

**I. CATALOG INFORMATION**

- A. Discipline: BIOLOGY
- B. Subject Code and Number: BIOL M12B
- C. Course Title: Manufacturing: Quality Control and Validation

## D. Credit Course units:

Units: 2

Lecture Hours per week: 1

Lab Hours per week : 3

Variable Units : No

## E. Student Learning Hours:

Lecture Hours:

Classroom hours: 17.5 - 17.5

Laboratory/Activity Hours:

Laboratory/Activity Hours 52.5 - 52.5**Total Combined Hours** in a 17.5 week term: 70 - 70

## 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 M02B

## I. Course Description:

Provides skills training in industrial biotechnology with emphasis on manufacturing of pharmaceuticals and medical devices. Introduces validation and quality control. Reviews manufacturing process, including formulation, lyophilization, packaging and filling. Focuses on validation, systems evaluations, testing and reporting.

## 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 M02B)

## 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 an operation in bioprocessing and medical device manufacturing.	Quiz, test, and practical
2	demonstrate competency in terminology and acronyms applicable to manufacturing, quality control and validation quality.	Quiz, tests and practical
3	demonstrate skills and knowledge in use of equipment.	Quiz, tests and practical
4	apply concepts to the production of a therapeutic protein and manufacturing of medical devices.	Quiz, tests and practical
5	identify and explain the function of validation in these operations.	Quiz, tests and practical
6	identify and explain the function of process equipment.	Quiz, tests and practical
7	demonstrate knowledge of and ability to use materials and supplies.	Quiz, tests and practical

## III. COURSE CONTENT

<b>Estimated %</b>	<b>Topic</b>	<b>Learning Outcomes</b>
<b>Lecture</b> (must total 100%)		
6.00%	Overview of steps in manufacturing	1, 2, 3, 4, 5, 6
6.00%	Lyphophilization	1, 2, 3, 4, 5, 6, 7
7.00%	Safety and soft skills	1, 2, 4
6.00%	Drug delivery systems	1, 2, 4
7.00%	Introduction to validation	1, 2, 4, 5, 6
6.00%	Process validation	1, 2, 4, 5, 6
6.00%	Industry tour	1, 2, 4, 5, 6

6.00%	Cleaning validation	1, 2, 4, 5, 6
6.00%	Metrology and calibration	1, 2, 3, 5, 6
6.00%	Computer validation	1, 2, 4, 5, 6
6.00%	Statistics for the Quality Control (QC) lab	1, 2, 4
6.00%	Raw material testing	1, 2, 3, 4, 5, 6, 7
3.00%	Resume writing/interview skills	3
6.00%	Formulation and aseptic filling	1, 2, 3, 4, 5, 6, 7
6.00%	SPC (statistical process control) and continuous testing	1, 2, 4, 5, 6
6.00%	Role of Quality Assurance(QA) and Quality Control (QC) in manufacturing of therapeutic proteins and medical devices	1, 2, 4
5.00%	Validation in medical device manufacturing	1, 2, 4, 5, 6
<b>Lab (must total 100%)</b>		
20.00%	Execute a computer validation protocol (e.g., validation protocol for Microsoft Office)	2, 3, 5, 7
20.00%	Write and execute a protocol for validating a protein assay	1, 2, 3, 4, 5, 7
20.00%	Write and execute a protocol for cleaning validation (for example: cleaning of a spinner flask)	1, 2, 4, 5, 7
20.00%	Write and execute validation protocol for a piece of equipment (e.g., a spectrophotometer)	1, 2, 3, 4, 5, 7
20.00%	Write and execute the validation protocol for manufacture of a simple medical device	1, 2, 3, 4, 5, 7

#### IV. TYPICAL ASSIGNMENTS

##### A. Writing assignments

Writing assignments are required. Possible assignments may include, but are not limited to:	
1	SOP design/writing.
2	BATCH record (or device history file) design/writing.
3	write reports of experimental results.
4	keep log books.
5	write a summary and analysis of guest lecture or other outside-of-class presentation.

##### B. Appropriate outside assignments

Appropriate outside assignments are required. Possible assignments may include, but are not limited to:	
1	read assigned writings and industry specific articles.
2	application and utilization of the CFR (Code of Federal Regulations).
3	cooperative group planning for oral presentations.

4	complete problem sets.
5	complete assigned readings from text and other sources such as those listed in Section VII of this course outline.

### C. Critical thinking assignments

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

## 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)  
Validation simulation activities, document analysis for various QA/QC documents etc.
- 
- 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)     |

Summary report on field trip.

## VII. REPRESENTATIVE TEXTS AND OTHER COURSE MATERIALS

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

Rathore, Anurag, and Gail Sofer. Process Validation in Manufacturing of Biopharmaceuticals. 3rd ed. CRC, 2012.

**VIII. STUDENT MATERIALS FEES** No  Yes**IX. PARALLEL COURSES**

<i>College</i>	<i>Course Number</i>	<i>Course Title</i>	<i>Units</i>
Solano Community College	BIOT 63	Biotechnology Instrumentation: Quality Control and Genetic Engineering	4
MiraCosta College	BTEC 120	Business and Regulatory Practices in Biotechnology	3

**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)
- 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 M12B: 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 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 effort 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; be knowledgeable of FDA requirements for the Biotech production facilities; explain the relationship between product quality and health and life of patient; read/interprets output from equipment.
4. Systems: the students will utilize GMP (Good Manufacturing Practices) for all documented protocols; demonstrate skills in environmental monitoring procedures and interpretation of results; describe role of HVAC (heating ventilating air conditioning), utilities, instrumentation and process control systems; demonstrate proficiency in performing basic chemical tests on water; explain layout of production plants.
5. Technology: the students will identify proper equipment for planned experiment or procedure (pH meter, balance, micropipettors, centrifuge, column, computers, incubators, etc.); explain and demonstrate use of above equipment; identify malfunction in equipment and evaluate validity of experiment 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. They will deal with applying mathematics to real world situations. They will understand the role of safety in the laboratory and manufacturing environment. Students will 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. They will be able to understand the importance of safety and compliance. Students will be able to complete complex tasks in a timely manner and document their activities.

#### **XV. DISTANCE LEARNING COURSE OUTLINE ADDENDUM**

BIOL M12B: Not Applicable

#### **XVI. GENERAL EDUCATION COURSE OUTLINE ADDENDUM**

BIOL M12B: Not Applicable

#### **XVII. STUDENT MATERIALS FEE ADDENDUM**

BIOL M12B: Not Applicable

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

BIOL M12B: Not Applicable

## **XIX. CURRICULUM APPROVAL**

Course Information:

Discipline: BIOLOGY

Discipline Code and Number: BIOL M12B

Course Revision Category: Outline Update

Course Proposed By:

Originating Faculty Jerry Mansfield 03/25/2015

Faculty Peer: \_\_\_\_\_

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

Department Chair: \_\_\_\_\_

Division Dean: \_\_\_\_\_

Approved By:

Curriculum Chair: Jerry Mansfield 04/10/2015

Executive Vice President: Lori Bennett 04/11/2015

Articulation Officer: \_\_\_\_\_

Librarian: \_\_\_\_\_

Implementation Term and Year: Fall 2015

Approval Dates:

Approved by Moorpark College Curriculum Committee: 04/07/2015

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

Approved by State (if applicable): 02/24/2016