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PHA5172: Pharmaceutical Biotechnology

Fall 2020

2 Credit Hours – A-E Grading

This course offers the students comprehensive information about research related to pharmaceutical biotechnology and the development of biopharmaceuticals. The students will gain an understanding in both scientific knowledge of designing and producing novel biologics, and business challenges including regulatory issues.

Teaching Partnership Leader

Sihong Song, Ph.D.

- Email: ShSong@cop.ufl.edu
- Office: HSC P3-31
- Phone: 352-273-7867
- Office Hours: See Canvas for office hours.

See Appendix A. for Course Directory of Faculty and Staff Contact Information.

Course-Level Objectives

Upon completion of this course, the student will be able to:

1. Explain scientific principles for biotechnology in pharmaceutical product development.
2. Describe advanced biotechnology in novel drug development
3. Describe the technologies used for recombinant protein production.
4. Describe the technologies for monoclonal antibody productions and their therapeutic applications.
5. Describe the mechanisms how vaccine works and approaches of novel vaccine development.
6. Describe commonly used gene therapy vectors and their applications.
7. Describe mechanisms of using RNA for the treatment of human diseases.
8. Describe advanced technologies for genome editing and their potential application in treatment of human diseases.
9. Describe advantages and challenges in applying stem cell mediated therapy.
10. Describe the mechanisms of exosome production and its potential for therapeutic application
11. Describe organization & processes in biotechnology and pharmaceutical industry for their operations and research and development including regulatory issues.
12. Explain challenges and opportunities in development of biologics and drugs in the pharmaceutical and biotechnology industry.

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Course Pre-requisites

1. Completion of all Year 1 Pharm.D. program coursework including milestones.

Course Co-requisites

1. There are no co-requisites for this course.

Course Outline

See *Appendix B: Course Outline*. Please routinely check your campus calendar and the Canvas course site for any messages about changes in the schedule including meeting dates/times, deadlines, and room changes.

Date and Time	Mod #	Activity Title	Contact Time [hr.]a	Responsible	Learning Objectives
11/30/20	1	Module 1: Introduction to Molecular Biology		Song,Sihong	1, 2
11/30/20	1	Watch: Introduction	0.65	Song,Sihong	
11/30/20	1	Watch: DNA Replication	0.67	Song,Sihong	
11/30/20	1	Watch: Gene Transcription	0.72	Song,Sihong	
11/30/20	1	Watch: Protein Biosynthesis	0.80	Song,Sihong	
11/30/20	1	Animations Related to the Topics of Biosynthesis of DNA, RNA, and Protein: Chromosome.swf bidirectional_DNA_repl.swf nucleotide_polym.swf telomere_replication.swf leading_lagging_strand.swf mRNA_splicing.swf transcript_mechanism.swf life_cycle_of_mRNA.swf life_cycle_protein.swf protein_sorting.swf secreted_proteins.swf protein secretion.swf	1.08	Song,Sihong	
12/01/20	2	Module 2: Biotechnologies		Song,Sihong	1, 2, 3
12/01/20	2	Watch: Biotechnology	1.07	Song,Sihong	
12/01/20	2	Animations Related to Individual Techniques: PCR.swf plasmid_cloning.swf reporter_constructs.swf dideoxy_sequencing.swf WB1-gel_electrophoresis.swf WB2-immunoblotting.swf screen arry.swf	0.58	Song,Sihong	
12/01/20	3	Module 3: Recombinant Proteins		Song,Sihong	1, 2, 3
12/01/20	3	Watch: Recombinant Protein (I and II)	0.95	Song,Sihong	
12/01/20	4	Module 4: Gene Pharming		Song,Sihong	3,4

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Date and Time	Mod #	Activity Title	Contact Time [hr.]a	Responsible	Learning Objectives
12/01/20	4	Watch: Transgenic Animals	0.58	Song,Sihong	
12/01/20	4	Watch: Transgenic Plants	0.63	Song,Sihong	
12/01/20	4	Explore Animation: Transgenic_mouse.swf	0.08	Song,Sihong	
12/02/20	5	Module 5: Monoclonal Antibodies		Song,Sihong	3,4
12/02/20	5	Watch: Monoclonal Antibody-1 antibody genes	0.73	Song,Sihong	
12/02/20	5	Watch: Monoclonal Antibody-2 Molecular Engineering	0.85	Song,Sihong	
12/03/20	6	Module 6: Vaccine and Gene Therapy		Song,Sihong	4, 5
12/03/20	6	Watch: Vaccine	0.40	Song,Sihong	
12/03/20	6	Watch: Gene Therapy 1	0.92	Song,Sihong	
12/03/20	6	Watch: Gene Therapy 2	0.65	Song,Sihong	
12/04/20 10am-12pm	1-6	Active Learning Session 1 (2 hours)	2.00	Song,Sihong	6, 7
12/04/20 10:00am - 12:00am	1-6	RAT 1		Song,Sihong	
12/07/20	7	Module 7: RNA Therapeutics		Song,Sihong	8
12/07/20	7	Watch: RNA Therapy (I and II)	1.60	Song,Sihong	
12/07/20	8	Module 8: Gene Editing		Song,Sihong	8
12/07/20	8	Watch: Gene Editing I	0.93	Song,Sihong	
12/07/20	8	Watch: Gene Editing II	0.73	Song,Sihong	
12/08/20	9	Module 9: Stem Cell Based Therapy		Song,Sihong	9
12/08/20	9	Watch: Cell Therapy 1-Stem Cells-iPS	0.83	Song,Sihong	
12/08/20	9	Watch: Cell Therapy 2-Adult Stem Cells	0.60	Song,Sihong	
12/08/20	9	Watch: Cell Therapy 3-Applications	0.97	Song,Sihong	
12/09/20	10	Module 10: Exosomes		Song,Sihong	10
12/09/20	10	Watch: Exosomes: Basics and Application	1.28	Song,Sihong	
12/10/20	11	Module 11: Challenges and Opportunities		Song,Sihong	11, 12
12/10/20	11	Watch: Challenges and Opportunities I	0.55	Song,Sihong	
12/10/20	11	Watch: Challenges and Opportunities II	0.50	Song,Sihong	
12/11/20 10am-12pm	1-11	Active Learning Session 2 (2 hours)	2.00	Song,Sihong	1-12
12/11/20 10:00am - 12:00am	1-11	RAT 2		Song,Sihong	
12/16/20 10am-12pm	1-11	Final Exam (2 hours)		Song,Sihong	
		Total Hours	23.37		

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Required Textbooks/Readings

There are no required textbooks for this course.

Suggested Textbooks/Readings

The following textbooks are recommended as supplementary material:

1. "Textbook of Biochemistry with Clinical Correlations" T.M. Devlin Editor, Wiley-Liss, John Wiley & Sons, Inc. 7th Edition 2010 (Recycled 5th or 6th editions of the same textbook can also be used).
 - a. Available via Access Pharmacy:
<https://uf.catalog.fcla.edu/uf.jsp?st=UF021950392&ix=pm&l=0&V=D&pm=1&fl=ba>
2. "Pharmaceutical Biotechnology: Drug Discovery and Clinical Applications", 2nd Edition (2012), Oliver Kayser (Editor) and Heribert Warzecha (Editor), Wiley-Black Well ISBN:978-3-527-32994-6.
3. "Drug & Biological Development, From Molecule to Product & Beyond" (2007); Evens RP, ed. Springer, NY, NY.
 - a. Available via Access Pharmacy:
<https://uf.catalog.fcla.edu/uf.jsp?st=UF021073034&ix=pm&l=0&V=D&pm=1&fl=ba>
4. "Pharmaceutical Biotechnology: Concepts and Applications" (2007), Gary Walsh, Willey, ISBN: 978-0-470-01244-4
5. Pharmaceutical Biotechnology. Fundamentals and Applications, Crommelin DJA, Sindelar RD, Meibohm B. 3rd edition, Informa Healthcare Publishers, 2007
6. "Biotechnology and Biopharmaceuticals: Transforming proteins and genes into drugs" (2003), Rodney JY Ho and Milo Gibaldi, Wiley-Liss ISBN: 0-471-20690-3.

Other Required Learning Resources

None

Materials & Supplies Fees

None

Student Evaluation & Grading

Evaluation Methods and How Grades are calculated.

Assessment Item	Grade Percentage
Individual Readiness Assessments	20%
Participation	10%
Final Exam	70%
Total	100%

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Table 1. Grading Scale

Percentage Range	Letter Grade
92.50-100%	A
89.50-92.49%	A-
86.50-89.49%	B+
82.50-86.49%	B
79.50-82.49%	B-
76.50-79.49%	C+
72.50-76.49%	C
69.50-72.49%	C-
66.50-69.49%	D+
62.50-66.49%	D
59.50-62.49%	D-
< 59.50%	E

Rounding of grades:

Final grades in Canvas will be rounded to the 2nd decimal place. If the decimal is X.495 or higher, Canvas will round the grade to X.50. The above scale depicts this policy and grades are determined accordingly. Grade assignment is made using this policy and NO EXCEPTIONS will be made in situations where a student's grade is "close."

Educational Technology Use

The following technology below will be used during the course and the student must have the appropriate technology and software.

1. ExamSoft™ Testing Platform
2. Canvas™ Learning Management System

For technical support, navigate to [Educational Technology and IT Support Contact Information](#) at this URL:

<http://curriculum.pharmacy.ufl.edu/current-students/technical-help/>

Pharm.D. Course Policies

The Policies in the following link apply to this course. Review the [Pharm.D. Course Policies](#) carefully, at this URL: <http://curriculum.pharmacy.ufl.edu/current-students/course-policies/>

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Appendix A. Course Directory

Teaching Partnership Leader/Course Director:

Sihong Song, Ph.D.

Email: ShSong@cop.ufl.edu

Office: HSC P3-31

Phone: 352-273-7867

Questions to Ask:

- Concerns about performance
- Guidance when there are performance problems (failing grades)
- General questions about content

Academic Coordinator:

Name: TBC

Email:

Office: HPNP 4312

Phone:

Absent/Tardy Email: absent2pd@cop.ufl.edu
or absent3pd@cop.ufl.edu

Instructional Designer:

Name: Elliot Tordoff

Email: etordoff@cop.ufl.edu

Office: HPNP 4309

Phone: 352-2945215

Educational Coordinators:

McKenzie Wallen

Email: mwallen@cop.ufl.edu

Office: Jacksonville Campus

Iverta Allen, M.P.A.

Email: iallen1@cop.ufl.edu

Office: Orlando Campus

Questions to Ask:

- Issues related to course policies (absences, make up exams, missed attendance)
- Absence requests (Only the Academic Coordinator handles absence requests)
- Questions about dates, deadlines, meeting place
- Availability of handouts and other course materials
- Assignment directions
- Questions about grade entries gradebook (missing grades, wrong grade)
- Assistance with ExamSoft® (Distant campus students may contact Education Coordinator for use of SofTest and assistance during exams. The Academic Coordinator is the contact person for issues related to grading and posting of ExamSoft grades.)