

**I. CATALOG INFORMATION**

- A. Discipline: BIOLOGY
- B. Subject Code and Number: BIOL M12C
- C. Course Title: Manufacturing: Cell Culture and Microbial Fermentation

## D. Credit Course units:

Units: 3

Lecture Hours per week: 1

Lab Hours per week : 6

Variable Units : No

## E. Student Learning Hours:

Lecture Hours:

Classroom hours: 17.5 - 17.5

Laboratory/Activity Hours:

Laboratory/Activity Hours 105 - 105**Total Combined Hours** in a 17.5 week term: 122.5 - 122.5

## F. Non-Credit Course hours per week \_\_\_\_\_

G. May be taken a total of:  1  2  3  4 time(s) for creditH. Is the course co-designated (same as) another course: No  Yes   
If YES, designate course Subject Code & Number: BIOT M02C

## I. Course Description:

Provides skills training in industrial biotechnology with emphasis on manufacturing pharmaceuticals. Introduces cell culture and microbial fermentation. Focuses on bacterial techniques, microbial assessment, mammalian cell culture, bioreactor fermentation, and media preparation. Compares small and large industrial scale cell culture.

## J. Entrance Skills

\*Prerequisite: No  Yes  Course(s)  
\_\_\_\_\_\*Corequisite: No  Yes  Course(s)  
\_\_\_\_\_Limitation on Enrollment: No  Yes   
\_\_\_\_\_Recommended Preparation: No  Yes  Course(s)  
\_\_\_\_\_Other: No  Yes   
\_\_\_\_\_

## K. Other Catalog Information:

(Same course as BIOT M02C.)

## II. COURSE OBJECTIVES

Upon successful completion of the course, a student will be able to:

|   |   | <b>Methods of evaluation will be consistent with, but not limited by, the following types or examples.</b> |
|---|---|--|
| 1 | explain the role and significance of cell culture and fermentation in bioprocessing.                      | Quiz, tests and practical  |
| 2 | demonstrate competency in terminology and acronyms applicable to cell culture and microbial fermentation. | Quiz, tests and practical  |
| 3 | demonstrate skills and knowledge in use of cell culture equipment.  | Quiz, tests and practical  |
| 4 | apply cell culture concepts to the production of a therapeutic protein.                                   | Quiz, tests and practical  |
| 5 | demonstrate proficiency in cell culture and microbial fermentation.                                       | Quiz, tests and practical  |
| 6 | demonstrate proficiency in clean room and aseptic technique.  | Quiz, tests and practical  |
| 7 | demonstrate knowledge of and ability to use materials and supplies in cell culture processes.             | Quiz, tests and practical  |

## III. COURSE CONTENT

| <b>Estimated %</b>               | <b>Topic</b>                   | <b>Learning Outcomes</b> |
|----------------------------------|--------------------------------|--------------------------|
| <b>Lecture</b> (must total 100%) |                                |                          |
| 5.00%                            | Basic concepts of microbiology | 1, 2, 3, 4, 5, 6, 7      |
| 5.00%                            | Bacterial identification       | 5, 6, 7                  |
| 4.00%                            | Aseptic technique              | 3, 5, 6, 7               |
| 5.00%                            | Mycoplasma                     | 1, 2, 3, 4, 5, 6, 7      |
| 5.00%                            | Cell culture media             | 1, 2, 3, 4, 5, 6, 7      |
| 5.00%                            | Small scale cell culture       | 1, 2, 3, 4, 5, 6, 7      |
| 5.00%                            | Overview of cell culture       | 1, 2, 3, 4, 5, 6, 7      |

|                              |  |                        |
|------------------------------|--|------------------------|
| 4.00%                        | Cell enumeration   | 1, 2, 3, 4,<br>5, 6, 7 |
| 5.00%                        | Large scale media preparation  | 1, 2, 3, 4,<br>5, 6, 7 |
| 5.00%                        | Spinner flask  | 1, 2, 3, 4,<br>5, 6, 7 |
| 5.00%                        | Bioreactor operation   | 1, 2, 3, 4,<br>5, 6, 7 |
| 5.00%                        | Large scale cell culture   | 1, 2, 3, 4,<br>5, 6, 7 |
| 5.00%                        | Cryopreservation   | 1, 2, 3, 4,<br>5, 6, 7 |
| 5.00%                        | Industry tour  | 1, 2                   |
| 4.00%                        | Molecular overview   | 1, 2, 3, 4,<br>5, 6, 7 |
| 4.00%                        | Microbial media  | 1, 2, 3, 4,<br>5, 6, 7 |
| 5.00%                        | Microbial fermentation   | 1, 2, 3, 4,<br>5, 6, 7 |
| 4.00%                        | Scale-up fermentation  | 1, 2, 3, 4,<br>5, 6, 7 |
| 5.00%                        | Emerging technologies such as stem cell culture, biofuels and single use equipment | 1, 2, 3, 4,<br>5, 6, 7 |
| 5.00%                        | Microbial media design and prep  | 1, 2, 3, 4,<br>5, 6, 7 |
| 5.00%                        | Metabolite analysis  | 1, 2, 3, 4,<br>5, 6, 7 |
| <b>Lab (must total 100%)</b> |  |                        |
| 3.00%                        | Basic concepts of microbiology   | 1, 2, 3, 4,<br>5, 6, 7 |
| 5.00%                        | Gram stain, fungal stain   | 1, 2, 3, 4,<br>5, 6, 7 |
| 3.00%                        | Bacterial identification   | 1, 2, 3, 4,<br>5, 6, 7 |
| 3.00%                        | LAF (Laminar Air Flow) use/cleaning  | 1, 2, 3, 4,<br>5, 6, 7 |
| 3.00%                        | Aseptic hood work  | 1, 2, 3, 4,<br>5, 6, 7 |
| 5.00%                        | Mycoplasma identification  | 1, 2, 3, 4,<br>5, 6, 7 |
| 3.00%                        | PCR (polymerase chain reaction), electrophoresis                                   | 1, 2, 3, 4,<br>5, 6, 7 |
| 3.00%                        | Cell culture media preparation   | 1, 2, 3, 4,<br>5, 6, 7 |
| 3.00%                        | Large scale media prep   | 1, 2, 3, 4,<br>5, 6, 7 |
|                              |  | 1, 2, 3, 4,            |

|        |  |                        |
|--------|--|------------------------|
| 3.00%  | Media and aseptic evaluation                       | 5, 6, 7                |
| 3.00%  | Initiate cultures                                  | 1, 2, 3, 4,<br>5, 6, 7 |
| 3.00%  | Review microscopy                                  | 1, 2, 3, 4,<br>5, 6, 7 |
| 3.00%  | Cell enumeration/viability                         | 1, 2, 3, 4,<br>5, 6, 7 |
| 9.00%  | Media prep/filtration                              | 1, 2, 3, 4,<br>5, 6, 7 |
| 3.00%  | Inoculate bioreactor                               | 1, 2, 3, 4,<br>5, 6, 7 |
| 10.00% | Maintain culture                                   | 1, 2, 3, 4,<br>5, 6, 7 |
| 3.00%  | Cryopreservation of culture                        | 1, 2, 3, 4,<br>5, 6, 7 |
| 3.00%  | Process evaluation                                 | 1, 2, 3, 4,<br>5, 6, 7 |
| 3.00%  | Cell culture tour                                  | 1, 2, 3, 4,<br>5, 6, 7 |
| 4.00%  | Protein expression/GFP (green fluorescent protein) | 1, 2, 3, 4,<br>5, 6, 7 |
| 5.00%  | Microbial media prep                               | 1, 2, 3, 4,<br>5, 6, 7 |
| 5.00%  | Bacterial growth                                   | 1, 2, 3, 4,<br>5, 6, 7 |
| 5.00%  | Microbial fermentation                             | 1, 2, 3, 4,<br>5, 6, 7 |
| 4.00%  | Scale-up and data analysis                         | 1, 2, 3, 4,<br>5, 6, 7 |
| 3.00%  | Metabolite analysis                                | 1, 2, 3, 4,<br>5, 6, 7 |

#### IV. TYPICAL ASSIGNMENTS

##### A. Writing assignments

|   |   |
|---|---|
| Writing assignments are required. Possible assignments may include, but are not limited to: |   |
| 1   | design and write batch record.  |
| 2   | write reports of experimental results.  |
| 3   | keep written log books.   |
| 4   | write a summary and analysis of guest lecture or other outside-of-class presentation. |
| 5   | design and write SOP (standard operation procedure).                                  |

##### B. Appropriate outside assignments

|   |   |
|---|---|
| Appropriate outside assignments are required. Possible assignments may include, but are not limited to: |   |
| 1   | apply and utilize the CFRs (Code of Federal Regulations). |
|   |   |

|   |   |
|---|---|
| 2 | plan group presentations.                               |
| 3 | complete problem sets.                                  |
| 4 | complete assigned readings from text and other sources. |

**C. Critical thinking assignments**

|   |   |
|---|---|
| Critical thinking assignments are required. Possible assignments may include, but are not limited to: |   |
| 1   | perform data evaluation.  |
| 2   | compose a written summary of experiments and data analysis.               |
| 3   | analyze written information on process support and environmental control. |
| 4   | solve problem sets.   |

**V. METHODS OF INSTRUCTION**

Methods of instruction may include, but are not limited to:

- Distance Education – When any portion of class contact hours is replaced by distance education delivery mode (Complete DE Addendum, Section XV)
- Lecture/Discussion
- Laboratory/Activity
- Other (Specify)  
Guest speakers, discussion forums and technique demonstrations.
- Optional Field Trips
- Required Field Trips

**VI. METHODS OF EVALUATION**

Methods of evaluation may include, but are not limited to:

- |  |   |   |
|--|---|---|
| <input checked="" type="checkbox"/> Essay Exam           | <input checked="" type="checkbox"/> Classroom Discussion    | <input checked="" type="checkbox"/> Skill Demonstration |
| <input checked="" type="checkbox"/> Problem Solving Exam | <input checked="" type="checkbox"/> Reports/Papers/Journals | <input checked="" type="checkbox"/> Participation       |
| <input checked="" type="checkbox"/> Objective Exams      | <input checked="" type="checkbox"/> Projects                | <input checked="" type="checkbox"/> Other (specify)     |

Lab practicals

**VII. REPRESENTATIVE TEXTS AND OTHER COURSE MATERIALS**

Moorpark College and Industry Partners. Industrial Biotechnology: A Training Manual. Cengage Learning, 2001.

Hu, Wei-Shou. Cell Culture Bioprocess Engineering. Wei-Shou Hu, 2012.

**VIII. STUDENT MATERIALS FEES**

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No  Yes**IX. PARALLEL COURSES**

| College                  | Course Number | Course Title                                | Units |
|--------------------------|---------------|---|-------|
| Skyline College          | BIOL 415      | Introduction to Biotechnology Manufacturing | 9     |
| MiraCosta College        | BTEC 201      | Advanced Cell Culture                       | 1     |
| Solano Community College | BIOT 62       | Cell Culture and Protein Recovery           | 4     |

**X. MINIMUM QUALIFICATIONS****Courses Requiring a Masters Degree:**

Master's degree in any biological science OR bachelor's degree in any biological science AND master's degree in biochemistry, biophysics, or marine science OR the equivalent.

**XI. ARTICULATION INFORMATION****A. Title V Course Classification:**

1. This course is designed to be taken either:

- Pass/No Pass only (no letter grade possible); or  
 Letter grade (P/NP possible at student option)

2. Degree status:

Either  Associate Degree Applicable; or  Non-associate Degree Applicable

**B. Moorpark College General Education:**

1. Do you recommend this course for inclusion on the Associate Degree General Education list?

Yes:  No:  If YES, what section(s)?

- A1 - Natural Sciences - Biological Science  
 A2 - Natural Sciences - Physical Science  
 B1 - Social and Behavioral Sciences - American History/Institutions  
 B2 - Social and Behavioral Sciences - Other Social Behavioral Science  
 C1 - Humanities - Fine or Performing Arts  
 C2 - Humanities - Other Humanities  
 D1 - Language and Rationality - English Composition  
 D2 - Language and Rationality - Communication and Analytical Thinking  
 E1 - Health/Physical Education  
 E2 - PE or Dance  
 F - Ethnic/Gender Studies

**C. California State University(CSU) Articulation:**

1. Do you recommend this course for transfer credit to CSU? Yes:  No:

2. If YES do you recommend this course for inclusion on the CSU General Education list?

Yes:  No:  If YES, which area(s)?

A1     A2     A3     B1     B2     B3     B4   
 C1     C2     D1     D2     D3     D4     D5   
  
 D6     D7     D8     D9     D10     E

D. University of California (UC) Articulation:

1. Do you recommend this course for transfer to the UC?    Yes:  No:
2. If YES do you recommend this course for the Intersegmental General Education Transfer Curriculum (IGETC)?    Yes:  No:

IGETC Area 1: English Communication

- English Composition
- Critical Thinking-English Composition
- Oral Communication

IGETC Area 2: Mathematical Concepts and Quantitative Reasoning

- Mathematical Concepts

IGETC Area 3: Arts and Humanities

- Arts
- Humanities

IGETC Area 4: Social and Behavioral Sciences

- Anthropology and Archaeology
- Economics
- Ethnic Studies
- Gender Studies
- Geography
- History
- Interdisciplinary, Social & Behavioral Sciences
- Political Science, Government & Legal Institutions
- Psychology
- Sociology & Criminology

IGETC Area 5: Physical and Biological Sciences (mark all that apply)

- Physical Science Lab or Physical Science Lab only (non-sequence)
- Physical Science Lecture only (non-sequence)
- Biological Science
- Physical Science Courses
- Physical Science Lab or Biological Science Lab Only (non-sequence)
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- Biological Science Courses
- Biological Science Lab course
- First Science course in a Special sequence
- Second Science course in a Special Sequence
- Laboratory Activity
- Physical Sciences

IGETC Area 6: Language other than English

- Languages other than English (UC Requirement Only)
- U.S. History, Constitution, and American Ideals (CSU Requirement ONLY)
- U.S. History, Constitution, and American Ideals (CSU Requirement ONLY)

**XII. REVIEW OF LIBRARY RESOURCES**

- A. What planned assignment(s) will require library resources and use?

The following assignments require library resources:

Using the Library's print and online resources to locate industry-related articles and to research topics for oral presentations.

- B. Are the currently held library resources sufficient to support the course assignment?

YES:  NO:

If NO, please list additional library resources needed to support this course.

**XIII. PREREQUISITE AND/OR COREQUISITE JUSTIFICATION**

BIOL M12C: Not Applicable

**XIV. WORKPLACE PREPARATION**

Required for career technical courses only. A career technical course/program is one with the primary goal to prepare students for employment immediately upon course/program completion, and/or upgrading employment skills.

Detail how the course meets the Secretary of Labors Commission on the Achievement of Necessary Skills (SCANS) areas. (For a description of the competencies and skills with a listing of what students should be able to do, go to:

<http://www.ncrel.org/sdrs/areas/issues/methods/assment/as7scans.htm>)

The course will address the SCANS competency areas:

1. Resources: the students will identify, read, and utilize standard operating procedures (SOP) for equipment calibration, equipment use, and equipment cleaning; develop a schedule for experiments, determine necessary supplies and required amounts for experiment or procedure, keep complete records of all supplies utilized, determine equipment to be utilized and allocate time required for each procedure.
2. Interpersonal: the students will participate in team efforts to plan experiments requiring collaborative effort, train fellow workers in equipment use and experimental protocol, actively participate in equipment maintenance/calibration,



plan with coworkers to develop schedules for equipment use.

3. Information: the students will record data from all experiments and keep laboratory notebooks, provide documentation of all processes utilizing SOPs, explain the relationship between product quality and health and life of patient, read/interpret output from equipment.
4. Systems: the students will utilize GMP (Good Manufacturing Practices) for all documented protocols, demonstrate role of HVAC (heating ventilating air conditioning), utilities, instrumentation and process control systems; demonstrate skill in performing basic chemical tests on water, explain layout of production plant.
5. Technology: the students will identify proper equipment for planned experiment or procedure (pH meter, balance, micropipettors, centrifuges, columns, computers, incubators, etc.), explain and demonstrate use of above equipment, identify malfunctions in equipment and evaluate validity of experiments or process involving such equipment, operate equipment using appropriate standard operating procedures, explain significance of proper gowning.

The course also addresses the SCANS skills and personal qualities:

1. Basic Skills: the students will understand the standard lab operating procedures including one or more of the following: safety, following directions, documentations, experimental design, data analysis, working with volumes, solutions, pH, and dilutions and sterile techniques.
2. Thinking Skills: the students will learn how to problem solve and learn how to troubleshoot when problems occur in the lab, deal with applying mathematics to real world situations, understand the role of safety in the laboratory and manufacturing environment, be able to understand the need and be able to apply the concepts of compliance and validation.
3. Personal Qualities: the students will be able to follow protocols and work in groups, be able to understand the importance of safety and compliance, be able to complete complex tasks in a timely manner and document their activities.

**XV. DISTANCE LEARNING COURSE OUTLINE ADDENDUM**

BIOL M12C: Not Applicable

**XVI. GENERAL EDUCATION COURSE OUTLINE ADDENDUM**

BIOL M12C: Not Applicable

**XVII. STUDENT MATERIALS FEE ADDENDUM**

BIOL M12C: Not Applicable

**XVIII. REPEATABILITY JUSTIFICATION TITLE 5, SECTION 55041**

BIOL M12C: Not Applicable

**XIX. CURRICULUM APPROVAL**

Course Information:

Discipline: BIOLOGY

Discipline Code and Number: BIOL M12C

Course Revision Category: Technical Course Revision

Course Proposed By:

Originating Faculty Subhash Karkare 10/10/2015

Faculty Peer: Audrey Chen 10/10/2015

Curriculum Rep: \_\_\_\_\_

Department Chair: Jazmir Hernandez 10/11/2015

Division Dean: Norman Marten 10/12/2015

Approved By:

Curriculum Chair: Jerry Mansfield 11/29/2015

Executive Vice President: Lori Bennett 02/01/2016

Articulation Officer: Letrisha Mai 10/15/2015

Librarian: Mary LaBarge 10/13/2015

Implementation Term and Year: Spring 2016

Approval Dates:

Approved by Moorpark College Curriculum Committee: 11/03/2015

Approved by Board of Trustees (if applicable): \_\_\_\_\_

Approved by State (if applicable): 02/03/2016