I. Description of Course:

1. Department/Course: BIOT - 113
2. Title: GMP/GLP and Writing SOPs
3. Cross Reference:
4. Units: 1.5
   Total Lecture Hours: 27.00
   Total Lab Hours: 0
   Total Contact Hours: 27.00
   Total Outside-of-Class Hours: 54.00
   Total Student Work Hours: 81.00
5. Repeatability: No
6. Grade Options: Grade Only (GR)
7. Degree/Applicability:
   Credit, Degree Applicable, Transferable - CSU (T)
8. General Education:
9. Field Trips: Optional
10. Requisites:

11. Catalog Description:
    This course gives an introduction to the concepts of Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP), and their applications in the biotechnological manufacturing of therapeutic products. The course will cover the concepts of GMP and GLP, the history of GMP/GLP, federal and international regulation for GMP/GLP, and how GMP/GLP are being applied in a bio-manufacturing facility. Writing of Standard Operating Procedures (SOPs) is included as part of the GMP curriculum. Students will learn to read, review, and write an SOP.

12. Class Schedule Description:
    This course trains students in Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) in biotechnology, and in writing Standard Operating Procedures (SOPs).

13. Counselor Information:
    This course is a required core course for all Biotechnology Certificates of Achievement and Associate of Science degrees, and is included in the Bioengineering curriculum.

II. Student Learning Outcomes
    Students will be able to:

1. Explain the basic GMP/GLP regulation requirements established by the FDA and other regulatory agencies as they relate to biotechnology laboratory and industrial settings.
2. Outline the process followed in meeting GMP/GLP standards.
3. Read, review, and write SOP documents for biotechnology.

III. Course Content:
A. History and Concept
   1. Concept of Good Manufacturing Practice (GMP)
   2. Concept of Good Laboratory Practice (GLP)
   3. Concept of Good Clinical Practice (GCP)
   4. Rationale of Writing Standard Operating Procedures (SOPs)
   5. History of Federal Regulation
B. Terms and Guidelines for GMP/GLP
C. Regulation and Requirements of GMP/GLP
   1. Requirements by FDA for Medicine and Medical Device: 21CFR 210,211
   2. Requirements of other International Regulatory Agencies
D. Quality assurance and quality control -- functions and concept of regulatory system
E. Manufacture process validation
F. Compliance Pathway
G. Standard operating procedure SOP
   1. Defining steps, procedures, and products
   2. Standards and regulations that must be met
   3. Defining objectives of SOP
   4. Formats for SOPs
   5. Procedures for developing SOPs
   6. Internal reviews
   7. External reviews
   8. Implementation of SOP
   9. Evaluation of SOP
   10. Effective writing

IV. Course Assignments:
   A. Reading Assignments
      1. Handouts and other material pertaining to GMP/GLP regulation requirements and case studies as provided by instructor.
   B. Projects, Activities, and other Assignments
      1. Class presentation: application of GMP regulatory rules to a virtual biotech company, and critique disclaimer on pharmaceutical advertisement according to GMP
      2. Participation in class discussions: Respond to instructor provided unit questions; Respond to other student responses
   C. Writing Assignments
      1. Design and write an SOP document, a case study of the process of SOP development through the review process.

V. Methods of Evaluation:
   A. Project presentation and discussion, evaluated based on quality and content of presentation, quantity and quality of feedback (SLO 1,2)
   B. Compliance with rules in writing SOP (SLO 3)
   C. Instructor evaluation of discussions based on use of appropriate terminology, quality of feedback, demonstration of understanding of key concepts (SLO 1,2)
D. Quizzes and exams on topics such as FDA regulations and GMP/GLP standards (SLO 1,2,3)

VI. Methods of Instruction:
   A. Lecture
   B. Discussion
   C. Audiovisual
   D. Collaborative Learning
   E. Distance Learning
   F. Web-enhanced

VII. Textbooks:

   Recommended

   Supplemental

VIII. Supplies:

   Approval Date: 05/08/2018
   CCC Number: CCC000551008
   TOP Codes: 0430.00
   C-ID Number: