BIOT M02B: MANUFACTURING: QUALITY CONTROL AND VALIDATION

Originator
skarkare

Co-Contributor(s)

Name(s)
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College
Moorpark College

Attach Support Documentation (as needed)
BIOT Labor Market Information 032718.docx

Discipline (CB01A)
BIOT - Biotechnology

Course Number (CB01B)
M02B

Course Title (CB02)
Manufacturing: Quality Control and Validation

Banner/Short Title
Manufact:Qual Cont/Validation

Credit Type
Credit

Start Term
Fall 2020

Co-listed (Same-as) Course(s)
BIOL M12B

Taxonomy of Programs (TOP) Code (CB03)

0430.00 - *Biotechnology and Biomedical Technology

SAM Priority Code (CB09)

C - Clearly Occupational

Control Number

CCC000452379

Primary Minimum Qualification

BIOLOGICAL SCIENCES

Department

Biology/Zoology (1021)

Division

MC EATM, Life & Health Sci

Catalog 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.

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
35.0
Maximum Outside-of-Class Hours
35.0

Total Student Learning

Total Student Learning
Total Minimum Student Learning Hours
105.0
Total Maximum Student Learning Hours
105.0

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 concepts of systems validation.
2	demonstrate the concepts of Quality Control (QC).

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

Course Content

Lecture/Course Content

1. **(6%) - Overview of steps in manufacturing**
2. **(6%) - Lyphophilization**
3. **(7%) - Safety and soft skills**
4. **(6%) - Drug delivery systems**
5. **(7%) - Introduction to validation**
6. **(6%) - Process validation**
7. **(6%) - Industry tour**
8. **(6%) - Cleaning validation**
9. **(6%) - Metrology and calibration**
10. **(6%) - Computer validation**
11. **(6%) - Statistics for the quality control (QC) lab**
12. **(6%) - Raw material testing**
13. **(3%) - Resume writing/interview skills**
14. **(6%) - Formulation and aseptic filling**
15. **(6%) - Statistical process control (SPC) and continuous testing**
16. **(6%) - Role of Quality Assurance(QA) and Quality Control (QC) in manufacturing of therapeutic proteins and medical devices**
17. **(5%) - Validation in medical device manufacturing**

Laboratory or Activity Content

1. (20%) Execute a computer validation protocol (e.g., validation protocol for Microsoft Office)
2. (20%) Write and execute a protocol for validating a protein assay
3. (20%) Write and execute a protocol for cleaning validation (e.g., cleaning of a spinner flask)
4. (20%) Write and execute validation protocol for a piece of equipment (e.g., a spectrophotometer)
5. (20%) Write and execute the validation protocol for manufacture of a simple medical device

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
Simulations

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 guide students on how to write and execute a protocol for validating a protein assay
- Demonstrate and guide students on how to write and execute a protocol for cleaning validation (for example, cleaning of a spinner flask)
- Show and guide students on how to write and execute validation protocol for a piece of equipment (for example, a spectrophotometer machine)

Representative Course Assignments

Writing Assignments

1. Write a Standard operating procedure (SOP) for the cleaning of a bioreactor.
2. Write the validation protocol for validating the operation of a pH meter.
3. Keep logbooks.
4. Write reports of experimental results.
5. BATCH record (or device history file) design/writing.

Critical Thinking Assignments

1. Create a design history record for a prototype medical device.
2. Analyze daily pH readings from a bioreactor using control charts, to determine if the bioreactor is in a state of control.
3. Formulate in writing a summary of experiments and data analysis.
4. Perform data evaluation.
5. Complete problem sets.

Reading Assignments

1. Read assigned writings and industry-specific articles on such topics as analytical validation in the biotech industry.
2. Read Food and Drug Administration's guidance on the "Quality Unit" for pharmaceutical companies.
3. Complete assigned readings from the text and other sources such as those listed in this course outline.

Skills Demonstrations

1. Demonstrate how to validate a pH meter.
2. Demonstrate cleaning and sterilizing procedures.

Outside Assignments

Representative Outside Assignments

1. Prepare a group presentation on Installation, Operational, and Performance Qualification (IQ, OQ, and PQ) of a buffer tank.
2. Complete assigned readings from the text and other sources assigned by the instructor.
3. Prepare a report on computer validation requirements for process control in bio-manufacturing.
4. Read assigned writings and industry-specific articles.

Articulation

C-ID Descriptor Number

BIOT 210X

Status

Approved

Equivalent Courses at other CCCs

College	Course ID	Course Title	Units
Citrus College	BIOT 125	Quality and Regulatory Practices in Biotechnology	3
Los Angeles Mission College	BIOTECH 6	Biotechnology: Quality Control	4
MiraCosta College	BTEC 120	Business and Regulatory Practices in Biotechnology	4

Attach Syllabus

M02B Course Syllabus 2014.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:

SPRING 2008

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

Resource Type
Textbook

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

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 International Society for Pharmaceutical Engineering's guidance on Cleaning Validation.

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
CCC000430296

DOE/accreditation approval date
MM/DD/YYYY