

Minnesota State University Moorhead

BCBT 520: 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.

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