USC School of Pharmacy

FALL 2017 - RXRS 411: Innovations in Medical Product Development
Subject to change
Friday: 10:00 AM -11:50 AM
Room: WPH 103

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Office Hours: By appointment

Course Weight: 4 Units

Introduction

The course introduces the student to the newest technologies that are being developed by the medical products industry and to give them a better understanding of the political, regulatory and reimbursement issues that may be associated with developing these new leading edge technologies. General subject matter to be covered include emerging technologies that are being used in the research, development and manufacturing of new drugs, medical devices, and biologics. This will included topics such as the use of 3D printers to manufacturer drugs and prosthetics, the use of light activated nanoparticles to deliver drug payloads directly to the site of tumors, computer modelling and simulations to predict the safety and efficacy of medical products and the use of gas filled microbubbles to transport large molecules across the blood brain barrier to treat neurological disorders. “Hot topics” will be presented such as the role of FDA in regulating the “do it yourself DNA kits” that are being marketed (e.g., 23andME). The course will also look at the ongoing discussion with regards to whether or not the US is still the best country to introduce these new innovations or are there other countries which are more receptive to adopting the use of new medical technologies. Successfully introducing a new technology is not just about the science it also involves navigating the clinical, regulatory and reimbursement issues associated with the development of these so called “first in class” products.

The topics covered in the course will change from year to year as new innovations are introduced into the industry. This course should have broad appeal to many science and non-science undergraduates including students interested in drug discovery research, chemistry, biology, pharmacology, formulations, pharmaceutical industry, FDA, business analysts, entrepreneurs and venture capitalist interested in understanding the pharmaceuticals industry.

Objectives

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

- Obtain a working knowledge of the past and current innovations that are being used in the research, development and manufacturing of new drugs, medical devices, and biologics
- Medical product lifecycle development and associated challenges with commercialization of new products
- What financing options are available for a new technology start up and the pros and cons of each
- The importance of understanding the regulatory hurdles and requirements associated with the introduction of new technologies during the research and development phase
- The importance of understanding the reimbursement issues, both in countries with socialized and private healthcare, associated with the introduction of new technologies

Assignments and Grading:

Students enrolled in this course will be graded as follows

10% Class Participation and Attendance: Attendance at all classes is expected. Participation will include weekly assignments where students are expected to come to class with a "current event" related to emerging technologies in the life science space. One student each week will be randomly selected to (informally) present their finding. All students are expected to ask questions and being actively engaged in classroom discussions. It is expected that students read any 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.

20% Quizzes: A series of four quizzes with multiple choice and short answer quizzes will be given in class with each being worth 5 points. The quiz will be based on the prior 1-2 weeks lecture topics.

20% Exam 1: The first exam will consist of an in class essay exam in which students will be given a series of questions from lectures and asked to select 2 topics from a list of 3 and to provide a well-structured and critical evaluation of the specific topic. This midterm exam will help students to generate a critical understanding of a key topic in this course and to convey their ideas and interpretations through the written word.

20% Exam 2: The second exam will consist of a take home exam in which students will be asked to describe the steps/lifecycle for product development based on an innovative medical product

of their choice. This midterm exam will help students to generate a critical understanding of a key topic in this course and to convey their ideas and interpretations through the written word.

30% Final: The Final Exam will be in the form of an in class examination. This examination will consist of multiple choice, True/False and short written answers to questions requiring specific knowledge of topics covered in the course as well as short opinion essays in response to questions designed to challenge current interpretations and will allow students to express their ideas based on facts derived from the course.

Course Readings

Due to the fact that the content of this course will change from year to year as new technologies are introduced into the medical field it will be very difficult to have a single standardized textbook and therefore readings will be assigned from the most current journal articles, newspapers etc.

Optional Textbook: The Business of Healthcare Innovation, 2nd Edition, Lawton R. Burns, Editor (2012).

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

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
1/ 8/25/2017	Introduction: Expectations and goals of this class. General overview of how innovation have been used in the development, delivery and manufacturing of new medical technologies.	Examples of new technologies that have had a major effect on the development of new medical devices, drugs and biologics.	Innovation in Medical and Device Development
2/ 9/1/2017	How the FDA and other regulators deal with the introduction of new technologies	An overview of the regulatory requirements related to the development of new medical technologies. This will look at both the preclinical and clinical requirements.	CDRH White Paper And FDA Regulation of Mobile Health Technology
3/ 9/8/2017	Wearable technologies	Introduction to the regulation and use of wearable health technologies. With the recent "explosion" of wearable devices and health "apps" we will examine which are considered regulated products and which are not and what this means for the future.	Mobile Medical and Health Applications And Mobile Health Tech
4/ 9/15/2017	The role of 3D printing (both liquid and solid) in the development and manufacturing of medical devices	Introduction to 3 D printing (both solid and liquid) technology and case studies of actual devices that utilize some facet of nanotechnology	3D Drug Printing Review 2013 And Three D Printing in Medicine And Medical Applications for 3D Printing
5/ 9/22/2017	Nanotechnology and the development of medical devices	Introduction to the area of nanotechnology and case studies of actual devices that utilize some facet of nanotechnology.	State of Nanomedicine
6/ 9/29/2017	Nanotechnology and the role it plays in the delivery of drugs and biologics	Introduction to the use of a nanotechnology as a drug/biologic delivery system and case studies of actual drugs and/or biologics that utilize a nanoparticle drug delivery system.	State of Nanomedicine
7/ 10/6/2017		**Exam 1 IN CLASS (ESSAY)**	
8/ 10/13/2017	Cardiovascular Technologies	A hands-on introduction to new pacemaker and defibrillator technologies as well as the use of electric ventricular devices (EVAD).	LVAD From Bench to Clinic And Unplugging the Artificial Heart
9/ 10/20/2017	Stem cell growth of new limbs, organs, tissues and bone	Introduction to the science of using stem cells to grow new organs, tissues, bones and even new limbs. Will also include case studies of actual devices that utilize stem cells.	Stem Cell Therapies: From Bench to Bedside And US Stem Cell Clinics
10/ 10/27/2017	The use of gas filled microbubbles for the imaging and treatment of cancer	Introduction to the use of microbubbles for the imaging and treatment of cancer and the delivery of large molecules across the blood brain barrier. Will also include case studies of actual devices that utilize microbubbles.	Ultrasound-mediated drug deliver using Microbubbles
11/ 11/3/2017	The evolution of genome and epigenome testing and where it is heading	Introduction to the use of genomic and epigenetic testing as both a diagnostic and development tool. Also introduce the concept of "personalized medicine"	23andMe and the FDA And A New Initiative on Precision Medicine
12/ 11/10/2017	The role of robotics in the development of prosthetic limbs.	Introduction to the use of computer algorithms and robotics to allow patients to control prosthetic limbs. Will also include case studies of actual devices that utilize stem cells.	Robotics Prosthetics

Week 13/Exam 2 TAKE HOME			
14/ 11/17/2017	Financing Considerations including opportunities for small start-ups and reimbursement policies to determine price	A look at financing opportunities for small start-ups including SBIR grants, venture capital, angel investors, industrial partners and banks. Developing a new technology is just one part of a successful introduction of a new medical technology into the marketplace.	Biomedical Innovation in a Challenging Fiscal Environment Barriers to Medical Device Innovation
15/ 12/1/2017	Strategies for the development and introduction of new technologies; is the US still the leading country for medical innovations	The trend towards medical drug and device companies (including US companies) doing their clinical trials and initial introduction into other regions including the European Union will be discussed and the future of global medical product development will conclude this course.	Global Markets for Emerging Medical Device Technology
Week 16 FINAL EXAM (CUMULATIVE): 12/11/2017 from 8-10 AM Room WPH 103			

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