

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 101

Course Weight: 4 Units

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

***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:

6 quizzes/assignments @ 10 pts each:	60 pts (15%)
1 midterm exam @ 80 pts:	80 pts (20%)
1 written report @ 60 pts:	60 pts (15%)
1 oral report @ 60 pts	60 pts (15%)
<u>1 final exam (partially cumulative):</u>	<u>140 pts (35%)</u>
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 (140 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?_id=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?_id=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 10, 12	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 17	No Class	Martin Luther King Jr. Day	
2 Jan 19	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 24, 26	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 31, Feb 2	Global Pharmaceutical and Medical Device Industry US Regulatory Environment	Companies, products, and markets FDA History	FDA.gov Baran and Kiani, Chapter 4
5 Feb 7, 9	US Regulatory Environment (cont'd)	FDA Structure and Function	Babler, Chapter 2-4 EvaluatePharma World Preview EvaluateMedTech World Preview
6	In-Class Midterm, Feb 14th		
6 Feb 14, 16	Regional and national regulatory authorities	How to get products onto the market?	Babler, Chapter 2-4, 12
Feb 21	No class	President's Day	
7 Feb 23	Global clinical trials Nancy Smerkanich, DRSc	Multifunctional product teams in an international environment	Babler, Chapter 10
8 Feb 28, Mar 2	Regional and national regulatory authorities OlgaLucia Parga	How to get products onto the market?	Babler, Chapter 2-4, 12
9	Written report, Mar 21st		
9 Mar 7, 9	Global Product Development Team Dynamics	Legality, logistics, and ethics of conducting global clinical trials	Babler, Chapter 8-9
Mar 14, 16	No Class	Spring Recess	
10 Mar 21, 23	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 28, 30	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 4, 6	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 11, 13	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 18, 20	Student Presentations	Student Presentations	
15 Apr 25, 27	Future outlook	Current issues, regulatory activities, market dynamics Latest events to be used as case studies	
16 May 2, 4	No class	Study Days	
	Final Exam, Friday, May 6, 2-4pm		

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Statement on Academic Conduct and Support Systems

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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 Part B, Section 11, “Behavior Violating University Standards” policy.usc.edu/scampus-part-b. Other forms of academic dishonesty are equally unacceptable. See additional information in SCampus and university policies on scientific misconduct, policy.usc.edu/scientific-misconduct.

Support Systems:

Counseling and Mental Health - (213) 740-9355 – 24/7 on call

studenthealth.usc.edu/counseling

Free and confidential mental health treatment for students, including short-term psychotherapy, group counseling, stress fitness workshops, and crisis intervention.

National Suicide Prevention Lifeline - 1 (800) 273-8255 – 24/7 on call

suicidepreventionlifeline.org

Free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week.

Relationship and Sexual Violence Prevention Services (RSVP) - (213) 740-9355(WELL), press “0” after hours – 24/7 on call

studenthealth.usc.edu/sexual-assault

Free and confidential therapy services, workshops, and training for situations related to gender-based harm.

Office of Equity and Diversity (OED) - (213) 740-5086 | Title IX – (213) 821-8298

equity.usc.edu, titleix.usc.edu

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

usc-advocate.symplicity.com/care_report

Avenue to report incidents of bias, hate crimes, and microaggressions to the Office of Equity and Diversity |Title IX for appropriate investigation, supportive measures, and response.

The Office of Disability Services and Programs - (213) 740-0776

dsp.usc.edu

Support and accommodations for students with disabilities. Services include assistance in providing readers/notetakers/interpreters, special accommodations for test taking needs, assistance with architectural barriers, assistive technology, and support for individual needs.

USC Campus Support and Intervention - (213) 821-4710

campussupport.usc.edu

Assists students and families in resolving complex personal, financial, and academic issues adversely affecting their success as a student.

Diversity at USC - (213) 740-2101

diversity.usc.edu

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

dps.usc.edu, emergency.usc.edu

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) 442-120 – 24/7 on call

dps.usc.edu

Non-emergency assistance or information.

Supplement: Zoom and Blackboard

Zoom

[Zoom](#) is a videoconferencing application that enables audio and video conferencing between multiple users on both desktop computers and mobile devices. It can allow faculty to host class lectures, discussions, share screens and files, and chat with students using a PC, tablet, or even a cell phone equipped with a camera. Zoom is available to all faculty and students at no cost.

- Instructors may host live class sessions on Zoom at the same day and time as their regular class.
- Instructors are required to [record all Zoom lectures](#) and discussions for ADA (Americans with Disabilities Act) compliance, but also to accommodate students who may not be able to keep to the original class schedule.

Links to the recordings of lectures will be posted and organized in Blackboard as soon as they are available.

1. Getting Started with Zoom:

- You might be required to use Zoom in this course, please familiarize yourself with it by thoroughly reading all of the materials and [the step-by-step instructions](#).
- You will access the Zoom meeting space in one of two ways:
 1. Log in via blackboard after you have followed the instructions to initially download, install, and login. Then enter the meeting by going to the link [USC Zoom Meetings](#) in the left-hand navigation pane. You will need to click the “Join” button next to the classroom for the time set for the meeting.
 2. Copy and paste the URL (or click on the web link) provided by your instructor at the time specified for the meeting. Launch the app (after initially downloading, installing, and logging in), and you will enter the meeting immediately.
- You may choose to use Zoom on your mobile device (phone or tablet).

2. Things to Know About Zoom:

- Because you sign in using your USC information, you have your own profile in Zoom.
- Attendance and participation can be tracked using your USC profile.

- You can find the privacy and accessibility policies for Zoom by clicking on the Learner Support tab in the left-hand navigation pane of your Blackboard course.

Blackboard

[Blackboard](#) is the University's Learning Management System (LMS) used by instructors across campus to distribute course materials, communicate with students in discussion boards, and to collect and assess student work through assignments, quizzes, and tests. A Blackboard course is created for every course at USC and should be the primary tool used for classroom management and communication.

Visit <https://blackboardhelp.usc.edu> to learn more about the various functions of Blackboard.