USC School of Pharmacy

RXRS 413: Globalization of the Biomedical Industry

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Spring 2019: **M, W 3:30-4:50pm** **Location: VKC201**

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:

Class participation:	20 pts (5%)
4 quizzes/assignments @ 10 pts each:	40 pts (10%)
1 midterm exam @ 80 pts:	80 pts (20%)
2 written reports @ 60 pts each:	120 pts (30%)
1 final exam (partially cumulative):	140 pts (35%)
Total:	400 pts.

Class Participation and Attendance (20 pts): On a scale of 20, 0-indicating no participation, 20-indicating best participation. You can therefore increase the probability of getting a higher mark by being proactive in terms of asking (relevant) questions in class and/or contributing to discussions.

Attendance at all classes is expected. 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 and be prepared to discuss background, current understanding, treatments, and gaps in knowledge for the topic in each lecture.

There will be 4 pop quizzes over the course of the semester that will primarily be based on questions pulled from the reading assignments and lecture materials. The instructor may post an assignment on blackboard in lieu of a pop quiz.

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 two written reports designed to demonstrate their critical thinking and understanding of the subject. The reports should be 10 pages each, Times New Roman 12pt font, 1 inch margins, and double-spaced. References, tables, and figures will not be included in the page count.

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

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

- **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

- **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

- 2018 and Beyond: Outlook and Turning Points (2018) https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/2018-and-beyond-outlook-and-turning-points.pdf

- 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 2016, Outlook to 2022 http://www.evaluategroup.com/public/reports/EvaluatePharma-World-Preview-2016.aspx

- EvaluateMedTech World Preview 2016, Outlook to 2022 http://www.evaluategroup.com/public/reports/EvaluateMedTech-World-Preview-2016.aspx

- The Economic Impact of the U.S. Biopharmaceutical Industry: National and State Estimates Prepared by TEConomy Partners, LLC Prepared for the Pharmaceutical Research and Manufacturers of America May 2016 http://phrma-docs.phrma.org/sites/default/files/pdf/biopharmaceuticaul-industry-economic-impact.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.

Recommended

- **Oxford Textbook of Global Public Health, 6th Edition (2015)** Oxford University Press; **ISBN-13:** 978-0-19-871930-4 (Vol. 1)

Course Outline

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 7, 9	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 through 2021
2 Jan 14, 16	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
Jan 21	No Class	Martin Luther King Jr. Day	
3 Jan 23	US Regulatory Environment	FDA Structure and Function	FDA.gov Baran and Kiani, Chapter 4
4 Jan 28, 30	US Regulatory Environment	FDA Structure and Function	FDA.gov Baran and Kiani, Chapter 4
5 Feb 4, 6	Global Pharmaceutical and Medical Device Industry	Companies, products, and markets	Babler, Chapter 2-4 EvaluatePharma World Preview 2016, Outlook to 2022 EvaluateMedTech World Preview 2016, Outlook to 2022 2018 and Beyond: Outlook and Turning Points (2018)
6	**In-Class Midterm, Feb 11th**		
6 Feb 13	Regional and national regulatory authorities	How to get products onto the market?	Babler, Chapter 2-4, 12
Feb 18	No class	President's Day	
7 Feb 20	Regional and national regulatory authorities	How to get products onto the market?	Babler, Chapter 2-4, 12
8 Feb 25, 27	Global clinical trials Nancy Smerkanich, DRSc	Multifunctional product teams in an international environment	Babler, Chapter 10
9	**Written report #1, Mar 4th**		
9 March 4, 6	Ensuring Quality in a Global Environment	How do you ensure quality of biomedical products in a global environment? Supply chain management, regulatory inspections, import/export considerations	Babler, Chapter 11
Mar 11, 13	No class	Spring break	
10 Mar 18, 20	Global Product Development Team Dynamics Nancy Smerkanich, DRSc	Legality, logistics, and ethics of conducting global clinical trials	Babler, Chapter 8-9
11 Mar 25, 27	Global product development strategies; Business and culture	Science, regulation, and ethics of developing biomedical products for a global market	Babler, Chapter 10

12	**Written report #2, April 1st**		
12 Apr 1, 3	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 8, 10	Risks in global project management	In-sourcing and Out-sourcing International business relationships	Babler, Chapter 5-7
14 Apr 15, 17	Commercialization	Marketing and selling products in a global market Reimbursement: Who pays for the products? Management of Healthcare in different societies	Battell (2014) The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and The Factors That Will Drive It IHI Global Use of Medicines PharmaFutures (2013) Pathways to Value: Pharma in a Changing World
15 Apr 22, 24	Future outlook	Current issues, regulatory activities, market dynamics Latest events to be used as case studies	World Health Organization (2011) Local Production for Access to Medical Products: Developing a Framework to Improve Public Health
16 Apr 29 May 1	No class	Study Days	
	Final Exam, Friday, May 3, 2-4pm, VKC201		

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Statement on Academic Conduct and Support Systems

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, http://policy.usc.edu/scientific-misconduct.

Support Systems:
Student Counseling Services (SCS) – (213) 740-7711 – 24/7 on call
Free and confidential mental health treatment for students, including short-term psychotherapy, group counseling, stress fitness workshops, and crisis intervention. engemannshc.usc.edu/counseling

National Suicide Prevention Lifeline – 1 (800) 273-8255
Provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week. www.suicidepreventionlifeline.org

Relationship and Sexual Violence Prevention Services (RSVP) – (213) 740-4900 – 24/7 on call
Free and confidential therapy services, workshops, and training for situations related to gender-based harm. engemannshc.usc.edu/rsvp

Sexual Assault Resource Center
For more information about how to get help or help a survivor, rights, reporting options, and additional resources, visit the website: sarc.usc.edu

Office of Equity and Diversity (OED)/Title IX Compliance – (213) 740-5086
Works with faculty, staff, visitors, applicants, and students around issues of protected class. equity.usc.edu

Bias Assessment Response and Support
Incidents of bias, hate crimes and microaggressions need to be reported allowing for appropriate investigation and response. studentaffairs.usc.edu/bias-assessment-response-support

The Office of Disability Services and Programs
Provides certification for students with disabilities and helps arrange relevant accommodations. dsp.usc.edu

Student Support and Advocacy – (213) 821-4710
Assists students and families in resolving complex issues adversely affecting their success as a student EX: personal, financial, and academic. studentaffairs.usc.edu/ssa

Diversity at USC
Information on events, programs and training, the Diversity Task Force (including representatives for each school), chronology, participation, and various resources for students. diversity.usc.edu

USC Emergency Information
Provides safety and other updates, including ways in which instruction will be continued if an officially declared emergency makes travel to campus infeasible. emergency.usc.edu

USC Department of Public Safety – UPC: (213) 740-4321 – HSC: (323) 442-1000 – 24-hour emergency or to report a crime. Provides overall safety to USC community. dps.usc.edu