PHA5172 Pharmaceutical Biotechnology

Fall 2023

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: Please see the Canvas course site for posted 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 the 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 biologicals and drugs in the pharmaceutical and biotechnology industry.

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. 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.

Required Textbooks/Readings

There are no required textbooks for this course.

Use UF VPN to access UF Libraries Resources when off-campus.
The UF HSC library staff can assist you with questions or issues related to accessing online library materials. For assistance contact your College of Pharmacy librarian or visit the HSC Library Website at this URL:http://www.library.health.ufl.edu/

Suggested Textbooks/Readings

The following textbooks are recommended as supplementary material:

1. "Pharmaceutical Biotechnology A Focus on Industrial Application". Edited By Adalberto Pessoa, Michele Vitolo, Paul Frederick Long, 1st Edition, eBook Published 15 July 2021. DOI: https://doi.org/10.1201/9781003178361.
2. "Biopharmaceuticals Challenges and Opportunities". Basanta Behera, 1st Edition, eBook Published 7 December 2020. DOI https://doi.org/10.1201/9781351013154.
3. Biotechnology The Science, the Products, the Government, the Business. Ronald P. Evens, 1st Edition, eBook Published 26 July 2020. DOI https://doi.org/10.1201/9780429399299.
4. "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).
5. "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.
6. "Pharmaceutical Biotechnology: Concepts and Applications" (2007), Gary Walsh, Willey, ISBN: 978-0-470-01244-4
7. Pharmaceutical Biotechnology. Fundamentals and Applications, Crommelin DJA, Sindelar RD, Meibohm B. 3rd edition, Informa Healthcare Publishers, 2007
8. "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.
[The Canvas© gradebook will be set-up using the percentages below to compute the grade.]

Table 1.1 Evaluation and Grading

Assessment Item	**Grade Percentage**
iRats (n = 2, 10% each)	20%
tRats (n = 2, 5% each)	10%
Participation (see below explanation)	10%
Final Exam	60%
Total	100%

Table 1.2 Grading Scale

Percentage	**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."

Participation grade:

Participation grade for this course will be based on attendance and by being actively/verbally engaged in class discussions.

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/

Artificial Intelligence Use

The use of artificial intelligence (AI) text generators such as ChatGPT on assignments, projects, quizzes, and exams is prohibited in this course. Use of AI text generators is considered evidence of academic dishonesty. If a student is uncertain about the use of AI technology, it is the student's responsibility to ask the instructor prior to beginning the assignment or assessment.

Pharm.D. Course Policies

The Policies in the following link apply to this course. Review the General Pharm.D. Course Policies carefully, at this URL: http://curriculum.pharmacy.ufl.edu/current-students/course-policies/

Attendance Policy

Attendance is mandatory for active learning sessions such as team-based learning sessions, case discussions, laboratory sessions, and other activities that the instructor designates as required. This course has 2 required sessions. A student who misses greater than 1 sessions (25% of the required active learning sessions/activities) or laboratory sessions for this course will receive an incomplete in the course and will retake the course during the next offering, resulting in delayed graduation.

Makeup Assignments

Makeup assignments may be required for excused absences from all Active Learning Sessions. Students will be required to complete the makeup assignment within one week of the missed session.

Late Assignments

N/A

Accessibility and Belonging Statement

The University of Florida College of Pharmacy strives to stimulate a culture that promotes diversity and inclusion within an exceptional community of students, faculty, and staff. It is our intent that students from all diverse backgrounds and perspectives be well served by this course, that students' learning needs be addressed both in and out of class, and that the diversity that students bring to this class be viewed as a resource, strength, and benefit.

We intend to present materials and activities that are respectful of diversity: gender, sexuality, disability, age, socioeconomic status, ethnicity, race, and culture. Your suggestions are encouraged and appreciated. Please let us know ways to improve the course's effectiveness for you personally or for other students or student groups.

If any of our class meetings conflict with any of your religious events, an excused absence will be provided when requested using the standard UF COP process as detailed in the UF COP Course policies.

If you feel that you have experienced or witnessed any bias/treatment that falls short of these expectations, you may submit a report through the UF COP *Student Mistreatment Report*.

Course Evaluation Process

Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. Guidance on how to give feedback in a professional and respectful manner is available at https://gatorevals.aa.ufl.edu/students/. Students will be notified when the evaluation period opens, and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via https://ufl.bluera.com/ufl/. Summaries of course evaluation results are available to students at https://gatorevals.aa.ufl.edu/public-results/.

Appendix A. Course Directory

Teaching Partnership Leader/Course Director(s):

Sihong Song, Ph.D.
- Email: ShSong@cop.ufl.edu
- Office: HSC P3-31
- Phone: 352-273-7867

Office Hours: Please see the Canvas course site for posted office hours

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

Instructional Designer

Chris Egan, M.Ed., NRP
- Email: cegan@ufl.edu
- Phone: 352-273-5636

Academic Coordinator Gainesville Campus:

Ashley Williams
- Email: acwilliams@ufl.edu
- Office: HPNP 4309
- Phone: 352-273-9951

Educational Coordinators:

Katie Orben
- Email: korben06@ufl.edu
- Office: Jacksonville Campus
- Phone: 904-244-9590

Jessica Linares
- Email: jnoriegalinares@ufl.edu
- Office: Orlando Campus
- Phone: 407-313-4087

Questions to Ask:
- Issues related to course policies (absences, make up exams, missed attendance)
- Absence/tardy 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 in gradebook (missing grades, incorrect grade)
- Assistance with ExamSoft® (Distance campus students may contact the Educational Coordinator for use of Examplify and assistance during exams. The Academic Coordinator is the contact person for issues related to grading and posting of ExamSoft grades.)

Appendix B: Course Outline

Date / Time	Mod #	Activity	Activity Title	Contact Time (hr)	Responsible
11/29/23	1	Module	Module 1: Introduction to Molecular Biology		Song,Sihong
11/29/23	1.1	Lecture Video	Watch: Introduction	1.25	Song,Sihong
11/29/23	1.2	Lecture Video	Watch: DNA Replication	1	Song,Sihong
11/29/23	1.3	Lecture Video	Watch: Gene Transcription	1	Song,Sihong
11/29/23	1.4	Lecture Video	Watch: Protein Synthesis: Translation and Posttranslational Modifications	1	Song,Sihong
11/29/23	1.5	Video Other	Animations Related to the Topics of Biosynthesis of DNA and RNA	0.2	Song,Sihong
11/29/23	1.6	Video Other	Animations Related to the Topics of Protein	0.15	Song,Sihong
11/30/23	2	Module	Module 2: Biotechnologies		Song,Sihong
11/30/23	2.1	Lecture Video	Watch: Biotechnology	1.4	Song,Sihong
11/30/23	2.2	Video Other	Animations Related to Individual Techniques	0.3	Song,Sihong
11/30/23	3	Module	Module 3: Recombinant Proteins		Song,Sihong
11/30/23	3.1	Lecture Video	Watch: Recombinant Protein (I and II)	1.28	Song,Sihong
11/30/23	4	Module	Module 4: Gene Pharming		Song,Sihong
11/30/23	4.1	Lecture Video	Watch: Transgenic Animals	1.14	Song,Sihong
11/30/23	4.2	Video Other	Animation Related to Transgenic Mouse	0.02	Song,Sihong
11/30/23	4.3	Lecture Video	Watch: Transgenic Plants	1	Song,Sihong
12/01/23	5	Module	Module 5: Monoclonal Antibodies		Song,Sihong
12/01/23	5.1	Lecture Video	Watch: Monoclonal Antibody-1 antibody genes	0.86	Song,Sihong
12/01/23	5.2	Lecture Video	Watch: Monoclonal Antibody-2 Molecular Engineering	1.18	Song,Sihong
12/04/23	6	Module	Module 6: Vaccine and Gene Therapy		Song,Sihong
12/04/23	6.1	Lecture Video	Watch: Vaccine	1.15	Song,Sihong
12/04/23	6.2	Lecture Video	Watch: Gene Therapy 1	1.24	Song,Sihong
12/04/23	6.3	Lecture Video	Watch: Gene Therapy 2	1.2	Song,Sihong
12/05/23	7	Module	Module 7: RNA Therapeutics		Song,Sihong
12/05/23	7.1	Lecture Video	Watch: RNA Therapy (I and II)	1.68	Song,Sihong
12/06/23	8	Module	Module 8: Gene Editing		Song,Sihong
12/06/23	8.1	Lecture Video	Watch: Gene Editing I	0.96	Song,Sihong
12/06/23	8.2	Lecture Video	Watch: Gene Editing II	1.06	Song,Sihong
12/07/23	9	Module	Module 9: Stem Cell Based Therapy		Song,Sihong
12/07/23	9.1	Lecture Video	Watch: Cell Therapy 1-Stem Cells-iPS	0.94	Song,Sihong
12/07/23	9.2	Lecture Video	Watch: Cell Therapy 2-Adult Stem Cells	0.82	Song,Sihong
12/07/23	9.3	Lecture Video	Watch: Cell Therapy 3-Applications	1.68	Song,Sihong
12/08/23	10	Module	Module 10: Exosomes		Song,Sihong
12/08/23	10.1	Lecture Video	Watch: Exosomes: Basics and Application	1.04	Song,Sihong

Date / Time	Mod #	Activity	Activity Title	Contact Time (hr)	Responsible
12/11/23 at 10-11:50am		Active Learning Session	Active Learning Session 1 -- WIll cover Modules 1-6	2	Song,Sihong
12/11/23		Quiz (In Class)	RAT 1 -- Will cover Modules 1-6		Song,Sihong
12/12/23	11	Module	Module 11: Challenges and Opportunities		Song,Sihong
12/12/23	11.1	Lecture Video	Watch: Challenges and Opportunities I	0.6	Song,Sihong
12/12/23	11.2	Lecture Video	Watch: Challenges and Opportunities II	0.84	Song,Sihong
12/13/23 at 10-11:50am		Active Learning Session	Active Learning Session 2 -- Will cover Modules 7-11	2	Song,Sihong
12/13/23		Quiz (In Class)	RAT 2 -- Will cover Modules 7-11		Song,Sihong
12/15/23 at 1 3pm	1 11	Exam	Final Exam (2 hours)		Song,Sihong
			Total Hours	28.99	