PGS 382V Spring 2017
Pharmaceutical Biotechnology
Dr. Maria A. Croyle
Friday 9 AM – Noon PHR 4.114
Course Syllabus

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Course Requirements:

Course grades will be based upon completion of 3 Tech Talks (10%), 3 research presentations (25%), a writing assignment (25%) and a final project (40%).

Useful References:

For those of you who may prefer additional readings on the basic concepts covered in the lecture, I recommend these texts:

1) Biotechnology. (David P. Clark, Nanette J. Pazdernik) 2nd Edition. Academic Cell 2016

2) Biopharmaceuticals (Biotechnology Revolution). (Monica K. Gill) Rosen Publishing 2016

3) Pharmaceutical Biotechnology. (Daan Crommelin, Robert D. Sindelar and Bernd Meibohm, Eds) 4th Edition. Springer 2013

4) Culture of Animal Cells. R. Ian Freshney 7th Edition. Wiley-Blackwell 2016

5) Lehninger's Principles of Biochemistry (Nelson, Cox eds.) 7th Edition. Macmillan Learning 2017

6) Molecular Cell Biology (H. Lodish, A. Berk, C.A. Kaiser, M. Krieger, A. Bretscher, H. Ploegh, A. Amon, K.C. Martin) 8th Edition W. H. Freeman, 2016

7) Janesway's Immunobiology (Kenneth Murphy, Ed) 9th Edition. Garland Science 2016

8) Basic Immunology: Functions and Disorders of the Immune System (A.K. Abbas, A. H. H. Lichtman, S. Pillai) 5th Edition. Elsevier 2016

Many relevant references from the primary literature will also be provided as handouts with each set of lecture notes.

Course Objectives:

As advances in technology accelerates, treatment strategies will soon involve the use of the traditional chemical entities (i.e. drugs) as well as recombinant proteins and genetic material (RNA, DNA).

This course is designed to provide pharmaceutics graduate students with a survey of the current technology used in basic science and the pharmaceutical industry to develop new medicines for the 21st century. After completing this course students should be able to:

* select and evaluate appropriate *in vitro* and *in vivo* models by which to test novel formulations or delivery methods

* understand the rationale and theory behind common techniques in the biotechnology field and use them to solve problems routinely encountered in the biotech industry.

* understand how the immune system works and how this influences the development of recombinant DNA therapeutics

* appreciate that modern therapeutics derived from the application of genetic techniques are often difficult to produce and handle but are highly specific for their biological sites of activity.

* understand the concept of gene therapy, where the field is currently, and how the pharmaceutical scientist can play a significant role in development of a product to treat a genetic disease.

* effectively interface with scientists involved in large scale production and processing of biological products with respect to formulation development and final product characterization.

2017 Lecture Schedule

Lecture	Date	Topic	Speaker
1	1/27	Bio 101: Cell Culture Part 1: Setting Lab Setup &Experimental Design	Croyle
2	2/3	Bio 101: Specialized Culture Techniques Part 2: Organotypic Cultures, Stem Cells, Large Scale Methods	Croyle
**	1/31	**23 & Me Lunch and Learn** W.C. Hogg 3.102 (NOT Hogg auditorium; the building between the Tower and Welch Hall)	
3	2/10	Molecular Bio 101: Principles of Recombinant DNA Technology	Croyle
*	2/17	**No Class! Dr. C. at NIH and Gates Foundation**	
*	2/24	**No Class! Dr. C. at Keystone Meeting**	
**4	**3/3**	***Educational Tour*** of Thermo Scientific (formerly Life Technologies) 2150 Woodward St, Austin, TX 78744 **Hosts: Sasha Vlassov and Susan Magdaleno**	
5	3/10	Molecular Biology 201 Recombinant Bugs, Mice, Monkeys, Fish and Plants – OH MY!!	Croyle
6	**3/17**	**No Class Spring Break!**	
7	3/24	Stem Cell Therapeutics and Technology for Regenerative Medicine	**Katy Moncivais, Ph.D.** Celling Biosciences
8	3/31	Protein Purification/Bioprocessing	Croyle
9	4/7	Immunology in the Pharmaceutical Industry/Vaccine Design	Croyle
10	4/14	Viruses as Medicines	**Anadita Seth, Ph.D**. Head Viral Based Therapeutics **Lonza, Houston, TX**
11	4/21	Gene Therapy 101: Viral and Non-Viral Vectors	Croyle
12	4/28	Systems Biology/ High Throughput Methodologies in Drug Development	**Ken Drake** **Serologix (Austin)**
13	5/5	Formulation and Pharmacokinetics of Nanotech-Based Products	Croyle

****Note this class will take place off campus!**

What is Biotechnology?

Literal Greek Translation of Biotechnology:

Industrial use of life forms.

10,000 years ago - growing crops and raising animals

Bio•tech•nol•o•gy *n* the use of living organisms or their products to enhance our lives and our environment.

6,000 years ago - production of bread and cheese using biological processes of microorganisms.

The Office of Technology Assessment of the United States Congress defines **biotechnology** as:

"Any technique that uses living organisms to make or modify a product to improve plants or animals or to develop microorganisms for specific uses".

Today biotechnology is generally thought of as a collection of technologies that capitalize on the attributes of cells, such as their manufacturing capabilities and put biological molecules such as DNA and proteins to work for a specific purpose.

Pharmaceutical Biotechnology

Use of living organisms or plants to develop medicinal products or devices.

All cells speak the same genetic language. The DNA information contained in one cell can be read and implemented by cells from other living things. Because of this characteristic, technologies based upon cells and biological molecules allow for great flexibility in the design of products and processes. In addition, the interaction between cells and biological molecules are **extremely specific**. As a result, biotechnology products often solve specific problems, generate gentler far fewer side effects and have fewer unintended consequences, making treatments more **specific** and **precise** and the outcomes of therapy more **predictable.**

Some Facts About Biotechnology

* **Over 200 million people worldwide** have been helped by the **more than 196 biotechnology drug products and vaccines** approved by the U.S. Food and Drug Administration (FDA).

*The modern biotech industry was born when **Genentech**, now a part of Roche, was founded in 1976. Scientists at the company started a long history of innovation in 1978 by successfully expressing a **human gene in bacteria** that allowed them to produce **human insulin**. It became the first genetically engineered human medicine approved by the FDA in 1982 with the help of Eli Lilly.

* There are **more than 370 biotechnology drug products and vaccines currently in human clinical trials and hundreds more in early development in the United States.** These medicines target more than 200 diseases including various cancers, Alzheimer's, heart disease, multiple sclerosis, AIDS, diabetes, arthritis and other conditions.

* Biotechnology is responsible for **hundreds of medical diagnostic tests** that keep the blood supply safe from the AIDS virus and detect other conditions early enough to be successfully treated. Home pregnancy tests are also biotechnology diagnostic products.

* Consumers are already enjoying **biotechnology foods** such as vine-ripened, longer-lasting tomatoes, papaya, soybeans and corn. Hundreds of biopesticides and other agricultural products such as Messenger® (EDEN Bioscience) which uses hairpin protein technology to naturally stimulate growth and defense pathways without altering the plant's DNA are also being used to improve our food supply and to reduce our dependence on conventional chemical pesticides.

* **Environmental biotechnology products** make it possible to more efficiently clean up hazardous waste by harnessing pollution-eating microbes without the use of caustic chemicals.

* Industrial biotechnology applications have **led to cleaner processes with lower production of wastes and lower energy consumption**, in such industrial sectors as chemicals, pulp and paper, textiles, food and fuels, metals and minerals and energy. For example, much of the denim produced in the United States is finished using biotechnology enzymes.

* **DNA fingerprinting,** a biotech process, has dramatically improved criminal investigation and forensic medicine, as well as afforded significant advances in anthropology and wildlife management.

* There are currently **2,772 biotechnology companies** in the United States of which 436 are publicly held. In 2014, ~70% of new healthcare-related IPOs in the US were biotechs.

* **Market capitalization**, the amount of money invested in the U.S. biotechnology industry in 2015 was approximately **$379.5 billion.**

* Approximately one-third of **biotech companies employ fewer than 50 employees**. More than two-thirds employ fewer than 135 people.

* The U.S. biotechnology industry currently **employs more than 854,000 people in high-wage, high-value jobs. Approximately 10% of these (92,000) work in the state of Texas.**

* Biotechnology is **one of the most research-intensive industries** in the world. The U.S. biotech industry spent $20.5 billion in research and development in 2003. The top five biotech companies **spent an average of $249,200 per employee on R&D. This compares with an average of $31,200 per employee for the top pharmaceutical companies.**

* The biotech industry is **regulated by the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA) and the Department of Agriculture (USDA).**

The Impending Biologics Patent Cliff – Up Next Biosimilars!