USC School of Pharmacy

RXRS 413: Globalization of the Biomedical Industry

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Spring 2017: **W 2-4:50pm** **Location: SOS B47**

Course Weight: 4 Units
(course meets 3 hours per week – one three-hour session plus 1 discussion section session)

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.

Lectures will compare the healthcare, business practices, laws, regulations and institutions governing medical products in United States with those of other countries and regions. The topics will also include cultural issues and harmonization efforts. 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.

Objectives

This course should have broad appeal to many USC undergraduates including Pre-Pharmacy, Pre-Medicine and other health and life science majors as well as students 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
- 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 considerations of globalization
- Opportunities and challenges of the expanding marketplace
- 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%)
8 quizzes @ 10 pts each	80 pts (20%)
2 midterm exams @ 80 pts each:	160 pts (40%)
1 final exam (partially cumulative):	140 pts (35%)
Total:	400 pts.

Class Participation and Attendance (20 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 8 pop quizzes over the course of the semester that will primarily be based on questions pulled from the reading assignments and lecture materials. The midterms (80 points each) will include multiple choice, T/F, and short answer questions (2-4 points each), and 1 short essay (20 points).

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 2nd 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

- Outlook for Global Use of Medicines through 2021. http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/outlook_for_global_medicines_through_2021

- Loffler, A., & Stern, S. (2006). The future of the biomedical industry in the era of globalization. Northwestern University, Kellogg School of Business. http://www.kellogg.northwestern.edu/biotech/faculty/articles/future_biomedical_industry.pdf

- National Research Council (2008). Innovation in Global Industries: U.S. Firms Competing in a New World (Collected Studies). Washington, DC: The National Academies Press. http://www.nap.edu/catalog/12112/innovation-in-global-industries-us-firms-competing-in-a-new

- 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

- Battell (2014) The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and The Factors That Will Drive It
  http://www.phrma.org/sites/default/files/pdf/2014-economic-futures-report.pdf

- PharmaFutures (2013) Pathways to Value: Pharma in a Changing World
  http://pharmafutures.org/wordpress/wp-content/uploads/2013/10/PharmaFutures-Global-Report-Pathways-to-Value-1.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)
- **Textbook of International Health: Global Health in a Dynamic World, 3rd Edition (2009)**
  Oxford University Press; **ISBN-13:** 978-0-19-530027-7

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.

Course schedule is as follows:

Week & Date	Topic	Subtopics to be Included	Assigned and Recommended Readings
Introduction and Background			
1 Jan 11	Introduction: expectations and goals of this class. General overview of the biomedical industry EP	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 18	Globalization, world economy, and world health Naomi Florea, PharmD	Understanding globalization and its impact on healthcare; contemporary health issues	IOM Global Risk Framework: Governance for Global Health Baran and Kiani, Chapter 1
3 Jan 25	US Regulatory Environment EP	FDA Structure and Function	FDA.gov Baran and Kiani, Chapter 4
4 Feb 1	Global Pharmaceutical and Medical Device Industry EP	Companies, products, and markets	Babler, Chapter 2-4 EvaluatePharma World Preview 2016, Outlook to 2022 EvaluateMedTech World Preview 2016, Outlook to 2022 Outlook for Global Use of Medicines through 2021
5		**In-Class Midterm #1, Feb 8th**	
5 Feb 8	Regional and national regulatory authorities EP or Kelli Moore (Legal Aspects)	How to get products onto the market?	Babler, Chapter 2-4, 12
6 Feb 15	Ensuring Quality in a Global Environment Michael Jamieson, DRSc	How do you ensure quality of biomedical products in a global environment? Supply chain management, regulatory inspections, import/export considerations	TBD
7 Feb 22	Business and culture EP	Impact of culture in the biomedical industry	TBD
8 Mar 1	Global Product Development Team Dynamics Nancy Smerkanich, DRSc	Multifunctional product teams in an international environment	Babler, Chapter 8-9
9	**In-Class Midterm #2, Mar 8th**		
9 Mar 8	Risks in global project management Robert Pacifici, PhD	In-sourcing and Out-sourcing International business relationships	Babler, Chapter 5-7
Mar 15	No Class	Spring Break	

Product Development			
10 Mar 22	Global product development strategies EP	Science, regulation, and ethics of developing biomedical products for a global market	Babler, Chapter 10
11 Mar 29	Global advertising and promotion Wilmar Estrada	International consideration in marketing biomedical products	TBD
10 Mar 22	Global product development strategies EP	Science, regulation, and ethics of developing biomedical products for a global market	Babler, Chapter 10
12 Apr 5	Commercialization EP	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
13 Apr 12	Harmonization efforts Michael Jamieson, DRSc	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
14 Apr 19	Future outlook EP	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
15 Apr 26	Global clinical trials Nancy Smerkanich, DRSc	Legality, logistics, and ethics of conducting global clinical trials	TBD
	Final Exam, Monday, May 8, 2-4pm		

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 Section 11, *Behavior Violating University Standards* https://scampus.usc.edu/1100-behavior-violating-university-standards-and-appropriate-sanctions. 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.

Discrimination, sexual assault, and harassment are not tolerated by the university. You are encouraged to report any incidents to the *Office of Equity and Diversity* http://equity.usc.edu or to the *Department of*

Public Safety http://capsnet.usc.edu/department/department-public-safety/online-forms/contact-us. This is important for the safety of the whole USC community. Another member of the university community – such as a friend, classmate, advisor, or faculty member – can help initiate the report, or can initiate the report on behalf of another person. *The Center for Women and Men* http://www.usc.edu/student-affairs/cwm/ provides 24/7 confidential support, and the sexual assault resource center webpage http://sarc.usc.edu describes reporting options and other resources.

Support Systems
A number of USC's schools provide support for students who need help with scholarly writing. Check with your advisor or program staff to find out more. Students whose primary language is not English should check with the *American Language Institute* http://dornsife.usc.edu/ali, which sponsors courses and workshops specifically for international graduate students. *The Office of Disability Services and Programs* http://sait.usc.edu/academicsupport/centerprograms/dsp/home_index.html provides certification for students with disabilities and helps arrange the relevant accommodations. If an officially declared emergency makes travel to campus infeasible, *USC Emergency Information* *http://emergency.usc.edu* will provide safety and other updates, including ways in which instruction will be continued by means of blackboard, teleconferencing, and other technology.

Emergency Preparedness/Course Continuity:
In case of emergency, and travel to campus is difficult, USC executive leadership will announce an electronic way for instructors to teach students in their residence halls or homes using a combination of Blackboard, teleconferencing, and other technologies. Instructors should be prepared to assign students a "Plan B" project that can be completed at a distance. For additional information about maintaining your classes in an emergency please access: http://cst.usc.edu/services/emergencyprep.html