

## **SYLLABUS 5505**

**3 Credits, Fall Semester**

**Location TBA**

**Class time 5:30 pm- 8 pm Monday**

**Instructors: Seema Freer**

**Guest lecturers: Harris Rotman, Jim Guare and Kurt Bachman**

The rapid growth of biotechnological applications and commercialization of these products has resulted in seemingly retroactive regulations and policies to govern the safe use of these technologies. This course, inspired by the groundwork laid by Dr. JACKIE TANAKA who taught this course for its first three years, will explore some examples of these advances and their unintended consequences. Examples of regulation and policy implemented 'after the fact' will be introduced through seminal papers and news articles and ethical implications of unintended consequences will be highlighted. One learning outcome is to provide awareness and an ethical framework to the future leaders of the Biotech sector who are in the Professional Science Master's program. Other learning outcomes will include a clear articulation of technical and scientific data through oral presentations and a final written paper. The class will also work in teams where each facet of the topic at hand will be presented by a different team. Assessments will include mid-term exam class participation, oral, and written presentations.

This class time will be structured to have approximately equal times of instructor presentation, discussion led by teams, and concluding group discussion. Students will also be provided with links and articles ahead of schedule and will be required to interact with the material provided in order to demonstrate understanding of content.

Office hours are by appointment with instructor who is also available by email [sfreer@temple.edu](mailto:sfreer@temple.edu)

Students' assessments will be based on:

Class interaction (team and individual) 40 % of grade

Midterm Case Study Part I of a FDA and Regulatory Affairs interaction in a documented case assigned by Harris Rotman- 20%

Final Paper on any topic covered in class(20%)

and

Presentation 5 min of final paper (20%)

Attendance is mandatory to class and absences have to be explained by written email and officially excused by instructor/s ahead of schedule

**Material for all topics, and links to every website used is posted on Blackboard and available to all students who're registered for the class.**

The instructors acknowledge the generosity of the Markkula Center for Applied Ethics at Santa Clara University for the use of the material for forming an ethical framework. Use of "making an ethical decision" app and information from the following link

<http://www.scu.edu/ethics/practicing/decision/framework.html>

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Week	Topic	LEAD	Dates
<b>Week 1</b>	Fraud in Science: Forming an Ethical Framework	Seema	29-Aug
	Office of Research Integrity		
	FRAUD AND RETRACTIONS research, publishing data		
	Case study: several from ORI websites		
<b>LABOR DAY</b>	no class	LABOR DAY	5-Sep
<b>Week 2</b>			
<b>Week 3</b>	Drug development process and delays. (Development pipeline.)	Seema	12-Sep
	<u>Wastewater from industry</u> Case study: Drug Resistance.		
	<a href="http://www.forbes.com/sites/judystone/2015/01/22/who-is-responsible-for-antibiotic-resistance/">http://www.forbes.com/sites/judystone/2015/01/22/who-is-responsible-for-antibiotic-resistance/</a>		
<b>week 4</b>	Ethics of Big Data analysis	KURT BACHMAN	19-Sep
<b>Week 5</b>	CRIXIVAN story as told by the co-inventor <b>JIM GUARE</b>	Jim Guare	26-Sep
	The halt of progression of HIV		
<b>Jim GuareWeek 6</b>	LIFE CYCLE ANALYSIS of drugs in our environment: <u>The 'unlabeled' wastewater</u> resulting drug production-who regulates this? Drugs, and hormones in our water supply such as antibiotics, estrogen and antidepressants. Triclosan MN case	Seema	3-Oct
	<a href="http://businessethicscases.blogspot.com/2014/02/colgate-palmolive-and-triclosan-danger.html">http://businessethicscases.blogspot.com/2014/02/colgate-palmolive-and-triclosan-danger.html</a>		
	<a href="http://www.cnn.com/2014/05/21/health/triclosan-ban-antibacterial/">http://www.cnn.com/2014/05/21/health/triclosan-ban-antibacterial/</a>		
<b>Week 7</b>	Precision medicine predicaments	Kurt Bachman	10-Oct
<b>Week 8</b>	3 topics in regulatory affairs Paper assigned	HARRIS ROTMAN	17-Oct

<b>Week 9</b>	ZIKA Analyzing the current epidemic, which came first, the pesticides or Mosquito borne Zika virus?	Seema	24-Oct
	LAST CLASS FOR BIOINFORMATICS students Final paper due	Seema	31-Oct
<b>Week 10</b>	Presentation Bioinformatics students		
	(MIDTERM PAPER DUE) Biotech and Bioinnovation		
	Final Paper Bioinformatics		
<b>Week 11</b>	TBA	Seema	7-Nov
	VACCINES-mandatory?		
<b>week 12</b>	Public suspicion vs public health	Seema	14-Nov
	Case study: Ebola/ malaria vs measles in CA		
<b>WEEK 13</b>	no class	Fall break	21-Nov
	FOOD SECURITY and Sustainability : Topic/s from Network of emerging leaders in Sustainability (NELS)	Seema	
<b>Week 14</b>	and		28-Nov
	Ethics of Climate Change studies		
<b>Week 15</b>	<a href="http://www.nature.com/news/chinese-scientists-genetically-modify-human-embryos-1.17378">http://www.nature.com/news/chinese-scientists-genetically-modify-human-embryos-1.17378</a>	Seema	5-Dec
	CRISPR CAS9 gene therapy		
	<a href="http://news.sciencemag.org/asiapacific/2015/04/chinese-paper-embryo-engineering-splits-scientific-community">http://news.sciencemag.org/asiapacific/2015/04/chinese-paper-embryo-engineering-splits-scientific-community</a>		
<b>Week 16</b>	Final Presentations: all students will present Final Paper due	ALL to attend	12-Dec

**Disability Disclosure statement:** Section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act (ADA) of 1990 protect students with a disability from discrimination. Students have the right to expect that disability-related information will be treated confidentially, and shared only on a need-to-know basis with Temple faculty or administrators. They should expect to be treated in a respectful and fair manner in interactions with other members of the university community. Students should expect appropriate accommodations in a timely manner, if requests are made in advance. Students have the right to appeal decisions regarding accommodations and auxiliary aids, if they believe the services are not appropriate. Prospective students are encouraged to meet with a DRS coordinator to learn more about resources and services available at Temple University. Please call 215-204-1280 or [email DRS drs@temple.edu](mailto:drs@temple.edu) to schedule an information session.

Student and Faculty Academic Rights and Responsibilities: The University and the faculty have a responsibility to provide students with opportunities and protections that promote the learning process in all its aspects and the policy can be accessed at this links <http://policies.temple.edu/PDF/313.pdf>