

This is a sample syllabus only. The instructor may make changes to the syllabus in future courses.

SYLLABUS

- BME 490/590 Special Topics in Industrial Bioprocessing and Biomanufacturing

Credit Hrs: 3 Credit Hours, Spring Semester. Provided every another year from Spring, 2017.

Contact Hrs: 37.5 Credit Hours

Instructor: **Dr. Xiaoguang (Margaret) Liu**

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Class Hours: 9:30AM - 10:45AM, Tuesday and Thursday

Location: BEC 158

Textbook: Cell Culture Technology for Pharmaceutical and Cell-Based Therapies. Wei-Shou Hu and Sadttin Ozturk. CRC Press, August 30, 2005. Hardcopy new book: \$592; EBook: \$192; Used book: various.

Reference Textbooks (Optional):

- 1) Biopharmaceuticals, an Industrial Perspective. G. Walsh and B. Murphy. Springer. 1999. ISBN 978-94-017-0926-2. Hardcopy and Softcopy: \$339.
- 2) Pharmaceutical Manufacturing Handbook: Production and Processes. Shayne Cox Gad. Wiley. 2008. ISBN: 978-0-470-25958-0
- 3) Biotechnology and Biopharmaceutical Manufacturing, processing, and Preservation. Kenneth E. Avis, Vincent L. Wu, March 31, 1996 by CRC Press. ISBN 9781574910162 - CAT# PH0167. New hardcopy or softcopy book: \$319; Used book: \$53.38.

Supplemental Materials:

Supplemental Handout

Course Information:

Catalog Description: Bioprocessing and biomanufacturing are the key technologies in biopharmaceutical and biotechnology industry. This course will introduce students the growing industries related to biomedical, biopharmaceutical and biotechnology. It is targeted to offer the students marketable skills to work in a vital area of economic growth and also convey some of the challenges and opportunities awaiting students in Biotech industry. Specifically, this course will cover fermentation, cell culture, bioreactor design, production and purification process development, scale-up, manufacturing, plant design, Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP). In addition, the successful bioproducts and biopharmaceuticals, such as therapeutic proteins, therapeutic cells, and biochemicals, will be used as examples to provide the students an overview of industrial biotechnology, with specific discussions of: 1) biotech business, including product development, manufacturing, marketing and project management, and 2) industrial requirements for career path in bioengineering. The students will get familiar

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with the growing industries related to biomedical, biopharmaceutical and biotechnology, which will offer them marketable skills to work in a vital area of economic growth.

Co-Requisites: Graduates and Undergraduates. BME 310 (Biomaterials), or BY 330 (Cell Biology), or CH 460 (Fundamentals of Biochemistry), or special approval from instructor

Course is elective

Learning Outcomes: Upon completion of this course, the students will be able to:

- (1) Understand industrial biotechnology unit operations, such as fermentation, cell culture, bioreactor design, production and purification process development, scale-up, and manufacturing.
- (2) Get familiar with industrial requirements for bioprocessing and biomanufacturing, such as plant design, Good Laboratory Practice (GLP), and Good Manufacturing Practice (GMP).
- (3) Understand the principle of Biotech business in biopharmaceutical development, bioproduct development, bioprocessing of production and purification, biomanufacturing, marketing, and project management.
- (4) Apply the genetic engineering, bioengineering, cell biology and molecular biology knowledge to design novel strains or cell lines for novel bioproducts production.
- (5) Apply the bioengineering knowledge to design bioproduction process, bioseparation process, and scaling-up strategies.
- (6) Apply the integrated technologies to plan the biomanufacturing facility to meet the marketing need of therapeutic proteins, therapeutic cells or biochemicals,
- (7) Design manufacturing plant to produce multiple bioproducts using mammalian cell culture or bacterial fermentation.
- (8) Evaluate and select the advanced biodevice and equipment.
- (9) Perform economic analysis of biopharmaceutical development and production.
- (10) Perform marketing analysis and estimate the biomanufacturing capacity.

Students Outcomes:

Project design of bioprocess and biomanufacturing for commercial production of various biopharmaceutical products in Biotech industry.

Topics:

Week 1: Cell culture technology

Week 2: Recombinant DNA technology and cell line development

Week 3: Medium development

Week 4: Cell culture bioreactors

Week 5: Instrumentation and process control

Week 6: Cell culture kinetics and model

Week 7: Mid-Term Exam I

Week 8: Fed-batch cell culture

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Week 9: Cell separation and product capture

Week 10: Downstream processing

Week 11: Formulation filling and packaging

Week 12: Validation and qualification

Week 13: Facility design

Week 14: Final Exam and Project submission

Professional Components:

Mathematics and basis sciences: Yes

Engineering topics: 3 credits

Significant engineering design: Yes

General education (academic Core): None

Grading:	Homework	10%
	Mid-Term Exam	30% (60%)
	Final Exam (Optional)	30%
	Project Report	30%

Final grade = Homework (10%) + Mid-Term Exam (30% or 60%) + Final Exam (30%, optional) + Report (30%)

* The grading criteria are different for BME 490 and BME 590.

- If you miss the exam with a certified medical excuse, you may take a makeup exam at a designated time near the end of the semester. Only one makeup exam will be given and it will be comprehensive. Exams missed without a medical excuse will be graded as zero.
- Homework is due at the start of the class – late assignments will not be accepted. Students may discuss homework outside of class, and are *strongly* encouraged to work together. Even when working in groups, you must turn in individual solutions to the homework. Expect 1 homework set every another week throughout the semester.
- All students in attendance at the University of Alabama at Birmingham (UAB) are expected to be honorable and to observe standards of conduct appropriate to a community of scholars. The University expects from its students a higher standard of conduct than the minimum required to avoid discipline. Academic misconduct includes all acts of dishonesty in any academically related matter and any knowing or intentional help or attempt to help, or conspiracy to help, another student. The Academic Misconduct Disciplinary Policy will be followed in the event of academic misconduct.
- Severe weather protocol: In the case of a tornado warning (tornado has been sighted or detected by radar; sirens activated), all university activities are automatically suspended, including all classes and laboratories. If you are in a building, please move immediately to the lowest level and toward the center of the building away from windows (interior classrooms, offices, or corridors) and remain there until the tornado warning has expired. Classes in session when the tornado warning is issued can resume immediately after the warning has expired at the discretion of the instructor. Classes that have not yet

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begun will resume 30 minutes after the tornado warning has expired provided at least half of the class period remains.

- Turn off cell phones in lecture or set to a vibrate alert.
- Grade Cutoff Points: 90.0 A, 80.0 B, 70.0 C, and 60.0 D. Note: Grades will be rounded to the nearest tenth of a point.

Note: This syllabus is subject to change