

## Section I: BASIC COURSE INFORMATION

Outline Status: **Approved Outline\***

1. **COLLEGE:** L.A. TRADE TECHNICAL COLLEGE
2. **SUBJECT:** BIOTECHNOLOGY
3. **COURSE NUMBER:** 010
4. **COURSE TITLE:** INTRODUCTION TO BIOMANUFACTURING I
5. **UNITS:** 4
6. **CATALOG COURSE DESCRIPTION:**

This course offers an introduction to the concepts and laboratory skills used in biomanufacturing. The process of biomanufacturing is explored. Students will investigate practices, facilities and techniques used by companies in producing biomanufactured products such as drugs.

9. **LAST UPDATE DATE:** 6/30/14

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:** No

**COREQUISITES:** No

**ADVISORIES:** No

## Section II: COURSE CONTENT AND OBJECTIVES

### 1. COURSE CONTENT AND OBJECTIVES:

<b>COURSE CONTENT AND SCOPE - Lecture:</b> 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	<b>COURSE OBJECTIVES - Lecture:</b> Upon successful completion of this course, the student will be able to
1. Overview: - history of biomanufacturing, biotechnology and biopharmaceuticals - current biomanufacturing production - drug development process (research, clinical trials, manufacturing)	4	1. Explain the history, purpose and current use of biomanufacturing
2. Operational Excellence: The qualitative process control practices in the biomanufacturing industry. - history of quality and effects - lean manufacturing - efficiency in the workplace - six sigma principles - usage of pareto charts and quality diagrams - interconnection of ISO9001 to quality	8	2. Explain different principles that affect and measure quality practices.
3. Facilities: Framework and biomanufacturing layouts . - Instrumentation - Forms of equipment - Facility security and access controls - Design and regulatory framework - Layout of functional areas - Utility support systems - Elements for sustaining the facility - Standard documents describing facility	8	3. Identify key features of biomanufacturing facilities and how they are sustained.
4. Metrology: A history of metrology and its essence in the work environment. - units of measurement - Traceability for regulatory compliance and standardization of equipment - Standardization and calibration - Specifications and tolerances - Accuracy, uncertainty and precision - Audit preparedness - Computer software preparedness - Calibration process using floor scale	7	4. Use metrics as it applies to the work environment.
5. Quality Assurance: Quality control in the development of pharmaceutical products . - Quality in relationship to biomanufacturing - Quality Control versus Quality Assurance - Organizational groups: Quality Assurance, Quality Control, Regulatory Affairs - Food and Drug administration (FDA) and European Medicines Agency (EMA) regulating agencies - Current Good Manufacturing Practices (CGMPs) and its association to the QA system - Documentation process	7	5. Understand the different aspects and organizations regulating quality assurance of pharmaceutical products.

6. Biology and chemistry behind Biomanufacturing - Basic chemistry - Cells and proteins - DNA structure - Protein Synthesis - Recombinant DNA technology - Host systems: prokaryotes vs. eukaryotes - Sterile techniques	6	6. Understand the foundational biology and chemistry used in the biomanufacturing process including microorganisms, cells, DNA, proteins and sterile technique.
7. Upstream Processing - Fermentation and cell culture - Fermentation process: equipment (Bioreactor), media, nutrients, sterilization, cell growth - Harvest - Day-to-day operations	6	7. Describe and evaluate the procedures for upstream processing including bioreactors, fermentation and cell growth.
8. Downstream Processing - overview of purification process- filtration - chromatography - electrophoresis	6	8. Describe and evaluate procedures for downstream processing for product purification including filtration, chromatography and protein assays.
Final Exam	2	
Total:		54
Total Hrs In Protocol:		54

### 1. (cont'd) LAB:

COURSE CONTENT AND SCOPE - <b>Lab:</b> 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 - <b>Lab:</b> Upon successful completion of this course, the student will be able to..(Use action verbs - see <a href="#">Bloom's Taxonomy</a> for 'action verbs requiring cognitive outcomes.')
1. Laboratory safety and good documentation	3	1. Write, follow and maintain laboratory protocols, standard operating procedures (SOPs) and batch production records
2. Laboratory Measurements: metrics, logarithms, graphing	3	2. Follow laboratory safety practices.
3. Solutions, dilutions, buffers and pH	6	3. Demonstrate proper use of equipment.
4. Metrology: Pipetting	3	4. Prepare solutions (dilutions, pH, buffers).
5. Spectrophotometry: optical density, growth curves	3	5. Apply sterilization techniques and validate sterility.
6. Media preparation, cell culture and aseptic technique	9	6. Apply procedures for upstream processing including cell culture, transformation and fermentation.
7. Bacterial transformation	3	7. Apply procedures for downstream processing including purification techniques such as centrifugation, filtration, chromatography and gel electrophoresis.
8. Microbial fermentation	3	
9. Centrifugation	3	
10. Filtration: sterile filtration, tangential flow	3	

filtration		
11. Chromatography: principles, affinity chromatography, ion-exchange chromatography, column packing and elution HPLC	9	
12. Gel electrophoresis (SDS page): separate and study proteins	3	
13. Validation of protein recovery and purification, calculation of yield, characterization of proteins	3	
	Total: 54	
	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>
<p>Students will demonstrate an understanding of the purpose, fundamentals and regulations of biomanufacturing.</p> <p>Students will understand the science underlying biomanufacturing.</p> <p>Students will apply techniques and procedures applicable to biomanufacturing.</p>	<p>Student will demonstrate knowledge of the background, main areas and regulations of biomanufacturing. A rubric will assess written examinations in which students will answer at least 70% of these questions correctly.</p> <p>Students will understand the basic biology and chemistry as it applies to biomanufacturing products. A rubric will assess the understanding of science as it relates to biomanufacturing in which students will answer at least 70% of these questions correctly.</p> <p>Students will perform procedures with proper technique and documentation in upstream and downstream processing essential to the biomanufacturing process. A rubric will assess competence and understanding of protocols and equipment. Students will answer questions or perform with at least 70% correct.</p>

## SLO Rubric

SLO	Excellent	Fair	Needs Improvement
Students will demonstrate an understanding of the purpose, fundamentals and regulations of biomanufacturing.	<ul style="list-style-type: none"><li>• Identification of the goal of biomanufacturing with at least 80% proficiency</li><li>• Explanation of at least 80% of the main areas (ie. facilities, metrology, upstream and downstream processes)</li><li>• Mastery of the different areas of regulation with at least 80%.</li></ul>	<ul style="list-style-type: none"><li>• Identification of the goal of biomanufacturing with at least 70% proficiency</li><li>• Explanation of at least 70% of the main areas (ie. facilities, metrology, upstream and downstream processes)</li><li>• Mastery of the different areas of regulation with at least 70%.</li></ul>	<ul style="list-style-type: none"><li>• Identification of the goal of biomanufacturing below 70% proficiency</li><li>• Explanation of less than 70% of the main areas (ie. facilities, metrology, upstream and downstream processes)</li><li>• Mastery of different areas of regulation is below 70%.</li></ul>
Students will understand the science underlying biomanufacturing.	<ul style="list-style-type: none"><li>• Explanation of at least 80% of the basic chemistry relevant to biomanufacturing</li><li>• Explanation of at least 80% of the biology relevant to biomanufacturing</li></ul>	<ul style="list-style-type: none"><li>• Explanation of at least 70% of the basic chemistry relevant to biomanufacturing</li><li>• Explanation of at least 70% of the biology relevant to biomanufacturing</li></ul>	<ul style="list-style-type: none"><li>• Explanation of less than 70% of the basic chemistry relevant to biomanufacturing</li><li>• Explanation of less than 70% of the biology relevant to biomanufacturing</li></ul>
Students will apply techniques and procedures applicable to biomanufacturing.	<ul style="list-style-type: none"><li>• Protocol and documentation performed with mastery and appropriate tools</li><li>• Equipment and instrumentation used with mastery</li><li>• (All the above completed with at least 80% correct)</li></ul>	<ul style="list-style-type: none"><li>• Protocol and documentation performed satisfactorily and with appropriate tools</li><li>• Equipment and instrumentation used with mastery</li><li>• (All the above completed with at least 70% correct)</li></ul>	<ul style="list-style-type: none"><li>• Protocol and documentation performed unsatisfactorily and without appropriate tools</li><li>• Equipment and instrumentation used unsatisfactorily</li><li>• (All the above completed with less than 70% correct)</li></ul>

## 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 by Northeast Biomanufacturing Center and Collaborative (NBC2), 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

### 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.

#### 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

## 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: <b>No</b>	c. Transferable to the California State University: <b>Yes</b>
b. <b>UC Approval Date:</b>	d. <b>College Approval Date:</b>

### 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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