

Section I: BASIC COURSE INFORMATION

Outline Status: **Approved Course**

1. **COLLEGE: L.A. VALLEY COLLEGE**
2. **SUBJECT: BIOTECHNOLOGY**
3. **COURSE NUMBER: 005**
4. **COURSE TITLE: BIOTECHNOLOGY: ENVIRONMENTAL CONTROL**
5. **UNITS: 2**
6. **CATALOG COURSE DESCRIPTION:**

This class provides an overview of biomanufacturing with an emphasis in environmental control and support processes within the biopharmaceutical industry. Skill sets introduced will focus on Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) as it relates to clean room procedures, environmental monitoring and required documentation.

7. **CLASS SCHEDULE COURSE DESCRIPTION:**

This class provides an overview of biomanufacturing with an emphasis in environmental control and support processes. Students will receive training in clean room procedures, environmental monitoring and required documentation.

8. **INITIAL COLLEGE APPROVAL DATE: 10/17/2013**
9. **LAST UPDATE DATE: 10/17/13**

10. CLASS HOURS:

	Standard Hrs Per Week (based On 18 weeks)	Total Hs per Term (hrs per week x 18)	Units
Lecture:	1	18	1
Lab/Activity (w / homework):	0	0	0
Lab/Activity (w /o homework):	3	54	1
Totals:	Lecture: 1	Lecture: 18	Lecture: 1
	Lab: 3	Lab: 54	Lab: 1
	Total: 4	Total: 72	Total: 2
Totals In Protocol:	Lecture: 1	Lecture: 18	
	Lab: 3	Lab: 54	
	Total: 4	Total: 72	Total: 2

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**

Subject	Course #	Title	Units	Approval Date

Corequisites: **No**

Subject	Course #	Title	Units	Approval Date

Advisories: **No**

Subject	Course #	Title	Units	Approval Date

OTHER LIMITATIONS ON ENROLLMENT (see Title 5, Section 58106 and Board Rule 6803 for policy on

12. allowable

limitations. Other appropriate statutory or regulatory requirements may also apply):

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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...(Use action verbs - see Bloom's Taxonomy for 'action verbs requiring cognitive outcomes.')
1. Biomanufacturing overview GMP- Good Manufacturing Practices GLP- Good Laboratory Practices	2	1. design a facility based on CFR and demonstrate good flow within that area
2. Facility design based on (CFR)	2	2. compare and contrast the uses and types of various process control systems (CIP, SIP, COP)
3. Facility environmental controls, ventilation and air classification	1	3. discuss the various levels and classes of aseptic areas
4. Flows- personnel, materials	2	4. discuss the various ways of environmental monitoring
5. Process control systems CIP- Clean -in- place COP- Clean-out of place SIP- Steam- in place	3	5. describe the importance of sterilization and sanitary design.
6. Gowning and gowning levels	3	6. describe good cleanroom behavior
7. Environmental process monitoring	2	
8. Sterilization & Sanitary Design	1	
9. Safety, cleanroom behavior, gowning	1	
10. Documentation- SOP, BATCH records,	1	
Total:	18	
Total Lecture Hours In Section I Class Hours:	18	

*Total lecture and laboratory hours (which include the final examination) must equal totals on page 1.

**In general "activity" courses or portions of courses are classified "laboratory."

1. (cont'd) LAB:

COURSE CONTENT AND SCOPE - Lab: 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 - Lab: Upon successful completion of this course, the student will be able to...(Use action verbs - see Bloom's Taxonomy for 'action verbs requiring cognitive outcomes.')
1. Clean-in place (CIP)	8	1. show a proficiency in using equipment for environmental monitoring.
2. Steam-in place (SIP)	4	2. gain experience in the loading and operation of an autoclave for sterilization.
3. Clean-out of place (COP)	4	3. analyze data collected from monitoring and control systems to determine follow up procedures.
4. Sterilization	4	
5. Gowning	4	
6. Flow	6	4. gown for an aseptic area (class 100).
7. Environmental Monitoring Techniques	6	

8. Manual Labware cleaning	3	5. apply their knowledge of flow by lab design and equipment staging. 6. employ the practice of good cleanroom behavior.
9. Small parts labware preparation	3	
10. DO & pH instrumentation	6	
11. Facilities cleaning & sanitation	3	
12. Control systems	3	
Total:	54	
Total Lab Hours In Section I Class Hours:		54

Essential Academic Skills: Reading and Communication

2. REQUIRED TEXTS AND SUPPLEMENTAL READINGS:

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

Title	Author	Year
Introduction to Biomanufacturing	Northeast Biomanufacturing Center & Collaborative	2012
Basic Laboratory Methods for Biotechnology	Siedman & Moore	2011
Industrial Biotechnology: A Training Manual	Moorepark College	2010

3. READING ASSIGNMENTS:

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

Assigned reading from the text, readings from scientific journal articles, reading of environmental control reports.

4. WRITING ASSIGNMENTS:

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

SOP design /writing, BATCH record design/ writing, reports of experimental results writing in Log books.

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.

Analysis of data, problem sets, summary of experiments, analyze written information on process support and environmental control.

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.

8. INFORMATION COMPETENCY:

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

Evaluation and Instruction

9. REPRESENTATIVE OUTSIDE ASSIGNMENTS (HOMEWORK):

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

Assigned reading from the text, Assigned writings, industry specific journal articles, Application of the Code of Federal Regulations (CFRs)

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):

Essay exams, problem solving, class discussions, skill demonstration, participation, projects, reports/papers/journals, objective exams.

11. METHODS OF INSTRUCTION:

Please Check All That Apply

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

12. SUPPLIES:

List the supplies the student must provide.

Lab coats, lab notebooks, gloves.

13. DIVERSITY:

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

14. 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.
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- 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: **No****

a. If yes, the course will be a portion of the “approved program” listed on the State Chancellor’s Inventory of Approved Programs (approved programs can be found on the State Chancellor’s Office website at <https://misweb.cccco.edu/webproginv/prod/invmenu.htm>..

NOTE: In order for a course to be approved as a requirement for an associate degree or certificate program, the program must be listed on the State Chancellor’s Office *Inventory of Approved Programs* AND the course must be listed in the college catalog as either a requirement or an elective for the program. If course is not part of an approved program at the college adopting the course, it will be considered to be a “stand-alone” course, and is subject to the State Chancellor’s approval criteria. The college must complete and submit the Chancellor’s Office “APPLICATION FOR APPROVAL OF CREDIT” form. Certain courses are granted “blanket approval” by the State Chancellor’s Office and do not require separate approval. See the Chancellor’s Office *Program and Course Approval Handbook* for details. LACCD Skills **Certificates are not State approved programs** and are not listed on the Chancellor’s Office *Inventory of Approved Programs*.

2. **GENERAL EDUCATION REQUIREMENTS FOR THE ASSOCIATE DEGREE STATUS:**

a. Area requested: **None**

b. Area requested: **None**

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: **No**

b. UC Approval Date:

d. College Approval Date:

2. GENERAL EDUCATION FOR TRANSFER:

IGETC Certification:

- a. Area requested:
- b. Date requested:
- c. IGETC Approval Date:

If applicable, provide an explanation of how the course meets the appropriate General Education parameters, as defined in IGETC Certification Guidelines.

CSU Certification:

- a. Area requested:
- b. Date requested:
- c. CSU Approval Date:

If applicable, provide an explanation of how the course meets the appropriate General Education parameters, as defined in CSU Certification Guidelines.

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IGETC Certification:

- a. Area requested:
- b. Date requested:
- c. IGETC Approval Date:

If applicable, provide an explanation of how the course meets the appropriate General Education parameters, as defined in IGETC Certification Guidelines.

CSU Certification:

- a. Area requested:
- b. Date requested:
- c. CSU Approval Date:

If applicable, provide an explanation of how the course meets the appropriate General Education parameters, as defined in CSU Certification Guidelines.

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3. MAJOR REQUIREMENT FOR TRANSFER:

Will this course be articulated to meet lower division major requirements?

List college/university and the majors:

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CAN NUMBER:

CAN Approval --

Date requested:

CAN SEQUENCE #:

Date approved:

Section V: SUPPLEMENTAL COURSE INFORMATION

1. DEPT/DIVISION NAME: **Biological Science**
2. DEPT/DIVISION CODE: **15**
3. SUBJECT CODE : **923**
4. SUBJECT ABBREVIATION : **BIOTECH**
5. RECOMMENDED MINIMUM QUALIFICATION AREA:
6. ABBREVIATION FOR TRANSCRIPTS : **ENV CONTROL**
7. DEGREE CREDIT:

Indicate whether the course meet the “standards for approval” for degree credit course set forth in Title 5, section 55002(a)(2), which requires the course to have a degree of intensity, difficulty, and vocabulary that the curriculum committee has determined to be at the college level: **Degree Applicable**

8. GRADING METHOD : **LETTER GRADE**
9. REPETITIONS: # of times repeated for credit : **0**

10. PRIOR TO TRANSFERABLE LEVEL

This course attribute applies to *English, Writing, ESL, reading and mathematics* courses ONLY. If applicable, indicate how many levels below the transferable level this course should be placed: **Not applicable**

11. CREDIT BASIC SKILLS

Title 5, section 55000(j) defines basic skills as “courses in reading, writing, computation, and English as a Second Language, which are designated as non-degree credit courses pursuant to Title 5, section 55002(b).” **No**

12. CROSS REFERENCE

Is this course listed as equivalent in content to existing College/District courses in another discipline? **No**

If Yes, list courses (documentation of cross-discipline agreement must be provided):

13. COURSE SPECIFICALLY DESIGNED FOR STUDENTS W/ DISABILITIES

Title 5, section 56029 allows a course to be repeatable when continuing success of the students with disabilities is dependent on additional repetitions of a specific class. Is this course designated as an “approved special class” for students with disabilities? **No**

If yes, provide an explanation of how this course meets the requirements of Title 5, section 56029.

14. COOPERATIVE EDUCATION STATUS -

Title 5, section 55252 allows for two types of Cooperative Education: 1) General Work Experience Education -- i.e., supervised employment, which is intended to assist students in acquiring desirable work habits, attitudes and career awareness, which need not be related to the students' educational goals; or 2) Occupational Work Experience Education -- i.e., supervised employment, extending classroom based occupational learning at an on-the-job learning station, which is related to the students' educational or occupational goal. Is this course part of the college's approved cooperative work experience education program? **No**

15. COURSE CLASSIFICATION: **Credit Course**

Note: A course's Classification, TOP Code and SAM code must be aligned – e.g., Courses with an “Occupational” Course Classification must have an “Occupational” TOP Code and a SAM Code of A, B, C, or D; courses that do not have an “Occupational” Course Classification cannot have an Occupational TOP Code and must have an “E” SAM Code. Courses coded as “basic skills” in #11 should be coded “Adult and Secondary Basic Skills.”

16. TOP CODE - (6 digits XXXX.XX) **0430.00**

Course content should match discipline description in Taxonomy of Programs found here: [Taxonomy Of Programs website](#)

17. SAM CODE (Student Accountability Model): **D**

18. FUNDING AGENCY CODE:

19. STATE COURSE ID:

Section VI: APPROVAL STATUS

1. APPROVAL STATUS:

	Approval Date Of	Board Date	Approved Effective Semester
a. <input checked="" type="checkbox"/> New Course	College: 10/20/13	Board: 1/15/14	Effective Semester:
b. <input type="checkbox"/> Addition of Existing District Course	College:	Board:	Effective Semester:
c. <input type="checkbox"/> Course Change*	College:		Effective Semester:
d. <input type="checkbox"/> Outline Update	College:		Effective Semester:
e. <input type="checkbox"/> Archive Course	College:		Effective Semester:
f. <input type="checkbox"/> Reinstate Course	College:	Board:	Effective Semester:

Section VII: APPROVAL INFORMATION FOR NEW OR ADDED COURSES

(complete in consultation with Department Chair and the appropriate Academic Administrator)

1. **ORIGINATOR: Byrd-Williams, Pamela**
2. **DEPARTMENT: Biological Science**
3. **IF THIS IS A NEW COURSE, INDICATE HOW THE COLLEGE PLANS TO MEET THE EXPENSE OF THIS COURSE:**

By additional funds. Describe:

Initial funding is through a Department of Labor grant in conjunction with Job Training. At the end of grant funding, additional FTEF will be needed after Fall 2015.

By deleting courses from the college catalog and course database. List specific courses to be deleted:

By deleting sections of existing course. List courses and number of sections to be deleted:

First Year: Second Year: Third Year:

By rotating sections of existing courses. List courses and number of sections to be rotated, as well as the semesters in which they will be offered:

4. IMPACT

IMPACT -- Will this course directly impact other course offerings and/or associate degree or certificate programs on campus?

(If yes, briefly explain how)

This course will be part of a stackable certificate program and may be part of an Associate Degree program in Biotechnology.

5. METHOD OF SUPPORT

-- Indicate how the college plans to support the proposed course:

A. Additional staff -- List additional staff needed:

Additional teaching staff is required for this class as well as a Laboratory Technician. Additional FTEF will be required of the college to support these positions after Fall 2015.

B. Classroom -- List classroom type needed:

Lecture and dedicated lab space. Class enrollment is limited to 20 due to space and safety concerns with equipment and supervision required to complete lab activities.

C. Equipment -- List new equipment needed and indicate funding source for any new equipment:

Laboratory equipment will be purchased from grant funds: 2 HPLC systems, 4 Bioreactor units, 2 LC Chromatography units, 1 Analyte Analyzer, 1 Spectrophotometer, 1 Top loading autoclave, 1 refrigerated centrifuge. After Fall 2015, the college will be required to pay for equipment service agreements and additional laboratory supplies.

D. Supplies- List supplies and indicate dollar value:

The cost of disposable supplies will be paid for by the grant until Fall 2015. Additional supplies after the grant will require support from the College. Service and maintenance agreements will need to be supplied by the college from the inception of the course. Supplies required will include media components, plastic disposables and gas tank refills. The class will cost approximately \$650 per offering.

E. Library/Learning Resources- The course initiator shall consult with the College Librarian and review the college library, book, periodical, and electronic resource collections relevant to this course. List additional titles and resources to be considered for purchase as funding permits:

Journal of Biotechnology (Elsevier) Journal of Manufacturing Science and Production Journal of Manufacturing Process Biotechnology and Bioprocess Engineering (Springer) Nature Biotechnology Journal of Biotechnology (Elsevier) Bioprocess and Biosystems Engineering (Springer) Applied Microbiology and Biotechnology (Springer) Biotechnology Journal (Wiley)

CERTIFICATION AND RECOMMENDATION

- This course meets Title 5 requirements for Associate Degree applicable college credit towards an Associate Degree.
- This course meets Title 5 requirements but does not satisfy the requirements for an Associate Degree applicable course.

We certify that the information and answers above properly represent this course.

Originator	
Department/Cluster Chairperson	
Articulation Officer	
Librarian	
Dean (If applicable)	
Curriculum Committee Chairperson	
Academic Senate President	
Vice President, Academic Affairs	
College President	

Section VIII: ADDENDA

(Uploaded Documents)

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Type	Addendum Description	File	Delete	To View
<i>General</i>	<i>New Course Addendum Environmental Control, Biot 005</i>	<i>New Course Addendum Environmental Control.doc</i>	<i>Delete</i>	<i>View It</i>
<i>SLO Addendum</i>	<i>SLO Addendum Environmental Control, Biot 005</i>	<i>CourseSLO BioT 005.doc</i>	<i>Delete</i>	<i>View It</i>