

# Minnesota State University Moorhead

## **BCBT 420: Intro to Working in a Regulated Biochemistry and Biotechnology Industry**

### **A. COURSE DESCRIPTION**

Credits: 4

Lecture Hours/Week: 4

Lab Hours/Week: \*.\*

OJT Hours/Week: \*.\*

Prerequisites: None

Corequisites: None

MnTC Goals: None

This course will cover the basic structure of the regulated workplace; introduction to regulatory affairs, introduction to regulatory language: FDA and USDA; an overview of good practices: good laboratory practices (GLP), good manufacturing practices (GMP) and good clinical practices (GCP); introduction to quality systems: quality control, quality assurance, ISO9000, and six sigma; introduction to validation. Student must be in junior standing in a bioscience or chemistry major.

**B. COURSE EFFECTIVE DATES:** 08/25/2008 - 05/12/2017

### **C. OUTLINE OF MAJOR CONTENT AREAS**

None

### **D. LEARNING OUTCOMES (General)**

None

### **E. Minnesota Transfer Curriculum Goal Area(s) and Competencies**

None

### **F. LEARNER OUTCOMES ASSESSMENT**

As noted on course syllabus

### **G. SPECIAL INFORMATION**

None noted