

**California State University, Channel Islands
COURSE SYLLABUS**

Faculty: **Maria Silva Elipe (MSE), PhD, Department of Chemistry;**
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Location: California State University Channel Islands (CSUCI)/Del Norte 1500

Time: Tuesdays: 6:00 – 8:50 pm

Office Hours : [Lu] Sage Hall 2151
Tuesday 5:15 – 6:00 pm, and 8:45 - 9:00 pm, OR by appointment
[Silva Elipe] Solano Hall 2124
Tuesday 4 :50-5 :50 pm (Days of MSE lectures only, but available upon request other Tuesdays)

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Exams: **MID-TERM EXAM:**
Tuesday, March 5 (week 7; 1st half of class)

FINAL EXAM:
Tuesday, May 14 (7:00 - 9:00PM)

Term Paper: Tuesday, April 9 (week 11), in class

Group Presentations: April 23, April 30, and May 7 (week 14, 15, and 16), in class

1. Course Description

The modern pharmaceutical industry has been one of the most innovative and dynamic sectors in the developed world. In the US, this industry has been praised by many for the science focused culture, the highly effective medicines against many previously untreatable diseases and conditions, the substantial and well compensated employment opportunities, and for being a global leader in net exports. On the other hand, the industry has no lack of critics, both in the US and globally. It has often been criticized for monopolist like pricing behavior, for engaging in unethical or illegal promotional activities for off-label usage of its products, and for under-reporting and misrepresenting important safety information. In this course, we will examine a number of aspects of this fascinating industry, including historical development, research methods and processes, regulatory hurdles, intellectual property issues, pricing and reimbursement, marketing, business ethics, generic and biosimilar drugs, and health outcomes research. Selected topics from these areas will be analyzed in depth.

It is hoped that the course will provide students with a better understanding of the industry: basic structures, common business strategies, and critical issues. It is also hoped that lessons from this industry may be applied to other sectors which rely on continuous innovations for survival. In addition, this course may also be useful for students who are interested in employment opportunities in the pharmaceutical industry.

2. Learning Objectives

- Understand the basic health science fundamentals and the industrial organization of pharmaceutical and biotechnology firms;
- Understand the R&D process and regulatory approval process in drug discovery and development, and appreciate the role of innovations in the longterm success of pharmaceutical firms including the patent system and its significance;
- Understand the commercialization of new pharmaceutical products, including the role of health insurance, basic marketing process, pricing and promotional strategy, and the economic evaluation of new medicines;
- Develop ability to learn, collaborate, and interact in a cross-disciplinary learning environment including working in multi-disciplinary teams;
- Understand industry best-practices in selected company and drug case studies and “the science of business & the business of science”

3. Value Proposition

Key value proposition of BUS ECON CHEM 341 is to demonstrate the value of the science-based, strongly R&D-driven pharmaceutical industry, and how deeply science (chemistry, biology, basic pharmacology), business, economics, and management are interconnected & integrated in this sector. The entire pharmaceutical value chain from basic research to product commercialization of both small molecules (chemistry) and large molecule biotherapeutics/biologics (biology) will be instructed, including high-level content, overall process, key milestones & decision points, best-practices and selected case studies.

4. Course Credit

Credit in BUS ECON CHEM 341 could be applied either as an elective course within the BS Business program (as BUS 341) or as an elective outside of the business program (as ECON 341 or CHEM 341). This course provides credit towards the Chemistry minor. Class target audience : Junior and Senior-level students, including, but not limited to, BUS ECON CHEM and STEM students. Underclassmen students with strong, college level academic records may be considered on a case-by-case basis.

5. Course Topics

The following broad topics will be covered in this course:

- **Overview of the Global Pharmaceutical Industry**
 - The BioPharma Industry (Big Pharma and Biotech)
 - Stages and phases of drug research and development (R&D)
 - Cost, risk, and timelines in BioPharma R&D
 - Mergers, acquisitions, and strategic alliances
 - Firm size and shifting business models

- **Introduction to US Healthcare System**
 - The organization of the US healthcare market
 - Health insurance and healthcare financing: Private
 - Health insurance and healthcare financing: Public
 - Health insurance and demand for pharmaceuticals
- **Discovery of Drug Targets and Drug Leads**
 - Historical sources of drug leads – natural products
 - New strategies for discovery – genomics and new technologies
 - Methods for drug discovery – from *in silico* to *in vivo*
 - Work processes and decision making in pharmaceutical R&D
 - Biologics drug discovery
- **Pharmaceutical Research and Development (R&D)**
 - Scientific methods in drug research and development
 - Lead optimization – chemical and biological approaches
 - Preclinical studies – efficacy, toxicity, ADME, and other factors
 - Pharmaceutical formulations and drug delivery systems
 - Biologics drug development
- **Clinical Trials**
 - The regulatory process – what is done in Phase I, II, and III trials
 - The role of the FDA – permissions, review, and oversight
 - Drug Safety and Pharmacovigilance (Phase IV or post-marketing trials)
- **Pharmaceutical Manufacturing and Production**
 - Scale-up from lab to pilot plant to full-scale manufacturing
 - The FDA and Good Manufacturing Practices (GMP) production
 - Work processes and decision making in scale-up and commercialization
 - The role of outsourcing in pharmaceutical development and manufacturing
 - Biologics manufacturing and production
 - Medical devices
- **Intellectual Property (IP) and Patent Protection**
 - The U.S. Patent System – requirements, process, and benefits
 - Patent life and market exclusivity for pharmaceutical products
 - The value and use of IP and patents - products, partnering, licensing
 - Landmark BioPharma patent cases at the US Supreme Court
- **Pricing of Pharmaceutical Products**
 - Basic Principles of Pricing
 - Value-based Pricing of Pharmaceutical Products
 - Price Regulations and Cost-Containment Efforts
 - Economic Evaluation of New Drugs
- **Sales and Marketing of Pharmaceutical Products**
 - The Marketing Process: What is it?
 - Channels of Pharmaceutical Promotions
 - Regulations of Pharmaceutical Promotions

- **The Rise of Generics and Biosimilars**
 - Historical development and growth in the U.S. and abroad
 - The regulatory pathway to generic pharmaceutical products
 - Regulatory policy and pathway for biosimilar products (Biosimilars)
- **Business Ethics**
 - Importance of Doing the Right Thing in Drug Development and Commercialization: what is legal vs. what is right
 - Company Vision, Mission, and Business Reality
 - Case studies in the pharmaceutical industry
- **A Look Ahead**
 - Affordable Care Act (Obamacare) and Future of Pharmaceuticals
 - Rise of Chinese and Indian Pharmaceutical Industries
 - Personalized Medicine (Pharmacogenomics): science and economics

6. Required Course Materials

[1] **“Science Lessons: What The Business of Biotech Taught Me About Management”** by Gordon Binder and Philip Bashe (Harvard Business Press, 2008). This book can be purchased online.

[2] **Cases (to be provided by instructors, posted on Canvas)** : All class materials including PowerPoint Presentations (PPTs), additional reading assignments, cases, final project, instructions for cases and projects etc., will be posted on **Canvas** <https://cilearn.csuci.edu/> in due time.

7. Recommended Course Materials

[1] **“Pharmaceutical Economics and Policy, 3rd edition”** by Stuart Schweitzer and Z. John Lu (Oxford University Press, 2018). This new book is written for upper division undergraduate and master level students in pharmaceutical economics, administration and public policy. Provides a good overview of key economic, scientific, regulatory, and policy issues facing the biopharmaceutical industry. If you have a serious interest in this industry, either for career or for graduate or professional school, this book is highly recommended. This book will also be useful for students who desire supplemental, written materials to help with their study. The book will be referred as S-LU 2018 in this syllabus.

[2] **“Devalued and Distrusted: Can the Pharmaceutical Industry Restore its Broken Image?”** by John LaMattina (John Wiley & Sons 2012). This recommended book discusses a number of issues facing the pharmaceutical industry from the perspective of a former industry executive. It will be quite useful to consult with when you write the term paper. Short in length and inexpensive in price.

[3] **“2015 Profile of the Biopharmaceutical Research Industry”**; Pharmaceutical Research and Manufacturing Association; Washington, DC. This annual report contains lots of useful and current statistics and information for the industry. Posted on **Canvas**.

[4] **“Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs”**; Joseph DiMasi (Tufts Center for the Study of Drug Development, 2014) This briefing provides an

overview of the costs, timelines, and risks involved in developing a new drug product. Posted on [Canvas](#).

It is also recommended that you periodically check on the following sources for up-to-date news and research materials for your book report and the class project: **FierceBiotech** (www.fiercebiotech.com), and **FiercePharma** (<http://www.fiercepharma.com>), both of which have a free daily subscription newsletter/blog. Also, *The Economist*, *Business Week*, *Forbes*, and *The Wall Street Journal*. The Broome Library carries these periodicals in both hardcopy and electronically.

8. Assignments & Projects

8.1 TEAM PRESENTATION on NEW DRUG (20%):

This team-based project is a key deliverable for this course, as it reflects the key modus operandi of most pharmaceutical companies. Key requirements are as follows:

- Students will form multi-disciplinary projects teams, consisting of 4 persons (range 3-5 with instructors' approval) from different disciplines. Every team must have at least 1 student, but no more than 2 students, with a biology/chemistry/STEM/nursing major, and at least 1 student, but no more than 2 students, with a business/econ/social science/health science major.
- Once organized (and possibly electing a project manager who serves as the captain of the team), the project team will select a new drug from a list provided in Section 14, study the background of the new drug, plan/allocate work amongst team members, prepare slides for individual parts, gather and rehearse at least 1-2 times, and jointly present to the whole class during one of the last three lectures which have been reserved solely for student group presentations (20 minute presentation, 5 minute QA, ~15-20 slides).
- Project teams should select a new drug ASAP, so as to have sufficient time to get organized, conduct research, and prepare the PowerPoint presentations and write up the executive summary reports (~250 words). Drug selection is first come, first serve. More detailed instructions and the new drug list will be provided in Section 14.
- All students on each Project Team must make contribution to the research, the preparation, the slides, and the Executive Summary Report. All students on the same team will receive the same score for this assignment.

Please note that all students must have formed a group by end of the 3rd lecture, or face a penalty equivalent to 1/20 of the grade (1.5 points out of a 30 points scale) from this project for each week you are delayed. For example, if you don't form a group until week 5, then the best score you will receive is 18% (27 pts.) out of the maximum score of 30.

Please also note that all groups must have selected a topic for presentation by end of the 5th lecture, or face a penalty equivalent to 1/20 (1.5 pts) of the grade from this project for each week you are delayed. For example, if you don't finalize the topic until week 7, then the best score you will receive is 27 pts out of the maximum score of 30 - assuming that you form a group by week 3 (so no penalty from that milestone).

8.2. TEAM BOOK REPORT (20%):

This is the 2nd team-based project in this course: the same team for the drug presentation will be for the book report as well.

“Science Lessons: What The Business of Biotech Taught Me About Management” (Harvard Business Press, 2008) is written by Gordon Binder, MBA, a former CEO at Amgen. It chronicles major events at Amgen and within the biotechnology industry leading up to early 2000, when Binder retired from Amgen, which by then had become the most successful and independent firm in the history of biotechnology. The book is about 280 pages long, and covers a number of important topics relevant to the understanding of the business of science, and the science of business, in this industry. It is a compelling read for anyone who is interested in a career in science, management, or entrepreneurship. These topics include:

- 1) Success achieved thru hardwork and preseverance
- 2) Business culture vs. Science culture: differences and similarities
- 3) Importance of intellectual property
- 4) Innovation in the drug industry
- 5) Business collaboration (between different firms; advantages and disadvantages)
- 6) Teamwork and Leadership
- 7) Clinical Trials: scientific and financial risks
- 8) Managing people: how to keep them motivated and driven for success
- 9) Managing a start-up company: risk, reward, quest for capital, and IPO
- 10) Business ethics

Your book report will summarize your reflections on this book. You should focus on a 3-4 key topics that strike you the most, and explain the lessons learnt in depth. Recommended length is 2,500 words excluding word count in the reference section – less than 2,250 or more than 3,000 words will incur penalty. Be sure to properly reference 6-8 articles you come across in your research, or your paper grade will be penalized. There are a number of book reviews written on this book, and you are welcome to read and cite them, but plageriasm (including audio/video sources) will NOT be acceptable (and your grade will be severely impacted). We want to see what you have learned from reading the book AND taking this course, not repeating what others have written. We can tell a book report written by a student vs. a business professor or business journalist.

All students on the same team will receive the same score for this assignment.

Please note that each group must submit a short abstract for the paper, primarily in terms of the topics your group will write on (3-4 from the list above), by end of the 10th lecture (See Course Schedule at end), or face a penalty equivalent to 1/20 of the grade (5 pts out of a 100 point scale) from this project for each week you are delayed. For example, if you turn in the abstract in Week 11, your best possible score will be 95 pts (out of a maximum of 100 for this project).

9. Course conduct, rules & attendance

BUS ECON CHEM 341 meets once a week for a total of 15 times (including midterm and student team presentations, but excluding the week of spring break). The class will be largely held in lecture/discussion/summary mode. Students are expected to a) be prepared for each lecture topic: relevant book chapters or materials will be provided by the instructor (posted on **Canvas**); b) be engaged in understanding the fundamentals of each topic; and c) use lecture

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time for Q/A. Your questions, engagement, participation and contributions will be the difference between a dull class and a fun class. Cell phones and laptop computers are limited to lecture recording and note-taking.

In order to be successful in this course, all students are expected to be in >90% attendance. Attendance will be taken in every lecture. You can miss one lecture without excuse without any penalty, after that each unexcused absence will cost you 1% of the course grade during regular lectures, and each unexcused absence during guest lectures (if any) and student presentations (last three lectures) will cost you 2%.

10. Evaluation & Grading

▪ Participation, QA, Engagement	10%
▪ Book Report	20%
▪ Midterm Exam	20%
▪ Team Case Study (content, presentation, teamwork)	20%
▪ Final Exam	30%

Failure to take the Mid-Term exam, or Final Exam, will result in a score of zero on that item. Makeup exams will be given in rare instances, and on a case-by-case basis, including clearly documented evidence (medical and family emergencies) provided by the student.

Grading Rules:

A/A+/A-	90-100%;
B/B+/B-	80-89%;
C/C+/C-	70-79%;
D/D+/D-	56% to 69%;
F	<56%

Final course grade cut-offs may change slightly based on grade distributions at the instructors' discretion.

11. Academic Dishonesty

This course will follow the CSUCI Policy on Academic Dishonesty (SP01-57). Academic dishonesty includes cheating, inventing false information or citations, plagiarism and helping someone else commit an act of academic dishonesty. It usually involves an attempt by a student to show possession of a level of knowledge or skill that he/she does not possess. The course instructors have the initial responsibility for detecting and dealing with academic dishonesty. If the Instructors believe an act of academic dishonesty has occurred, the instructors are obligated to discuss the matter with the student(s) involved. Instructors will ensure that there is reasonable evidence of academic dishonesty. However, if circumstances prevent consultation with student(s), instructors may take whatever action (subject to student appeal) as deemed appropriate.

12. CSUCI Disability Statement

CSU Channel Islands is committed to equal educational opportunities for qualified students with disabilities in compliance with Section 504 of the Federal Rehabilitation Act of 1973 and the Americans with Disabilities Act (ADA) of 1990. The mission of Disability Accommodation Services is to assist students with disabilities to realize their academic and personal potential.

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Students with physical, learning, or other disabilities are encouraged to contact the Disability Accommodation Services office at (805) 437-8510 for personal assistance and accommodations. Handouts are available in alternative accessible formats on request.

13. SUBJECT-2-CHANGE Disclaimer Statement

All information contained in this syllabus, other than that mandated by the University, may be subject to change with advance notice, as deemed appropriate by both Instructors.

14. List of New Drugs for Team Project (Each Team Picks One Drug; maximum 2 groups per drug)

Development of a Launch Strategy for Name of Drug

Required readings (on [Canvas](#)):

- 1) "Forecasting Denosumab"; T. Calkins; Kellogg School of Management, 2011 (Case No: KEL 531)

In the article by Tim Calkins: "Forecasting Denosumab", he describes how Amgen is anticipating, planning, and forecasting the launch of Denosumab, considered by many industry experts as the next blockbuster innovative drug therapy for patients with osteoporosis (a bone disorder) and for patients with bone metastasis (experienced in many late stage cancers).

You (your group) are now asked to create a launch plan for one of the following newly approved drugs (select ONE per group – at most 2 groups per drug) in the US, using a similar approach to the one taken Calkins:

- **Parsabiv (etelcalcetide)**: by Amgen; for secondary hyperparathyroidism in chronic kidney disease; approved in February 2017.
- **Calquence (acalabrutinib)**: by AstraZeneca; for mantle cell lymphoma; approved on October 2017.
- **Alunbrig (brigatinib)**: by Takeda Pharmaceutical; for ALK-positive non-small cell lung cancer; approved on April 2017.
- **Rydapt (midostaurin)**: by Novartis; for FLT3-positive acute myeloid leukemia; approved on April 2017.
- **Tremfya (guselkumab)**: by Johnson & Johnson; for psoriasis; approved July 2017. Mechanism of action: IL-23 inhibitor. It is an antibody.
- **Verzenio (abemaciclib)**: by Eli Lilly & Co.; for breast cancer; approved on September 2017.
- **Prevymis (letermovir)**: by Merck & Co.; for infection prevention after bone marrow transplant; approved on November 2017.
- **Hemlibra (emicizumab)**: by Roche; for hemophilia A; approved on November 2018.

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- **Sterglatro (ertugliflozin)**: by Merck & Co./Pfizer; for type 2 diabetes; approved on December 26, 2017. Mechanism of action: SGLT2 inhibitor. It is a small molecule.
- **Giapreza (angiotensin II)**: by La Jolla Pharmaceutical; for hypotension in sepsis or critical illness; approved on December 2017.

In this plan, you are expected to analyze/discuss:

- A description of the company launching the drug
- The disease the drug is indicated for and the existing treatment options prior to the new drug approval.
- Summary of key clinical trial results, efficacy, side effects on the new drug. How the new drug may be better than the existing treatment options?
- How the price for the new drug compares to the existing treatment options. Does the price reflect its value? Why or why not?
- Briefly discuss the promotional plan for the new drug (which channels of promotion to focus on)
- Potential challenges facing the new drug in the near future (using the SWOT framework)

You are encouraged to research company annual reports, published literatures on the disease and treatment options, FDA website and announcements, and press coverages on these new drugs. Be sure to properly reference all sources.

The deliverable for this project is 1) a 250 word executive summary in Microsoft WORD (excluding title or references; 2) a 18-20 slide deck in PowerPoint; and 3) group presentation to the whole class at end of the semester (~20 minutes + 5 minutes Q&A).

Please note that we are not looking for a perfect launch plan with this exercise. We are looking to see how you can comprehensively apply the knowledge learnt in this class to a real world scenario. An early start of this project is very important, as it will require a significant amount of work. Feel free to check with us along the way.

Tentative Course Schedule

(subject to change per Instructors' discretion)

Date	Lecture Topic	Items Due	Instructor (JL, MSE)	Required Course Materials
1/22 Week 1	Class introduction and syllabus; Introduction to the global biopharmaceutical industry	Purchase required book (for book report); Forming groups for class project	MSE, JL	Slides S-LU 2018 (Chap 1&2)
1/29 Week 2	Introduction to Healthcare System and its relationship to Drug Development	Forming groups for class project	JL	Slides
2/5 Week 3	Discovery of Drug Targets and Drug Leads	Last Day for Forming groups for group project and book report w/o penalty	MSE	Slides + JLL
2/12 Week 4	Pharmaceutical Research and Development	Selection of Class Project Topic	MSE	Slides + JLL
2/19 Week 5	Intellectual Property and the Patent System	Last Day for Drug Selection in Group Project w/o penalty	JL	Slides S-LU 2018 (Chap 11)
2/26 Week 6	Clinical Trials	Study for Mid-term	MSE	Slides + JLL S-LU 2018 (Chap 12)
3/5 Week 7	Midterm (65 minutes); Value and Pricing of Pharmaceutical Products	Prepare abstract for book report	JL, MSE for exam; JL for lecture	Slides S-LU 2018 (Chap 7)
3/12 Week 8	Economic Analysis of Pharmaceuticals	Prepare abstract for book report	JL	Slides S-LU 2018 (Chap 8)
3/19 Week 9	Spring Break			
3/26 Week 10	Pharmaceutical Manufacturing and Production	Last day to submit abstract for book report w/o penalty	MSE	Slides + JLL
4/2 Week 11	Importance of Generics and Biosimilars; Opioid Crisis	Write book report	JL	Slides S-LU 2018 (Chap 3)
4/9 Week 12	Pharmaceutical Marketing and Promotion; Business Ethics and the Drug Industry	Book Report Due	JL	Slides S-LU 2018 (Chap 10)
4/16 Week 13	Case Study: Development of Lipitor at Pfizer	Prepare in-class presentation on new drug	MSE	Slides + JLL
4/23 Week 14	Course project presentations I (all groups); First Day extra credit	Final project PT slides; Word executive summary report	JL, MSE	

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4/30 Week 15	Course project presentations II(all groups)	Final project PT slides; Word executive summary report	JL, MSE	
5/7 Week 16	Course project presentations III (all groups); Wrap up and Final Exam Prep	Final project PT slides; Word executive summary report	JL, MSE	
5/14	Final Exam 7-9 pm		JL, MSE	

S-LU = "Pharmaceutical Economics and Policy, 3rd edition" by Stuart Schweitzer and Z. John Lu (Oxford University Press, 2018).

JLL = "Devalued and Distrusted : Can the Pharmaceutical Industry Restore its Broken Image?" by John LaMattina (John Wiley & Sons 2012).

A-F Handouts from "Drugs : From Discovery to Approval" by Rick Ng (Wiley Blackwell, 2015) :

A = Drug Discovery Target Receptors

B = Drug Discovery Small Molecule Drugs

C = Drug Discovery Large Molecule Drugs

D = Drug Development & Preclinical

E = Clinical Trials

F = Manufacturing & Production