BIOT M02A: ENVIRONMENTAL CONTROL AND PROCESS SUPPORT

Originator
skarkare

Co-Contributor(s)

Name(s)
Chen, Audrey (achen)

College
Moorpark College

Attach Support Documentation (as needed)
BIOT Labor Market Information 032718.docx
Biotech Job Postings South Central Region Sept 2017- Aug 2018.xlsx
Biotech LMI data South Central Region 2017-22.xlsx

Discipline (CB01A)
BIOT - Biotechnology

Course Number (CB01B)
M02A

Course Title (CB02)
Environmental Control and Process Support

Banner/Short Title
Envir Control/Process Support

Credit Type
Credit

Start Term
Fall 2020

Co-listed (Same-as) Course(s)
BIOL M12A

Taxonomy of Programs (TOP) Code (CB03)

0401.00 - Biology, General

SAM Priority Code (CB09)

C - Clearly Occupational

Control Number

CCC000452378

Primary Minimum Qualification

BIOLOGICAL SCIENCES

Department

Biology/Zoology (1021)

Division

MC EATM, Life & Health Sci

Catalog Course Description

Provides skills training in manufacturing of biopharmaceuticals and medical devices. Presents an overview of the manufacturing process and introduces environmental control and process support with a focus on Good Laboratory Practices (GLP)/Good Manufacturing Practices (GMP), clean room procedure, monitoring techniques, and required documentation.

Taxonomy of Programs (TOP) Code (CB03)

0430.00 - *Biotechnology and Biomedical Technology

Course Credit Status (CB04)

D (Credit - Degree Applicable)

Course Transfer Status (CB05) (select one only)

B (Transferable to CSU only)

Course Basic Skills Status (CB08)

N - The Course is Not a Basic Skills Course

SAM Priority Code (CB09)

C - Clearly Occupational

Course Cooperative Work Experience Education Status (CB10)

N - Is Not Part of a Cooperative Work Experience Education Program

Course Classification Status (CB11)

Y - Credit Course

Educational Assistance Class Instruction (Approved Special Class) (CB13)

N - The Course is Not an Approved Special Class

Course Prior to Transfer Level (CB21)

Y - Not Applicable

Course Noncredit Category (CB22)

Y - Credit Course

Funding Agency Category (CB23)

Y - Not Applicable (Funding Not Used)

Course Program Status (CB24)

1 - Program Applicable

General Education Status (CB25)

Y - Not Applicable

Support Course Status (CB26)

N - Course is not a support course

Field trips

Will not be required

Grading method

Letter Graded

Alternate grading methods

Student Option- Letter/Pass
Pass/No Pass Grading

Does this course require an instructional materials fee?

No

Repeatable for Credit

No

Is this course part of a family?
No

Units and Hours

Carnegie Unit Override
No

In-Class

Lecture
Minimum Contact/In-Class Lecture Hours
17.5
Maximum Contact/In-Class Lecture Hours
17.5

Activity

Laboratory
Minimum Contact/In-Class Laboratory Hours
52.5
Maximum Contact/In-Class Laboratory Hours
52.5

Total in-Class

Total in-Class
Total Minimum Contact/In-Class Hours
70
Total Maximum Contact/In-Class Hours
70

Outside-of-Class

Internship/Cooperative Work Experience

Paid

Unpaid

Total Outside-of-Class

Total Outside-of-Class
Minimum Outside-of-Class Hours
35
Maximum Outside-of-Class Hours
35

Total Student Learning

Total Student Learning
Total Minimum Student Learning Hours
105
Total Maximum Student Learning Hours
105

Minimum Units (CB07)
2
Maximum Units (CB06)
2

Student Learning Outcomes (CSLOs)

	Upon satisfactory completion of the course, students will be able to:
1	demonstrate the important skills necessary to support the operation of a biotech manufacturing plant.
2	identify ALL five critical behaviors necessary to work in clean rooms.

Course Objectives

	Upon satisfactory completion of the course, students will be able to:
1	explain the role and significance of an operation in bioprocessing and in medical device manufacturing.
2	demonstrate competency using terminology and acronyms applicable to environmental control and process support.
3	demonstrate skills and knowledge in use of equipment.
4	apply concepts to the production of therapeutic proteins and medical devices.
5	utilize Good Manufacturing Procedures (GMP) for all documented protocols.
6	demonstrate proficiency in clean room procedures.
7	demonstrate knowledge of and ability to use materials and supplies appropriately.

Course Content

Lecture/Course Content

1. **(6%) Manufacturing overview**
2. **(6%) Computer application**
3. **(6%) Gowning**
4. **(5%) Resume writing/interview**
5. **(6%) Introduction to Good Laboratory Practice/Good Manufacturing Practice (GLP/GMP) -- Quality system**
6. **(6%) Documentation -- Standard Operating Procedures (SOP)/batch records/device history files**
7. **(5%) Control systems**
8. **(5%) Safety**
9. **(5%) Water and steam**
10. **(5%) Facilities cleaning and sanitization**
11. **(5%) Sanitization**
12. **(5%) Environmental monitoring techniques**
13. **(5%) Labware cleaning**
14. **(5%) Small parts/labware preparation**
15. **(5%) Dissolved oxygen (DO) and pH instrumentation**
16. **(10%) Methods of sterilization used in biotechnology and medical device industry**
17. **(10%) Sanitary design in biotechnology and medical device manufacturing**

Laboratory or Activity Content

1. **(20%) - Documentation including lab notebook record keeping, SOP writing, and GMP records**
2. **(20%) - Environmental monitoring and control: bacterial identification, endotoxin measurement, environmental monitoring techniques**
3. **(20%) - Clean room concepts: Gowning, facility design and layout, facility sanitization**
4. **(20%) - Equipment cleaning and sterilization: Labware cleaning, autoclaving, Cleaning-in -lace/sterilization-in-place (CIP/SIP)**
5. **(20%) - Instrumentation and control systems: Dissolved Oxygen (DO) and pH instruments and controls**

Methods of Evaluation

Which of these methods will students use to demonstrate proficiency in the subject matter of this course? (Check all that apply):

Problem solving exercises
Skills demonstrations
Written expression

Methods of Evaluation may include, but are not limited to, the following typical classroom assessment techniques/required assignments (check as many as are deemed appropriate):

Classroom Discussion
Computational homework
Essay exams

Group projects
Individual projects
Journals
Laboratory activities
Laboratory reports
Objective exams
Oral presentations
Projects
Problem-solving exams
Participation
Quizzes
Reports/Papers/Journals
Reports/papers
Research papers
Skills demonstrations

Instructional Methodology

Specify the methods of instruction that may be employed in this course

Computer-aided presentations
Collaborative group work
Class activities
Class discussions
Case studies
Demonstrations
Field trips
Group discussions
Guest speakers
Instructor-guided interpretation and analysis
Instructor-guided use of technology
Internet research
Laboratory activities
Lecture
Practica
Small group activities

Describe specific examples of the methods the instructor will use:

- Demonstrate and teach cleanroom procedures in the lab.
- Teach Good Manufacturing Procedures (GMP) for all documented protocols, and students will practice them in the class.
- Teach proper lab notebook record-keeping and Standard Operating Procedures writing.

Representative Course Assignments

Writing Assignments

1. Document the purpose, materials and methods, procedure, results, and conclusion for the Autoclave Sterilization experiment in a lab notebook.
2. Write reports of experimental results.
3. Write a Standard Operating Procedure (SOP) for cleaning diaphragm valves.
4. Write a summary and analysis of guest lectures or other outside-of-class presentations.

Critical Thinking Assignments

1. Analyze written information on process support and environmental control topics such as cleanroom particle counts.
2. Analyze the data from the autoclave validation lab to determine if the autoclave cycle used is effective in sterilizing a media load.
3. Perform data evaluation.
4. Complete problem sets.

Reading Assignments

1. Read assigned Cleaning Validation articles from Bioprocessing International or similar trade journals.
2. Complete assigned readings from the text and other sources discussed in this course outline.
3. ReadFederal Drug Administration regulations for pharmaceutical manufacturing (CFR 21 parts 210 and 211) as they relate to environmental control in bio-manufacturing.

Skills Demonstrations

1. Demonstrate aseptic gowning procedure.
2. Demonstrate how to identify potentially contaminating microorganisms.
3. Demonstrate cleaning and sterilizing procedures.

Outside Assignments

Representative Outside Assignments

1. Prepare and “adjacency diagram” showing the location of various areas of a bio-manufacturing plant.
2. Prepare a group presentation on the design of a bio-manufacturing facility showing air, people, and material flows.
3. Application and utilization of the Code of Federal Regulations 21 parts 10 and 11.
4. Read assigned writings and industry-specific articles.

Articulation

Equivalent Courses at other CCCs

College	Course ID	Course Title	Units
MiraCosta College	BTEC 110	Basic Technologies in Biotechnology	4
San Diego Mesa College	CHEM 255	Inside the Pharmaceutical Industry	3

Attach Syllabus

M02A Course Syllabus Fall 2017.pdf

District General Education

A. Natural Sciences

B. Social and Behavioral Sciences

C. Humanities

D. Language and Rationality

E. Health and Physical Education/Kinesiology

F. Ethnic Studies/Gender Studies

Course is CSU transferable

Yes

CSU Baccalaureate List effective term:

FALL 1999

CSU GE-Breadth

Area A: English Language Communication and Critical Thinking

Area B: Scientific Inquiry and Quantitative Reasoning

Area C: Arts and Humanities

Area D: Social Sciences

Area E: Lifelong Learning and Self-Development

CSU Graduation Requirement in U.S. History, Constitution and American Ideals:

IGETC

Area 1: English Communication

Area 2A: Mathematical Concepts & Quantitative Reasoning

Area 3: Arts and Humanities

Area 4: Social and Behavioral Sciences

Area 5: Physical and Biological Sciences

Area 6: Languages Other than English (LOTE)

Textbooks and Lab Manuals

Resource Type
Textbook

Description
Whyte, William. *Clean Technology: Fundamentals of Design, Testing, and Operation.* 2nd ed., Wiley, 2011.

Resource Type
Textbook

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

Library Resources

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

Sufficient Library Resources exist
Yes

Example of Assignments Requiring Library Resources
Use the online library resources to research the Code of Federal Regulations 21 parts 10 and 11, as they apply to preventing cross-contamination in a bio-manufacturing facility.

Primary Minimum Qualification
BIOTECHNOLOGY

Review and Approval Dates

Department Chair
11/19/2019

Dean
11/19/2019

Technical Review
12/05/2019

Curriculum Committee
01/21/2020

DTRW-I
MM/DD/YYYY

Curriculum Committee
MM/DD/YYYY

Board
MM/DD/YYYY

CCCCO
01/24/2020

Control Number
CCC000433677

DOE/accreditation approval date
MM/DD/YYYY