines.

Written Consent—required from all departments affected.

Go to: *http://graduate.fau.edu/gpc/* to download this form and guidelines to fill out the form.

Email this form and syllabus to *sfulks@fau.edu* and *eqirjo@fau.edu* one week ***before*** the University Graduate Programs Committee meeting so that materials may be viewed on the UGPC website by committee members prior to the meeting.

Biotechnology Business Development

Gary Castrogiovanni
Email: castrogi@fau.edu
Phone: (561) 297-2523
Office: DS 207D
Office Hours: Mon. 4:00-7:00 p.m.

ENT 6188 **3 Credits**

Course Description

This course focuses on the critical decisions and action steps that entrepreneurs must make in both planning and executing a new venture. Students develop new venture implementation plans, and learn how to manage their execution.

Prerequisites: None.
Corequisites: None.
Other Requirements: Graduate Standing.

Primary Learning Outcomes

Global Goal. To understand the relationship between biotech business and biotech science.

Instructional Objectives. Biotechnology is an applied science that transforms basic science discoveries into practical uses. Disciplines that typically benefit from biotechnology are agriculture, medicine, non-food agriculture (biofuels) and the environment. All four disciplines have some of the same components; science and improving needs of humanity, but all are also driven by a business component. To understand the relationship of business and biotechnology is the goal of this course.

Course Materials

Required Textbook:

> *Science Business: The Promise, the Reality, and the Future of Biotech*, First Edition by Gary P. Pisano (Harvard Business School Press, ISBN 1-59139-840-1)

Supplementary Materials:

> Recent research and review papers, which will be posted on blackboard or given as handouts.

Method of Instruction

A combination of lectures, classroom exercises, single and group assignments, discussion, and presentations will be used.

Grading

The student will be assessed on their roll play in each of four positions during company simulations, as a new company scientist, as a new company business person, as an acquiring/licensing company scientist and as an acquiring/licensing company business person.

Roll/Activity	100%
NewCo Scientists	20
NewCo Business person	20
BigCo Scientists	20
BigCo Business person	20
Class Participation	10
Attendance	10

Final course grades will be determined according to the following scale:

- A = 90-100%
- B = 80-89%
- C = 70-79%
- D+ = 60-69%
- F = <60%

(Grades may be curved to adjust to 100%.)

It is the responsibility of the student to withdraw from this class, should that status be desired - the instructor cannot withdraw students from the course. The instructor will not give the grade of "I" in lieu of a grade of "D" or "F". The grade of "I" will be considered only in exceptional cases (such as serious illness) for students who are presently performing at a "C" or higher level in the course.

Graded Activities

Roll Playing. Each student will be assigned a roll in a company in each four different fictitious biotech company scenarios that each student group will develop. The goal is for each student to play a different roll in each of the four scenarios and to be graded on each roll as outlined above in the assessment section. This will provide the student a chance to see what it is like to be in four different rolls involving the business of biotech companies. The assignments will be made early in the course so that each group can formulate their company and strategies and each student can prepare for their roll.

Class Participation. Participation in class will be assessed based on reasonable questions asked in class or after class for each lecture session.

Attendance. Students are expected to attend all scheduled classes. If a student misses a class they are responsible for ALL the material covered during that class, including lecture material and rules and regulations about the course.

Course Policies

Students in this course are expected to conform to all university policies. Additionally, students should note the following.

HONOR CODE

Students at Florida Atlantic University are expected to maintain the highest ethical standards. Academic dishonesty, including cheating and plagiarism, is considered a serious breach of these ethical standards, because it interferes with the University mission to provide a high quality education in which no student enjoys an unfair advantage over any other. Academic dishonesty is also destructive of the University community, which is grounded in a system of mutual trust and places high value on personal integrity and individual responsibility. Harsh penalties are associated with academic dishonesty. For more information, see http://www.fau.edu/regulasitons/chapter4/4.001 Honor Code.pdf

STUDENTS WITH DISABILITIES

In compliance with the Americans with Disabilities Act (ADA), students who require special accommodations due to a disability to properly execute coursework must register with the Office for Students with Disabilities (OSD) located in Boca Raton, SU133 (561-297-3880), in Davie-MOD 1 (954-236-1222), in Jupiter SR117 (561-799-8585) or at the Treasure Coast- CO 128 (772-873-3305), and follow all OSD procedures.

Tentative Course Schedule

Week *Topic*

1 Course Introduction

2 Business in the context of biotechnology

- Overview of biotechnology field
- Biotechnology as a function of science and business
- Company structures versus other non-biotech companies
- Functional units

Groups will be assigned

3 Company structure and functions

- Science/development, the idea and its development
  - Pharmaceutical drug development
  - Medical device product development
  - Technology product development
  - Other biotech product development, such as biofuels, bioengineered foods, etc.
- CEO/CFO, the funding
  - Sources of funding
  - Obligations
  - Exit strategy for funding entities

4 Company structure and functions (cont'd)

- Legal
  - Patents
  - Confidentiality
  - Licensing agreements
- Business Development/Licensing
  - Strategy
  - Business plan
  - Marketing
  - Business dealing

5 ***Roll-Play #1: New company simulations with presentations and discussions***

6 Business Development and Licensing company organizations

- Department structure and function
  - Business Development and Licensing
    - Business versus science
    - Technology versus compound v product/business
    - Staff experience
  - Staff dedicated versus borrowed
  - Business Development and Licensing support
- Licensing data
  - How much licensing going on in biotech field?
  - Why is there a licensing need?
- Licensing strategy
  - Basic hurdles: IP type, drug class, use, development stage
  - Positive list
  - Negative list

7 Business Development and Licensing company organizations (cont'd)

- Seek
  - Sources
  - Types of items to license
- Evaluate
  - Preliminary
  - Due diligence
- Scientific input

8 ***Roll-Play #2: New company simulations with presentations and discussions***

9 Business Development department functions

- Commercial/financial evaluation
  - What is included?
  - Where do the deal dollar amounts originate?
  - Where does mergers and acquisition fit in?
- Negotiation
  - Term sheet
  - Give and take
  - Pathway to approval with companies, licensor and licensee
- Done deal, what does it mean?
  - Bio dollars versus real dollars
  - Key biotech requests

10 Business Development department functions (cont'd)

- Miscellaneous
  - Alliance management
  - Mergers and Acquisitions
  - Deal outliers and why

11 ***Roll-Play #3: New company simulations with presentations and discussions***

12 Other company functions

- Marketing/Sales
- Marketing research
- Competitive intelligence
- Manufacturing

13 Case studies

- Company
- Licensing/partnering

14 Careers in biotechnology and general discussion

15 ***Roll-Play #4: New company simulations with presentations and discussions***

Final Course Wrap-Up and Debriefing Session (during the Final Exam Period per the University schedule)

Key dates are highlighted in ***bold and italics*** above. It is imperative that you participate in those sessions. *Late assignments are unacceptable.* If you must miss one of the role play sessions, the instructor may give a make-up assignment at his/her discretion, depending on your reason for missing and when you contacted the instructor to explain why you missed and to see if you would be allowed a makeup assignment.

Additional Reading

AGGARWAL, S. 2007. What's fueling the biotech engine? Nature Biotechnology 25: 1097.

ANNONOMOUS. 2007. Abbott molecular business overview, Des Plaines, IL., 18p

_____. 2008. Speed of integration improves M&A success, 38p.

ASCHWANDEN, C. 2008. Managing to Excel at Science. Cell 132: 911.

BULLEN, A. 2008. Microscopic imaging techniques for drug discovery. Nature Review Drug Discovery 7: 54.

COOK, V. J., JR., W. MOULT, J. SPAETH. 2007. Marketing meets finance. 48p.

COOPER, T., R. MARCELLO, B. ANIMASHAUN. 2008. The changing face of R&D in the future pharmaceutical landscape. Deloitte Life Sciences and Health Care, New York City, New York, 9p.

CZEREPAK, E. A., S. RYSER. 2008. Drug approvals and failures: implications for alliances. Nature Review Drug Discovery 7: 197.

DICKSON, M., J. P. GAGNON. 2004. Key factors in the rising cost of new drug discovery and development. Nature Review Drug Discovery 3: 417.

DOOLEY, J. F., III, J. F. DOOLEY, JR. 2009. Convincing a venture capitalist to invest in your idea. Bioentrepreneur May 27.

EHLERS, M. R. 2008. Pacific Biomarkers, Inc. Biomarkers in Medicine 2: 221.

ESPOSITO, R. S., M. J. OSTRO. 1999. Strategic consolidation: The biotechnology business model for the 21st century. Nature Biotechnology 17: BE16.

KARLBERG, J. P. E. 2008. Trends in disease focus of drug development. Nature Review Drug Discovery 7: 639.

KOCH, W. H. 2004. Technology platforms for pharmacogenomic diagnostic assays. Nature Review Drug Discovery 3: 479.

KOLA, I., J. LANDIS. 2004. Can the pharmaceutical industry reduce attrition rates? Nature Review Drug Discovery 3: 711.

KOSS, A.-M. 2007. Best practice guidance for angel groups - deal structure and negotiations. New York University, New York City, New York, 12p.

KRAMER, J. A., J. E. SAGARTZ, D. L. MORRIS. 2007. The application of discovery toxicology and pathology towards the design of safer pharmaceutical lead candidates. Nature Review Drug Discovery 6: 636.

LAWRENCE, S. 2009. Compensation continues rise. Nature Biotechnology 27: 14.

LOU, K., M. DE ROND. 2006. The 'not invented here' myth. Nature Review Drug Discovery 5: 451.

MATHER, J. 2008. Moving on. Nature Biotechnology 26: 1.

NICOLL, D., W. M. DETMER. 1997. Basic principles of diagnostic test use and interpretation. In L. M. Tierney, Jr., S. J. McPhee, and M. A. Papadakis [eds.], Current Medical Diagnosis & Treatment 1997. Appleton & Lange.

PARKER, B., C. WENDIN, C. WHITTENMORE. 2005. Personalized medicine: the emerging pharmacogenomics revolution, New York City, New York, 40p.

PISANO, G. P. 2006. Science Business: The Promise, The Reality, and The Future of Biotech. Harvard Business School Press, Boston, MA, 237p.

PRESS, M., S. SEELIG. 2007. Lessons learned from Her-2 testing and Herceptin, 27p.

RAWLINS, M. D. 2004. Cutting the cost of drug development? Nature Review Drug Discovery 3: 360.

ROBBINS, N. W. 2007. Strength in numbers. American Venture Magazine Q3-2007: 28.

RYAN, T. P., J. L. STEVENS, C. E. THOMAS. 2008. Strategic applications of toxicogenomics in early drug discovery. Current Opinion in Pharmacology 8: 654.

RYCHLIK, B., M. DOPIERRO. 2009. Executive compensation at private life science companies in trouble economic times. Nature Biotechnology 27: 98.

SCHNEIDER, C. K., G. SCHAFFNER-DALLMAN. 2008. Typical pitfalls in applications for marketing authorization of biotechnological products in Europe. Nature Review Drug Discovery 7: 893.

SHUKLA, R. 2008. Entrepreneurial outreach. Nature Biotechnology 26: 265.

SKUKLA, R. K., C. PACHON, M. CHEIM. 2008-09. Federal technology funding guide: A Guide to Navigating Government Programs Supporting Innovation R&D & Beyond, 215p.

SRINIVASAN, R. 2008. Biomarkers-A paradigm shift in Drug Discovery to Development, 11p.

SWEN, J. J., T. W. HUIZINGA, H. GELDERBLOM, E. G. E. DE VRIES, W. J. J. ASSENDELFT, J. KIRCHHEINER, H.-J.

GUCHELAAR. 2009. Translating pharmacogenomics: challenges on the road to the clinic. PLosMed 4: e209.

TERSTAPPEN, G. C., C. SCHLUPEN, R. RAGGIASCHI, D G. GAVIRAGHI. 2007. Target deconvolution strategies in drug discovery. Nature Review Drug Discovery 6: 891.

TURNER, L. 1999. Building a better biotech company. Nature Biotechnology 17: BE5.

VISTOLI, G., A. Pedretti, B. Testa. 2008. Assessing drug-likeness - what are we missing? Drug Discovery Today 13: 285.

WEISS, S. T., H. L. MCLEOD, D. A. FLOCKHART, M. E. DOLAN, N. L. BENOWITZ, J. A. JOHNSON, M. J. RATAIN, K. M. GIACOMINI. 2008. Creating and evaluating genetic tests predictive of drug response. Nature Review Drug Discovery 7: 568.

WILLIAMS, S. A., D. E. SLAVIN, J. A. WAGNER, C. J. WEBSTER. 2006. A cost-effectiveness approach to the qualification and acceptance of biomarkers. Nature Review Drug Discovery 5: 897.

WILLMANN, J. K., N. VANBRUGGEN, L. M. DINKELBOR, S. S. GAMBHIR. 2008. Molecular imaging in drug development. Nature Review Drug Discovery 7: 591.

YESKEL, A. 2007. Excerpts from a benchmarking study of in-licensing in the pharmaceutical industry, New York City, New York, 12p.