USC School of Pharmacy

RXRS 413: Globalization in the Biomedical Industry

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Spring 2021: **M, W 3:30-4:50pm** **Location: CPA/DMC 210**

Course Weight: **4 Units**

Course Hours: **Meets 3 hours per week – two 1.5-hour sessions**

Office Hours: **M, W 12-1pm (by appointment)**

Catalogue description: *Globalization; pharmaceuticals, biologics, medical devices, and combination products in advanced, emerging, and developing markets; regional and national regulations, global and regional harmonization efforts, ethical considerations*

Introduction

The marketplace for biomedical products is global. For the industry that develops, manufactures, and commercializes these products, the ability to successfully navigate the international regulatory and business landscape is critical to grow global sales and ensure the financial viability of the company. In addition, discovery, development, clinical testing and manufacturing of products are increasingly conducted overseas, which adds complexity to managing processes, projects, and relationships in this highly regulated field. This course is designed to provide students with an understanding of the international regulatory and business aspects of the biomedical industry (pharmaceutical, biotechnology, and medical device companies) in the context of local and regional differences in culture, economy, and healthcare. While this industry was historically dominated by the advanced economies of US, Europe, and Japan, the recent seismic shift in the dynamics of global economy has moved the revenue growth centers to China, India, and other emerging regions. This has profound implications on the industry's business model including research and development (R&D), regulatory, and commercialization strategies.

Objectives

This course, designed to meet the requirements of the GE-G (Global Perspectives: Citizenship in a Diverse World), will expose students to a diverse set of topics that compare the healthcare, business practices, laws, regulations and institutions governing medical products in United States

with those of other countries and regions. To facilitate their learning experience, course content will cover cultural, historical, ethical, and political elements that influence discovery, development and delivery of therapeutics. Difference in behavioral and cultural adaptation to changes in economic, political, or social settings and how this affects the delivery of medicines to patients in advanced and developing countries will be presented and discussed in the classroom. Moreover, students will become familiar with the regulations shaping the structure and conduct of preclinical and clinical trials in other countries, including developing countries where ethical considerations are often very important to understand. The course will include case studies to examine strategies employed by multinational companies to expand their business globally as well as those employed by local companies and national authorities to stimulate domestic innovation and provide their patients access to medical products. This course should have a broad appeal to many USC undergraduates, including but not limited to, those pursuing Pre-Pharmacy, Pre-Medicine and other health and life science majors as well as students interested in biomedical engineering, psychology, business, international studies, law and sociology.

Upon successful completion of this course, the student should be able to demonstrate a working knowledge of:

- Globalization as it relates to healthcare and the biomedical industry
- The biomedical industry and its major stakeholders; importance of stakeholder engagement in developing policies
- The process of bringing biomedical products to the market: discovery, development, clinical testing and manufacturing
- Differences between healthcare, business practices, laws, regulations and institutions governing medical products in United States with those of other countries and regions
- Ethical and cultural considerations of globalization
- Opportunities and challenges of the expanding marketplace; examine the relationship between health and wealth of nations; as well as that between health and healthcare spending across nations
- The regulatory framework for obtaining market access for products in the major regions around the world
- The history and evolution of the global biomedical marketplace including the dynamics among advanced, emerging, and developing markets
- The role and accomplishments of the International Council for Harmonization and other harmonization efforts
- Current issues of concern when clinical trials are conducted in underdeveloped countries

Assignments and Grading:

8 quizzes/assignments @ 10 pts each:	80 pts (20%)
1 midterm exam @ 80 pts:	80 pts (20%)
1 written report @ 60 pts:	60 pts (15%)
1 oral report @ 60 pts	60 pts (15%)
1 final exam (partially cumulative):	120 pts (30%)
Total:	400 pts.

Attendance at all classes is expected unless prior arrangements have been made. Participation will include asking and answering questions and being actively involved in the discussion. It is expected that the students read the assigned papers prior to the lecture (if instructed to do so) and be prepared to discuss background, current understanding, treatments, and gaps in knowledge for the topic in each lecture.

There will be 8 quizzes or short assignments over the course of the semester that will primarily be based on questions and topics pulled from the reading assignments and lecture materials.

The midterm (80 points) will include multiple choice, T/F, and short answer questions (2-4 points each), and 1 short essay (10-20 points). Students will be required to write one written report designed to demonstrate their critical thinking and understanding of the subject. The reports should be 10 pages, Times New Roman 12pt font, 1-inch margins, and double-spaced. References, tables, and figures will not be included in the page count. In addition, there will be one oral presentation assigned during the semester.

The final exam (120 points) will include multiple choice, T/F, and short answer questions (2-4 points each) and one or two short essays (20 pts). The final exam will be cumulative but will emphasize material covered after the midterm.

There are no make-up exams. If exceptional circumstances prevent you from attending an exam, your reason for missing it must be accompanied by a written statement from a third party (e.g. a note from a medical doctor).

Notes, books, calculators, electronic dictionaries, regular dictionaries, cell phones or any other aids are not allowed during exams.

Students will be asked to complete an anonymous critical evaluation of the course at its completion.

Course Readings (should all be available online)

Required Readings (specific chapters/pages will be specified on blackboard)

- **Kim, R. (2019) Economics and management in the biopharmaceutical industry in the USA: evolution and strategic change.** Routledge.

  https://uosc.primo.exlibrisgroup.com/discovery/fulldisplay?docid=alma991043400285003731&context=PC&vid=01USC_INST:01USC&lang=en&search_scope=MyInst_and_CI&adaptor=Primo%20Central&tab=Everything&mode=Basic

- **Healthcare and Biomedical Technology in the 21st Century (2014) Baran, G.R., Kiani, M.F., and Samuel, S. P.** Springer, **ISBN-13:** 978-1-4614-8541-4

- **Pharmaceutical and Biomedical Project Management in a Changing Global Environment (2010), by Babler, Scott D.** John Wiley & Sons, Inc; **ISBN-13:** 978-1-118-05821-3

- The Changing Landscape of Research and Development (2019) https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-changing-landscape-of-research-and-development.pdf?_=1578605270527

- The Global Use of Medicines in 2019 and Outlook to 2023 (2019) https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023.pdf?_=1578605496447

- Institute of Medicine (2016). Global Risk Framework: Governance for Global Health: Workshop Summary. http://iom.nationalacademies.org/Reports/2016/GHRF-Governance.aspx

- Institute of Medicine (2013). International Regulatory Harmonization Amid Globalization of Drug Development: Workshop Summary. Washington, DC: The National Academies Press. http://www.nap.edu/catalog/18324/international-regulatory-harmonization-amid-globalization-of-drug-development-workshop-summary

- EvaluatePharma World Preview 2019, Outlook to 2024 https://www.evaluate.com/thought-leadership/pharma/evaluatepharma-world-preview-2019-outlook-2024

- EvaluateMedTech World Preview 2018, Outlook to 2024 https://www.evaluate.com/thought-leadership/medtech/evaluatemedtech-world-preview-2018-outlook-2024#download

- 2019 Global Life Sciences Outlook https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-ls-outlook-2019.pdf

- Biopharmaceuticals in Perspective (2019) https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/PhRMA_2019_ChartPack_Final.pdf

- World Health Organization (2011) Local Production for Access to Medical Products: Developing a Framework to Improve Public Health http://www.who.int/phi/publications/Local_Production_Policy_Framework.pdf

Other course materials including but not limited to the syllabus, supplemental reading assignments and additional handouts will be posted on http://blackboard.usc.edu/. The students will also be encouraged to use the online discussions among fellow classmates via Blackboard.

Course Outline *(DRAFT)*

This course will be in the format of a directed seminar/lecture under the guidance of the instructor for the specific session. During each weekly session, the instructor will engage the students with questions and draw comments or interpretations primarily based on the assigned reading. Students are expected to ask questions and participate in an interactive fashion.

Week & Date	Topic	Subtopics to be Included	Assigned and Recommended Readings
1 Jan 9, 11	Introduction: expectations and goals of this class. General overview of the biomedical industry	Global biomedical market: pharmaceutical, biotechnology, medical device, diagnostics Case studies of global development and commercialization of high profile products	Babler, Chapter 1. Additional readings to enrich subject matter will be posted on Blackboard. Outlook for Global Use of Medicines
Jan 16	No Class	Martin Luther King Jr. Day	
2 Jan 18	General overview of the biomedical industry	Global biomedical market: pharmaceutical, biotechnology, medical device, diagnostics Case studies of global development and commercialization of high profile products	Baran and Kiani, Chapter 1
3 Jan 23, 25	Globalization, world economy, and world health	Understanding globalization and its impact on healthcare; contemporary health issues	IOM Global Risk Framework: Governance for Global Health Baran and Kiani, Chapter 1
4 Jan 30, Feb 1	Global Pharmaceutical and Medical Device Industry US Regulatory Environment	Companies, products, and markets FDA History	FDA.gov Baran and Kiani, Chapter 4
5 Feb 6, 8	US Regulatory Environment (cont'd)	FDA Structure and Function	Babler, Chapter 2-4 EvaluatePharma World Preview EvaluateMedTech World Preview
6	**In-Class Midterm, Feb 13th**		
6 Feb 13, 15	Regional and national regulatory authorities	How to get products onto the market?	Babler, Chapter 2-4, 12
Feb 20	No class	President's Day	
7 Feb 22	Europe	Multifunctional product teams in an international environment	Babler, Chapter 10
8 Feb 27, Mar 1	Regional and national regulatory authorities	How to get products onto the market?	Babler, Chapter 2-4, 12
9	**Written report, Mar 8th**		
9 Mar 6, 8	Global Product Development Team Dynamics	Legality, logistics, and ethics of conducting global clinical trials	Babler, Chapter 8-9
Mar 13, 15	No Class	Spring Recess	
10 Mar 20, 22	Ensuring Quality in a Global Environment Susan Bain, DRSc	How do you ensure quality of biomedical products in a global environment? Supply chain management, regulatory inspections, import/export considerations	Babler, Chapter 11
11 Mar 27, 29	Global product development strategies; Business and culture Group Presentations	Science, regulation, and ethics of developing biomedical products for a global market Group Presentations	Babler, Chapter 10

12 Apr 3, 5	Harmonization efforts	International regulatory harmonization for the global industry. How regulatory policies impact the industry	Institute of Medicine (2013) International Regulatory Harmonization Amid Globalization of Drug Development
13 Apr 10, 11	Commercialization	Marketing and selling products in a global market Reimbursement: Who pays for the products? Management of Healthcare in different societies	
14	**Oral Report, April 19th**		
14 Apr 17, 19	Student Presentations	Student Presentations	
15 Apr 24, 26	Future outlook	Current issues, regulatory activities, market dynamics Latest events to be used as case studies	
16 May 1, 3	No class	Study Days	
	Final Exam, Friday, May 5, 2-4pm		

Course Content Distribution and Synchronous Session Recordings Policies

USC has policies that prohibit recording and distribution of any synchronous and asynchronous course content outside of the learning environment.

Recording a university class without the express permission of the instructor and announcement to the class, or unless conducted pursuant to an Office of Student Accessibility Services (OSAS) accommodation. Recording can inhibit free discussion in the future, and thus infringe on the academic freedom of other students as well as the instructor. (Living our Unifying Values: The USC Student Handbook, page 13).

Distribution or use of notes, recordings, exams, or other intellectual property, based on university classes or lectures without the express permission of the instructor for purposes other than individual or group study. This includes but is not limited to providing materials for distribution by services publishing course materials. This restriction on unauthorized use also applies to all information, which had been distributed to students or in any way had been displayed for use in relationship to the class, whether obtained in class, via email, on the internet, or via any other media. (Living our Unifying Values: The USC Student Handbook, page 13).

Academic Integrity

The University of Southern California is foremost a learning community committed to fostering successful scholars and researchers dedicated to the pursuit of knowledge and the transmission of ideas. Academic misconduct is in contrast to the university's mission to educate students through a broad array of first-rank academic, professional, and extracurricular programs and includes any act of dishonesty in the submission of academic work (either in draft or final form).

This course will follow the expectations for academic integrity as stated in the USC Student Handbook. All students are expected to submit assignments that are original work and prepared specifically for the course/section in this academic term. You may not submit work written by others or "recycle" work prepared for other courses without obtaining written permission from the instructor(s). Students suspected of engaging in academic misconduct will be reported to the Office of Academic Integrity.

Other violations of academic misconduct include, but are not limited to, cheating, plagiarism, fabrication (e.g., falsifying data), knowingly assisting others in acts of academic dishonesty, and any act that gains or is intended to gain an unfair academic advantage.

The impact of academic dishonesty is far-reaching and is considered a serious offense against the university and could result in outcomes such as failure on the assignment, failure in the course, suspension, or even expulsion from the university.

For more information about academic integrity see the student handbook or the Office of Academic Integrity's website, and university policies on Research and Scholarship Misconduct.

Statement on Academic Conduct and Support Systems

Academic Integrity:
The University of Southern California is a learning community committed to developing successful scholars and researchers dedicated to the pursuit of knowledge and the dissemination of ideas. Academic misconduct, which includes any act of dishonesty in the production or submission of academic work, comprises the integrity of the person who commits the act and can impugn the perceived integrity of the entire university community. It stands in opposition to the university's mission to research, educate, and contribute productively to our community and the world.

All students are expected to submit assignments that represent their own original work, and that have been prepared specifically for the course or section for which they have been submitted. You may not submit work written by others or "recycle" work prepared for other courses without obtaining written permission from the instructor(s).

Other violations of academic integrity include, but are not limited to, cheating, plagiarism, fabrication (e.g., falsifying data), collusion, knowingly assisting others in acts of academic dishonesty, and any act that gains or is intended to gain an unfair academic advantage.

The impact of academic dishonesty is far-reaching and is considered a serious offense against the university. All incidences of academic misconduct will be reported to the Office of Academic Integrity and could result in outcomes such as failure on the assignment, failure in the course, suspension, or even expulsion from the university.

For more information about academic integrity see the student handbook or the Office of Academic Integrity's website, and university policies on Research and Scholarship Misconduct.

Please ask your instructor if you are unsure what constitutes unauthorized assistance on an exam or assignment, or what information requires citation and/or attribution.

Students and Disability Accommodations:

USC welcomes students with disabilities into all of the University's educational programs. The Office of Student Accessibility Services (OSAS) is responsible for the determination of appropriate accommodations for students who encounter disability-related barriers. Once a student has completed the OSAS process (registration, initial appointment, and submitted documentation) and accommodations are determined to be reasonable and appropriate, a Letter of Accommodation (LOA) will be available to generate for each course. The LOA must be given to each course instructor by the student and followed up with a discussion. This should be done as early in the semester as possible as accommodations are not retroactive. More information can be found at osas.usc.edu. You may contact OSAS at (213) 740-0776 or via email at osasfrontdesk@usc.edu.

Support Systems:

Counseling and Mental Health - (213) 740-9355 – 24/7 on call
Free and confidential mental health treatment for students, including short-term psychotherapy,

group counseling, stress fitness workshops, and crisis intervention.

988 Suicide and Crisis Lifeline - 988 for both calls and text messages – 24/7 on call
The 988 Suicide and Crisis Lifeline (formerly known as the National Suicide Prevention Lifeline) provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week, across the United States. The Lifeline is comprised of a national network of over 200 local crisis centers, combining custom local care and resources with national standards and best practices. The new, shorter phone number makes it easier for people to remember and access mental health crisis services (though the previous 1 (800) 273-8255 number will continue to function indefinitely) and represents a continued commitment to those in crisis.

Relationship and Sexual Violence Prevention Services (RSVP) - (213) 740-9355(WELL) – 24/7 on call
Free and confidential therapy services, workshops, and training for situations related to gender- and power-based harm (including sexual assault, intimate partner violence, and stalking).

Office for Equity, Equal Opportunity, and Title IX (EEO-TIX) - (213) 740-5086
Information about how to get help or help someone affected by harassment or discrimination, rights of protected classes, reporting options, and additional resources for students, faculty, staff, visitors, and applicants.

Reporting Incidents of Bias or Harassment - (213) 740-5086 or (213) 821-8298
Avenue to report incidents of bias, hate crimes, and microaggressions to the Office for Equity, Equal Opportunity, and Title for appropriate investigation, supportive measures, and response.

The Office of Student Accessibility Services (OSAS) - (213) 740-0776
OSAS ensures equal access for students with disabilities through providing academic accommodations and auxiliary aids in accordance with federal laws and university policy.

USC Campus Support and Intervention - (213) 740-0411
Assists students and families in resolving complex personal, financial, and academic issues adversely affecting their success as a student.

Diversity, Equity and Inclusion - (213) 740-2101
Information on events, programs and training, the Provost's Diversity and Inclusion Council, Diversity Liaisons for each academic school, chronology, participation, and various resources for students.

USC Emergency - UPC: (213) 740-4321, HSC: (323) 442-1000 – 24/7 on call
Emergency assistance and avenue to report a crime. Latest updates regarding safety, including ways in which instruction will be continued if an officially declared emergency makes travel to campus infeasible.

USC Department of Public Safety - UPC: (213) 740-6000, HSC: (323) 442-1200 – 24/7 on call
Non-emergency assistance or information.

Office of the Ombuds - *(213) 821-9556 (UPC) / (323-442-0382 (HSC)*
A safe and confidential place to share your USC-related issues with a University Ombuds who will work with you to explore options or paths to manage your concern.

Occupational Therapy Faculty Practice - *(323) 442-2850 or* otfp@med.usc.edu
Confidential Lifestyle Redesign services for USC students to support health promoting habits and routines that enhance quality of life and academic performance.