BIOT M02E: BUSINESS & GOVERNMENT REGULATION

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 LMI data South Central Region 2017-22.xlsx
Biotech Job Postings South Central Region Sept 2017- Aug 2018.xlsx

Discipline (CB01A)
BIOT - Biotechnology

Course Number (CB01B)
M02E

Course Title (CB02)
Business & Government Regulation

Banner/Short Title
Business & Govern. Regulation

Credit Type
Credit

Start Term
Fall 2020

Co-listed (Same-as) Course(s)
BIOL M12E

Taxonomy of Programs (TOP) Code (CB03)

0401.00 - Biology, General

SAM Priority Code (CB09)

C - Clearly Occupational

Control Number

CCC000528400

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 pharmaceuticals. Examines manufacturing from the perspective of company operations involved with the drug or medical device development process. Focuses on business practices and governmental regulations.

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
35
Maximum Contact/In-Class Lecture Hours
35

Activity

Laboratory

Total in-Class

Total in-Class
Total Minimum Contact/In-Class Hours
35
Total Maximum Contact/In-Class Hours
35

Outside-of-Class

Internship/Cooperative Work Experience

Paid

Unpaid

Total Outside-of-Class

Total Outside-of-Class
Minimum Outside-of-Class Hours
70
Maximum Outside-of-Class Hours
70

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	identify the requirements of the regulatory process involved in therapeutic drug development.
2	apply the concepts of regulatory processes to the operations of a drug manufacturing plant.

Course Objectives

	Upon satisfactory completion of the course, students will be able to:
1	explain the role and significance of cross-functional drug/device development, regulatory environment, and manufacturing operations in the drug/device development process.
2	demonstrate competency in terminology and acronyms applicable to the topic.
3	apply concepts to the production of a therapeutic protein and manufacturing of medical devices.
4	explain the role of government oversight in manufacturing.
5	explain the role of international regulations in industrial biotechnology and medical device manufacturing.
6	discuss the role of bioethics in industrial biotechnology and medical device manufacturing.

Course Content

Lecture/Course Content

1. (18%) Regulatory Aspects of Medical Device Development
2. (6%) Biotech Business Profile - Business Models
3. (6%) General Business Design
4. (6%) Drug Development and Commercialization: Drug Discovery
5. (11%) Drug Development and Commercialization: Pre-clinical and Clinical Development, including Good Laboratory Practices (GLPs) and Good Clinical Practices (GCPs)
6. (6%) Drug Development and Commercialization: Commercialization Project.
7. (6%) Federal Drug Administration (FDA) Regulation: Chemistry, Manufacturing and Controls Submission
8. (6%) Global Regulation: IND (Investigational New Drug), BLA (Biologic License Application), and NDA (New Drug Application) Submissions, International submissions, ICH (International Conference on Harmonisation) ISO (International Organization for Standardization)
9. (11%) FDA Regulation: Current Good Manufacturing Practices
10. (6%) Global Good Manufacturing Practices
11. (6%) Regulatory Inspections
12. (6%) Ethics and Bioethics
13. (6%) Intellectual Property, Generic Drug, Biosimilar

Laboratory or Activity Content

None.

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
Distance Education
Demonstrations
Field trips
Group discussions
Guest speakers
Instructor-guided interpretation and analysis
Instructor-guided use of technology
Internet research
Laboratory activities
Lecture

Describe specific examples of the methods the instructor will use:

- Cite and review case studies from pharmaceutical, biologicals, and medical device regulatory submissions.
- Examine the drug and medical device development process with students.
- Go over and review papers discussing FDA regulation of pharmaceutical, biological, and medical device manufacturing.

Representative Course Assignments

Writing Assignments

1. Write a report describing the regulatory submission process for the approval of a protein therapeutic drug.
2. Write project management plans (for instance, Gantt charts which illustrate a project schedule).

Critical Thinking Assignments

1. Analyze written information on regulatory actions such as FDA warning letters, or similar materials.
2. Analyze case studies from pharmaceutical, biologicals, and medical device regulatory submissions.
3. Perform data evaluation.

Reading Assignments

1. Read The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.
2. Read and interpret procedures and analyze the current business environment and international regulatory expectations.

Outside Assignments

Representative Outside Assignments

1. Prepare a report on “lessons learned” from an FDA warning letter involving manufacturing problems at a Biotechnology company (warning letters are available on the FDA website).
2. Complete problem sets, such as preparation of a Gantt Chart.
3. Apply and utilize the CFRs (Code of Federal Regulations).

Articulation

Equivalent Courses at other CCCs

College	Course ID	Course Title	Units
MiraCosta College	BTEC 120	Business and Regulatory Practices in Biotechnology	3
Solano Community College	BIOT 52	Business, Regulatory, and Quality Practices in Biotechnology	3

Attach Syllabus
Syllabus - BIOL M02E_M12E Spring 2018 Chang_v2-2.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
Ng, Rick. *Drugs: From Discovery to Approval*. 3rd ed., Wiley-Blackwell, 2015.

Library Resources

Assignments requiring library resources
Research, preparing for writing a paper, using the Library's print and online resources.

Sufficient Library Resources exist
Yes

Example of Assignments Requiring Library Resources
Use the online library resources to research warning letters issued by the Food and Drug Administration (FDA).

Distance Education Addendum

Definitions

Distance Education Modalities
Hybrid (51–99% online)
Hybrid (1–50% online)
100% Online

Faculty Certifications

Faculty assigned to teach Hybrid or Fully Online sections of this course will receive training in how to satisfy the Federal and state regulations governing regular effective/substantive contact for distance education. The training will include common elements in the district-supported learning management system (LMS), online teaching methods, regular effective/substantive contact, and best practices.
Yes

Faculty assigned to teach Hybrid or Fully Online sections of this course will meet with the EAC Alternate Media Specialist to ensure that the course content meets the required Federal and state accessibility standards for access by students with disabilities. Common areas for discussion include accessibility of PDF files, images, captioning of videos, Power Point presentations, math and scientific notation, and ensuring the use of style mark-up in Word documents.
No

Regular Effective/Substantive Contact

Hybrid (1%–50% online) Modality:

Method of Instruction	Document typical activities or assignments for each method of instruction
Asynchronous Dialog (e.g., discussion board)	Discussion forums, online messaging between students and instructor and between students
E-mail	Questions and answers between students and instructor, class announcements and memos, assignment submissions by students
Other DE (e.g., recorded lectures)	Recorded lectures, links to websites
Synchronous Dialog (e.g., online chat)	Synchronous online lectures, online chat forums
Video Conferencing	Video-conferenced lectures, discussion forums, office hours

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100% online Modality:

Method of Instruction	Document typical activities or assignments for each method of instruction
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E-mail	Questions and answers between students and instructor, class announcements and memos, assignment submissions by students
Other DE (e.g., recorded lectures)	Recorded lectures, links to websites
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Examinations

Hybrid (1%–50% online) Modality
Online
On campus

Hybrid (51%–99% online) Modality
Online
On campus

Primary Minimum Qualification
BIOTECHNOLOGY

Review and Approval Dates

Department Chair
11/21/2019

Dean
11/21/2019

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
CCC000528401

DOE/accreditation approval date
MM/DD/YYYY