INTD 7074
Topics in Translational Medical Product Development

Spring 2017

CLASS DAYS and TIME: Every Thursday/ 3:30-5:00pm

CLASSROOM: ALTC, Room 203

COURSE FACULTY: Andrea Giuffrida, PhD – Course Director

OFFICE LOCATION and HOURS: By appointment; Office 425A

EMAIL: Giuffrida@uthscsa.edu

TELEPHONE: 567-4219

READ THIS DOCUMENT CAREFULLY - YOU ARE RESPONSIBLE FOR ITS CONTENTS.

COURSE DESCRIPTION AND OBJECTIVES

To be competitive in the life science industry, it is crucial to understand the intricate process of translating basic research into market driven products. This course will offer students the opportunity to interact with local CEOs, integrate their basic science education with industry-relevant training, and explore the marketing and regulatory process through which a biomedical product is developed and commercialized.

Pre-requisites – None

Semester credit hours – 1

By the end of this course, each student should be able to:

- Define and explain practices and regulatory frames for the development of different biomedical products
- Familiarize with intellectual property considerations, business plan development and fundraising
- Identify resources needed for research and development, manufacturing and commercialization strategies
- Explore various development models for small businesses through analysis of case studies.

COURSE ORGANIZATION

The main teaching modalities used in this course include:

1) Conventional didactic lectures in which information is delivered to the class;
2) Discussions of case-studies, encouraging interaction between the instructor and the class, and requiring student active participation in the learning process;
3) Field trips to local biotech companies.

Materials – Presentations are given in the common lecture format and are accompanied by PowerPoint slide files that are shared with the students. Medical device prototypes or other medical products are displayed in class and their respective development illustrated via videos.

Computer Access – Exams require access to a computer with internet capabilities

Reading Assignments – Reading assignments are emailed to students before class. Readings and Audiovisual material for the testing exams are available on an online platform shared with UTSA (Entrepreneurial Academy)

ATTENDANCE

In order to achieve the expected level of competency, students must be fully engaged. Therefore, attendance for every class session is expected.

TEXTBOOKS

Required: N/A

Recommended: USPTO – Frequently Asked Questions about Patents

http://www.uspto.gov/web/offices/pac/doc/general/faq.htm

USPTO - General Information Concerning Patents

http://www.uspto.gov/web/offices/pac/doc/general/index.html

The European Patent Office (EPO) http://www.european-patent-office.org/

Intellectual Property Ideas for Posterity by J. David Livingston (2005) The Journal of World Intellectual Property 8 (4), 499–516.

Do's and Don'ts for Keeping Lab Notebooks. Fish & Richardson P.C.
http://www.fr.com/news/articledetail.cfm?articleid=72

The importance of getting inventorship right by Diane Sheiness and Karen Canady. Nat Biotechnol. 2006 Feb;24(2):153-4.

Protecting innovation in biotechnology startups by Eric K. Steffe and Timothy J. Shea Jr
Nature Publishing Group; Published online: 23 June 2003

Basics of preclinical drug development
http://www.biomedcentral.com/1471-2377/9/S1/S2

Therapeutics for neglected diseases
http://www.ncats.nih.gov/research/rare-diseases/trnd/trnd.html

GRADING POLICIES AND EXAMINATION PROCEDURES

Describe in detail how grades for assignments/projects/tests will be weighted and factored into final grades, also include other information relevant to grading if applicable – for example information about extra credit, examination protocol, make-up exams, etc.

Grading System

Evaluation is based on Class Participation (50%), Assignments and Case Presentations (50%)
Students will be assigned a pass/fail grade based on their overall performance and completion of a test offered online via the UTSA Entrepreneurship Academy platform. Students are expected to complete all readings, engage in discussion at every class and participate to field trips and case presentations.

REQUESTS FOR ACCOMODATIONS FOR DISABILITIES

In accordance with policy 4.2.3, **Request for Accommodation Under the ADA and the ADA Amendments Act of 2008 (ADAAA)**, any student requesting accommodation must submit the appropriate request for accommodation under

the American with Disabilities Act (ADA, form 100). to his/her appropriate Associate Dean of their School and a copy to the ADA Coordinator. Additional information may be obtained at http://uthscsa.edu/eeo/request.asp.

ACADEMIC INTEGRITY AND PROFESSIONALISM

Any student who commits an act of academic dishonesty is subject to discipline as prescribed by the UT System Rules and Regulations of the Board of Regents. Academic dishonesty includes, but is not limited to, cheating, plagiarism, collusion, the submission for credit of any work or materials that are attributable in whole or in part to another person, taking an exam for another person, signing attendance sheets for another student, and any act designed to give unfair advantage to a student or the attempt to commit such an act. Additional information may be obtained at http://catalog.uthscsa.edu/generalinformation/generalacademicpolicies/academicdishonestypolicy/

TITLE IX AT UT Health San Antonio

Title IX Defined:
Title of the Education Amendments of 1972 is a federal law that prohibits sex discrimination in education. It reads "no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance."

University of Texas Health Science Center San Antonio's Commitment:
University of Texas Health Science Center San Antonio is committed to maintaining a learning environment that is free from discriminatory conduct based on gender. As required by Title IX, UT Health San Antonio does not discriminate on the basis of sex in its education programs and activities, and it encourages any student, faculty, or staff member who thinks that he or she has been subjected to sex discrimination, sexual harassment (including sexual violence) or sexual misconduct to immediately report the incident to the Title IX Director.

In an emergency, victims of sexual abuse should call 911. For non-emergencies, they may contact UPD at 210-567-2800. Additional information may be obtained at http://students.uthscsa.edu/titleix/

EMAIL POLICY

Every student is issued a University e-mail address and account at the time of enrollment. As a matter of University Policy, communications between students and faculty that occur using the student's University e-mail address is considered official business. Therefore, students are expected to check their university email inboxes on a regular basis so that any announcements, instructions, or information regarding this course will be received in a timely way. Missed communications due to inadequate monitoring of incoming emails on the University's email server will never be a valid excuse for unsatisfactory academic progress.

USE OF RECORDING DEVICES

Recording of lectures and other learning activities in this course by any means (e.g., video, audio, etc.) is only permitted if approved by the instructor or required for compliance with Americans with Disabilities Act (ADA).

ELECTRONIC DEVICES

Cell phones must be turned off during all class meetings and exams. Computers and electronic tablets are allowed only for participating in classroom activities (e.g., viewing slides presented in lecture or conference materials). No texting, tweeting, emailing, web-surfing, gaming, or any use of electronic devices that is not directly connected with classroom activities is permitted.

INTD 7074
Entrepreneurs Academy
Course Director: Andrea Giuffrida, Ph.D.

Topics in Translational Medical Product Development			
DATE	**TOPIC**	**LECTURER**	**READINGS**
Thursday, February 02, 2017	**Overview and Intellectual Property** (medical product development, healthcare industry and market trends, FDA regulatory pathways, introduction to commercialization, writing strong tech descriptions, copyrights and trademarks, patents and trade secrets, drug exclusivity and licensing, IP valuation)	1) Andrea Giuffrida, Ph.D., *VP for Research* *2)* Mike Villarreal, JD, *Patent Attorney*	**Watching for NIH Innovation in 2017-and Drug Pricing, Trade Deals** http://www.xconomy.com/san-diego/2017/01/02/watching-for-nih-innovation-in-2017-and-drug-pricing-trade-deals/?utm_source=Xconomy&utm_campaign=ba51265cb3-NEWSLETTER_Texas&utm_medium=email&utm_term=0_2aa91c0bc9-ba51265cb3-293242485
Thursday, February 09, 2017	**Development of Therapeutics** (target validation and pre-clinical activities, extrapolating from animals to humans, product optimization, clinical studies, NIH and NCATS programs, role of contract research organizations	William Bauta, Ph.D., *Senior VP Research & Development, Therapeutics* Luis Martinez, Ph.D., *Director for Innovation & Entrepreneurship*	
Thursday, February 16, 2017	**Development of Medical Devices** (idea generation/market validation, design and planning, feasibility testing, prototyping, pilot production, scale-up manufacturing, product launch)	1) Morris Miller, *CEO* 2) Dr. R. Lyle Hood, Ph.D., *Asst. Professor*	
Thursday, February 23, 2017	**Product Development: Quality Requirements** (animal studies (GLP); quality assurance and manufacturing controls (GMP), clinical practices and protection of human subjects (GCP); clinical studies (Phase 1-IV), FDA challenges and industry concerns	1) Drs. John Hart, Ph.D. and Stan McHardy 2) Dr. Allison Komiyama, Ph.D., RAC, *Principal consultant*	**White Paper: FDA and Accelerating the Development of the New Pharmaceutical Therapies** http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm439082.htm#2
Thursday, March 2, 2017	**Non-Dilutive Capital: SBIR/STTR Program** (participating federal agencies, phases and funding mechanisms, evauation areas and review criteria, IP issues, RFA examples	1) Mike Kurek, Ph.D., MBA, *Sr. Consultant*	
Thursday, March 9, 2017	**Market and Finance Your Technology** (market validation, effective pitch presentations, product development costs, capital sources; NewCo, exit strategies)	1)Mark Standeford, PMP,*CEO & President*	https://therivardreport.com/cardiovate-develops-first-bioabsorbable-vascular-graft/
Thursday, March 23, 2017	**Corporate Partnering and Strategic Alliances** (collaborative arrangements, i.e. outsourcing, licensing, joint ventures, etc), choosing a partner, academia-industry)	1) Becky Cap, MBA, *Chief Operating Officer*	**BioBridge Global-led biotech team awarded $7.8 million MTEC contract** biobridgeglobal.org/news?page=1
Thursday, March 30, 2017	**Life Science Commercialization** (biotech model, start-up and early-stage experiences, tactical tips for licensing opportunities, case studies)	R. Dana Ono, Ph.D., *Managing Partner*	
Thursday, April 6, 2017	**Reimbursement Strategy and Health Economics** (medicare and medicaid programs, billing regulations, limitations on payments, payer contracting)	Kris Kieswetter, Ph.D., MBA, Sr. Director, Innovation and Strategic Marketing	
Thursday, April 13, 2017	**Balancing Act: Scientist, Professor, Clinician, and Entrepreneur** (academic and business endeavors, managing conflicts of interests, identifying business partners, benefits of entrepreneurial undertaking)	1) Dr. Ken Hargreaves, DD.S, Ph.D.. *Professor* 2) Dr. Jaime Garza, MD, DD.S., *Surgeon*	
Thursday, April 20, 2017	**Tours of Life Sciences Companies**	Xiao-Dong Chen, MD, Ph.D., co-founder	

No class on March 16 Spring Break week