

LOS ANGELES TRADE TECH COLLEGE

Spring 2015

BIO TECH 012, Section 1604, 4 Units

PREREQUISITES: No prerequisites required.

DESCRIPTION: This course describes a detailed study of the manufacture of biopharmaceuticals/biologics from quality requirements and agency regulations, to industrial techniques within the biotechnology field. Special topics include the Quality Assurance/Control, Validation, Process Development and Good Manufacturing Practices of biomanufacturing, the basic biology and chemistry as it applies to the manufacture of biological products, and procedures, proper techniques, and documentation of the biomanufacturing process.

STUDENT LEARNING OBJECTIVES:

1. Students will demonstrate an understanding of the purpose, fundamentals and regulations of biomanufacturing.
2. Students will understand the science underlying biomanufacturing.
3. Students will apply techniques and procedures applicable to biomanufacturing.
4. Students will perform experiments in the laboratory to illustrate these concepts following safety practices in the laboratory.

INSTRUCTOR: Manuel Acosta, M.S.

CONTACT INFORMATION: e-mail: acostam2@lattc.edu

OFFICE HOURS: TTh 9:40 pm – 10:20 pm, Cedar Hall, K-464/K-423

LECTURE SECTION: TTh 5:00 pm – 6:25 pm, Magnolia Hall (Bldg MH), Room 301

LABORATORY SECTION: Th 6:35 pm – 9:40 pm, Cedar Hall (Bldg K), Room 464

REQUIRED TEXT: Lecture section – *Introduction to Biomanufacturing, 1st edition* by Northeast Biomanufacturing Center and Collaborative (NBC2)

Laboratory section – Lab Handouts for experiments will be given free of charge.

REQUIRED MATERIALS: Lab coat, Safety Goggles, Bound Laboratory Notebook, and Scientific Calculator only (No cell phones or programmable/graphing calculators).

READING & HOMEWORK: You should attempt to **read** the assigned chapters **before** the related topic is covered in lecture. Suggested homework problems are assigned at the beginning of each week. Homework is turned in at the beginning of class the day of the exam and will be checked for completion. *It is your responsibility to do (at least) the assigned homework in order to master the material covered.* Allocate ~ 8 hours of independent study per week for this course.

EXAMINATIONS: Three exams are tentatively scheduled for **Thursdays, March 12, April 23, and May 21**; all will be given during the regular lecture time slot. The 2-hour Final Exam is scheduled for **Thursday, June 4, 2015 @ 5:00 pm – 7:00 pm; site to be determined. No make-up exams will be given.** Students that foresee an absence due to work schedule, medical issue, or religious holiday will have to take the exam before the scheduled exam date. **If by chance a make-up is allowed, there will be a 10% penalty added to the exam. NO ONE** will be permitted to take the final exam either earlier or later than the scheduled time, and no one can receive a passing grade for the course without taking the final exam! Cell phones are not allowed during exam.

LABORATORY: The laboratory schedule is in the syllabus. Each week's experiment(s) is designed to give the student practical experience in the biomanufacturing process. You are expected to have read each week's experiment(s) before attending lab section. The post-laboratory report and calculations are due 1 week after completion of lab. Failing to attend and complete **THREE (3)** or more laboratories will result in a lab course grade of "F". Make-up lab policy will be discussed during the first lab meeting.

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GRADING: The final grade in the course will consist of the following: homework assignments (10%), the sum of all three exam scores (30%), the laboratory grade (30%), and the final exam (30%).

Homework Assignments (10%) + Exams (30%) + Lab (15%) + Lab Performance (15%) + Final (30%) = Total(100%)

The final letter grades will be assigned according to the following scale:

A (90–100%) B (80–89%) C (70–79%) D (55–69%) F (below 55%)

Dates to drop the course: **Without a “W”, Sunday, February 22, 2015; With a "W", Sunday, May 10, 2015.**

ACADEMIC and ADMINISTRATIVE HOLIDAYS affecting this class:

Tuesday, March 31, 2015 (Chavez Day).

Monday, April 6 – Friday, April 10, 2015 (Spring Break)

ACCOMODATIONS AND OTHER INFORMATION

Attendance Policy: Students are expected to attend every class meeting, arrive on time, and stay throughout the class period. Students may be dropped from class for excessive tardiness and absenteeism, failure to attend/appear on the first day of class or entire first week of class.

Academic Dishonesty Policy: As described in the LACCD Student Code of Conduct (Board Rule 9803.28), “Violations of academic integrity of any type by a student provides grounds for disciplinary action by the instructor of college. Violations of Academic Integrity include, but are not limited to, the following actions: cheating on an exam, plagiarism, working together on an assignment, paper or project when the instructor has specifically stated students should not do so, submitting the same term paper to more than one instructor, or allowing another individual to assume one’s identity for the purpose of enhancing one’s grade.” For more information on the Standards of Student Conduct, refer to the college catalog available in hardcopy and online at www.lattc.edu. Cell phones are not allowed during an exam or quiz.

A NOTE ON CHEATING: Cheating is any behavior that violates academic integrity and honesty. Cheating is not condoned in any form. If a student is caught cheating, the penalty is a zero for the assignment and an “F” in the course. No exceptions!!!

Disability Support Services (DSS) Accommodation: “Students with disabilities who need any assistance or accommodations should contact the instructor”. The DSPS office is available to assist with accommodating a disabled student at x3733 and is located in (Mariposa Hall) MA 100.

Disclaimer: Syllabus/Lab Schedule subject to change.

Learning Skills Center: “To further your success, reinforce concepts, and achieve the stated learning objectives for this course, I refer you to Learning Skills Center for learning assistance services. You will be automatically enrolled in Supervised Tutoring, a free noncredit course that does not appear on your transcripts. Services are located in (Mariposa Hall) MA 109.

Topics and Readings in Introduction to Biomanufacturing by NBC2

Week	Dates (T,Th)	Chapter Topic	Homework
1	2/10, 2/12	Overview/Intro	All problems in <u>Check Your Knowledge</u> section at end of each Chapter.
2	2/17, 2/19	Chap 7 – Quality Assurance	
3	Sun, Feb 22	Last day to drop classes Online Without a “W”	
3	2/24, 2/26	Chap 7 – Quality Assurance / Chap 9 – Quality Control	
4	3/3, 3/5	Chap 9 – Quality Control	
5	3/10	Chap 4 – Validation	
5	Thur, 3/12	Exam 1 (100 pts): Chapters 7 & 9	
6	3/17, 3/19	Chap 4 – Validation	
7	3/24, 3/26	Chap 4 – Validation / Good Manufacturing Process	
8	Tue, 3/31	Holiday – Cesar Chavez’s Day	
8	4/2	Good Manufacturing Process	
	4/7, 4/9	Spring Break (Mon 4/6 thru Fri 4/10)	
9	4/14, 4/16	Good Manufacturing Practices / Chap 12 – Process Development	
10	4/21	Chap 12 – Process Development	
10	Thur, 4/23	Exam 2 (100 pts): Chapters 4 and GMP	
11	4/28, 4/30	Chap 12 – Process Development / Microbiology	
12	5/5, 5/7	Molecular Biology/Fermentation and Protein Chemistry	
13	Sun, May 10	Last Day to drop classes Online With a “W”	
13	5/12, 5/14	Protein Separation and Purification	
14	Tues, 5/19	Biomanufacturing Processing	
14	Thur, 5/21	Exam 3 (100 pts): Chapter 12, Microbiology/ Molecular Biology /Fermentation/Protein Chemistry and Purification	
15	5/26, 5/28	Biomanufacturing Processing / Final Product and Patient Care	
16	Thur, 6/4	5:00 pm – 7:00 pm, Final Examination, Site TBD (300 pts)	

Student Learning Objectives: This Syllabus lists all the information students are expected to know by the end of the course.

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Week	Dates (Thursdays)	Experiment Topic
1	2/12	Lab 1: Lab Safety and Good Documentation Practices
2	2/19	Lab 2: Media Preparation
3	Sun, Feb 22	Last day to drop classes Online Without a "W"
3	2/26	Lab 3: Media Growth and Monitoring; Aseptic Technique Solutions, Dilutions, Buffers, and pH
4	3/5	Lab 4: Filtration
5	3/12	Lab 5: Spectrophotometry
6	3/19	Lab 6: Chromatography
7	3/26	Lab 7: Chromatography (continued)
8	4/2	Lab 8: Cell and Tissue Culture Growth
	4/9	No Class: Spring Break (Mon 4/6 thru Fri 4/10)
9	4/16	Lab 9: Bioreactor (continued) and Centrifugation
10	4/23	Lab 10: Filtration
11	4/30	Lab 11: Chromatography
12	5/7	Lab 12: Chromatography (continued)
13	Sun, May 10	Last Day to drop classes Online With a "W"
13	5/14	Lab 13: Chromatography (continued) and Gel Electrophoresis
14	5/21	Lab 14: Validation of Protein Recovery and Purification, Calculation of Yield, and Characterization of Proteins / Laboratory Cleanup and Checkout
15	5/28	Laboratory Cleanout / All Lab Reports due

LAB GRADING: The sum of all Lab Reports and Lab Participation will account for 30% of the final grade in the course.

Note: Lab Coats and Safety Goggles are Required! You will not be allowed to enter or participate in the laboratory without them.

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