SOUTHEAST COMMUNITY COLLEGE
DIVISION OF ARTS AND SCIENCES
Sciences
Revision Date: 07-01-19

I. CATALOG DESCRIPTION

Course Number:	BIOT2441
Course Title	Quality Assurance for Biosciences
Prerequisite(s):	None, High school algebra and High school biology suggested
Catalog Description:	This course provides and introduction to Good Laboratory Practice (GLP) Good Manufacturing Practice (GMP) and Good Clinical Practice (GLP) as well as a comprehensive coverage of all steps involved with the regulatory approval process for biotechnology-derived products. Preparation for clinical studies, facilities inspection and scientific and regulatory principles will be covered as well as a discussion of when, where, and how the Food and Drug Administration (FDA) plays a role in these processes. Additionally, students will learn the rationale for writing standard operating procedures (SOP) in a biotechnology environment. The course will cover the procedures, formats, and writing styles used in writing, implementing, and evaluating SOPs.
Credit Hours:	3.0
Class Hours:	45
Lab Hours:	0
Total Contact Hours:	45

II. COURSE OBJECTIVES: *Course will*:

A. Introduce student to quality principles as they apply to the biotechnology, biopharmaceutical, and biomedical device industries

B. Challenge students to apply critical thinking skills to their readings, class activities, laboratory exercises, and classroom discussions about current topics in biotechnology

C. Present theories and application of quality assurance and quality control for systems such as cGMP, ISO9000, Six Sigma and Lean.

D. Focus on quality in the bioscience workplace.

E. Prepare the student for more advanced Biotechnology courses

III. STUDENT LEARNING OUTCOMES AND GENERAL EDUCATION LEARNING OUTCOMES

A. Student Learning Outcomes: *Student will be able to*:

1. Understand and use terminology of the field

2. Utilize the internet to research current regulations

3. Participate in class discussions

4. Communicate results

5. Coordinate with a team

6. Produce documentation

B. General Education Learning Outcomes

1. GELO #1: Oral Communication
Outcome: Develop a central idea for presentations.
Outcome: Organize information clearly and logically, in an outline format, citing sources when appropriate.

2. GELO #3: Critical Thinking & Problem Solving
Outcome: Collect, identify, interpret and analyze data.
Outcome: Synthesize information to arrive at reasoned solutions to problems.
Outcome: Evaluate ideas presented in writing, media, speech, or artistic presentations.

Outcome: Acquire and integrate knowledge and construct relationships across disciplines.

3. GELO #5: Analytical, Quantitative, and Scientific Reasoning

Outcome: Apply mathematical and scientific methods to solve problems from an array of contexts and everyday situations.

Outcome: Understand and create logical arguments supported by quantitative and scientific evidence and communicate those arguments in a variety of formats.

Outcome: Effectively develop strategies, algorithms, or experiments (or performing experiments) to better describe the systems or to solve the problems.

Outcome: Manipulate formulas, data sets, graphs, tables, etc. in a way to produce a meaningful outcome.

IV. CONTENT/TOPICAL OUTLINE (*course outline may provide more detailed information*)

A. Organization of a Biotechnology Company
B. Quality Philosophies of Yesterday and Today
C. An Introduction to Quality
D. An Introduction to Quality Systems
E. The Regulation of Medical and Food Products
F. The Lifecycle of Pharmaceutical Products
G. Documentation
H. Quality Systems in the Laboratory and Production Facility
I. Quality Assays

V. INSTRUCTIONAL MATERIALS

A. Required Text(s):

1. Roy, Michael J. Biotechnology Operations: Principles and Practices, 2nd ed., CRC Press, 2016. ISBN 9781315367750.

VI. METHODS OF PRESENTATION/INSTRUCTION

A. Methods of presentation typically include a combination of the following:

1. Lecture = Power Point lectures plus occasional short videos
2. Demonstration
3. Computer based data analysis

VII. METHODS OF EVALUATION

A. Methods of evaluation typically include a combination of the following:

1. Exams
2. Quizzes
3. Homework from lecture and lab
4. In-class assignments
5. Oral presentation

B. SCC GRADING SCALE

A+	95-100	C+	75-79	F	59 or less
A	90-94	C	70-74		
B+	85-89	D+	65-69		
B	80-84	D	60-64		

VIII. SPECIFIC COURSE REQUIRMENTS

A. None.