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

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	

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.