

Section I: BASIC COURSE INFORMATION

Outline Status: **Approved Outline***

1. **COLLEGE:** L.A. TRADE TECHNICAL COLLEGE
2. **SUBJECT:** BIOTECHNOLOGY
3. **COURSE NUMBER:** 012
4. **COURSE TITLE:** INTRODUCTION TO BIOMANUFACTURING II
5. **UNITS:** 4
6. **CATALOG COURSE DESCRIPTION:**

This course expands on concepts from Introduction to Biomanufacturing I. It focuses on cell cultures, proteins and separation techniques as it applies to manufacturing products. The course also emphasizes environmental control in the industry. Laboratory focuses on applying techniques in molecular biology and chemistry to produce and assess a final product.

9. **LAST UPDATE DATE:** 10/26/15

10. **CLASS HOURS:**

	Standard Hrs Per Week (based On 18 weeks)	Total Hs per Term (hrs per week x 18)	Units
Lecture:	3	54	3
Lab/Activity (w / homework):	0	0	0
Lab/Activity (w /o homework):	3	54	1
Totals:	Lecture: 3	Lecture: 54	Lecture: 3
	Lab: 3	Lab: 54	Lab: 1
	Total: 6	Total: 108	Total: 4

11. **PREREQUISITES, COREQUISITES, ADVISORIES ON RECOMMENDED PREPARATION, and LIMITATION ON ENROLLMENT:**

Note: The LACCD's *Policy on Prerequisites, Corequisites and Advisories* requires that the curriculum committee take a separate action verifying that a course's prerequisite, corequisite or advisory is an 'appropriate and rational measure of a student's readiness to enter the course or program' and that the prerequisite, corequisite or advisory meets the level of scrutiny delineated in the policy.

PREREQUISITES: Yes

	Subject	Number	Course Title	Units	Validation Approval Date
	BIOTECHNOLOGY	010	INTRODUCTION TO BIOMANUFACTURING I	4	10/23/15

COREQUISITES: No

ADVISORIES: No

*selected sections

Section II: COURSE CONTENT AND OBJECTIVES

1. COURSE CONTENT AND OBJECTIVES:

COURSE CONTENT AND SCOPE - Lecture: Outline the topics included in the lecture portion of the course (<i>Outline reflects course description, all topics covered in class</i>).	Hours per topic	COURSE OBJECTIVES - Lecture: Upon successful completion of this course, the student will be able to..(<i>Use action verbs - see Bloom's Taxonomy for 'action verbs requiring cognitive outcomes.'</i>)
1. Overview: - review of biomanufacturing, biotechnology and biopharmaceuticals - diversity in biotechnology	3	1. Define controlled and critical processes in biomanufacturing
2. Good Manufacturing Practices - operator training - changes to process procedures - risk analysis - procedures and specifications - internal and external auditing - cGMP in Biomanufacturing	3	2. Discuss, explain and demonstrate good manufacturing practices
3. Good Documentation Practices - history and purpose of documentation - good record keeping techniques - rules for documentation - importance of traceability - forms of documentation	3	3. Discuss, explain and demonstrate good documentation practices
4. Molecular Biology - Cell structure and function - Review DNA structure and function - Review protein synthesis	3	4. Describe biological molecules including DNA, proteins and protein synthesis
5. Biotechnology - Recombinant DNA technology: gene libraries, DNA purification, PCR, restriction enzymes, gel electrophoresis - Transformation and cloning - Biotechnology products and applications - Implications on health, environment and ethics	6	5. Relate basic concepts and techniques of biotechnology to its use in biomanufacturing and impact on society
6. Microbiology - Bacteria, fungi, mycoplasma - Inoculation, culture and bacterial identification - Host systems: prokaryotes vs. eukaryotes - Cell lines: common sources, equipment, safety, contaminants - Control of impurities: endotoxins, viruses, microbes, prions - Aseptic techniques: cleaning and sterilization - Instrumentation/equipment for microbial testing - current blood donation techniques	9	6. Explain the role of microbiology in biomanufacturing

7. Fermentation - review basic concepts, equipment and process - phases of cell growth - different types and applications of fermentation	3	7. Examine the role and procedure of cell culture and fermentation in biomanufacturing
8. Protein Chemistry - structure and function - macromolecules and enzymes - immunochemistry: antibodies/proteins	3	8. Explain basic concepts of proteins and techniques to separate and purify
9. Protein separation and purification techniques - Cell disruption - Solid/liquid separation - Filtration - Purification operations: evaporation, precipitation crystallization, liquid extraction, column chromatography - Protein analysis techniques: SDS-PAGE, ELISA	9	9. Distinguish between upstream and downstream processing
10. Control Systems and Monitoring - general process operations - operations in biomanufacturing - environmental control and monitoring - aseptic environments - cleanroom and cleanroom behavior - gowning qualifications and levels - manufacturing technician training	7	10. Explain the importance of control systems and monitoring including aseptic technique
11. Final Product and Patient Care - history of product use - future production - dual cost of product - responsible parties	3	11. Apply all concepts to the production of a biomanufactured product such as biopharmaceuticals.
Final Exam	2	
	Total: 54	
	Total Hrs In Protocol: 54	

1. (cont'd) LAB:

COURSE CONTENT AND SCOPE - Lab: Outline the topics included in the laboratory portion of the course (<i>Outline reflects course description, all topics covered in class</i>).	Hours per topic	COURSE OBJECTIVES - Lab: Upon successful completion of this course, the student will be able to...
1. Review laboratory safety and good documentation	3	1. Write, follow and maintain laboratory protocols, standard operating procedures (SOPs) and batch production records
2. Cell and tissue culture growth - design and media preparation - transformation of <i>E. coli</i>	9	2. Follow laboratory safety practices.

- scale-up production		<p>3. Apply techniques for cell culture and identify contaminants.</p> <p>4. Apply techniques for bioseparation and purification such as, but not limited to, centrifugation, chromatography, electrophoresis.</p> <p>5. Perform proper characterization analyses using appropriate instrumentation and equipment.</p> <p>6. Apply upstream and downstream processes to produce and validate a final product.</p> <p>7. Understand and practice environmental monitoring, sterilization, and good cleanroom behavior.</p>
3. Cell and tissue culture monitoring - calibration of growth curves - cell quantification - aseptic technique and contaminants - test for bacteria, fungi, mycoplasma: gram, fungi, DNA stains - equipment and safety	6	
4. Filtration - Sterile filtration - tangential flow filtration	3	
5. Chromatography - HPLC - Affinity chromatography - Ion-exchange chromatography - Resins, packing and elution - Scale-up production	12	
6. Gel electrophoresis: SDS-PAGE, agarose gel	6	
7. ELISA	3	
8. Validation of protein recovery and purification, calculation of yield, characterization	3	
9. Biofuels applied to the biomanufacturing process	3	
10. Environmental monitoring - Instrumentation - Facilities cleaning and sanitation - Sterilization - Labware cleaning - Gowning	6	
Total:		
Total Hrs In Protocol:		54

1. (cont'd) SLO:

STUDENT LEARNING OUTCOMES - <i>(Quote the appropriate Institutional SLO's in this column):</i>	HOW WILL THESE STUDENT LEARNING OUTCOMES BE ASSESSED - <i>(Explain how each outcome will be assessed in this column):</i>
Students will explain relevant biology and chemistry concepts as it applies to biomanufacturing.	Students will identify biological, chemical and biotechnological structures and processes and explain how they apply to biomanufacturing. A rubric will assess the understanding of these concepts as it relates to biomanufacturing in which

<p>Students will apply techniques and procedures used in biomanufacturing to produce and assess a final product.</p> <p>Students will demonstrate an understanding of the lab environment and current good manufacturing practices.</p>		<p>students will answer at least 70% of these questions correctly.</p> <p>Students will apply procedures with proper technique to produce a final biomanufactured product. Students will document, assess and analyze results. A rubric will assess understanding and execution of protocols to produce a product. Students will answer questions or perform with at least 70% correct.</p> <p>Students will demonstrate an understanding of facilities. Students will show appropriate behavior including following protocol and proper documentation. A rubric will assess facility knowledge and lab behavior. Students will answer questions or perform with at least 70% correct.</p>

SLO Rubric

SLO	Excellent	Fair	Needs Improvement
<p>Students will explain relevant biology and chemistry concepts as it applies to biomanufacturing.</p>	<ul style="list-style-type: none"> • Explanation of biological structures and processes including biotechnology with at least 80% proficiency • Explanation of chemical structures and processes including protein separation with at least 80% proficiency. • Application of biological and chemical concepts to biomanufacturing with at least 80% proficiency. 	<ul style="list-style-type: none"> • Explanation of biological structures and processes including biotechnology with at least 70% proficiency • Explanation of chemical structures and processes including protein separation with at least 70% proficiency. • Application of biological and chemical concepts to biomanufacturing with at least 70% proficiency. 	<ul style="list-style-type: none"> • Explanation of biological structures and processes including biotechnology with less than 70% proficiency • Explanation of chemical structures and processes including protein separation with less than 70% proficiency. Application of biological and chemical concepts to biomanufacturing with less than 70% proficiency.
<p>Students will apply techniques and procedures used in biomanufacturing to produce and assess a final product.</p>	<ul style="list-style-type: none"> • Protocol and procedures performed with mastery and appropriate tools. • Excellent assessment of product. • Final product exceeds quality standards. • (All the above completed with at least 80% correct) 	<ul style="list-style-type: none"> • Protocol and procedures performed satisfactorily and appropriate tools. • Adequate assessment of product. • Final product meets quality standards. • (All the above completed with at least 70% correct) 	<ul style="list-style-type: none"> • Protocol and procedures performed unsatisfactorily and without appropriate tools • Poor assessment of product. • Final product does not meet quality standards. • (All the above completed with less than 70% correct)

<p>Students will demonstrate an understanding of the lab environment and current good manufacturing practices.</p>	<ul style="list-style-type: none"> • Identification and understanding of lab facilities and environment with mastery. • Demonstration of excellent laboratory behavior and practices. • (All the above completed with at least 80% correct) 	<ul style="list-style-type: none"> • Identification and understanding of lab facilities and environment with satisfaction. • Demonstration of adequate laboratory behavior and practices. • (All the above completed with at least 70% correct) 	<ul style="list-style-type: none"> • Identification and understanding of lab facilities and environment without satisfaction. • Demonstration of poor laboratory behavior and practices. • (All the above completed with less than 70% correct)
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Essential Academic Skills: Reading and Communication

2. REQUIRED TEXTS:

Provide a representative list of textbooks and other required reading; include author, title and date of publication:

Introduction to Biomanufacturing, Northeast Biomanufacturing Center & Collaborative, 2012

3. READING ASSIGNMENTS:

If applicable, reading assignments in this course may include but are not limited to the following:

Standard Operating Procedures, Batch Production Records, current articles, experimental protocols, regulation reports, Biomanufacturing company reports

4. WRITING ASSIGNMENTS:

Writing assignments, as required by Title 5, in this course may include, but are not limited to the following:

Experimental protocols, Standard Operating Procedures, Batch Production Records, essays on exams and lab reports, research proposals and papers, article analysis, final report on product

Essential Academic Skills: Critical Thinking and Other Course Components

5. REPRESENTATIVE ASSIGNMENTS THAT DEMONSTRATE CRITICAL THINKING:

Provide examples of assignments, as required by Title 5, that demonstrate critical thinking.

Students must do problem solving in analytical calculations for dilutions, measurements and error. Students must also use critical thinking skills to analyze experimental errors, troubleshoot and interpret results.

6. SELF-REFLECTIVE LEARNING:

If applicable, describe how students will reflect on their development as active learners. Provide representative examples below.

7. COMPUTER COMPETENCY:

If applicable, explain how computer competency is included in the course.

Computers are needed to run certain equipment and simulations. In addition, computers are needed to document and display data.

8. INFORMATION COMPETENCY:

If applicable, explain how information competency is included in the course.

Students may be required to research a biomanufacturing company and use that information to explain or simulate product design, mass production and marketing.

Evaluation and Instruction

9. REPRESENTATIVE OUTSIDE ASSIGNMENTS (Homework):

Out of class assignments may include, but are not limited to the following:

Reading the textbook or assigned articles, problem sets, completion of lab worksheets, research and preparation of group projects.

10. METHODS OF EVALUATION:

Title 5, section 55002 requires grades to be 'based on demonstrated proficiency in subject matter and the ability to demonstrate that proficiency, at least in part, by means of essays, or, in courses where the curriculum committee deems them to be appropriate, by problem solving exercises or skills demonstrations by students.' Methods of evaluation may include, but are not limited to the following (please note that evaluation should measure the outcomes detailed 'Course Objectives' at the beginning of Section II):

Exams, quizzes, written lab documentation and reports, proficiency in executing lab procedures, final report and presentation

11. METHODS OF INSTRUCTION:

Methods of instruction may include, but are not limited to the following.

- Discussion
- Activity
- Field Experience
- Independent Study
- Purposeful Collaboration
- Other (Please Explain)

12. SUPPLIES:

List the supplies the student must provide.

Textbook, laboratory manual, gloves, calculator

13. DIVERSITY:

If applicable, explain how diversity (e.g., cultural, gender, etc.) is included in the course.

13. SCANS COMPETENCIES:

(required for all courses with vocational TOP Codes; recommended for all courses)

SCANS (Secretary's Commission on Necessary Skills) are skills the Department of Labor identified, in consultation with business and industry leaders, which reflect the skills necessary for success in the workplace. Check the appropriate boxes to indicate the areas where students will develop the following skills (please note that all SCANS competencies do not apply to all courses):

RESOURCES

- Managing Time:** Selecting relevant goal-related activities, ranking them in order of importance, allocating time to activities, and understanding, preparing and following schedules.
- Managing Money:** Using or preparing budgets, including making cost and revenue forecasts; keeping detailed records to track budget performance, and making appropriate adjustments.
- Managing Material and Facility Resources:** Acquiring, storing, allocating, and distributing materials, supplies, parts, equipment, space or final products in order to make the best use of them.

INTERPERSONAL

- Participating as Member of a Team:** Working cooperatively with others and contributing to group's efforts with ideas, suggestions and effort.
- Teaching Others New Skills:** Helping others learn needed knowledge and skills.
- Exercising Leadership:** Communicating thoughts, feelings, and ideas to justify a position, encouraging, persuading, convincing or otherwise motivating an individual or group, including responsibly challenging existing procedures, policies or authority.
- Negotiating:** Working toward agreement that may involve exchanging specific resources or resolving divergent interests.
- Working with Cultural Diversity:** Working well with men and women and with people from a variety of ethnic, social, or educational backgrounds.

INFORMATION

- Acquiring and Evaluating Information:** Identifying a need for data, obtaining the data from existing sources or creating them, and evaluating their relevance and accuracy.

- ☑ **Organizing and Maintaining Information:** Organizing, processing and maintaining written or computerized records and other forms of information in a systematic fashion.
- ☑ **Interpreting and Communicating Information:** Selecting and analyzing information and communicating the results of others, using oral, written, graphic, pictorial, or multimedia methods.
- ☑ **Using Computers to Process Information:** Employing computers to acquire, organize, analyze and communicate information.

SYSTEMS

- ☑ **Understanding Systems:** Knowing how social, organizational and technological systems work and operating effectively with them.
- ☑ **Monitoring and Correcting Performance:** Distinguishing trends, predicting impacts of actions on system operations, diagnosing deviations in the functioning of a system/organization, and taking necessary steps to correct performance.
- ☑ **Improving or Designs Systems:** Making suggestions to modify existing systems in order to improve the quality of products or services and developing new or alternative systems.

TECHNOLOGY

- ☑ **Selecting Technology:** Judging which sets of procedures, tools or machines, including computers and their programs, will produce the desired results.
- ☑ **Applying Technology to Tasks:** Understanding overall intent and proper procedures for setting up and operating machines, including computers and their reprogramming systems.
- ☑ **Maintaining and Troubleshooting Equipment:** Preventing, identifying, or solving problems with equipment, including computers and other technologies.

Section III: RELATIONSHIP TO COLLEGE PROGRAMS

1. THIS COURSE WILL BE AN APPROVED REQUIREMENT FOR AN APPROVED ASSOCIATE DEGREE OR CERTIFICATE PROGRAM: **Yes**

Section IV: ARTICULATION INFORMATION

(Complete in consultation with College Articulation Officer)

1. TRANSFER STATUS:

a. Transferable to the University of California: No	c. Transferable to the California State University: Yes
b. UC Approval Date:	d. College Approval Date: 9/15/15

CERTIFICATION AND RECOMMENDATION

This course meets Title 5 requirements for Associate Degree applicable college credit towards an Associate Degree.

Section VIII: ADDENDA

(Uploaded Documents)

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