



**Bioprocess Technology Credential:
Certificate in BioQuality Technology
C50440QA**

This program prepares individuals with a background in manufacturing to function in the quality assurance area of a biological product manufacturing facilities. Course work includes basic bioprocessing operations, cGMP, quality systems, auditing, and validation. Graduates should be qualified to work in a bioprocess quality assurance environment.

Applicants must have previous industrial experience.
Program Length: 2 semesters
Career Pathway Options: Certificate in BioQuality Technology, Associate in Applied Science Degree in BioQuality Technology.
Program Site: Lee Campus – Day or Evening Program

Course Requirements for BioQuality Technology Certificate

A. Required Major Core Courses (5 SHC)		
BPM 110	Bioprocess Practices	3-4-5
B. Other Courses (8 SHC)		
ISC 175	Quality Assurance Fundamentals	1-0-1
ISC 278	cGMP Quality Systems	2-0-2
ISC 279	Auditing for cGMP	2-2-3
ISC 280	Validation Fundamentals	1-2-2

Total Semester Hours Credit required for graduation: 13

Semester Curriculum for BioQuality Technology Certificate

1st Semester (Fall)		C-L-SHC
BPM 110	Bioprocess Practices	3-4-5
ISC 175	Quality Assurance Fundamentals	<u>1-0-1</u>
		4-4-6
2nd Semester (Spring)		
ISC 278	cGMP Quality Systems	2-0-2
ISC 279	Auditing for cGMP	2-2-3
ISC 280	Validation Fundamentals	<u>1-2-2</u>
		5-4-7

Total Semester Hours Credit: 13

COURSE DESCRIPTIONS

BPM 110 Bioprocess Practice 3-4-5
This course provides a study of plant operations including various plant utility systems and detailed study of the varied plant environments in a bioprocessing facility. Emphasis is placed on quality mindset and principles of validation through applications of monitoring procedures. Upon completion, students should be able to appreciate the rigors of industry regulation and its necessity.

ISC 175 QA Fundamentals 1-0-1
This course is designed to increase fundamental knowledge in the philosophies, principles, and practice of quality in the work environment. Topics include the history and basics of quality, philosophies of quality, daily application of principles, and roles of quality professionals with emphasis on cGMP environment. Upon completion, students should be able to discuss quality fundamentals, components of quality systems, and identify standards and programs of quality.

ISC 278 cGMP Quality Systems 2-0-2
This course focuses on the development, implementation, and on-going maintenance of a quality system in a cGMP environment. Topics include the cGMP standard, components of cGMP quality systems, quality function roles and training, development of documentation such as SOPs, and system review procedures. Upon completion, the student should be able to identify the components of a quality system and develop a quality system manual utilizing the cGMP standard.

ISC 279 Auditing for cGMP 2-2-3
*Prerequisites: COE*112*
This course provides basic knowledge in internal audit planning, implementation, and reporting utilizing cGMP as the standard. Topics include auditing basics and types, phases of the audit process, regulatory requirements, auditing tools, auditor qualifications and skills, and behaviors while being audited. Upon completion, students should be able to identify the components of an audit program, develop a plan based on cGMP standards, and demonstrate reporting techniques.

ISC 280 Validation Fundamentals 1-2-2
This course covers the fundamental concepts and components of a validation program in a cGMP environment. Emphasis is placed on FDA requirements concerning validation, types of validation, documentation, procedures, and the QA role. Upon completion, students should be able to discuss the purpose of validation, identify the steps in the validation process, and effectively utilize sample documentation.