

Montgomery County Community College
 BIT 232
 Biomanufacturing
 4-3-3

COURSE DESCRIPTION:

The course provides a solid foundation in the biomanufacturing process of biopharmaceuticals, including producing them under current Good Manufacturing Practices. Students use bacteria, mammalian, and/or yeast cells to produce human proteins using the tools of manufacturing, such as upstream and downstream procedures and quality control of protein production. This course is subject to a course fee. Refer to <http://mc3.edu/adm-fin-aid/paying/tuition/course-fees> for current rates.

REQUISITES:*Previous Course Requirements*

- BIT 123 Basic Techniques and Instrumentation in Biotechnology

Concurrent Course Requirements

None

COURSE COMMENT

Students with a science-related degree and/or biotechnology and pharmaceutical experienced may be able to complete this course as a stand-alone course.

LEARNING OUTCOMES Upon successful completion of this course, the student will be able to:	LEARNING ACTIVITIES	EVALUATION METHODS
1. Describe the role of a biomanufacturing company and the various job categories involved in the developing of a biopharmaceutical product.	Lecture Guest Lecturers from Industry Small Group Discussions Daily Reading Assignments 1 or 2 Industry Field Trips Oral presentation	Section Examinations Final Comprehensive Examination Written Assignment
2. Define and describe the role of regulatory agencies in the biomanufacturing industry.	Lecture Guest Lecturers from Industry Small Group Discussions Daily Reading Assignments Case Studies Oral presentation	Section Examinations Final Comprehensive Examination Written Assignment

LEARNING OUTCOMES	LEARNING ACTIVITIES	EVALUATION METHODS
3. Analyze the role of Quality Assurance and Quality Control in the manufacturing process including the development and utilize of the major documentation strategies, including SOPs, batch records and training records.	Lecture Guest Lecturers from Industry Small Group Discussions Daily Reading Assignments 1 or 2 Industry Field Trips Written Assignment Case Studies Group Exercise	Section Examinations Final Comprehensive Examination Written Assignment Written Laboratory Reports
4. Perform techniques involved in Upstream Processing – including growing bacteria, mammalian cells and/or yeast cells, in a controlled environment.	Lecture Guest Lecturers from Industry Small Group Discussions Daily Reading Assignments Industry Field Trips Written Assignment Laboratory Experiments or Demonstrations	Section Examinations Final Comprehensive Examination Written Assignment Written Laboratory Reports
5. Perform techniques involved in downstream processing including purifying proteins and monitoring purity and activity using appropriate techniques, including but not limited to filtration, chromatography, ELISA, SDS-PAGE and activity assays.	Lecture Guest Lecturers from Industry Small Group Discussions Daily Reading Assignments Industry Field Trips Written Assignment Laboratory Experiments or Demonstrations	Section Examinations Final Comprehensive Examination Written Assignment Written Laboratory Reports
6. Perform techniques that pertain to microbiological control including, LAL and mycoplasma detection assays, microbial identification, and environmental monitoring.	Lecture Guest Lecturers from Industry Small Group Discussions Daily Reading Assignments 1 or 2 Field Trips Written Assignment Laboratory Experiments and Demonstrations	Section Examinations Final Comprehensive Examination Written Assignment Written Laboratory Reports

At the conclusion of each semester/session, assessment of the learning outcomes will be completed by course faculty using the listed evaluation method(s). Aggregated results will be submitted to the Associate Vice President of Academic Affairs. The

benchmark for each learning outcome is that *70% of students will meet or exceed outcome criteria.*

SEQUENCE OF TOPICS:

1. Introduction to the Biomanufacturing Industry
2. Operational Excellence in the Industry
3. Facilities and Environmental Health and Safety
4. Metrology
5. Validation
6. Quality Assurance
7. Upstream Processing
8. Quality Control Microbiology
9. Quality Control Biochemistry
10. Downstream Processing
11. Process Development
12. Manufacture of a drug product

SEQUENCE OF LABORATORY ACTIVITIES

(with the use of SOPs and other important documentation)

1. Balance Calibration and Operation
2. pH Meter Calibration and Operation
3. Micro Pipetman Operation and Calibration
4. Autoclave Validation
5. Sample MSDS Sheets Validation
6. Upstream Processing, Cell Culture, Use of Bioreactor, Harvest, TFF filtration
7. Environmental Monitoring and Microbial identification
8. Downstream Processing, Purification of Protein
9. Chromatography- AKTA System
10. QC – ELISA, SDS PAGE

LEARNING MATERIALS:

Textbook:

Introduction to Biomanufacturing; NBC2 First Edition; January 2013; Lulu online publishing. Class copy provided. Also available on line at www.biomaufacturing.org.

Laboratory Manual:

MCCC Biomanufacturing Laboratory Manual; available at college bookstore

Other reading materials (scientific journal articles, on-line exercises) will be used throughout the course as needed.

Other learning materials may be required and made available directly to the student and/or via the College's Libraries and/or course management system.

COURSE APPROVAL:

Prepared by: Margaret Bryans, Ph.D. Date: 2/12/2013
Assistant Professor Biotechnology

VPAA/Provost or designee Compliance Verification: Date: Fall 2013
Victoria L. Bastecki-Perez, Ed.D.

Revised by: Margaret Bryans, Ph.D. Date: 11/14/2017
Assistant Professor Biotechnology

VPAA/Provost or designee Compliance Verification: Date: 1/8/2018



This course is consistent with Montgomery County Community College's mission. It was developed, approved and will be delivered in full compliance with the policies and procedures established by the College.